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Original Paper

# A Smartphone App for Attentional Bias Retraining in Smokers: Mixed Methods Pilot Study

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## Abstract

**Background:** Smoking is a global health threat. Attentional bias influences smoking behaviors. Although attentional bias retraining has shown benefits and recent advances in technology suggest that attentional bias retraining can be delivered via smartphone apps, there is a paucity of research on this topic.

**Objective:** This study aims to address this gap by exploring the use of attentional bias retraining via a novel smartphone app using a mixed methods pilot study. In the quantitative phase, it is hypothesized that participants in the training group who undertake attentional bias retraining via the app should have decreased levels of attentional bias, subjective craving, and smoking frequency, compared with those in the control group who do not undertake attentional bias retraining. The qualitative phase explores how the participants perceive and experience the novel app.

**Methods:** In all, 10 adult smokers (3 females and 7 males) between the ages of 26 and 56 years (mean 34.4 years, SD 9.97 years) were recruited. The participants were randomly allocated to the training and control groups. In weeks 1 and 3, participants from both groups attempted the standard visual probe task and rated their smoking frequency and subjective craving. In week 2, the participants in the training group attempted the modified visual probe task. After week 3, participants from both groups were interviewed about their views and experiences of the novel app.

**Results:** The results of the quantitative analysis did not support this study's hypothesis. The qualitative data were analyzed using thematic analysis. The results yielded 5 themes: ease, helpfulness, unhelpful aspects, barriers, and refinement.

**Conclusions:** Findings from the qualitative study were consistent with those from previous studies on health-related smartphone apps. The qualitative results were helpful in understanding the user perspectives and experiences of the novel app, indicating that future research in this innovative area is necessary.

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**KEYWORDS**

attentional bias retraining; smartphone app; mixed methods; smoking; mobile phone

## Introduction

**Background**

Smoking remains a global health threat [1,2], and it is compounded by adverse relationships with depression and anxiety [3], as well as the consequences of secondhand smoke [4]. During the COVID-19 pandemic, the issue of tobacco smoking has become salient, as there is increasing evidence

suggesting that smoking is associated with COVID-19 severity [1]. Despite the growing impetus for smoking cessation efforts [1,2], as smoking is prevalent, smokers are constantly exposed to smoking-related cues in the environment [2,5]. Hyperattention to such stimuli imposes obstacles to any attempts at abstinence owing to the unconscious process of attentional bias [5,6]. Theories of attentional bias underscore the relationship between attentional bias and subjective craving, which is a potent

predictor of smoking relapse. Attentional bias perpetuates the cycle of addiction, and smokers who exhibit greater attentional bias are more likely to relapse [7]. Incentive sensitization produces attentional processing bias toward substance-related cues because of increased saliency and exacerbates craving toward the substance [8]. In addition, there is a bidirectional relationship between attentional bias cues and subjective craving for a substance [9]. Through classical conditioning, substance-related stimuli become more salient, which increases subjective craving [10]. Consequently, attentional bias toward the substance is further increased, which consolidates the cycle of craving and attentional bias in addiction.

The elaborated intrusion theory of desires makes similar predictions about the reciprocal relationship between attentional bias and subjective craving [11]. Cognitive elaboration on the substance perpetuates craving, which increases the likelihood of consumption. Subjective craving can initially be experienced as an intrusive thought, triggered by external substance-related cues [12], which drives cognitive elaboration. This increases attentional allocation to substance-related stimuli, which, in turn, strengthens craving. The theory of current concerns also supports the relationship between attentional bias toward cue-related substances and subjective craving [13]. Overall, although various theories suggest different mechanisms by which attentional bias develops, they converge on the idea that attentional bias and subjective craving have a bidirectional causal relationship with each other.

Common conceptual frameworks and measures to investigate attentional bias in substance use include the modified version of the Stroop task and the visual probe task. The modified version of the Stroop task in studies of substance builds upon the classical Stroop task [14-16]. Several studies using the Stroop task elicited evidence of smokers' attentional bias toward smoking-related stimuli [17,18]. These studies found that smoking-related stimuli interfered with smokers' performance in the Stroop task, suggesting that attention was drawn to such stimuli, thus impairing their performance on the specified tasks [19]. Although the Stroop task is a well-established attentional measure, alternative mechanisms may also explain the impaired performance. When modified for addiction studies, caution must be exercised in drawing the same conclusion on attentional bias underlying the results [20-24]. Another common measure involves the visual probe task [25], which uses images related to smoking and neutral images. Related studies expectedly yielded results showing that smokers displayed attentional bias [26]. The visual probe task has clear advantages over the Stroop task as a measure of attentional bias toward smoking-related stimuli. First, the visual probe task minimizes any response bias because of the motivational state of the participant [25]. Second, it more accurately reflects the real-life scenarios that a smoker faces. The visual probe task requires the participants to split attention between 2 different stimuli. In the real world, smokers constantly have to split their attention between different stimuli; thus, the visual probe task can better capture this aspect, which allows its results to be more generalizable.

## Attentional Bias Retraining in Smoking

Despite advancements in experimental psychology, the field of attentional bias retraining in smoking is relatively new. Emerging research indicates that attentional bias retraining holds potential clinical utility as an adjunct tool to complement smoking interventions. Both theoretical and empirical evidence supports attentional bias retraining. Theories of attentional bias have indicated that attentional bias results from the repeated pairing of cues, such as the sight of cigarettes, which leads to sensitized reactions to such cues, and thus they become more salient. Their saliency perpetuates the vicious cycle as it increases attention to smoking cues, which are related to smoking cessation outcomes [7]. In contrast to smokers who have increased attentional bias toward smoking-related cues, former smokers show avoidance of such cues [27]. Thus, attentional bias retraining in smokers may be crucial for successful smoking cessation.

The first attempt at attentional bias retraining in smokers used a modified version of the visual probe task [28]. This modified version used the same conceptual framework as the original visual probe task, with the only difference being that the dot probe always replaced the neutral stimuli. The results revealed a significant decrease in posttraining attentional bias toward smoking-related stimuli compared with that before training, suggesting that attentional bias retraining can alter such bias. However, subsequent studies using single-session training on smokers were unable to replicate the results [29,30]. Conversely, it was found that multiple sessions of attentional bias retraining produced robust changes in attentional bias toward smoking-related stimuli [31]. However, the challenge lies in convincing the participants to commit to multiple sessions because of the inconvenience these sessions bring to their personal schedules. An efficient way to curtail this difficulty would be to conduct the sessions over mobile devices, given their benefits in high-dosage treatment delivery, prevalent use, and convenience. With the rising trend in e-technology [32-34], the advancement of smartphones has ushered in an era where smartphone apps can be used to enhance the delivery of interventions. The use of mobile devices is widespread worldwide, and this ubiquity enables people with no access to mental health services to have opportunities to seek early treatment with convenience [35,36].

Currently, there is a dearth of research on attentional bias retraining for smokers via mobile devices. We have conducted a literature review and found a paucity of research in the area [37], indicating that research on this topic is pertinent. In the first study of its kind, Kerst et al [38] used PDAs to deliver attentional bias retraining to smokers. The results showed that attentional bias toward smoking-related stimuli and subjective craving decreased over the week in the attentional bias retraining group. However, the generalizability of the results was limited by the sample group, as a large proportion of the sample were African American. Recent research [39,40] has cautioned against assumptions that outcomes from studies conducted in Western countries could be generalized to the native Asian population, as the implementation of any effective intervention should consider the local sociocultural context. Despite this, the study is the first of its kind to report the use of attentional bias

retraining intervention via mobile devices and holds promise that warrants further exploration in the local context.

## Objectives

The literature review indicated the absence of studies exploring the use of smartphone apps in retraining attentional bias in smokers [37]. This study aims to address this gap in the literature. As recommended by previous research [41], the employment of a mixed methods study design will be useful in exploring the impact of the novel smartphone app. A mixed methods approach in this study entails the use of both quantitative and qualitative methods [42], with the overall objective of exploring the perspectives and experiences of the novel smartphone app, as well as to evaluate the outcomes of attentional bias retraining. Specifically, although the understanding of user perspectives and experiences of the novel app would be explored using qualitative methodology, the specific outcomes of attentional bias, craving, and smoking frequency would be evaluated using quantitative methodology.

Similar to previous research [41], in this pilot study, we investigated attentional bias retraining delivered via the novel smartphone app by quantitatively analyzing the attentional bias to smoking cues, subjective craving of smoking, and smoking frequency of current adult smokers who did and did not undertake attentional bias retraining. It was hypothesized that participants who did and did not undertake attentional bias retraining via the novel smartphone app would differ in their attentional bias, subjective craving, and smoking frequency. Specifically, participants in the training group who underwent attentional bias retraining would have decreased attentional bias, subjective craving, and smoking frequency when compared with participants in the control group (who did not undertake attentional bias retraining). The qualitative study would be exploratory in nature with the aim of exploring the perceptions and experiences of all the participants who had used the novel app. The research question for the qualitative study was as follows: “How do participants perceive and experience the novel smartphone app?”

## Methods

### Participant Recruitment

The participants were recruited through snowball sampling and by word of mouth. The inclusion criteria were as follows: at the time of the study, the participants should be adult smokers who had been smoking for the past 2 years and they should have access to mobile phones using the Android (Google, Inc) operating system. The exclusion criterion was that the participants were regular users of tobacco products other than cigarettes (eg, electronic cigarettes and waterpipes). In total, 10 participants (3 females and 7 males) completed the study, and their ages ranged from 26 to 56 years (mean 34.4 years, SD 9.97 years). There were 4 Chinese, 4 Malay, and 2 Indian participants. As this was the first study of its kind on a novel smartphone smoking app in the local context, the sample size was kept small, similar to a previous local-level study using a mixed methods design [41].

The visual analog scale was used to measure subjective craving. It consisted of a sliding response from 1 to 10 (1=no craving and 10=extreme craving) to the question “How much are you craving to smoke a cigarette right now?” Higher scores indicated higher subjective cravings. The numerical response to the question “How many cigarettes did you smoke daily for the past week?” was used to measure the smoking frequency. Higher scores indicated a higher smoking frequency.

### App Development

The novel smartphone app was developed on the Android platform in collaboration with our industry partner and coauthor (MWBZ). To the best of our knowledge, this is the only smartphone app that has been developed to retrain attentional bias in smokers. The app used for this study was developed using the research platform by Zhang et al [43] for substance use disorders. The app was developed by our coauthor (MWBZ), along with a freelance developer, using Unity 3D (Unity Technologies Inc), and it was programmed to be compatible with the Android platform. Within the app, participants could undertake either an attention bias assessment task or a bias modification task. The stimulus images used were similar to those used in previous studies [44]. Pictures of smoking-related stimuli and correspondingly matched neutral stimuli were acquired from Woud et al [44], and permission was obtained to embed them in our app. The smartphone app contained a standard visual probe task (assessment task) and a modified visual probe task (attentional bias retraining). A button feature to toggle between either task was also coded into the smartphone app.

### Task Design

A standard visual probe task [26] was used to measure attentional bias. The task comprised 100 trials, with each trial having a smoking-related image and a correspondingly matched neutral image. In each trial, participants were shown a fixation cross for 500 milliseconds before both images were displayed for 500 milliseconds. Following that, an asterisk replaced one of the images. In half of the trials, neutral images were replaced. Participants responded by clicking on the button at the position of the asterisk. The next trial would begin once a response had been recorded, or after 2000 milliseconds had passed, whichever came first.

In the assessment task, participants were presented with a fixation cross centered on the screen. Following the disappearance of the fixation cross, they were presented with a pair of stimulus images, with one image being related to smoking cues and the other being a neutral image but matched in terms of color and complexity. When these images disappeared, the participants were presented with a probe, and they had to register the position of the probe (left or right side of the screen) by pressing on the left or right on-screen buttons. In the assessment task, half of the trials involved the pairing of the probe with the smoking-related stimuli, and the other half involved pairing the probe with neutral stimuli. The modified visual probe task (attentional bias retraining) used the same task parameters as the standard visual probe task, the only difference being that the dot probe was consistently paired with the neutral stimuli to affect a shift in the attentional process.



The attentional bias score was tabulated as the median reaction time for trials in which the dot probe replaced the neutral image minus the median reaction time for trials in which the dot probe replaced the smoking image. A positive attentional bias score indicated a faster response to probes replacing smoking images than to probes replacing neutral images, suggesting attentional bias to smoking images. A negative attentional bias score indicated a faster response to probes replacing neutral images than to probes replacing smoking images, suggesting an attentional shift away from smoking images.

## Study Design

### *Approval and Consent*

Ethics approval (approval number H7616) was obtained from the human research ethics committee at the institution that hosted the study. Before the start of the study, participants were provided with an information sheet and an informed consent form. They were notified that their participation was voluntary and that they had the right to withdraw at any time without explanation or prejudice. Participants were randomized into two groups: 5 in the control group and 5 in the training group. Each participant completed a demographic questionnaire. Subsequently, they were given a link to download and install the novel smartphone app on their Android phone. Each participant was allocated a personal log-in code and password to access the app.

### *Phase 1: Quantitative Trial*

Similar to previous research [41], phase 1 involved the quantitative pilot trial, whereby 10 participants were randomly assigned to two groups—a training group (group 1) and a control group (group 2). Participants in the training group were informed about their allocation to group 1 and were asked to access the novel smartphone app in weeks 1, 2, and 3 of the study. Participants in the control group were informed about their allocation to group 2 and were asked to access the smartphone app in weeks 1 and 3 of the study. In week 1, participants from both groups attempted the standard visual probe task. They were instructed to respond quickly and accurately to the location of the dot probe that replaced either the smoking-related or the neutral stimulus. In week 2, the participants from group 1 attempted the modified visual probe task. Participants were instructed to complete this task in week 2 across 3 sessions. In week 3, participants from both groups attempted the standard visual probe task.

In week 1, participants in both groups (groups 1 and 2) were asked to complete a brief demographic questionnaire and rate their smoking frequency and subjective craving. Participants in both groups were also reminded to rate their smoking frequency and subjective craving in week 3.

### *Phase 2: Qualitative Process*

Similar to previous research [41], phase 2 involved the qualitative process, whereby all 10 participants from both the training group (P1, P2, P3, P4, and P5) and control group (P6, P7, P8, P9, and P10) were invited to a semistructured interview after week 3. All participants were asked to describe their views and experience of the novel app, discuss specific areas that could

be problematic, and provide their recommendations. Before the interviews, an interview guide was developed to ensure that all participants received similar prompts from the interviewer and to facilitate consistency in eliciting data. The interviews were audio-recorded and transcribed verbatim.

## Data Analysis

For the qualitative analysis, as in the study by Davies et al [45], 2 researchers coded the transcripts independently and manually using a thematic matrix technique within the framework of inductive coding. Upon completion of the coding, analyses were compared, any discrepancies were considered, and a consensus was reached. Similar to a previous study conducted on a novel smartphone app [41], thematic analysis was used to analyze the data from the interviews. The following six phases of analysis were employed: familiarization with the data, generating initial codes, searching for themes, reviewing themes, defining and naming themes, and final reporting using selected extracts. Before progressing into the coding phase, the data from the interviews were read and reread several times, resulting in data immersion. The codes identified the most basic features of raw data relevant to the research question. The coding process involved a constant backward and forward movement within the dataset to analyze the extracts that had been initially identified. Rigorous notetaking was undertaken in the coding process, and coding schemes were identified through the annotation of ideas. Using a thematic map, the codes were then sorted according to their similarities into identified themes. Additional reviews were conducted to ensure that no codes were omitted. All initial codes relevant to the research questions were incorporated into a theme.

A theme was composed of coded data grouped together according to their similarity [46,47]. In the context of our study, a theme would have to be relevant to our research topic of exploring participants' perceptions and experiences of using the novel smartphone app. After the candidate themes were identified, a process of refinement of this collection of themes was undertaken. Per expert guidelines [46], this process involved reviewing the collated codes and themes, looking for internal and external homogeneity, and checking for coherence and accuracy of themes in relation to the data set as a whole. Various links and distinctions between the themes were drawn. The purpose of this refinement process was to ensure that the themes were all broadly related to one another in relation to the research question, while being distinct enough to be conceptualized on their own. The naming process of the themes involved a clear definition with a detailed analysis. Specific examples of each theme were selected to illustrate the different elements of each theme. These will be detailed in the *Results* section.

To enhance the credibility of the qualitative study and trustworthiness of the data, a few strategies were used. To accomplish investigator triangulation, 2 researchers independently analyzed the data. The researchers discussed and finalized the coded data from the interviews with the research supervisor to ensure that the themes best represented the participants' perspectives. This also helped uncover any researcher bias that may have affected the integrity of the data. Both quantitative and qualitative results have been presented

in the *Results* section, and their integration has been discussed in the *Discussion* section.

## Results

### Quantitative Analysis

We performed all quantitative analyses using SPSS (version 22.0; IBM, Inc). For the visual probe tasks, those with reaction times <200 milliseconds and incorrect responses were excluded.

We analyzed the median reaction times to reduce the influence of the outliers. Quantitative data were analyzed using a series of Mann–Whitney *U* tests to examine the difference between the 2 groups (training vs control) with scores on attentional bias, subjective craving, and smoking frequency as the dependent variables over 2 time points (weeks 1 and 3). Descriptive statistics such as the means and SDs for attentional bias, subjective craving, and smoking frequency are presented in [Table 1](#).

**Table 1.** Means and SDs of attentional bias scores, subjective craving, and smoking frequency for the study participants (n=10).

Time point	Training group (n=5) score, mean (SD)	Control (n=5) score, mean (SD)
<b>Attentional bias</b>		
Week 1	–23.93 (80.26)	91.00 (161.40)
Week 3	–27.24 (57.20)	2.89 (30.67)
<b>Subjective craving</b>		
Week 1	5.00 (21.60)	5.00 (1.63)
Week 3	4.00 (0.82)	4.70 (1.71)
<b>Smoking frequency</b>		
Week 1	18.75 (9.43)	20.00 (11.43)
Week 3	15.25 (9.84)	18.75 (11.12)

Participants in the training group were hypothesized to have decreased levels of attentional bias, subjective craving, and smoking frequency, as compared with participants in the control group. We conducted Mann–Whitney *U* tests to examine differences between the 2 groups (training vs control) with scores on attentional bias, craving, and smoking frequency as the dependent variables over 2 time points (weeks 1 and 3).

In week 1, the attentional bias score of those in the training group (mean rank 3.75) was not significantly different from the scores of those in the control group (mean rank 5.25;  $U=3.00$ ;  $z=-1.44$ ;  $P=.20$ , 2-tailed). Similarly, subjective craving of participants in the training group (mean rank 4.38) was not significantly different from that of participants in the control group (mean rank 4.63;  $U=7.50$ ;  $z=-0.15$ ;  $P=.89$ , 2-tailed). Similarly, the smoking frequency of those in the training group (mean rank 4.50) was not significantly different from that in the control group (mean rank 4.50;  $U=8.00$ ;  $z=0.00$ ;  $P=.99$ , 2-tailed).

In week 3, the attentional bias score of those in the training group (mean rank 4.00) was not significantly different from that in the control group (mean rank 5.00;  $U=6.00$ ;  $z=-0.58$ ;  $P=.69$ , 2-tailed). Similarly, the subjective craving of participants in the training group (mean rank 4.00) was not significantly different from that of participants in the control group (mean rank 5.00;  $U=6.00$ ;  $z=-0.60$ ;  $P=.69$ , 2-tailed). Similarly, the smoking frequency of those in the training group (mean rank 4.00) was not significantly different from that in the control group (mean rank 5.00;  $U=6.00$ ;  $z=0.59$ ;  $P=.69$ , 2-tailed).

### Qualitative Analysis

#### Overview

For the qualitative analysis, the thematic analysis process that was applied to the textual data elicited key concepts that were evident in the data. The codes were categorized into the following 5 themes: ease, helpfulness, unhelpful aspects, barriers, and refinement. The following subsections include the extracts that capture the essence of the respective theme without unnecessary complexity.

#### Ease

The theme of ease captured the participants' perspectives on ease and simplicity, which enhanced the users' experience. There was consensus among all participants regarding the ease of use of the app:

*It has a straightforward design and simple interface; The simplicity is good.* [P1]

*It's rather intuitive and easy to use. I like that it's very easy to use.* [P2]

*Simple design.* [P5]

*It's just simple.* [P6]

*Simple game. Very easy to use.* [P8]

*Pretty easy to use. Straightforward.* [P9]

#### Helpfulness

The theme of helpfulness captured the perspectives expressed by participants in the training group. When describing their views and experience of the benefits, 60% (3/5) of participants from the training group who undertook attentional bias retraining noticed that they smoked less, and 40% (2/5) of participants perceived that their craving had decreased:



*After using the app I seem to smoke less.* [P1]

*Very helpful. After doing the app I really smoked a lot less. And I like it helped me reduce smoking.* [P3]

*Quite helpful. I smoke a bit less now.* [P5]

### Unhelpful Aspects

The theme of unhelpful aspects captured the perspectives expressed by participants in the control group on aspects that were unhelpful. When describing their views on the app, 40% (2/5) of participants from the control group who did not undertake attentional bias retraining felt that the app was not helpful and 60% (3/5) of them noticed no difference in their craving or frequency of smoking:

*Same, I still smoke one pack every day.* [P6]

*No effect, I still smoke the same.* [P8]

*Don't think it was helpful. Not even sure how it's supposed to help with smokers.* [P9]

*I don't think it was helpful. No, still one pack every day.* [P10]

### Barriers

The theme of barriers captured the perspectives that barriers included the amount of time needed to use the app, the lack of motivation, and forgetting to use the app because of busy personal schedules:

*Time-consuming.* [P1]

*Time-consuming...busy until forget [to] do...* [P2]

*Quite a lot (of) time...3 times a week.* [P4]

*Too long...forget [I] must do so many times.* [P5]

*Take a lot of time.* [P7]

*A little boring.* [P9]

*Take up time.* [P10]

### Refinement

The theme of refinement encapsulated the perspectives on features that could enhance the users' experience, including details such as reminders, intervals, reduction in the number of items, task duration and frequency (once a week), lengthening the duration of each picture by 1 to 2 extra seconds, removing the password or having automatic log-in on subsequent use, and clicking on the picture instead of the button.

### Other Subthemes

Pertaining to the subtheme of item reduction, 3 comments were made (P1, P7, and P5). On the subtheme of slower picture transition, 3 comments were made (P3, P6, and P7). With regard to the subtheme on the reminder, 2 comments were made (P5 and P8), and the subtheme on pause and break had 2 comments (P9 and P10). On the subtheme of password removal, auto log-in for subsequent use, and pressing on the photo instead of the green button, one comment was made by P2, P7, and P4:

*Less items. About five minutes is good.* [P1]

*So many photos.* [P7]

*Half the number of pictures [is] best...do once a week [is] better.* [P5]

*Password is unnecessary.* [P2]

*Auto-login for subsequent use.* [P7]

*The time from one picture to next [is] too fast...1 extra second each time will be good.* [P3]

*The pictures change too fast...1 to 2 [extra] seconds will be good.* [P6]

*Make it so the change [is] not too fast.* [P7]

*Just let us press on the photos [is] less confusing.*

*Green button [is] unnecessary.* [P4]

*I need reminder to do.* [P5]

*Alarm to remind us to do.* [P8]

*Interval for break amidst the task.* [P9]

*Give the option to pause and break.* [P10]

## Discussion

### Main Findings

This pilot study aimed to explore the use of a novel smartphone app in attentional bias retraining in smokers by using a mixed methods design. The main findings of the quantitative phase did not support the hypothesis that participants in the training group who undertook attentional bias retraining via the smartphone app would have decreased attentional bias, smoking craving, and smoking frequency, as compared with participants in the control group. The findings were not consistent with previous research, for example, by Kerst et al [38], who had found that attentional bias retraining delivered over a week led to a decrease in attentional bias and subjective craving for smokers in the training group. Although the outcome from the quantitative phase did not support the hypothesis, the outcome of the qualitative phase provided some preliminary evidence that participants in the attentional bias retraining group expressed no report of unhelpfulness.

### Strengths and Limitations

The perceived benefits from those who undertook attentional bias retraining included a decrease in craving and smoking frequency. However, the limitations should also be acknowledged. The major limitation of this study is the small sample size. Future studies should use a larger sample size informed by a power analysis. Nevertheless, findings from this pilot study can be used to inform the refinement of the novel app, which can then be used in a larger scale project, involving collaborations with community and industry partners at the local level and within the region.

There might be extraneous variables inherent in the sample at baseline. As cultural variations can contribute to vulnerabilities and resilience in a range of health issues [40], which might include nicotine dependence, future research should endeavor to collate further details on culture and incorporate a questionnaire such as the Fagerström Test for Nicotine Dependence [48] to assess nicotine dependence at baseline.

Another limitation was regarding the choice of stimulus materials, which should be informed by findings from a preliminary focus group. The design of the questions in the focus group can be conceptualized to examine the questions

posed by the research by Woud et al [44]. The purpose of the focus group can include examining sensitivity to the variety of smoking-related images, the effect of the duration of exposure, the order of materials, and the pairing of images. The outcome can then be used to inform the choice of neutral images, as well as the final design of the stimulus materials.

Further improvements can be made to the research design. In our study, the participants were randomly assigned to the experimental and control groups. The design can be improved if both groups matched in their key characteristics. In addition, the scales used in this study (ie, the visual analog and smoking frequency scales) are both based on self-reports, and thus, subject to recall bias and social desirability bias. There could also be other extraneous factors, as described in the subsequent sections.

First, our study was the first of its kind to deliver attentional bias retraining for smokers via a novel smartphone app. Unlike the study conducted by Kerst et al [38], which provided participants with a PDA and previous laboratory studies, there might be possible distractions from personal mobile notifications while our participants undertook attentional bias retraining on their mobile phones. This might contribute to loss of focus, which could lead to a decreased possibility of attentional bias change [49]. Second, unlike our study, which comprised 3 sessions of attentional bias retraining over a week, Kerst et al [38] delivered attentional bias retraining 3 times daily over a week. The lower training frequency in our study might have been insufficient to produce significant changes in attentional bias. This suggests that attentional bias may be relatively less malleable to change unless there was a higher load of training involved. Hence, future studies can adhere to multiple training sessions daily for at least a week, as previous research has demonstrated that only those studies that used multiple trainings daily for a week or more had robust results [38,50].

Future studies can include features to block incoming calls and notifications to minimize distractions on mobile phones while participants are engaged in the training. This can maximize their focus and minimize extraneous factors that might diminish the effect of the training [49]. The study can also be replicated with increased training frequency and provision of incentives for completion, which might enhance the motivation to commit to the multiple sessions of daily training required. Using hospital-based samples or recruiting from smoking cessation programs in the community might also enhance engagement and minimize attrition rates.

### Themes Identified

The qualitative study aimed to explore the participants' perceptions and experiences of the novel smartphone app. The following 5 themes emerged from their responses: ease, helpfulness, unhelpful aspects, barriers, and refinement. The theme of ease was consistent with previous research that described the benefits of health-related mobile apps. Our finding was consistent with a recent study [51] that explored the perspectives of participants on the use of mobile health apps. Similarly, the app was viewed favorably with regard to its ease of use and convenience. Ease of use is often correlated with sustained use [52], and coupled with the convenience of mobile

devices [53], this could maximize treatment adherence to attentional bias retraining, given the high frequency of attentional bias retraining required for robust outcomes.

The themes of ease of use and helpfulness were consistent with previous research [54] and aligned with effort expectancy, which is a construct based on the idea that there is a relationship between ease of use and the rewards from the effort [55]. Previous studies found that the harder the participants perceived it was to operate a mobile app, the less they used it to reap its benefits [56]. Therefore, the ease of use and the convenience of attentional bias retraining in the novel app can help enhance its use among smokers.

The theme of helpfulness was consistent with a recent qualitative study [54], which explored the benefits of a mental health mobile app. Participants perceived the app to be helpful in their recovery process, as well as a good complement to traditional follow-up methods for posttrauma symptoms. In contrast, participants in our control group did not undertake attentional bias retraining and subsequently perceived the aspect of the app they received as being unhelpful, thus providing preliminary evidence on perspectives that demarcated the training and control groups.

The theme of barriers perceived by the participants was consistent with that of a recent study [56]. Similar to Peng et al [56], where participants perceived that a lack of discipline and time commitment contributed to the barrier to their smartphone app use, the smokers in our study found that the required time commitment was a barrier for their consistent use of the app. Future studies should engage in comprehensive usability testing to determine ideal scheduling while maintaining robust outcomes. Further in-depth interviews can uncover the underlying factors that might enhance the commitment to sustained and consistent engagement with the app. In future research, the use of in-built personalized reminder features can also help facilitate the participants to use the mobile app at a time that is most convenient to them. The theme of refinement is aligned with the study by Anderson et al [51], where suggestions were made to improve their novel mobile health apps. Specifically, the suggestions included fine-tuning of certain features. Further enhancement of our app could include an auto log-in function, scheduling of intervals, and a more intuitive button response within the app. In addition, future studies can consider gamification of such applications to increase engagement and sustain motivation [57] or incorporate rewards to encourage use and investigate their pros and cons. Owing to time and resource constraints, follow-up was not possible in this study. Ideally, it would be best if the themes elicited could be presented to the participants for checking and further refinement. In hindsight, it would be optimal to design the research question for phase 1 by incorporating the barriers and operationalize it by investigating the specific duration of time that participants spent each week on the app.

### Conclusions

This study provides findings from both quantitative and qualitative research methods. Although the quantitative outcome did not support the hypothesis, the qualitative outcome provided preliminary support for the benefits of the novel smartphone app. The identified themes of ease, helpfulness (pertaining to

those who undertook training), unhelpful aspects (pertaining to those who did not undertake training), barriers, and refinement were consistent with previous research. This study provides preliminary evidence to support some benefits of the novel smartphone app for smokers. The qualitative findings can be used to refine the app for use in larger scale studies to further explore the effects of the novel mobile app, which might lead

to the future possibility of its use in smoking cessation programs. However, the overall findings of this study should be interpreted with caution, as its small sample size is a limitation. Nonetheless, the qualitative results were useful in understanding the perspectives and experiences of participants who used the novel app and can further inform future research on this pertinent topic.

### Authors' Contributions

Administrative help was provided by YZT and supervised by CCC. Data were collected by YZT and supervised by CCC. The app was developed by MWBZ in collaboration with CCC. The publication cost for this study was funded by MWBZ.

### Conflicts of Interest

None declared.

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Original Paper

# The Interplay Between Technology Performativity and Health Care Professionals in Hospital Settings: Service Design Approach

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## Abstract

**Background:** The unexpected outbreak of the COVID-19 pandemic and the preventive measures of physical distancing have further necessitated the application of information and communication technologies (ICTs) to enhance the efficiency of work activities in health care. Although the interplay between human agency and technology performativity is critical to the success or failure of ICTs use in routine practice, it is rarely explored when designing health ICTs for hospital settings within the sub-Saharan Africa context.

**Objective:** The objective of this study is to explore how the service delivery quality is being influenced by the technology-enabled activities of health care professionals at points of care using a service design strategy.

**Methods:** An interpretivist stance was assumed to understand the socially constructed realities of health care professionals at points of care in a hospital setting. A service design strategy was identified as suitable for engaging health care professionals in co-design sessions to collect data. A purposive sampling technique was used to identify the participants. Open-ended questions were administered to gain insights into the work activities of physicians and nurses at points of care. Qualitative (textual) data were analyzed using thematic analysis. Ethical concerns about the safety and privacy of participants' data were addressed as per the university ethics review committee and provincial department of health.

**Results:** The findings show that the attributes of human agency and technology features that drive technology performativity result in an interplay between social concepts and technical features that influence the transformation of human-machine interactions. In addition, the interplay of the double dance of agency model can be divided into 2 successive phases: intermediate and advanced. Intermediate interplay results in the perceived suitability or discomfort of health ICTs as experienced by health care professionals at initial interactions during the execution of work activities. Subsequently, the advanced interplay determines the usefulness and effectiveness of health ICTs in aiding task performance, which ultimately leads to either the satisfaction or dissatisfaction of health care professionals in the completion of their work activities at points of care.

**Conclusions:** The adopted service design strategy revealed that the interaction moments of the tasks performed by health care professionals during the execution of their work activities at point of care determine the features of health ICTs relevant to work activities. Consequently, the ensuing experience of health care professionals at the completion of their work activities influences the use or discontinuation of health ICTs. Health care professionals consider the value-added benefits from the automation of their work activities to ultimately influence the quality of service delivery. The major knowledge contribution of this study is the awareness drawn to both the intermediate and advanced interplay of human-machine interaction when designing health ICTs.

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**KEYWORDS**

agency; health care professionals; technology performativity; sub-Saharan Africa; service design; work activities; mobile phone

## Introduction

### Background

This study highlights how the work activities of health care professionals' shape or are shaped by technology performativity at points of care. The quality of health care services delivered to patients is largely dependent on the ability of health care professionals to productively execute their work activities [1]. Moreover, enabling and contextual conditions influence how health care professionals execute their work activities. Existing literature shows that public health care sectors, particularly in sub-Saharan Africa, are continuously plagued by the prevalent burden of diseases and other recurrent challenges in their health care systems [2]. Some of the challenges are characterized by infrastructural deficiencies, long waiting times, limited accessibility to health care, shortage of skilled personnel, and other human-induced factors [3]. These challenges contribute to some of the contextual conditions that enable or inhibit how health care professionals execute their work activities.

As the number of individuals who require access to health services increases, especially in the public health sector, health care professionals' work activities require adequate facilitating conditions to perform actions more effectively through the use of relevant tools. The tools relevant to the work activities of health care professionals are paper-based and technology-enabled in the form of health information and communication technologies (ICTs). Health ICTs enable health care professionals to collect, store, and retrieve any health-related information in electronic or digital format to make informed decisions related to diagnosis and treatment. However, when the health ICTs are not adequately designed to align with the work activities and use-case scenarios in hospital settings, they may not adequately serve health care professionals [4]. Therefore, this paper contributes to the literature on how health care professionals perceive the suitability of health ICTs in executing their work activities.

### Challenges Associated With Health Care Work Activities in Sub-Saharan Africa

This paper aims to contribute to how health care professionals can use health ICTs to execute their work activities at points of care in hospital settings. In sub-Saharan Africa, the work activities of health care professionals are usually inhibited by contextual challenges that influence the efficiency of job performance, quality of health care services, and patient satisfaction [5]. These challenges may often result in decision-making errors and a decline in the job performance of health care professionals, which ultimately affects the quality of service delivery. Some of the contextual challenges lead to patients experiencing longer waiting times during visits and, in some instances, a lack of access to health care services [2]. However, to mitigate some of the contextual challenges, health care institutions have invested in health ICTs to enable work activities because of their value-added benefits. These benefits include improved data management, constructive decision-making, improved ease of communication, and enhanced productivity [6].

### Benefits of Technology-Enabled Health Care Work Activities

The goal of introducing ICTs in the health care sector is to enhance the execution of work activities by health care professionals and improve health care service delivery [7]. The use of health ICTs at points of care during and after patient visits helps in improving information administration, collaboration between health care professionals, and in some cases efficient decision-making and diagnosis as well as adherence to treatment. Technology-enabled activities have the potential to positively transform clinical practice and the quality of service delivered by health care professionals.

Depending on the activities being performed, health care professionals can collect, record, and store patient information using hospital information systems both locally and remotely [8]. This enables easier access and retrieval of clinical notes and patient records, including medical history, laboratory tests, and medical images, to assist in decision-making. The use of computers and mobile technologies to facilitate the exchange of information and instant messaging has improved communication and coordination between health care professionals, especially to collaborate or to seek a third specialist's opinion [9].

Health care professionals rely on software apps and web-based resources to access medical journals and databases [10,11]. These resources enable health care professionals to identify up-to-date medical literature and recommendations that support decision-making regarding drug reference prescription, diagnosis, and at points of care during service delivery. The benefits of health ICTs have resulted in improved efficiencies of manual processes and enabled accountability to manage the frequency of human errors that may occur during the work activities of health care professionals.

Unfortunately, there are isolated instances where health ICTs continue to fail because of suboptimal performance, being unsuitable for clinical-related tasks at points of care, and resistance to change as exhibited by frontline technology users [12]. Other reasons for health ICTs failing postimplementation can be attributed to the lack of adequate consideration for users' behavioral attributes, particularly agency, during different use cases by the technology designers or hospital management [13].

The technology initiatives of health ICTs in sub-Saharan contexts prioritize primary health and field data collection by community caregivers, patient administration, and billing systems or technology that target special types of diseases such as tuberculosis and HIV monitoring. However, there are only a few studies on how health ICTs enable health care professionals to ensure quality service delivery at points of care in a hospital setting [2]. This paper contributes to the existing literature on how health care professionals perceive the effectiveness of health ICTs during the execution of their work activities at points of care. For this paper, the double dance of agency was used as a lens to identify the theoretical concepts of interplay between health care professionals and technology performativity in a hospital setting.



## The Double Dance of Agency Model

### Overview

The double dance of agency model incorporates key concepts that show attributes of human agency, the process of agency translation, material performativity, and mediation of contextual conditions [14]. The concepts are strongly rooted within the contexts in which human and nonhuman actors exercise some form of agency and its effects on the intended outcomes of an activity. In this paper, conditions are defined as the circumstances that make certain course of actions more favorable or unfavorable than their alternatives. The root constructs of the conditions include personal histories, social structures, and situational networks. For example, human agency can be influenced by inefficiencies experienced as a result of poor enabling conditions or an overwhelmed system that manages a large population with limited skilled workers. These conditions have a negative effect on the quality of service delivery.

Some of the lived experiences of health care professionals are either enabled or restricted by the elements of social structures such as cultures, rules such as the code of medical practice, strategies, and available resources [15]. However, human actors reserve the willingness to interact in alignment with or against the constructs of these conditions [16]. In the context of health care, professionals use health ICTs based on the presumption of their usefulness and perceived value-added benefits. This is often informed by the desire to improve the inefficiencies of work activities. Subsequently, the properties of human agency and technological capabilities significantly influence the goals and outcomes of work activities during service delivery.

The degree of autonomy associated with agency in machines is influenced by the conditions of human agency in a human-machine network [17]. For instance, a machine does not ordinarily possess the capability to exhibit awareness of self-input and adapt as a reaction to unintended consequences in a context, for instance, a hospital information system. However, it is acknowledged that artificial intelligence (AI) machines have been developed using complex algorithms such as machine learning to offer a relative degree of autonomy to machines [18]. In AI systems, the machine is aware; it can interpret and continuously adapt to a change in the conditions of the human environment, for example recommender systems. In this study, the hospital information systems and mobile apps were not built with advanced AI. The health ICTs in this study were legacy machines that required the input, negotiation, and transformation of human efforts into desired outcomes.

### Human Agency

Agency is defined by Giddens [19] as the “capability to make a difference,” whereas in the social cognitive theory it is defined as “choice to act intentionally” [20]. At face value, these definitions extend to human actors and machines; however, the degree of agency is influenced by conditions such as personal history, social structure, and situational networks [14]. For instance, human agency is characterized by attributes of self-awareness, context-awareness, and intentionality [21]. These attributes enable humans the autonomy and choice to make

conscious decisions that influence the outcome of their activities. Technology is designed by humans as part of the solutions informed by their adverse lived experiences, expectations, intended outcomes, and their desire to exhibit power. Therefore, the authors argue that in health care, agency is ascribed mainly to humans in a human-machine interaction, whereas technology is an enabling tool to efficiently facilitate interactions of humans when performing tasks.

Users have sometimes made efforts to accept and adapt to how ICTs are designed to work for meeting their needs and expectations or interests. A study on the Internet of Things (IoT) [22] investigated the balance between human agency and object agency. This study explored the perceptions and attitudes of IoT users. The findings showed that users expressed dissatisfaction with the limited ability to exercise their agency, suggesting that future designs of IoT technologies should be aligned with the affordances and habitual needs of its end users and at the same time guarantee more control to humans. Technology designers could inadvertently focus on the capabilities of a technology innovation for a particular purpose without extensive consideration of the user agency and the context of use. Therefore, technologies might yield results anticipated by the designer but not necessarily informed by the users' requirements.

### Technology Performativity (Machine Agency)

Unlike human actors, machines do not have a degree of agency to act independently [14]. A machine translates its input instructions as instructed by human actors to yield a defined output or outcome, which is referred as material or technology performativity [23]. For instance, a machine does not possess the capability to exhibit awareness of self-reflection and adjustment in reaction to the unintended consequences in a pre-established context. Typically, the capability of health ICTs is attributed to their features [24]. These features may include, but not restricted to, the screen size, type of keypad, computing power or processor, amount of storage memory, wired or wireless-enabled technologies, sensors, in-built cameras, and hands-free functions [25,26].

In the context of health care, professionals use health ICTs such as hospital information systems and mobile apps, which are perceived as useful in improving the inadequacies of paper-based and manual systems [10]. This perceived usefulness influences the routine use of health ICTs, as informed by their value-added benefits [27]. Conversely, the need for humans to discard or adapt to an implemented technology often arises from scenarios in which a technology does not adequately serve the intended purposes of work activities in a timely manner [28]. Thus, claims of machine agency [29] in a sociotechnical network within the health care context leaves more questions to be addressed than answers.

In this paper, authors draw from existing literature on the concepts of human agency, the perceived machine agency, and the interplay between these 2 concepts to understand the effect of health ICTs on the work activities of health care professionals in a public tertiary hospital setting.

## Methods

### Service Design Approach

The authors adopted a service thinking approach to particularly understand how the work activities executed by health care professionals in a hospital setting are enabled or inhibited by health ICTs during service delivery. The research was qualitative in nature and adopted a service design strategy to collect the desired information from a sample of health care professionals within the research population of a hospital. The service design double diamond model was adopted as a strategy because it enables human-centered collaboration that visualizes human interactions along a timeline and the values-in-use of a service [30]. The authors engaged with health care professionals to understand how they executed their work activities and to identify how they used health ICTs. The strength of this strategy was that the authors could compare the similarities or differences between *what participants say* and *what they actually do* through co-design sessions. In this study, the application of service design was adopted to engage with participants and obtain a holistic understanding of how work activities are currently executed by health care professionals and does not seek to change the established medical practice workflow at the points of care. The service design double diamond model provided a human-centric approach to acquire primary data on the work activities executed by health care professionals.

The service design double diamond model is broadly categorized into 4 phases. In this study, the authors adopted the first 3 phases to collect data from the participants. In the first phase, the authors engaged with secondary data or existing literature to identify how health ICTs have been used by health care professionals at points of care in hospital settings. This prompted the objective of this study. In the second phase, the researchers used open-ended questions to define the touch points of health care professionals' work activities. Touch points are instances where human actors and objects interact [31]. The touch points enabled the authors to break down the interaction moments of the activities performed by health care professionals during health care service delivery at points of care.

In this paper, touch points are the cluster of interaction moments where health care professionals perform tasks during the execution of their work activities to deliver services. In the third phase, the researchers identified the features relevant to the design of health ICTs, as informed by interaction moments identified in the previous phase. Only 3 phases were applied in a cross-sectional approach, as the fourth phase required a longitudinal investigation to deploy and evaluate a physical artifact, which would have been dependent on permissions from the provincial department of health.

### Recruitment

#### *Clinical Setting Context*

Hospital H is an academic hospital in the Western Cape province of South Africa that provides specialized health care services, trains higher education institution medical students and promotes research. As of 2016, hospital H catered to >3.4 million people in the geographic area where it is situated, of which over 599,885 patients visited the hospital per year. The hospital is notable for its progress in the implementation of eHealth information systems, such as hospital information systems and mobile health (mHealth) apps.

#### *Data Collection Process*

Before engaging with the participants, we applied for an ethical clearance to collect data from the university ethics research committee before approaching the Western Cape Provincial Department of Health. The researcher (OO) was contacted by the manager of hospital H after deliberations by the provincial and the hospital's ethics committee, who indicated that ethical concerns had been mentioned and addressed. After ethical clearance was granted, emails were sent to the heads of clinical departments of hospital H, to explain the purpose of the research and obtain buy-ins from the top management of the hospital.

Purposive sampling was used to identify the participants. The sample size was selected from the clinical units that provided medical imaging and reporting. The rationale for this sample selection was that the doctors and nurses involved in medical imaging and reporting used different technologies to execute their work activities that involved text and image diagnosis, treatment, and reporting. Informed consent was signed by the participants, indicating that they understood the implications of participating or withdrawing their participation willingly from the research and that their details would be kept confidential when reporting the findings.

Other key stakeholders in the health sector, such as patients, hospital managers, vendors of health ICTs, and policy makers, were not involved in the service design process because this study specifically focused on how the types of health ICTs used by health care professionals were perceived to shape their work activities at points of care during service delivery.

The health care professionals included 4 nursing staff, 6 orthopedics, and 2 ophthalmologists, as described in the profile table (Table 1). The initial sample size was 20, but health care professionals are one of the most difficult research populations to contact, arguably because of their busy schedules [32]. The saturation point was guaranteed because the research focus was on work activities and not on individual behaviors or attitudes. Furthermore, the work activities were similar for each group of health care professionals, which guaranteed the likelihood of no new additional information [33].

**Table 1.** Profile of health care professionals in hospital H<sup>a</sup>.

Participant ID	Area of specialty	Estimated years of practice	Method of engagement
RH_1	Ophthalmology registrar	6	Interview
RH_2	Ophthalmology registrar	8	Interview
RH_3	Orthopedic consultant	10	Interview and co-design
RH_4	Orthopedic registrar	7	Interview and co-design
RH_5	Orthopedic registrar	1	Interview
RH_6	Orthopedic registrar	3	Interview
RH_7	Orthopedic registrar	4	Interview
RH_8	Orthopedic registrar	5	Interview
RH_9	Deputy nursing manager	32	Interview
RH_10	Nursing area manager, theater	25	Interview and co-design
RH_11	Nursing area manager, intensive care unit	20	Interview and co-design
RH_12	Nursing area manager, trauma	25	Interview and co-design

<sup>a</sup>The respondents have been addressed here using pseudonyms starting with RH\_, where R denotes respondent and H denotes hospital.

### ***Co-design With Open-ended Questions***

The co-design activities were performed in a comfortable location within the hospital as selected by the participants; subsequently, the research objective was explained to the participants. The facilitator (OO) provided cut-out graphic representations of the doctors, nurses, and tools used for work activities to the participants, as observed in the literature. Then, large sheets of paper, pencils, erasers, and stickers were provided as writing materials for the participants to illustrate their workflow. According to Debrah et al [34], the cut-out probes of actors and tools provide an opportunity for participants to visually express their actions and make sense of the drawbacks of their work activities.

The facilitator asked the participants to visually illustrate how they performed their tasks and the different tools they used. Participants used the paper cut-outs to represent themselves as actors on a large piece of paper using stickers and provided

practical descriptions of their actions at points of care. The outcome of the first task was a visual illustration of the user journey maps of health care professionals from the first encounter with a patient until they were discharged or deceased ([Multimedia Appendix 1](#)).

Subsequently, the researcher used the visual illustrations to identify the touch points within the service delivery process. The facilitator then inquired about any challenges experienced by health care professionals using open-ended questions. Participants described their work activity challenges and the resulting effects attributed to the use of health ICTs. The discussion between the facilitator and participants hinted at how health ICTs could be best suited for their work activities. The outcome of the discussion summarized the characteristics of the expected features of a fit-for-purpose technology as shown in the summary of co-design analysis from engagement with physicians and nurses ([Table 2](#)).

**Table 2.** Summary of co-design analysis.

Themes and touch points of work activities	Interaction moments of touch points	Tools
<b>Illustration of work activities</b>		
Patient consultation	Verbal communication	Voice
Patient consultation	Notes writing	Pen and paper
Patient consultation	Referrals and communication	Smartphone
Booking and retrieval of clinical examinations	Requests of laboratory tests and imaging using a screen and keyboard	Desktop computer
Booking and retrieval of clinical examinations	Access and retrieval of tests and image results using a screen and keyboard	Desktop computer
Nursing administration of patient care	Triage patient admission, transfer, or discharge	Voice; pen and paper
Nursing administration of patient care	Report writing	Voice; pen and paper
Nursing administration of patient care	Communication with other professionals	Voice; pen and paper
<b>Challenges of work activities</b>		
During patient consultation	Notes writing; delayed access to digitized paper record	Pen and paper; desktop computer
Referrals	Uncontrolled interruption	Smartphones
Nursing administration of patient care	Cumbersome report writing	Pen and paper
<b>Features for ideal technology-enabled work activities</b>		
Remote consultation	Record verbal communication	Mobile device with readable screen size and voice recorder or voice recognition
Remote consultation	Write or update feature	Mobile device with readable screen size and voice recorder or voice recognition
Nursing administration of patient care	Report writing	Tablet or smartphone with touchscreen and a preloaded database
Nursing administration of patient care	Triage patient admission, transfer, or discharge	Tablet or smartphone with touchscreen and a preloaded database

### Data Analysis Process

In this study, the findings were dependent on the operationalization and frequency of attribute occurrences that defined the key concepts of the research objective. The co-design sessions with the participants were recorded and transcribed from audio to verbatim text. Each co-design activity lasted for 60 minutes. We analyzed the collected data using the thematic analysis technique to identify the attributes that implied words or phrases in the research objective. This technique was guided by conceptualization and operationalization.

Conceptualization process involved identifying and defining key concepts embedded within the phenomenon being investigated. To further simplify the analysis process, the attributes that determined or quantified each key concept were identified from the data transcripts; this is known as operationalization.

The words or phrases identified were assigned descriptive codes in a process known as open coding. In this study, open coding was applied to the transcribed qualitative data to identify and categorize how service delivery was being shaped by technology-enabled activities of health care professionals at points of care ([Multimedia Appendix 2](#)). Hence, coding was performed in several iterations to exhaustively sort the data

according to the hermeneutics circle prescribed for interpretive studies [35].

## Results

### Overview

The outcome of co-design with the participants showed that health care professionals used technology in the form of mobile devices and desktop computers and were aware of technology features relevant to their work activities at points of care.

The data analysis process showed that work activities are characterized by patient care and information administration, diagnosis, and treatment to improve the state of the patient's well-being. Therefore, the authors sought to establish the tasks performed by health care professionals, the technologies used to execute work activities, and the expected outcomes of specified technology-enabled work activities.

### Background to a Health Care Professional's Work Activities

The nature of health care professionals' work activities requires mobility—from wards to clinics to theaters within the hospital. When asked to describe their daily work activities, the doctors mentioned patient consultations at clinics or wards and clinical



procedures on patients (respondents RH\_1, RH\_2, RH\_3, RH\_4, and RH\_5). One participant responded as follows:

*A typical day for us at the moment will be one of two things, either a theatre day where we would go to theatre after our morning discussion, operate the patients and after the case is in theatre we do a ward round. We will have our morning meetings...after, we go to the clinic where we see our patients after which we would also do a ward round of the patients we have in-hospital and obviously we have the days that we are on call for the hospital. [RH\_4]*

These activities require administrative tasks, particularly the documentation of patient information that are newly generated or modified. For instance, it was necessary for a health care professional to have quick access to patients' records in cases of emergency, scheduled visits, and unscheduled follow-up visits:

*The nurse does the checklist...checks the patient's files. Now, she checks for the x-rays and all the necessary docs. For example, the consent form. During the surgery she (the nurse) writes down the complete recordings in the theatre book before taking it to the data capture or scan centre. [RH\_10]*

The responses indicated that the clinical and administrative functions of health care professionals require information administration enabled by essential tools. These essential tools were paper-based methods and health ICTs to facilitate the collection, storage, update, retrieval, and exchange of patient information locally or remotely to aid decision-making and provide quality health care services.

### **Purpose of Health ICTs During Work Activities at Points of Care**

Health care professionals indicated the use of hospital information systems to manage patients' records and facilitate booking requests. For instance, physicians perform remote consultations and communications that require the exchange of information with colleagues from other health care institutions. Health care professionals described the purposes for which health ICTs have assisted in automating their work activities. The health ICTs described included the iSite (Philips) picture archiving and communication system (PACS), enterprise content management (ECM; Oracle Corporation) system, nursing information management system (a computerized procurement system developed by the Western Cape Provincial Department of Health, South Africa), and the VULA mobile app (developed by Dr William Mapham, a South African ophthalmologist).

When asked to mention the ICTs used to support their work activities, the doctors described the VULA app as a mobile app used to facilitate referral management. One physician described VULA as follows:

*smartphone based app where doctors and health care professionals, that includes more than just the doctors, can have direct communication with the on-call doctor or Orthopedics person, to ask for advice or refer patients to us. That's by a means of a list of questions that we ask or that's asked on the*

*app and photos of X-rays that can be sent through to us. [RH\_4]*

The VULA app was described as a mobile app designed to enable health care professionals consult with each other and facilitate communication in the form of exchanging patient history, asking or receiving medical advice and sending clinical images, and making informed decisions remotely. It is used to manage trauma referrals from private and other public peripheral hospitals to tertiary hospitals:

*In our clinics, for all patients that are seen notes are made by hand and those notes as well as all referrals goes into a patient's folder. All those notes are sent to the scan department, get scanned into our ECM and eventually do become available on a computer. [RH\_3]*

The ECM and PACS are systems mostly used by physicians to access patient records and to request or retrieve medical and pathology test results from the clinical laboratory. Participants from the nursing department confirmed that a technology tool was used to support administrative activities involved in the admission, care, discharge, or transfer of patients. Nurses referred to the technology as a nursing information management system. One of the nurses explained as follows:

*The ICT tools are used by the nurses to register patients as they are being admitted; to transfer patients; to take patients off the system if they are discharged or die in the hospital; we use it to order food and we use it to order stock in the hospital environment. [RH\_9]*

Health care professionals mostly recounted the value-added benefits associated with the use of health ICTs for their work activities regarding electronic documentation of patient records, access and availability, referrals, communication, and consultation.

### **Strengths in Technology-Enabled Work Activities of Health Care Professionals**

The evidence of a transformed work process is usually evident in the value-added benefits attributed to the use of technology and its outcomes because health ICTs are designed to improve on the inefficiencies of work activities and enable quality health care services. The study findings show that health care professionals experience easier and quicker access to the patients' information by using ICTs. When asked how the ECM system assists work-related activities, one of the doctors responded as follows:

*It helps to quickly access the patient's folders and previous notes, previous history of the patient and it speeds up especially when you see the patient on follow up. [RH\_1]*

Clearly, access to patient information at points of care is important to health care professionals' work activities. However, this information must be available in an electronic format in a timely manner. Regarding the PACS and the VULA mobile app, another participant mentioned the following:

*Before PACS and VULA app, we had the hardcopy X-rays. And they would get lost or misplaced somewhere or you would want to discuss a case here and then the X-rays would be in the ward. So just to have the PACS on any computer, you would have the X-rays available and then do your planning and everything as well. And you could draw your lines or do your templating on the PACS itself...You can't lose the X-rays. [RH\_3]*

The responses imply that health ICTs have transformed the work activities of health care professionals in tertiary health care settings, based on their contribution to the effectiveness of performing tasks and time efficiency. For instance, clinical notes that were handwritten on paper, hard copy X-ray images, and other medical scans are being documented electronically on the ECM and the PACS. The patients' records are readily accessible and retrievable digitally using desktop computers or mobile devices, regardless of the location of a health care professional within the hospital. Physicians RH\_2 and RH\_3 expressed that the management of patient referrals had improved as the process had simplified and the number of unnecessary referrals had reduced. One physician stated that the mobile app helped as follows:

*Lessens trauma burden on our emergency department and Orthopedics. Because we saw that lot of times, people were referred here that didn't need to be referred here; that could be managed at a primary or secondary level hospital. I think we have achieved that, to try and limit unnecessary referrals...That has helped a lot. [RH\_3]*

The use of mobile devices such as smartphones and software apps such as the VULA app enables physicians to manage referrals and reduce unnecessary visits to the hospital, thereby reducing the number of patients seen at outpatient clinics. This saves time and cost implications associated with mobility for patients and health care professionals, especially in terms of consultation and communication. Health care professionals can communicate directly, view necessary medical images remotely, and save time on patients' diagnosis without having to arrange for scheduled visits and physical contact.

### **Limitations in Technology-Enabled Work Activities of Health Care Professionals**

The adoption and the continued use of health ICTs are often regarded as complex exercises, especially given the peculiarities of contextual and infrastructural conditions such as the number of patients attended to by the health care professionals, interruptions in health ICTs, and internet connectivity. Subsequently, these factors result in challenges and may inhibit the execution of technology-enabled work activities. The research findings indicate that paper inadequacies, technology downtime, and time inefficiencies are the main challenges experienced by health care professionals. For instance, one of the health care professionals explained that the VULA mobile app negatively disrupts patient consultation:

*During the day it actually interferes and it slows you down massively. Definitely, because you have a lot of patients that you need to see, you need to answer*

*the phone at ER, you need to answer your bleeps and then you also get VULA referrals. [RH\_1]*

Health care professionals also expressed concerns that attending to their phones during physical consultations might be perceived as unprofessional by patients. Similarly, another physician mentioned the following:

*The biggest challenge with VULA app is to be able to find time during patient consultations to also answer to referral doctor's questions; it takes a lot of multitasking. And when disrupted by calls and VULA referrals, it takes much longer to complete a consultation with a patient. [RH\_2]*

Despite the benefits of the VULA mobile app to enable teleconsultation and facilitate communication between health care professionals, there were claims that it disrupted work activities and extended the time taken to complete these activities. A participant expressed a preference for paper-based tools to perform tasks over ICTs because of their impact on job performance in case of imminent failures:

*I prefer paper based for note taking but IT based for outside referrals. The problem with technology is that when there is a problem with it and we need to revert to paper based work it causes issues and delays; it's all good until the ICTs fails. [RH\_5]*

The PACS or ECM downtime impedes workflow in the sense that health care professionals are unable to perform tasks that largely depend on the use of electronic systems. Subsequently, the doctors would revert to a paper-based system to facilitate the progress of their work activities at points of care:

*When the ECM is down then it's a big problem because then you basically can't go on with your work. You can't book a patient for any surgery. If you haven't screened your patients yet; you need to access that information...but then you have to see the patient again. Then it's basically the same as falling back onto paper system [RH\_1]*

*With regards to the PAC system, the negative part to that is not all computers always work. I think that's the biggest challenge, is when electronics don't work. Then it's a massive irritation, if we can't see X-rays and you've got a clinic full with 40 patients. [RH\_4]*

The responses reflect the contextual conditions of multitasking and the number of patients that need the attention of health care professionals at points of care. Regarding infrastructure, the participants suggested a shortage in desktop computers and unreliability in the ones available. Unfortunately, the mobile app being used to manage referrals and facilitate the exchange of patient information can be disruptive and time consuming during the execution of work activities.

The analysis of the findings indicates that technology-enabled work activities executed by health care professionals are influenced by contextual factors and the extent to which health ICTs fit the tasks being performed at points of care. Furthermore, the health ICTs being used at the points of care are associated with unintended consequences that inhibit the work activities of health care professionals during service

delivery. Despite the ensuing inhibitions caused by the unintended consequences experienced during technology-enabled activities of health care professionals, the findings show that there is a continued use of the health ICTs. The findings have been interpreted in the *Discussion* section to clarify the essence of these analyses.

## Discussion

### Principal Findings

In health care settings, information is generated by health care professionals at every point of care; hence, there is a need to consolidate the information trail. Before the introduction of technology in hospital settings, the process of managing information required ample use of paper to keep records [36].

The search for paper-based records takes a lot of time, thereby increasing patient waiting times; paper folders are susceptible to being easily misplaced when transferred to and from clinics or between health care professionals [37]. These are some of the challenges experienced by health care professionals during their work activities at points of care. However, the introduction of health ICTs has automated many tasks, making it easier, faster, and safer for health care professionals to execute their work activities.

Therefore, the analysis of the findings is categorized using the concepts from the double dance of agency model to discuss the effects of technology performativity on the work activities of health care professionals and their unintended consequences on the interplay between the attributes of human agency and technology performativity.

### Effects of Technology Performativity on the Work Activities of Health Care Professionals

The findings show that human agency, lived experiences, contextual conditions, and needs are the underlying drivers of technology performativity. Health ICTs enhance efficiencies associated with tasks relating to consultations, referrals, and treatment plans for health care professionals at points of care. In particular, mHealth ICTs offer a platform for health care professionals to communicate, retrieve, and exchange information in a context where physical distancing is required in order to reduce the spread rate of COVID-19 within the African context.

An improved quality of health care service delivered by doctors and nurses is the desired goal and anticipated outcome of the decision-making process at points of care [1]. Despite the infrastructural glitches, health care professionals expressed their lived experiences on the impacts of health ICTs on their tasks during work activities. Doctors continue to make use of health ICTs based on the presumptions and experiences of their suitability and capabilities in improving the inefficiencies in their work activities in a timely manner. This is often informed by a comparative measure of the past experiences of health care professionals while performing tasks and a desire to improve the efficiency of their work activities. For example, duplication of paper records and the susceptibility of hard copy records to loss or damage from incessant handling are reduced significantly

because of the use of health ICTs. This relates to the studies conducted by Bervell et al [37].

In this study, the authors established that although the intent of technology-enabled work activities is to improve efficiency, the suitability of health ICTs to perform tasks and technology features determines the quality of service delivery outcomes. One of the themes identified from the data analysis is unintended consequences, which have an underlying effect on the efficiency of how hospital information systems facilitate the retrieval of digitized records by doctors. Another example is the reported interruptions during face-to-face consultations between physicians and patients from trauma referral notifications on the physicians' VULA mobile app.

### Unintended Consequences of Technology Performativity on Technology-Enabled Work Activities

The properties of human agency and technology performativity jointly influence the outcomes of work activities [13]. When there is a lack of synergy or overdependence between the attributes of human agency and technology features, it results in unintended consequences. These consequences are more like surprises or occurrences of unplanned outcomes other than desired intentions [38]. The findings indicate that there are differences between the use of health ICTs and the nature of work activities executed by health care professionals. Being conscious and self-aware of the timeous nature of care service provision, health care professionals tend to experience discomfort when health ICTs interrupt the timely completion of their work activities. According to Adeleke et al [39], time constraint is a major inhibiting factor in the use of health ICTs by health care professionals at the points of care. Despite the perceived suitability of the VULA mobile app and the ECM system in reducing unnecessary referrals and facilitating quicker access to patient records, respectively, sometimes these tools increase the workload of doctors and delay the completion of work activities at points of care.

Mobile devices and health apps can facilitate consultation and communication between health care professionals. However, health care professionals felt it was improper to constantly stare at their phones to input a function or to receive an output, such as accessing or retrieving records, while attending to patients. In this case, it is evident that the design functionalities of mHealth ICTs influence how health care professionals execute their work activities. The participants expressed concern about how their patients would interpret their constant interaction with the mobile device. According to Yahya et al [40], some health care professionals are concerned that the use of mHealth ICTs might be misconstrued by their patients during consultations at points of care.

In this research, it is argued that self-awareness is a key mediator that can influence how health care professionals perceive the suitability or discomfort attributed to the use of health ICTs. However, this finding contrasts with the study by Kabanda et al [32], where the authors found that participants were comfortable using their mobile devices during consultations. The inconsistency of results within the same research context further clarifies that the interplay between human agency and technology performativity can be experienced differently and



is not generalizable across clinical settings, especially because of the effects of choice and self-awareness.

Technology abuse is another unintended consequence that may be experienced by health care professionals. In addition, the increased workload of multiple referrals during patient consultation could be attributed to how the VULA mobile app was designed, that is, without adequate consideration of its impact on patient-physician interaction at the points of care. For example, one of the participants stated that “most people are quite negative about it because it gets abused.” The response indicated that the use of the VULA mobile app drew negative feelings because there were little to no restrictions on the extent of its use by referring doctors “but no one really complains.” It is evident that, after a period of time, health care professionals eventually become used to a system that is fit-for-purpose in the course of their work activities. This aligns with the longitudinal study conducted by Vaghefi et al [24] on the continued use of mHealth technologies. Subsequently, health care professionals pay less attention to the few challenges and ultimately make a choice to either adapt and be satisfied or be dissatisfied and eventually discard the implemented health ICTs.

The manner in which health ICTs are used by health care professionals to enable the interaction moments of tasks at points of care is influenced by the capabilities of tools to enhance the productivity of work activities and the knowledge of health care professionals. However, the benefits of health ICTs, including mHealth technologies, to enable communication, retrieval, and exchange of information during work activities of health care professionals may be partially realized, as indicated by Martin et al [41].

Workarounds are examples of desired unintended consequences. Workarounds can be defined as the use of technology other than its intended use [42]. In this paper, a workaround is described as the use of an alternative means to efficiently perform certain tasks effectively and achieving the intended outcome in situations where the initial means of action are perceived as inappropriate. Workarounds establish that human agency attributes ultimately influence perceived technology performativity in the event that a technology is unavailable or is associated with usability challenges.

The authors conclude that during technology-enabled work activities, health care professionals can use tools such as mHealth technologies to perform and coordinate their work actions, particularly to address the issues of timeliness associated with location constraints. The interplay between attributes of human agency and technology performativity influences the acceptance or nonacceptance and use and ultimately transforms the purpose of the work activities into intended outcomes [43]. On the basis of the continued use of health ICTs in clinical settings of hospital H despite challenges experienced by health care professionals, the authors have concluded that there are levels to the interplay between human agency and technology performativity.

## Levels to the Interplay Between Human Agency and Technology Performativity

Despite the unintended consequences experienced by health care professionals, they continued using mHealth apps or devices and hospital information systems for their work activities. For this study, the interplay explained by Rose and Jones [14] is further broken down into levels that are characterized as intermediate interplay and advanced interplay. These 2 levels are determined by the interaction between humans and machines and are the reasons because of which health care professionals continue to use health ICTs for technology-enabled work activities at points of care.

At the intermediate interplay level, health care professionals use health ICTs to enable the tasks of their work activities based on the capabilities of its features at initial interaction. The lived experience of the initial interactions results in a perception of the suitability or discomfort of the technology during work activities [44]. Here, it is argued that health ICTs are fit-for-purpose but not particularly useful because of the contextual conditions of use. Ultimately, health care professionals are likely to discard health ICTs or adopt an alternative technology that is not specifically designed for health-related tasks such as instant messaging through social media apps or revert to using paper.

In the advanced interplay level, health care professionals eventually adapt despite the contextual conditions of use. In this study, health care professionals tended to become more familiar with the use of health ICTs, largely because of their many benefits in contrast to the challenges experienced during and after work activities. Hence, it can be inferred that the continued use of health ICTs indicates that health care professionals are able to negotiate and become satisfied or dissatisfied. According to Cresswell et al [45], sociotechnical systems become complex over time and hence, it is important to understand how technology is eventually normalized by social actors in their context of use. Hence, the benefits of using health ICTs may outweigh the issues that inhibit their seamless use by health care professionals or the system may ultimately be discarded [46]. In these 2 levels of interplay presented by the authors, the lived experiences and cost-benefit analysis of health care professionals during technology-enabled work activities determine the eventual acceptance or nonacceptance of health ICTs.

The authors acknowledge that both humans and technology can make a difference in human-machine interactions. However, the types of health ICTs identified and used in the context of this research do not act intentionally. The technology is designed by humans as part of a solution informed by historical events of adverse lived experiences, perceived expectations, desired outcomes, and the need for humans to exhibit some level of power. Hence, we argue that in health care, agency is ascribed mainly to humans in a human-machine interaction, and technology is viewed as an enabling tool to facilitate the actions of humans or in the interaction moments of tasks.

This study established that the outcome of work activities is largely dependent on how the attributes of human actors necessary to perform the tasks are interleaved with the perceived

capabilities of the means of action. In other words, the interplay between health care professionals and implemented health ICTs is influenced by intentionality, self-awareness, medical practice, and the capabilities of the technology features.

### Limitations and Future Research

The limitation of this qualitative study is that it is subjective and context-based to a tertiary hospital in Cape Town, South Africa. Hence, the findings are not generalizable, but could be relevant for environments with the same contextual factors as Western Cape province, South Africa. The service design approach enabled the strategy used for data collection; however, its fourth phase needs to be executed to contribute toward the richness of the approach. In the future designs of health ICTs by user experience and interaction designers for the sub-Saharan context, factors such as adaptability, workarounds, and infusion should be extensively addressed before the development phase. Other stakeholders such as policy makers, business analysts, and even health care professionals need to periodically evaluate the existing health ICTs to identify the unintended consequences of technology-enabled work activities at points of care to prevent an abrupt discard of the technologies.

### Conclusions and Contribution

In this study, human agency and contextual conditions are the underlying driving agents for technology performativity. Service

design contributed toward making a sense of the findings that health ICTs address the perceived inefficiencies of work activities. Although a change cannot be influenced by the current flow of work activities within the clinical settings, the tasks performed at points of care shape how health ICTs could be designed and improve the lived experiences of health care professionals at points of care during the overall service delivery process. Therefore, the interplay highlighted by Rose and Jones [14] should be expanded to include an intermediate and advanced interplay between human agency and technology performativity.

Designers and implementers of health ICTs need to take into account the information-intensive nature of health care settings; hence, a networked desktop or mobile system that easily facilitates read, write, search, and edit actions on patient records would ensure up-to-date health information at all times. An updated electronic record available to doctors and nurses would improve decision-making and the accuracy of diagnosis during health care service delivery. Thus, this paper contributes to claims on the cost-benefit analysis of automation and the synergy between human agency and technology performativity in health care contexts.

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### Conflicts of Interest

None declared.

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#### Multimedia Appendix 1

Sample of user journeys generated from co-design sessions with physicians and nurses.

[PDF File (Adobe PDF File), 875 KB - [formative\\_v6i1e23236\\_app1.pdf](#) ]

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#### Multimedia Appendix 2

Analysis and coding process of co-design transcripts.

[PDF File (Adobe PDF File), 476 KB - [formative\\_v6i1e23236\\_app2.pdf](#) ]

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## Abbreviations

- AI:** artificial intelligence
- ECM:** enterprise content management
- ICT:** information and communication technology
- IoT:** Internet of Things
- mHealth:** mobile health
- PACS:** picture archiving and communication system

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Review

# Implications and Preventions of Cyberbullying and Social Exclusion in Social Media: Systematic Review

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## Abstract

**Background:** The growth of social networking has created a paradigm in which many forms of personal communication are being replaced by internet communication technologies, such as social media. This has led to social issues, such as cyberbullying. In response, researchers are investigating cyberbullying to determine its implications in various life sectors.

**Objective:** This manuscript reviews the methods, results, and limitations of the current cyberbullying research and discusses the physical and mental repercussions of cyberbullying and social exclusion as well as methods of predicting and counteracting these events. On the basis of the findings, we discuss future research directions.

**Methods:** Using ScienceDirect, ACM Digital Library, and PubMed, 34 research articles were used in this review. A review was conducted using the selected articles with the goal of understanding the current landscape of cyberbullying research.

**Results:** Studies have analyzed correlations between depressive and suicidal ideations in subjects as well as relationships in the social, educational, and financial status of the perpetrators. Studies have explored detection methods for monitoring cyberbullying. Automated detection has yet to become effective and accurate; however, several factors, such as personal background and physical appearance, have been identified to correlate with the likelihood that a person becomes a survivor or perpetrator of web-based cybervictimization. Social support is currently common in recovery efforts but may require diversification for specific applications in web-based incidents.

**Conclusions:** Relations between social status, age, gender, and behaviors have been discovered that offer new insights into the origins and likeliness of cyberbullying events. Rehabilitation from such events is possible; however, automatic detection is not yet a viable solution for prevention of cyberbullying incidents. Effects such as social exclusion and suicidal ideations are closely tied to incidents of cyberbullying and require further study across various social and demographical populations. New studies should be conducted to explore the experiences of survivors and perpetrators and identify causal links. The breadth of research includes demographics from China, Canada, Taiwan, Iran, the United States, and Namibia. Wider ranges of national populations should be considered in future studies for accurate assessments, given global internet communication technology activity. The studies emphasize the need for formal classification terminology. With formal classification, researchers will have a more definite scope, allowing specific research on a single definable topic rather than on general bullying events and symptoms. Of all the studies, 2 used a longitudinal design for their research methodology. The low number of longitudinal studies leaves gaps between causation and correlation, and further research is required to understand the effects of cyberbullying. Research addressing ongoing victimization is required for the various forms of cyberbullying; social support offers the most effective current standard for prevention.

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**KEYWORDS**

cyberbullying; cybervictimization; cyberaggression; bullying; mental health; social isolation; social media; mobile phone

## Introduction

### Background

Internet communication technologies (ICTs) include a wide variety of platforms, ranging from social media, instant messaging, and chat rooms to email [1]; all of these affect our normal modes of communication [2]. The use of ICTs is increasing; meanwhile, negative consequences such as cybervictimization are being overlooked. Cybervictimization, colloquially *cyberbullying*, is a phenomenon proliferating through rising rates of interaction with social media [1]. Cyberbullying can be best defined as “an aggressive, intentional act carried out by a group or individual, using electronic forms of contact, repeatedly over time against a victim who cannot easily defend him or herself” [3]. This could be a distressing message about a victim’s appearance, delivered by a perpetrator over several web-based interactions with the purpose of delivering emotional or mental harm. Cyberaggression is formally defined as the intentional harm delivered by the use of electronic means to a person or group of people irrespective of their age who perceive such as offensive, derogatory, harmful, or unwanted [4]. One example is a mocking tweet regarding someone’s race or ethnicity, sent during a web-based interaction. Cyberaggression is inflicted on any individual and is a description of a singular incident as opposed to being repeated and targeted. Cyberbullying relates a cyberaggression event to a cybervictim, and correlates to a history of abuse where the opposing parties know each other on a personal level [5]. This implication does not hold for general cyberaggression [5]. As we are investigating cyberbullying and not cyberaggressions at large, it is important to recognize this distinction. Discourse surrounding cyberbullying is still new and has only seen consistent studies from 2007 to 2020 [3,5,6]. Researchers from fields such as sociology and psychology, now studying the phenomenon, struggle to classify it concisely because of the various forms it can take and its relation to traditional bullying. Several cyberbullying studies disagree regarding the overlap of cyberbullying and traditional bullying and use separate definitions to discern them from one another [5]. The tension stems from the assertion that cyberbullying is more soundly defined within the purview of cyberaggression [7]. Cyberbullying narrows the classification of instances of cyber-based attacks to those done over length of time; however, many in the field believe this is detrimental to the identification of events that may happen only once or between strangers [7]. In this review, we define cyberbullying and cyberaggression by their formal definitions and examine cyberbullying events on multiple occurrences.

Cybervictimization has a wide reach given the interconnectivity of each user [8]. Youth (ie, aged 11-18 years) are especially susceptible to this form of victimization [8] given the influence of peer interactions on social development in early life and conventional [9] standards. Several cases of suicide and suicidality and the presence of suicidal ideations and behaviors [10] have been found to have direct correlations to cyberbullying

[11]. There are correlations between cyberbullying and mental health consequences, including depressive symptoms, particularly among youth and student populations [12]. Issues with mental health and social strain are also accumulating among college students and young adults, especially those in the age group of 18 to 24 years, who have screened 19% positivity for experiences of psychological distress because of cyberbullying incidents [10].

Social exclusion is a phenomenon that occurs when someone is forcibly or voluntarily separated from groups with whom they perform social interaction on a daily basis [13]. In clinical studies, social exclusion is associated with depressive symptoms and an increased risk of mortality [14]. It is possible that there are relations between the domains of cyberbullying, internet communications, and social exclusion, given an attack on a cybervictim being received through their preferred avenue of social interaction [1]. The likelihood of cyberbullying events among youth and adolescents suggests a considerable risk of social isolation to these populations [1]. Correlations between social isolation and workplace bullying have been drawn in adult studies [15]. These relations should be explored in school and in web-based environments so that a crisis among young people can be identified and prevented.

### Objectives

We review the current research in cyberbullying and mental health, its social outcomes, predictive factors, and novel approaches to management and suppression. We look to contribute a contextual understanding of cyberbullying unbound in the domain, make connections to social isolation and other sociological and psychological effects, and investigate methods to prevent the overall manifestation of these events. This analysis sheds light on current measures taken and future opportunities to combat the prevent the spread of cybervictimization.

## Methods

### Search Strategy

The primary electronic databases that were used in the review are Elsevier, ScienceDirect, PubMed, and ACM Digital Library. Each of these libraries is a globally recognized and reputable medical or scientific database, and they are ubiquitously used in medical and scientific research. Indexing terms for ScienceDirect and ACM Digital Library were used and were presented through the search as *social isolation* OR *social exclusion* OR *social alienation* AND *cyberbullying* AND *social media*. MeSH terms were used for PubMed and were presented through search as *social isolation* OR *social exclusion* OR *social alienation* AND *cyberbullying* AND *social media*. These searches were conducted in accordance with the 2009 Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines. These searches were completed on February 23, 2020.



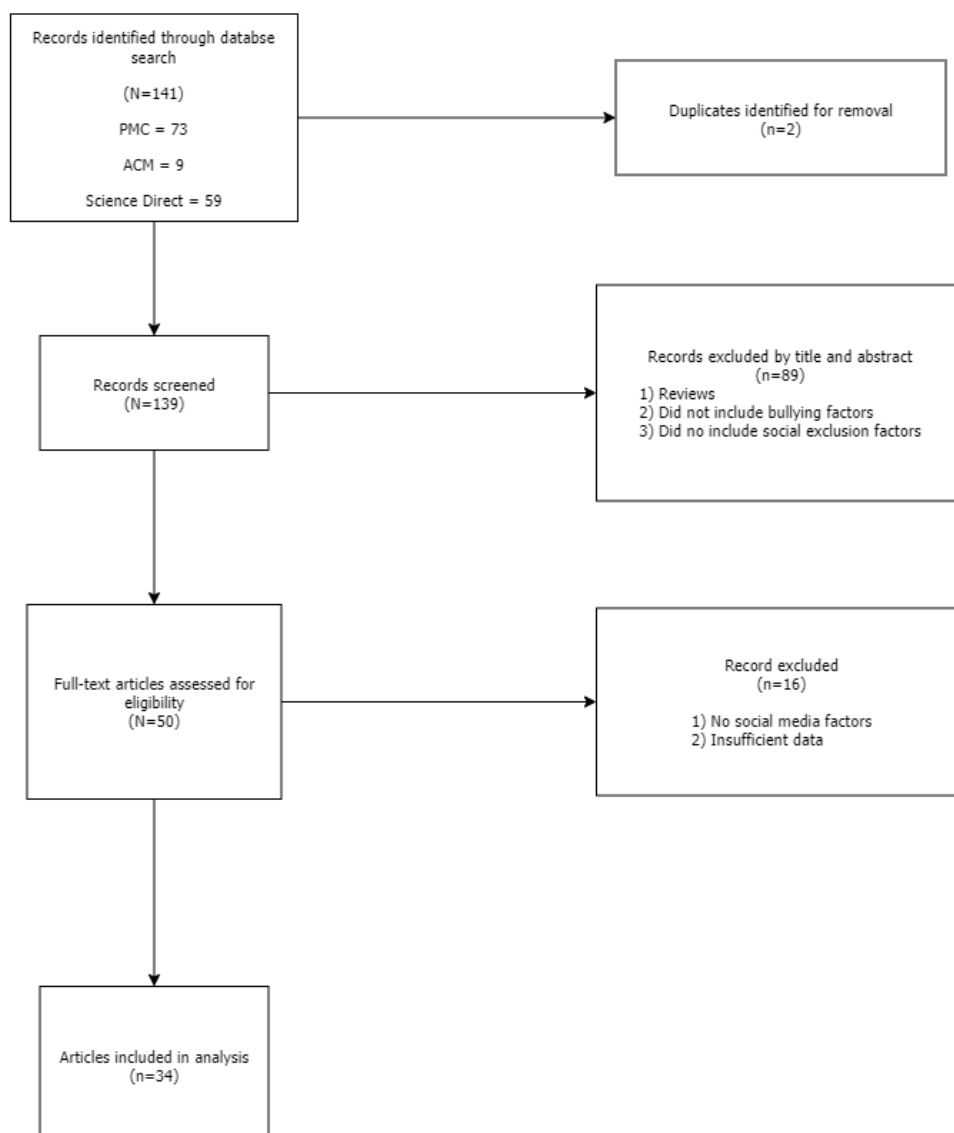
## Study Screening

This study's scope covers cyberbullying factors in their relations to psychological and sociological disorders, social media, and intervening technologies. For these aims, a noted definition of cybervictimization sourced from an article by Smith et al [3] describes it as "an aggressive, intentional act carried out by a group or individual, using electronic forms of contact, repeatedly over time against a victim who cannot easily defend him or herself."

The criteria for inclusion of the articles were defined by certain expectations. First, the articles were all original research studies that did not involve secondary reviews of underlying study categories. It was imperative that all studies involve primary data for accurate synthesis of the reviewed information. Second, all articles were required to include some form of cyberbullying factors and the effects they incur. Several articles only involved information about social exclusion or only information about

social media and were excluded because they were unrelated to the primary topic. Conversely, it was imperative that all articles include social exclusion factors, given its relation to cyberbullying. Social exclusion factors relate specifically to the phenomena of social distance in reaction to a negative social event. The first screening required all articles to be nonreview, on the topic of bullying, and with factors relating to social exclusion. The articles were curated under these constraints and then screened further for 2 additional metrics. In the second screening, articles were excluded if they did not have significant social media factors, even if the included references to cyberbullying and social isolation, given that the research explicitly focuses on the sociological implications. Finally, the full-text screening involved a complete reading of the articles to determine the relevance of their findings. All records with insufficient information or data, such that they did not provide relevant or citable information, were excluded. The full screening is displayed in [Figure 1](#).

**Figure 1.** Screening flowchart.



## Results

### Landscape of Cyberbullying Research

The research surveyed from 2011 to 2020 focuses on the psychological effects of the phenomenon, with 10 of the 34 articles focusing on factors such as suicidal ideations, social agency, and depression [1,4,11,13,16-21]. Automated detection studies are studies that dealt with automated identification of cyberbullying events; this takes place through processing of text from logged chat room conversations [22]. A total of 3 articles dealt with methods of automated detection. Text filtering was a common strategy, using machine learning to perform sentiment analysis. Risk factor studies focus on characteristics that put someone at risk of cyberaggression [23]. Furthermore, 5 articles dealt with risk factors, such as age, oversharing tendencies, financial disposition, educational background, social media activity, and social status [1,23-26]. Predictive factors are behaviors that correlate with involvement in cyberbullying or cybervictimization, and 4 articles dealt with predictive factors of cybervictimization [17,24,27,28]. Predictive factors included parental status, access to goods, academic standings, and

personal identity. Several articles focused on relationships between cyberbullying and traditional bullying, demographics, motivations, and information security. These articles provided information regarding the similarities and differences of web-based and in-person behavior and how they affect attitude and perception of events.

The articles dealt with several different ICT platforms, including Facebook, Twitter, Instagram, Tumblr, and many others. Articles that used a direct social media source aimed to discover behaviors and trends that could be used to map potential victims and perpetrators to quantifiable decisions and habits. Facebook and Twitter were the most common platforms used by researchers [29].

The research objectives are displayed in Table 1. The widest range of articles were related to psychological effects. These effects are often the focal point of research in cyberbullying. Predictive factors, risk factors, and demographic factors also have a substantial presence in the body of research. There is a smaller emphasis on technological applications in security awareness and automation throughout the research.

**Table 1.** Research objectives investigating cyberbullying.

Research objective	Study
Victimization risk factors	[1,23-26]
Perpetration predictive factors	[17,24,27,28]
Psychological effects	[1,4,11,13,16-21]
Security awareness	[1,28,30]
Automated detection	[22,31,32]
Cyberbullying demographics	[1,9,22,23,25,33-35]
Cyberbullying versus in-person bullying	[19,36]

### Forms of Cyberbullying

Limitations relating to the establishment of concrete definitions are an issue in cyberbullying research; however, a new body of research, which began in 2014, created new definitions for cybervictimization and differentiated it from traditional bullying [35]. Cyberbullying events can occur in many ways [34]. The most prominent methods are flaming, when a person sends angry or vulgar messages; harassment, when there is a consistent stream of offensive messages; denigration, when damaging messages about the target are sent to other associates of the target; masquerading, when the victim’s identity is stolen to imitate harmful or damaging messages produced by another entity; trickery, when the victim is deceived into providing personal information; exclusion, when a victim is ostracized from a social group [34]; stalking, when a person hacks or obtains personal information from a victim’s social media profile to determine their location and whereabouts; and blackmailing, when anonymous emails, telephone calls, and private messages are sent to a person to solicit money or actions from the victim [34].

### Demographics

The demographics in this review included children, adults, both genders, and various social groups. People of any age or status can be the subject of a cyberbullying incident [33]. Incidents present threats in several circles of interpersonal relations. Employed adults experience work position as a risk factor; 40% of people cyberbullied in the workplace are in some supervisory position [33]. Furthermore, 10% of working adults are survivors of cyberbullying [33]; however, adolescents between the ages of 13 and 21 years are more vulnerable to peer victimization [22]. Internet anonymity and the ability to interact with anyone anywhere pose severe risks [22]. Adolescents are using technological resources at the record rates [25]. Smartphones are the most common ICTs used by adolescents and can be accessed from any location with cellular service [1]. Large percentages of females are exposed to threatening messages (50%), stalkers (32%), requests for sexual information (27%), requests for self-sexual images (20%), and cyberbullying (17%) [1]. Adolescent males who had access to social media through ICTs became exposed to threatening messages (26%), requests for sexual information (15%), cyberbullying (14%), stalkers (14%), and requests for self-sexual images (10%) after use [1]. The variability in risks, such as substance abuse, self-harm,

cybervictimization, and depressive symptoms, caused by these forms of exposure on various age groups is still new in academic study [1].

Studies suggest adolescent females are victimized at the highest rates [35]. They are more at risk in their teenage years than males, facing cyberbullying rates of 18% at the age of 13, 15% at 14, 24% at 15, and 21% at 16 [1]. Studies among college students showed that 44% of the female students reported experiencing some form of cybervictimization [35]. Cyberbullying is experienced by both males and females, yet

there are many differences in the frequency of victimization that requires investigation.

University students reported that 50% of the cyberbullying they experienced was from classmates, 57% was from outside sources, and 43% was from unrelated individuals [34]. Cyberbullying has become a commonplace in higher education, with half of the college age students encountering it in some form. The investigated demographics are listed in Table 2.

Age, gender, and social status provided the most contextual information in the research. These factors may imply trends in cyberbullying.

**Table 2.** Demographics investigated by researchers.

Investigated demographics	Study
Gender	[1,35]
Social status	[33,34]
Age	[1,9,22,23,25,33]

## Causes

Predictive factors indicate where cyberbullying may occur. A factor may provide information about the perpetrator or the survivor. The literature identifies several factors that range from visual appearance to personal history. Studies have shown [4,23,24,37-39] several initiators of cyberbullying. The leading factor among cyberbullying perpetrators is the presence of normative thinking, peer pressure, and involvement in normatively aggressive peer groups [37]. The peer group is often the most influential group in a person's social experience, especially among youth [37]. Low self-control and difficulty discerning moral identity are factors that allow peer pressure to inform a person's actions [4]. When a social event is normalized in the peer group, the subject views the interaction as agreeable even when it contradicts pre-existing moral values [37].

An individual's perspective on their performance affects their decisions, this is known as self-concept [19]. Self-concept is formally defined as "the relatively stable schemata of oneself that are generalized to the extent that they refer to an individual's view of him- or herself across different situations" [19]. Social success is a salient indicator of happiness and a driver of behaviors [19]. In a study on psychological outcomes in social media interactions, a positive correlation was found between high self-concept and social success in peer groups [19]. An individual's view of themselves is affected by environmental factors, such as household income, parental marriage status, gender, and their access to social resources and community [18,19,26]. In a study in Iran by Kabiri et al [4], poor performance in school and growing up in a low-income household also had positive correlations with perpetration likelihoods [4]. Another study of male boarding students corroborated the correlation of low-income students and cyberbullying [23]. These students are more likely to be

perpetrators and have a higher vulnerability to peer victimization [24], given that early age interactions and social development may be limited when certain activities are prevented by a payment gap. Weak emotional bonds with parents and high discipline levels are common in perpetrators [26]. Both genders present similar likelihoods of becoming cyberaggressors [38].

Trends in the studies show the social behaviors of participants who reported receiving negative remarks, unwanted sexual suggestions or images, negativity from peers, humiliating targeted posts or had their accounts hacked [28]. The first major identifier was the tendency to post indiscreet information and content on social platforms without security [28]. This factor is positively associated with victimization likelihood and accounts for 18% variance in data [28]. There is a correlation between security and victimization incidents. Often, those who are victimized lack security on their social media profiles or are not equipped with the skills to implement security on their own [28]. A study by Saridakis et al [30] demonstrated that higher awareness of security risks and an ability to control generated information actively creates safer and more user-friendly environments, critical in preventing the likelihood of victimizing events.

Another contributing factor is facial features. A study on visual perception found that survivors of social ostracization (ie, exclusion by general consent from social acceptance of a group) are likely to be those whose faces are perceived as being incompetent and *cold* (unfriendly) [39].

Causes of cybervictimization events include factors of the environment, individual behavior, and ideations of the self and the environment. Several initiators complicate prediction and may need to be addressed individually.

A detailed list of studies related to causes of perpetration and victimization is shown in Table 3.

**Table 3.** Causes of cyberbullying perpetration and victimization events.

Causes	Study
Social pressures: peer grouping, social success	[4,19,37]
Web-based behavior: security awareness, social tendencies	[28,30]
Self-concept: identity development, social status, educational status	[19,37]
Public perception: perceived appearance, nonverbal interactions	[39]
Familial issues: marital status, home environment, parental relationships	[4,23,26]

## Effects of Cyberbullying

Effects are a crucial portion of the research because they contain results related to suicide and depression. Survivors of cybervictimization present high psychological distress, depression, and substance abuse [21]. This phenomenon is distinct from traditional bullying in its psychological effects

**Table 4.** Negative psychological outcomes of survivors of cyberbullying.

Negative psychological effects	Study
Social exclusion	[13,18,19,32,39]
Self-harm	[1,10,21]
Depressive symptoms	[11,12,17,28,40,41]
Substance abuse	[10,17,21,26,40]

Social isolation, the experience of a person who has been ostracized from a social group, is a common effect of cybervictimization, as exclusion is a main tactic used in web-based cyberbullying [13]. When a person is ostracized, it is common for them to lose a sense of agency because of removal from the group that facilitated their social mobility [13]. Social agency is the feeling of control over one's actions and the effects of those actions [13]. In some cases, bullies may use others within a social circle to isolate a person without directly involving themselves [32]. Facial features that fail to evoke feelings of empathy from viewers play a role in the likelihood of social exclusion [39]. High amounts of supplementary web-based communication have been closely associated with feelings of social isolation [19]. When a person has been socially ostracized, they find it harder to rally social support, as being isolated may corrode most of their social connections [18]. Still, it is uncommon for cyberbullying to spill over into real-world interactions. A study by Pabian et al [36] found cases often stay exclusively on the internet or offline.

Disadvantaged adolescents are often involved with the misuse of ICTs and become tangentially exposed to self-harm, substance abuse, and suicidal ideations [21]. These youth tend to develop habits of misusing personal data and neglecting social relationships and schoolwork, leading to sexual abuse, blackmail, threats, and, in some cases, the incitation of violence [1]. Events such as social exclusion, self-harm, substance abuse, and depressive symptoms were emphasized heavily in the literature.

## Methods of Prevention and Amelioration

There is limited research on approaches for deterring or recovering from cybervictimization. Social support is a

[40]. Stress posting and oversharing are behaviors that often have a heavy correlation with cyberbullying [41]. These behaviors also cause the individual to become more likely to be targeted by a cyberbully [41] and suggest the possibility of cyclical processes. The scope of negative psychological outcomes of cyberbullying is summarized in Table 4.

generalized approach for social issues brought into the domain of cybervictimization. New research on technical prevention is scarce and have limited effectiveness. We found 3 studies that investigated potential methods for cyberbullying detection [22,31,42]. A study on the social networking site ASKfm provides research on a machine learning support vector machine classifier that detects instances of aggressive communication [22]. Experiments showed that 64% was the highest accuracy achieved by the algorithm [22]. A study by Ptaszynski et al [31] in 2016 found that natural language processing tested a 30% drop in performance over just a year of testing.

Cybervictimization incidents are embarrassing events, which can cause repression of experiences and discourage social support requests [43]. Social support is the tangible and intangible assistance from friends, partners, family members, and others [11]. Members in a community encourage and affirm an individual to stabilize their mental health and improve their self-concept [11]. Social support can occur on the internet or in-person. Web-based intervention is useful in isolation as it benefits those without in-person social support systems [11]. Assistance through social support occurs before or after an individual encounters cyberaggression [24]. Social support has produced reliable results in ameliorating cybervictimization effects [24]. Adolescents who perceived high levels of social support from family members were less likely to experience cyberbullying [24]. Social support actively reduces the effects of ongoing cyberbullying [11]. On average, males required more social support in these instances than females [24]. Multiple intersections of gender in the literature may prove to be a salient factor for future research. There were articles on investigating methods of prevention [22,31,42] and on investigating amelioration [22,31,42].



## Research Methods of Current Studies

We identified 4 research methods: exploratory, experimental, longitudinal, and cross-sectional. For this review, exploratory design is defined as research conducted in domains with little or no previous study. These studies are often foundational for future research and promote familiarity with the scope of the research. Experimental design is defined as an approach where the researcher has control of all the variables being manipulated and observed. The focus of these studies is accurately predicting and modeling an outcome based on a hypothesis. Longitudinal design is defined as a study that takes place with a recurring sample over a fixed length of time. Longitudinal studies focus on changes and patterns that develop over long time frames.

Cross-sectional design does not rely on time and focuses on existing differences between sample members for one-time data collection. Cross-sectional studies were the most common, given quick access to information through population surveys. The study designs are displayed in [Table 5](#).

There are 2 types of data analysis in the studies: qualitative and quantitative analyses. Qualitative analysis is defined as descriptions of specific situations; for example, the use of interviews, observations, and documents to describe things. Quantitative analysis is defined as data that are represented in numerical form, such as frequencies and averages: these are measurements. In this study, quantitative analysis was the most prominent. The analysis types by article are listed in [Table 6](#).

**Table 5.** Designs of the reviewed studies.

Design	Study
Cross-sectional	[1,4,11,12,18,19,23,25-28,30,34,35,37,38,41,42,44,45]
Experimental	[13,16,20,31,32,43]
Longitudinal	[21,40]
Exploratory	[22,24,36,39]

**Table 6.** Methods of analysis in the reviewed studies.

Data type	Study
Quantitative analysis	[1,10-12,16,18-21,23-26,28,30-32,34,35,37-41,43,45]
Qualitative analysis	[4,16,22,27,36,42]

Throughout the review, important factors across the articles were determined. [Multimedia Appendix 1](#) [1,4,10-13,16,18-28,31-44] summarizes salient information relating to the research processes used in each study. The author's findings and limitations are summarized for reference. Methods for the deployment of individual studies were recorded as well as the target age demographics. Information relevant to the scope of the review discovered was recorded under social media factors.

## Discussion

### Principal Findings

Our review examines current articles relating to cyberbullying and identifies trends in perpetration and victimization. This contributes to the discussion of cyberbullying prevention approaches given the lack of sufficient technologies to censor it from its victims, likely perpetrators and victims, and consequences of their occurrence. The results provide predictive information relating to age, social status, and gender as well as information on types of cyberbullying, where they occur, and their effects.

We found various forms of cyberbullying in the literature that carry specific psychological effects. Gaps in research design limit the understanding of these events. Cyberbullying incidents carry serious mental health effects for victims leading to psychological disorders and suicidal ideations. New studies have shown that cyberbullying leads to real-world decisions, such as self-harm, abuse, and substance abuse [1,6,10]. Our

review discerned information about the types of people and behaviors associated with cyberbullying victimization and perpetration. Most of those who are affected are adolescents and college students as well as children. Cyberbullying perpetration varies by age, social class, family life, and academic standing. The resources a person has in their community also affect the way someone can cope with being victimized. Cyberbullying is preventable and mitigatable. The most successful form of prevention of cyberbullying is robust social support systems, as technology cannot provide solid methods for counteraction in real time.

There is a lack in information on cybervictimization perpetrators because of the self-report nature of most surveys [23]. First, many involved in cyberaggression and victimization refuse to participate in studies even when anonymity is ensured by the facilitators [23]. Second, a wide margin of the survey-based studies used cross-sectional methods making it difficult to discern causation of the discovered effects [2,10,21,23,24,26,27,38]. It is not possible to make concrete causal links to behaviors without a long-term process [34]. Of the studies that used longitudinal methods, causal links, such as the direct relation to victimization and substance abuse, were discovered [21]. Third, given the emergent status of cybervictimization, there are various discoveries throughout the literature that reveal new factors not previously associated with cybervictimization that have value in its scope [33,39]. The impact of technologies on social relationships is likely an important factor relating to risk factors [33]. Fourth, there are significant limitations on the basis of demographics surveyed

in many of the cross-sectional studies [18,42,46]. Cybervictimization is closely linked with social habits that may vary across different countries and in different social spheres [12,19,28,30,37,41,42]. Most of the literature focuses on participants above the age of 17; however, there are several indications that it may become rampant in children and teenage social spheres [1,12,17,23]. Trends in access to technology allow vulnerable age groups to access ICTs [1]. Research should focus on these phenomena using longitudinal design to interpret the unique issues in child cyberbullying. Finally, studies that included text monitoring systems did not experience acceptable success rates within their testing periods [22,32,42]. High rates of accuracy are required for filtering methods to be efficient; among the studies, 65% accuracy was the highest rate produced given the limitations in syntactic nuance [22]. Syntactic analysis of aggressive interactions is difficult to discern from healthy interactions given disparate standards of communication across web-based platforms [22]. Research on language in insular internet communities should be investigated to expand understandings of web-based communication.

### Forms of Cyberbullying

Among the types of cyberbullying (flaming, harassment, denigration, masquerading, trickery, exclusion, stalking, and blackmailing), some give rise to dangerous effects, such as social isolation and suicidal ideations. Information on the frequency of the various types of cyberbullying events should be investigated to determine the implications of each form. Research should be driven on the forms that have the highest correlation to suicidality and depressive symptoms. Behaviors that lead to physical harm and death require the quickest responses.

### Demographics

Recent reviews of cyberbullying literature lack detailed information on salient factors in predicting and preventing its occurrence in youth and adults. Given that cyberbullying is beginning to be seen in places such as elementary schools, with as high as 85% rates of web-based messaging use in preteen populations, research is crucial to assure the mental health of younger students. Adults are less vulnerable; yet, more research is required to fully understand the complex relations in the workplace surrounding cybervictimization [23]. Gender may play a role in the likelihood of victimization, as females see higher rates of exposure to cyberbullying [1,35]. Females receive more consistent support than males [11]. Peer groups and setting plays a large role in determining if someone may cyberbully or be victimized. Developing children are exposed to fluctuations of these dimensions of their social experience before understanding the complexities of social interactions [9]. Counseling resources are effective in handling distress in cyberbullying event. Those who are likely to be victimized share information at high frequencies on social media accounts, have high engagement levels with social media platforms, and have very little understanding of the importance of personal information security [23,28,30]. This emphasizes the need for research on young children with access to ICTs.

### Negative Mental Health Outcomes

Cybervictimization can result in negative mental health outcomes, including depressive symptoms, suicidal ideations, and substance abuse, which are prevalent for young adults and adolescents between the ages of 15 and 23 [10]. These victimization events cause depression and can lead to the deterioration of self-concept and academic performance of students. Social exclusion, a process where individuals are excluded from their social circles, can cause them to lose their perceived agency and expediate other negative mental processes [13]. This can result in unhappiness that drives victims to depend on web-based interactions for social experience [12]. The dangers as well as mental abuse, sexual abuse, and drug use are even more of a threat to younger victims as they will have less utility to navigate social complexities than their older counterparts [1]. This is problematic in a time when intentional studies prove that victimization events on occasion escalate to face-to-face interactions and altercations [1,8].

### Effective Cyberbullying Prevention

The effects of cyberbullying can be ameliorated by social support [11]. Web-based social support is effective for those who lack strong social connections [11]. College students and working age adults who are away from family environments for work or school could benefit from these web-based systems. Children and adolescents whose families are present in day-to-day life benefit more from in-person social support intervention, where development of communication and support practices occur through pre-existing relationships. One challenge for social support outreach is that social ostracization can cause victims to lose their sense of agency and steer away from forms of social support [24]. Negative feelings associated with cyberbullying can cause victims to feel incapable of expressing their experiences and suppress them [43]. During these events outreach can only be initiated if the victim is willing to divulge information about the instance. Given the volatility of events after initiation and the tendency for victims to become isolated, preventive measures are key in protecting the mental stability of the victim [13].

The current methods of automatic detection [22,31] struggle with nuance in web-based communications. Ptaszynski et al [31] extracted phrases and categorized them by harmfulness, based on seed words detected in specific phrases. This study used syntactic positioning of words to determine harmfulness within the messages [31]. This approach achieved up to 90% accuracy but dropped in performance because of the limitations in further data extraction and issues categorizing nonharmful phrases [31]. Future models should continue optimization and include nonharmful entries and neutral phrases. Van Hee et al [22] used ASKfm training data sets for phrase annotation with the objective of classifying the role of the participants of the cyberbullying event and the type of cyberbullying that occurred. This approach achieved up to 64% accuracy but lacked context for concise classification of cyberbullying types and could not accurately determine participant roles [22]. A new model that detects sentiments of the victim, rather than incitement from the perpetrator should be studied for more accurate determination of cyberaggression [22]. The language of different

social groups can take many forms in web-based discourse and can range a wide spectrum of literal and coded speech that is rarely clear cut for unexperienced readers. The model should identify speech patterns on the basis of a sizable history of interaction to make accurate predictions rather than simply classifying based on detected words and phrases.

Early intervention is a potential approach for prevention. Research should be headed to investigate the effects of poverty, social stressors, parent marital status, and environment on internet behaviors and tendencies [4,37]. Cyberbullying can be combated by intervention, with different methods for web-based spaces. Given additional data, victim prevention and treatment can be improved. Research on how cyberbullying effects specific geographic regions, ethnic groups, and age ranges [1,18,21,23] should also be continued; these factors may often determine the psychological outcomes of the victim. New research should offer new perspectives for preventing the proliferation of cyberbullying and social isolation.

There are many technologies that are in development today that could be beneficial if applied to the study and prevention of cyberbullying [22,31,32,39]. Natural language processing is widely studied today and can be the basis for understanding and preventing cyberbullying [32,42]. Methods of recovery are also being studied through social support programs [24]. Recovery efforts are common for general depression and anxiety and should be improved to focus on issues specifically related to cyberbullying. An example of this is social support programs that promote emotional health [11]. Similarly, a method of deployment of social support programs to isolated individuals using technology should be further investigated to provide for the event of social isolation caused by cyberbullying

### Limitations

The review was limited to 3 specific databases, therefore information about surveys and other research studies on other major and minor databases is excluded from this review. This narrows the scope of information available for consideration in the review to the largest and most beneficial database but may omit potentially useful granular data. The search did not include any articles that lacked information specific to cyberbullying, this means that information pertaining to more general bullying studies that proved pertinent was included. Articles on young children were limited in data about social phenomena

influencing behaviors relating to ICTs, making it more difficult to assess the relationship between young children and cyberbullying trends. More longitudinal studies would assist in the understanding of perpetrators and the relations of victim likelihood within adult and child populations [26]. In future research, longitudinal studies are required [26] for tracking cyberbullying victims and perpetrators to support a comprehensive evaluation of their behaviors and outcomes.

### Conclusions

Cyberbullying is a newly emerging phenomenon that has proliferated through the global rise of ICTs that began to converge internationally between 2000 and 2008 [2]. Previous reviews have highlighted the severity of the phenomenon [6,47,48], yet do not address solutions combating the rapid advance of cybervictimization in the social media era. To confront cybervictimization in the social media era, reevaluation of factors in the scope of the current research and longer-term longitudinal studies for causal links to be ascertained regarding suicidal or depressive symptoms is required. A larger emphasis on demographic groups should be taken to make clear determinations about how cyberbullying effects people of varying age, race, gender, and economic class. Ho et al [2] noted a wide range of ICT activity across resource-limited and transitional countries; however, few countries have been explicitly studied. Future research should be carried out in more geographic locations, as it requires holistic representation of disparate racial and gender populations. Relations between cyberbullying and predictive factors, such as low socioeconomic status, gender, and the presence of divorce, were identified in addition to studies drawing associations between cybervictimization and mental health outcomes, such as depressive and suicidal ideations. Ideations have been shown to lead to lower academic performance, retaliatory action, and suicide. Detection is a relevant method of counteracting the effects of cyberbullying on youth and adult populations and needs consistent research to keep pace with the rate of ICT growth. Detecting instances of cyberaggression is a challenging process given the nuances of web-based communication and the self-report nature of events [12]. Discovery of ongoing victimization incidents is necessary to reach current victims of cyberbullying, while predictive factors and preventive measures are required to halt future growth.

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### Conflicts of Interest

None declared.

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Multimedia Appendix 1

Summary of individual studies.

[[DOCX File, 30 KB - formative\\_v6i1e30286\\_app1.docx](#) ]

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**Abbreviations**

**ICT:** internet communication technology

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Original Paper

# Exploring the Experiences of Family Caregivers of Children With Special Health Care Needs to Inform the Design of Digital Health Systems: Formative Qualitative Study

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## Abstract

**Background:** Family caregivers of children with special health care needs (CSHCN) are responsible for managing and communicating information regarding their child's health in their homes. Although family caregivers currently capture information through nondigital methods, digital health care applications are a promising solution for supporting the standardization of information management in complex home care across their child's health care team. However, family caregivers continue to use paper-based methods where the adoption of digital health care tools is low. With the rise in home care for children with complex health care needs, it is important to understand the caregiving work domain to inform the design of technologies that support child safety in the home.

**Objective:** The aim of this study is to explore how family caregivers navigate information management and communication in complex home care for CSHCN.

**Methods:** This research is part of a broader study to explore caregivers' perspectives on integrating and designing digital health care tools for complex home care. The broader study included interviews and surveys about designing a voice user interface to support home care. This formative study explored semistructured interview data with family caregivers of CSHCN about their home care situations. Inductive thematic analysis was used to analyze the information management and communication processes.

**Results:** We collected data from 7 family caregivers in North America and identified 5 themes. First, family caregivers were *continuously learning to provide care*. They were also *updating the caregiver team* on their child's status and *teaching caregivers about their care situation*. As caregiving teams grew, they found themselves working on *communicating with their children's educators*. Beyond the scope of managing their child's health information, family caregivers also *navigated bureaucratic processes* for their child's home care.

**Conclusions:** Family caregivers' experiences of caring for CSHCN differ contextually and evolve as their child's condition changes and they grow toward adulthood. Family caregivers recorded information using paper-based tools, which did not sufficiently support information management. They also experienced significant pressure in summarizing information and coordinating 2-way communication about the details of their child's health with caregivers. The design of digital health care systems and tools for complex home care may improve care coordination if they provide an intuitive method for information interaction and significant utility by delivering situation-specific insights and adapting to unique and dynamic home care environments. Although these findings provide a foundational understanding, there is an opportunity for further research to generalize the findings.

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**KEYWORDS**

children; caregiver; digital health; home care; qualitative research; technology

## Introduction

### Background

Caring for children with special health care needs (CSHCN) in a home environment involves several complex processes, significant use of health care services, dependence on medical technology, and increased responsibilities for sharing information by family caregivers [1]. Mapping the interconnections for the most complex CSHCN reveals multilayer interactions and operations between several systems and subsystems of the health care system, all of which encompass the family caregiver and their child. These systems include but are not limited to the child's medical teams, physical and psychological development teams, diagnostics teams, educational teams, and other medical support [1].

Home care is considered an ideal environment for CSHCN [1,2]. In hospitals, the risk of errors and adverse events is significant for children with complex health needs who require support through medical technology, enteral feeding, complex medication regimens, and mental health services [2]. However, the available technologies, services, and policies designed to assist family caregivers in coordinating care in a child's home do not currently meet their needs [1,3]. Nondigital documentation methods that caregivers use create increasing amounts of physical health data in the home, potentially leading to errors, adverse events, and rehospitalizations because of the communication challenges and information management limitations associated with manual record keeping [4].

Although the literature identifies a need for developing electronic health records (EHRs) to organize, integrate, and communicate health information in complex home care [1], the development of EHRs remains a fundamental challenge for complex home care [5-10]. Paper-based records continue to be used as there are no substantial digital technologies available that are flexible, reliable, and trusted [11-13]. In the context of interoperability in health care, the goal is to *provide information where and when it is required* [12]. However, when billions of documents are still being created on paper, it becomes challenging to collaborate in real time, find information, and analyze and understand its meaning [12].

Personal EHR applications and web-based portals connected to hospitals or home care agencies can improve the organization and communication of health information across caregiver teams [14]. Unfortunately, caregiver engagement with these technologies is low. The annual adoption rates for web-based portals range from 5% to 12.4% [14,15]. The digital health care technologies currently being studied do not encompass caregivers' complete information needs [16-18]. In addition, interacting with these tools is often associated with challenges that involve visual hierarchies of information, increasing the interaction burden [11]. With limited engagement in emerging digital health care tools to support home care, caregivers do not experience the potential benefits of improving home-based health management and communication [14,19].

### Study Objective

Understanding the complex work domain of family caregivers who provide home care services is critically important, given the increasing life spans of CSHCN and the growing prevalence of home care [20,21]. Few studies have investigated the potential engagement and impact of novel home care technologies for supporting caregivers. There is also a limited evidence-based understanding of how family caregivers navigate information and develop their management and communication processes. To support the design and refinement of digital health tools that can be integrated to intentionally facilitate better communication, improve the sharing of health-focused information, and ultimately contribute to improving home care, this study captures the diverse experiences and perspectives of family caregivers of CSHCN.

## Methods

### Study Design

This research is part of a broader mixed methods study on the design of digital technology to support caregivers in complex home care, which involves interviews, surveys, and a modified Wizard-of-Oz interaction [22]. In the modified Wizard-of-Oz interaction, participants listened to and provided their perspectives on prerecorded audio examples of someone interacting with different designs of a voice user interface in a home care context. The focus of this paper is to address the gap in understanding the experiences of family caregivers of CSHCN in managing and communicating health information in their homes. We conducted qualitative, semistructured interviews guided by the principles of storytelling in narrative medicine to enhance knowledge and used inductive thematic analysis to analyze the interview data [23,24].

This study was conducted remotely in North America. This research received ethics approval from the University of Waterloo research ethics committee.

### Eligibility Criteria

Eligible participants were aged  $\geq 18$  years and were family caregivers for CSHCN in their homes in North America. In the context of this study, CSHCN included children who had any combination of the following: chronic conditions, mental health issues, medication-related problems, and social vulnerability. A family caregiver was anyone who provided or coordinated care for CSHCN; they assisted the child with medication, feeding, medical treatments, medical technology use, or other health-related tasks in the home.

### Recruitment

COVID-19 restrictions led to fully web-based recruitment between June 28, 2020, and September 25, 2020. We contacted hospitals and home health care and caregiver support agencies or groups via email and social media platforms such as Twitter and Facebook, and then snowball sampling was performed on existing contacts. Study participants were sent a thank you letter



for their participation after the study, and no remuneration was given for participation.

### Data Collection

A total of 2 researchers (RT and KM) conducted the interviews. Microsoft Teams was used to record the interviews, and only audio recordings were used for transcription. One of the interviewing researchers was an experienced interviewer and qualitative researcher (KM), and the other was an MASc candidate in systems design engineering with prior experience in conducting interviews (RT). After each interview, field notes were completed. There were 2 parts to this exploratory qualitative study: caregiver demographics and caregiver work domain. Participants were interviewed over video from their homes, where they provided care for their children. The first part of the interview focused on understanding the caregivers' backgrounds and their home care situations. The second part of the interview captured the caregivers' work domain to manage and communicate information and care responsibilities in their homes. The interviewers asked the participants to describe how they navigate caring for someone in their home and communicate with other caregivers and the factors that influence their home care environment.

### Data Analysis

The interview data were analyzed through inductive thematic analysis using the following steps: (1) the interviews were transcribed verbatim; (2) members of the research team read the transcripts and listened to the audio recordings to familiarize themselves with the data; (3) core team members thematically coded the data; (4) initial codes and themes were developed;

and (5) the data were presented to the whole team for discussion and refinement. Data were stored and organized using QSR NVivo 12 and Microsoft Excel 2021. All names and identifiers were made anonymous during the transcription process. Triangulation of the data was achieved using various geographic areas, multiple coders, and a multidisciplinary team of researchers interpreting the results. Data saturation was reached after 7 interviews when no additional themes were identified.

## Results

### Study Population

A total of 7 family caregivers of CSHCN participated in this study (Table 1). Of these 7 caregivers, 2 (29%) family caregivers participated from the United States, and 5 (71%) family caregivers participated from Canada. Of the 5 participants from Canada, 4 (80%) were from Ontario. The youngest participant in this study was aged 33 years, and the oldest was aged 40 years. All participants identified as female, and the caregivers' experience of providing care in their home for their child ranged from 4 to 18 years. Medical equipment and tools that family caregivers operated to support their children in their homes ranged from gastrostomy or gastrojejunostomy tubes and cough assist machines to ventilators and mobility devices. Although the sample size was small, the objectives of this study were to explore the rich experiences of a diverse group of participants based on age, caregiving experience, and location, which led to the development of meaningful themes regarding information management and communication in this complex health care domain.

**Table 1.** Participant demographics and caregiving characteristics (N=7).

Characteristics	Family caregivers, n (%)
<b>Age (years)</b>	
25-34	2 (29)
35-44	5 (71)
<b>Gender</b>	
Female	7 (100)
Male	0 (0)
<b>Location</b>	
Ontario, Canada	4 (57)
Alberta, Canada	1 (14)
Missouri, United States	1 (14)
Minnesota, United States	1 (14)
<b>Caregiving experience (years)</b>	
0-5	1 (14)
6-10	3 (43)
11-15	2 (29)
16-20	1 (14)
<b>Medical equipment or tools</b>	
Cough assist machine	1 (14)
Gastrostomy or gastrojejunostomy tube	3 (43)
Orthotics	2 (29)
Oxygen concentrator	2 (29)
Oxygen tank	1 (14)
Percussion tool	1 (14)
Pulse oximeter	2 (29)
Shake vest	1 (14)
Shunt	2 (29)
Suction unit	2 (29)
Ventilator	3 (43)
Wheelchair or walker	2 (29)

### Thematic Analysis

Coding conducted by the research team led to the identification of 47 codes (Table 2). The list of codes was developed into 5

themes and 4 subthemes describing the information management and communication processes of family caregivers of CSHCN in a home care domain.

**Table 2.** Themes in communication and management of information in complex home care.

Themes and subthemes	Codes
Continuous learning to provide care	<ul style="list-style-type: none"> <li>• Connecting with other families</li> <li>• Learning from health care professionals</li> <li>• Learning from therapists and technicians</li> <li>• Learning from training</li> <li>• Learning about medical technology</li> <li>• Learning by observing</li> <li>• Figure it out on my own</li> <li>• Navigating through information for complex children</li> <li>• Learning what to do in emergencies</li> <li>• Learning procedures</li> </ul>
<b>Updating the caregiver team</b>	
Maintaining records	<ul style="list-style-type: none"> <li>• Physical documentation</li> <li>• Identifying patterns</li> <li>• Burden of documentation</li> <li>• Documenting vitals, health status, and medications</li> <li>• Documenting holistic aspects of care</li> <li>• Documenting equipment settings</li> <li>• Desire for digital records</li> <li>• Adapting documentation as a child's condition changes</li> <li>• Transparency of record keeping</li> <li>• Concerns for information security</li> <li>• Desire to ease record keeping</li> </ul>
Sharing the right information with the right person at the right time in the right way	<ul style="list-style-type: none"> <li>• Posting information around the home for other caregivers</li> <li>• Feeling pressure</li> <li>• Financial consequences</li> <li>• Communicating with health care professionals</li> <li>• Ensuring situation awareness</li> <li>• Summarizing changes</li> <li>• Memorizing information</li> </ul>
Strategizing care with the caregiver team	<ul style="list-style-type: none"> <li>• Sharing recent health information</li> <li>• Troubleshooting health care issues</li> <li>• Identifying appropriate therapies and treatments</li> </ul>
<b>Teaching caregivers about their care situation</b>	
Communication challenges in teaching caregivers	<ul style="list-style-type: none"> <li>• Teaching through documentation</li> <li>• Requiring background knowledge of caregivers</li> <li>• Sharing their child's journey</li> <li>• Share care expectations for home care tasks (eg, feeding)</li> </ul>
Communicating with their child's educators	<ul style="list-style-type: none"> <li>• Struggling with the consensus of caregiver training</li> <li>• Effectiveness of training</li> <li>• Trust in caregivers</li> </ul>
Navigating bureaucratic processes	<ul style="list-style-type: none"> <li>• Receiving health updates from the school</li> <li>• Creating health care tracking documents for the school</li> </ul>
	<ul style="list-style-type: none"> <li>• Transferring information to governing bodies</li> <li>• Preparing caregiver schedules</li> <li>• Negotiating personal care hours</li> <li>• Managing caregiver hiring</li> <li>• Acquiring funding</li> <li>• Documenting caregiver information</li> <li>• Impacts of COVID-19 on home care services</li> </ul>

### Continuous Learning to Provide Care

Family caregivers of CSHCN explained that they were continuously gathering information to learn about their child's condition and then applying this knowledge in their home. They explained that they collected information from various sources,

including trained professionals (3/7, 43%); media such as books, videos, and other documentation (4/7, 57%); by observing other caregivers (2/7, 29%); and from family caregiver networks that connected them with caregivers of children with similar conditions (2/7, 29%).

At the onset of navigating through their home care situation, Participant 1 and their caregiver team of nurses received specific medical information and training from their local children's hospital:

*As soon as we got our team hired, we were able to send them all to [the hospital] for training, which is where my husband and I had to pass a course...to basically show we could save our [child's] life before we were discharged from the NICU. [Participant 1]*

However, with the uniqueness of CSHCN conditions and treatments, which can sometimes be rare and difficult to diagnose, the family caregivers in this study had varied experiences concerning the professional training or resources provided to them:

*There's only one type of parenting guidance that's out there. [Having a] child with all these complex needs...and you are expected to just know how to navigate or facilitate your way through all of it. [Participant 4]*

Family caregivers who did not receive specialized training relied on their observation skills to mimic the required processes that they saw in clinics or hospitals:

*With our suction machine, when we initially came home with it, the day of discharge from the hospital, I was handed the suction machine, "Here's your machine. Go home bye." Nobody showed me...I have never seen a user manual for those ever...At that point, I had gotten used to seeing them at the hospital...the wall-mounted suction machines. I kind of had a basic idea...Like, "OK, can somebody at least show me how to turn it on?" [Participant 5]*

Family caregivers who communicated on the web with caregiving networks explained that these were tools to reduce their reliance on their health care team. They used this network to discuss their concerns and work together with others whose children had been through similar experiences:

*I get a lot of information from a mom's group...You don't necessarily want to be calling the clinic every time something comes up...unless it's serious...So, you know, we might say, "Oh, I noticed she's starting to get stomach aches. What has the group seen?" That kind of thing. It also helps us to try a few things before we call the clinic and say, "She's experiencing these symptoms. We've already tried X, Y and Z," which those X, Y and Z I usually get from the mom's group, for things that they've gone through similarly. They're the people who know, they've been there. [Participant 3]*

## Updating the Caregiver Team

### Overview

Family caregivers of CSHCN are often the primary knowledge holders for information about their children [25]. In this study, each participant discussed the pressure to maintain awareness of their child's history and current health status among all caregivers to ensure that their child received the best possible

care. Their communication responsibilities are summarized with the following subthemes: *maintaining records*, *strategizing care with the caregiver team*, and ensuring that they share *the right information with the right person at the right time in the right way*.

### Maintaining Records

A critical process that family caregivers carry out to update their caregiver teams is documentation. Caregiver in this study implemented paper-based documentation at the start of managing their child's condition and recorded information such as vitals and medications (5/7, 71%), the status of their child's life-supporting equipment (2/7, 29%), or other holistic aspects such as behaviors and feelings (2/7, 29%). Of the 7 caregivers, 3 (43%) continued to record detailed information about their children in paper-based records every day, with children aged 4 to 13 years at the time of this study. The other caregivers (4/7, 57%) documented health information infrequently.

Retaining detailed information about their child's care was a burden for the family caregivers in this study who were documenting every day, which was apparent when they described having to continuously condense and summarize this knowledge for other caregivers. For example, Participant 4 expressed the challenges associated with the amount of information that they had retained and the impact that this had on the expectation for them to remain the primary knowledge sharer in their caregiver team:

*There are always people added and incoming, and it seems like it's always on the parent to fill in the next carer, the next professional, on what's going on and answer their questions of what they may have from the previous professional. And it all comes down to the whole concept of the parent is the expert in their child...But we shouldn't have to be that role all the time, and that's very frustrating...We have team meetings at the school once a month with teachers and board members and all that stuff, and I'm expected to come in with my binders of information and fill them in on everything that's happened in the last month...It's crazy exhausting. It was stressing me out considerably. [Participant 4]*

Maintaining their children's health documentation in the home was not a responsibility that some family caregivers in this study mentioned conducting on their own. Multiple caregivers (4/7, 57%) described sharing documentation responsibilities with other caregivers and developing methods to ease their documentation processes through checklists and sign-off sheets:

*I also have a binder that I, well, technically, I have three, but let's not get carried away. I have one I call [my child's] Bedroom Binder. And in [my child's Bedroom Binder] is the medication schedule and a check-off or a sign-off sheet so on every day of the month there is an opportunity to sign off every medication dose that [my child] receives that day, who gave... [Participant 2]*



*I would just have them like do a little checklist so that they wouldn't forget to do a med or something like that.* [Participant 7]

However, because of the COVID-19 pandemic, there was a reduction in paper-based records and verbal communication with other caregivers. One of the caregivers expressed that they were spending more time using email to receive updates from other caregivers about their child's condition:

*[We were using paper records and having conversations in-person] until recently, and now they will email me an update... "Today we found... This is what you need to be working on..."* [Participant 4]

Ultimately, no participants in this study described using a digital health tool to document and track information, despite their excitement and hope toward digitizing their current processes. Only 1 participant (Participant 6) used a Google Home voice assistant to remind their child about medications and appointments. Another participant (Participant 2) explicitly expressed frustrations with a software application they tried to use to support care information management in their home. However, the associated steps involved in navigating the application and the limited customization rendered it useless:

*One of the most annoying things about it is that it's an app on my phone, and I have to sign into it every time I click on it. It pisses me off... I actually don't use this because it doesn't accept a couple of [my child's] diagnoses. It doesn't recognize them. It doesn't recognize some of [their] medications, and it has rendered itself useless because these are [the] things we do every day... I had pretty high hopes and was really excited. And I'm just really frustrated and disappointed that it's not what I wanted it to be.* [Participant 2]

### **Strategizing Care With the Caregiver Team**

Along with providing care, participants described that their caregiver teams were also responsible for developing and implementing strategies to improve care quality in their homes. Capturing their child's health information was a critical step in the process of strategizing care, where many family caregivers in this study (5/7, 71%) explained that they provided their caregiving teams with the necessary details for identifying correlations and patterns in their child's health:

*When [my child] sees the complex care team at [the children's hospital], we'll take the chart with us if we need [the] clinicians to troubleshoot something with us.* [Participant 1]

*Between school and home, and for behaviours and possible seizures, we were recording [them] so we could take it to the doctors... I wasn't there [at school], and I was just trying to go by [what their educators were saying].* [Participant 6]

### **Sharing the Right Information With the Right Person at the Right Time in the Right Way**

A factor related to the documentation and communication of health information about their child was sharing the correct

information with the right person at the right time in the right way. The caregivers in this study expressed the cognitive demands and consequences associated with properly filtering large amounts of information wherein they had to ensure that they effectively shared the necessary details with those who needed it:

*I think that remembering to share the right information with the right person at the right time in the right way so that they hear what they need to hear so that they will be willing to help us is the precipice of my existence... I feel that pressure in every conversation I have about [them].* [Participant 2]

The financial consequences of remembering to share specific details with the right person at the right time also affected family caregivers' stress (2/7, 29%):

*If we go into an appointment with a physical medicine specialist and I forget to tell [them] that [my child's] got really good range of motion in [their] feet, so [they] only needs rigid [ankle foot orthotics (AFOs)]... I can miss getting that prescription for AFOs. And without that prescription, I can't get them covered or made because vendors in this area won't even make you a pair of AFOs if you don't have government funding.* [Participant 2]

## **Teaching Caregivers About Their Care Situation**

### **Overview**

Information management and health communication played an essential role for family caregivers who discussed teaching and training caregivers about their home environments, care plans, and specialized medical technology, which took time away from their child's care (6/7, 87%). Participants expressed that they needed a range of 3 to 80 hours to train each new caregiver. Participant 2 explained that they often needed to train new caregivers every 6 months.

To support caregiving education and ensure that the caregivers in their home understood the nuances of their child's care needs, the family caregivers in this study developed their child's health care information into physical teaching materials, documentation, and training methods. Among several binders that Participant 2 created in their home, 1 binder was specific to teaching other caregivers how to communicate with their child effectively:

*[The] binder also has stuff about basic communication with [my child], and I have developed what I call a gesture dictionary... I start [my hired caregivers] with that piece right away: "You need to read this. You need to reference it when you can't figure out what [they're] telling you. This is really important."* [Participant 2]

Along with physical documentation, the family caregivers in this study also relied on in-person training to communicate their home care's subtle nuances:

*Picking up on [my child's] little signs that [they do], that's where... I have to tell them cause... that's kind of hard to have it written down. It really is a*

*show-and-tell...you have to hear it to understand it.*  
[Participant 5]

*And it's trying to teach the workers how to tell the difference between "I don't want to" versus "I can't."*  
[Participant 6]

Although sharing the information related to their child's care and the specific processes involved was one aspect of their training, one of the caregivers specifically expressed the additional importance of communicating their child's growth:

*The information I always wanted to share is where [my child] has come from...The fact that [they were] in a vegetative state for the longest time, [they] couldn't walk, [they] couldn't talk, [they] couldn't do anything and now [they run], [they do] track and field, [they play] basketball, [they] can talk...[They] can do a lot of stuff...I think it's important for people to always know where you've been.* [Participant 6]

### **Communication Challenges in Teaching Caregivers**

Despite the family caregivers' resiliency in this study, they still experienced communication challenges in their roles as caregiving educators (3/7, 43%). This was especially evident when participants expressed the challenge of training caregivers who already had a knowledge base and their own best practices:

*Someone who has a willing heart, and mind, and a desire to look upon our world is easier to train than [a health care assistant] or [licensed practical nurse] that's worked in the field, in institutions, for ten plus years because they've got patterns and rhythms and things that are important to them that I'm not really bloody interested in having in my home.* [Participant 2]

Participant 6 described the challenge of their hired caregivers being receptive to the training and their child's specific needs:

*...and the information that you're willing to accept, right? Like I can train you on how to do a transfer 100 times, but if you're not receptive to the training, you're going to do it the way you want to.* [Participant 6]

Training caregivers was especially challenging in the context of the COVID-19 pandemic. For example, Participant 2 expressed challenges in communicating with their hired caregivers about proper mask wearing in their home:

*I have a really hard time right now in this whole COVID situation. Getting the girls that come into my home to wear their masks effectively and appropriately...The biggest problem I have is that they are always touching their face, and it's like, every time you touch your mask on your face, you have to wash your hands.* [Participant 2]

The effectiveness of their training was an additional concern for the participants in this study. They expressed uncertainty about whether their caregivers applied their training knowledge appropriately to provide care for their children:

*I have several women that work for me who have no medical background at all...I can explain to them why I want them to do this, and they don't really get it. They don't understand contamination...And I don't know how to effectively explain that to people and get them to work through it. That's really difficult.*  
[Participant 2]

Their inability to trust that their training was being implemented was one reason why Participant 7 no longer hired caregivers:

*I cannot trust people to do things or do it right or make the right decision. And even if they can't make the right decision...just knowing to call me. Some of the times where they brought [my child] to the hospital when [they] didn't need to go to the hospital, and they brought [them] to the wrong hospital rather than just calling me and asking...* [Participant 7]

### **Communicating With Educators**

Family caregivers of CSHCN attending school often had the additional challenge of navigating communication methods and information management with their child's educators (3/7, 43%). Sharing information with their child's school was done through verbal communication in person or by phone and written notes or email. Some family caregivers in this study experienced difficulties in receiving valuable information to track how their child was developing to continue building on this development at home:

*Who [my child is] at school is...very different...than who [they are] at home...We need to know what's going on there so we can mimic here...How did we get to this year with this many children who have needs and their people still don't understand how to do these communications.* [Participant 4]

The technologies used to support the sharing of information among their child's educators were not consistent. Caregivers described different methods that educators used to collect and transfer information about their child, which raised concerns about their child's safety:

*It's a verbal chat, or it's an email or...we have been using emails more often because I don't answer my phone anymore...I like to have things written down. Or there's like a scrap piece of paper in [their] lunch pail or something...I do know now with the different portals, and stuff that different doctors have would have been easier in the moment...I had three adults that were being paid...[my child's] school supports...videotaping [my child] and walking around with that on their cell phone. So, there's no security or confidence that...it just opened up a whole can of worms. Or it had a potential of opening up a whole can of worms, but it's all we had...If there were secure ways of doing it, it would have been a little bit safer.*  
[Participant 6]

In other situations, the family caregivers in this study (2/7, 29%) requested that their child's educators continue to track their child's health care metrics using their personally designed tracking sheets while being cognizant of workload:

*You would think—and there's only like four to six kids in [their] class—you would think that [their] teacher would be able to like fill out a quick form...but she never did it. So, then I realized like “OK, maybe it's because she feels like it's too much work,” so I altered it to just be...kind of the general just circle it...So, the more people have to fill out, the less likely they are to do it. That's what I've realized...People are lazy, is what I've learned. [laughs] Even the really good ones. She's a fabulous woman, but like they're still lazy. [Participant 7]*

Another family caregiver used a communication book; however, despite their child's educators writing in them, the information did not provide insight into their child's care or development:

*[Their] communication book would come back, and it would be like, “today [they] had a great day.” [Participant 4]*

### Navigating Bureaucratic Processes

Although not directly related to health information management, navigating the management of their child's information with the bureaucracy of home care was a process that added another level of complexity, which was expressed by some participants in this study (2/7, 29%). The participants expressed their responsibility to organize the necessary paperwork to have hired caregivers, such as scheduling, timesheets, and payroll:

*The main criticism of the family-managed homecare program is the amount of paperwork that's required of families. But now that we've been doing this for two years, between my husband and I, it may take two to three hours a month to do payroll and the paperwork. [Participant 1]*

*Payroll is something that I have kind of hired out, so I have to make the schedule and tally the timesheets, but then I have a really lovely company that I've been interacting with since day one, and they have saved my butt more times than I can count, and they charge me a nominal [fee], and they do all of my EI and CPP, and they interact with the CRA on my behalf. They interact with WCB on my behalf. I send them signed checks. This is how much I trust this company, and they have never done anything wrong. If anything, they have saved my butt. [Participant 2]*

The impact of the COVID-19 pandemic further influenced the ability of participants to acquire home care support and services, requiring them to manage more aspects of their child's health information and communication on their own. The participants in this study reported having reduced support because of public health restrictions or their own choice—to limit their child's exposure—and the pressing need for home care solutions in the era of the COVID-19 pandemic:

*So we actually lost all of our care...I would say 98% of the families out there in Ontario lost all of their services when the COVID lockdown happened because they were not deemed essential...We went from having 11 hours of support a week to having zero. [Participant 6]*

*I know that families that I speak with, we're all struggling to find ways to get support without being able to bring in support. [Participant 4]*

## Discussion

### Principal Findings

This exploratory study examines how family caregivers navigate information and the processes involved in health communication in complex home care to support the designing of digital health information systems. The family caregivers of CSHCN in this study were underserved concerning the tools available to support them in managing their child's health care in their homes [11]. Given that children with medical complexities account for one-third of all health care spending on child health in some North American regions, it is critical to understand their experiences to inform the design of digital information management tools that can improve home care [26].

### Critically Important Contexts of Home Care Delivery

Although recognizing that all CSHCN are fundamentally unique [27,28], the context of family caregivers' home care situations plays a critical role in information management and communication experiences for CSHCN. The social determinants of health have been shown in prior literature to influence inequities in health care delivery [29]. There is also a need to use digital health tools to better account for these inequalities in our health care system in clinical settings [29]. As observed in this study, the design of digital health technology needs to consider supporting the context of home care. For example, for the participants in this study, information support provided by the health care system was either easily accessible or required significant work on behalf of the family caregiver to be accessed. Opportunities for formally trained hired caregivers were also readily available or nonexistent. Life-supporting medical equipment is often a significant component of complex care for families of CSHCN [27,30]. However, some families in this study were also not able to access the necessary instructions or formal training and took on considerable responsibility to ensure their child received safe and high-quality care by gathering information on their own and developing standard care practices for their home. Schaepe et al [31] argue that family caregivers are necessary and provide value and knowledge to their child's home care. However, there are significant risks to patient safety in life-threatening situations if family caregivers are not formally provided access to the required knowledge [31]. A recommendation provided by Foster et al [32] was to improve home care policies for families of children with medical complexities by including home health training through partnerships with pediatric health care systems. In the context of digital health tools, there is potential to design information technology that can provide accessible health care knowledge and training information. Universal access to information on the web or through mobile platforms can address inequalities for families who otherwise do not have the means to safely coordinate home care and provide health care services for their children with complex conditions.



In the context of the social attributes for providing home care with respect to caregiving stress and the support for caregiving services, some family caregivers shared specific issues around having access to medically trained hired caregivers for respite care. Keilty et al [33] identified severe consequences for family caregivers of a child with a medical complexity who experience sleep disturbance, which may be relieved by addressing respite needs. Although some participants in this study eventually received access to professionally trained caregivers to support their 24-hour home care, others navigated the hiring process and medical training and supervised hired caregivers independently. One may argue that these processes mirror those of a small business or full-time job [34,35]. The challenge with receiving respite care in this study was either because of the limited availability of professionally trained caregivers from local agencies or geographic location, specifically when families live in rural regions where local agencies do not exist, as identified by Weaver et al [36]. With digital technologies disrupting conventional business models and delivery services, especially during the COVID-19 pandemic [37], digital health tools have increasing potential to support respite care by making connections with hired caregivers a more effective and efficient experience for family caregivers of CSHCN.

The additional challenge of training a stranger with no medical experience places considerable pressure on family caregivers who may not be in a position where they have the time, resources, and overall capacity. They simultaneously maintain the health and safety of their children while training someone about their developed methods and processes for performing care. Respite care for the family caregiver may be minimal while effectively training someone with no medical experience. As this study identified, training a new caregiver may require up to 80 hours through several 1- to 8-hour shifts before the family caregiver and trainee are comfortable caring for the child independently. This study further identified that the resources provided to support training are often scarce. When they are available, the family caregiver is responsible for sharing the materials in an organized manner to support effective and efficient learning. With the compounding responsibilities for providing care, many family caregivers quit their full-time jobs to stay at home and provide for their child's health care needs on their own [27].

### **The Evolutionary Home Care Complexities for Family Caregivers of CSHCN**

Information management and communication processes are dynamic for family caregivers of CSHCN [38]. However, this study identified that family caregivers remain steadfast users of paper-based systems, which do not entirely support the needs of their caregiving tasks. As their child grows older, the types of support they need change, and new caregivers enter and exit their child's caregiver team. In addition, caregivers continuously learn new information about their child's health conditions. As a result, the information they track may change from recording vitals when first providing care to recording holistic aspects of care such as behaviors and feelings. They also design alternate versions of these forms for other caregivers to use. In some situations, family caregivers may record information less frequently. The family caregiver may only need to track

information if their child is experiencing unusual symptoms to identify the underlying patterns and trends and report them to their clinician team in an email. Email messaging does not provide a standardized or secure method for effectively communicating health information. In addition, the paper-based methods that the caregivers used in this study to support dynamic processes needed to be continuously adapted by the family caregiver by updating their nonstandardized record-keeping templates created on a computer or by designing and printing new templates.

Although documentation processes may change or reduce in frequency based on their child's evolving health care needs, new challenges emerge for navigating 2-way communication of their child's care while attending school, which has also been identified by Mikles et al [39]. Although educators are often not trained medical professionals or health communicators, they can be considered a part of the caregiver team when they become responsible for supporting CSHCN in their classrooms. The caregivers in this study currently use technologies such as email, voicemail, and written notes to meet information exchange methods between their homes and their children's schools. No caregiver in this study described using digital health applications designed to support health information management and communication. With the technologies they were using, mainly including paper-based documents or keeping information on photograph and video storage applications on others' devices, privacy concerns exist for misplacing sensitive information or for individuals to have unsecure access to information.

Nonstandardized methods of communication that do not follow defined protocols for the type of information that needs to be shared are also associated with challenges. These challenges include communicating health insights that provide value toward improving the child's care and facilitating the organization of this information for efficient access by caregivers in the future. Although technology supports, such as web-based portals, have been developed to securely communicate health information from hospitals and other care facilities, and in some situations, there are standard physical documentation and handoff protocols that can be provided to a family to support the communication of a child's development in school [39], the general needs of family caregivers of CSHCN to facilitate 2-way communication with their child's educators have not been considered in the design of digital technologies.

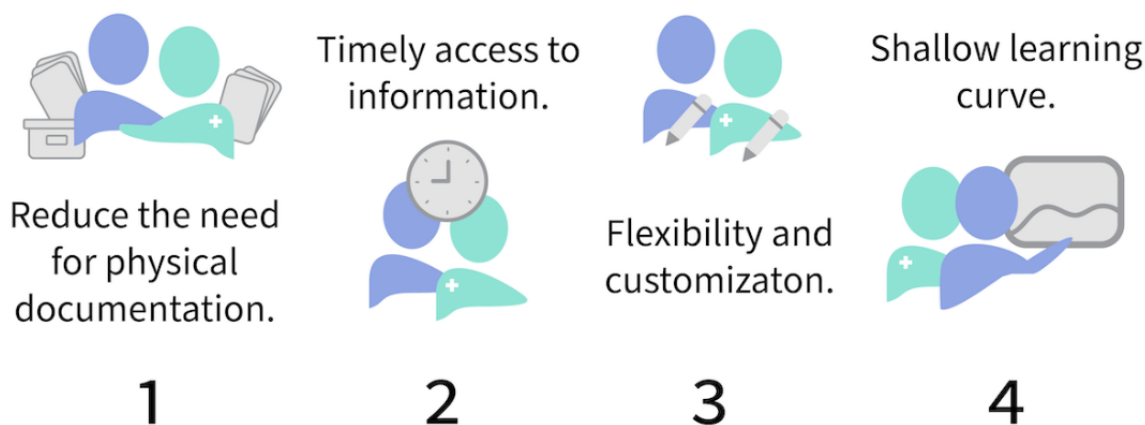
### **Design Recommendations for Digital Health Care Technology**

This study identified a significant cognitive and time burden for family caregivers of CSHCN to share complete information accurately and concisely regarding their child's health with other caregivers [40-42]. Information sharing occurs within caregiver handoffs in the home, at caregiver team meetings in clinics and schools, and with their child's physicians and specialists [39]. Digital health tools have a significant potential to reduce the pressure on family caregivers while managing their children's information [11,43,44]. With the work that family caregivers currently perform to overcome challenges related to the lack of caregiving support and resources, it is critical to design digital tools to support natural interactions



while providing significant utility. The design recommendations are shown in [Figure 1](#).

**Figure 1.** Design recommendations for digital health tools in complex home care.



First, the focus should be directed toward designs that reduce the need for family caregivers to physically organize their collected information manually, preventing accidental duplication and reducing workload. Many of the current tools available to caregivers require laborious data entry, are rigid systems that do not permit customization, and do not link health care professionals or other caregivers in real time [11,45]. A similar recommendation has been made in the context of health insurance tracking for families of CSHCN [46]. Although systems to automatically monitor health conditions exist, such as wearable devices (eg, Apple Watch, Fitbit, Garmin, and Polar) or other ambient, noncontact tracking systems [47,48], the complexity and uniqueness of home care for CSHCN with respect to the child and the data that is required to track may not always be suited to the use of these technologies. There may also be other barriers that prevent the introduction of these technologies to family caregivers in their homes. As a potential solution, voice interaction technologies to collect spoken health metrics or other information may be an alternative to enabling caregivers to track data without requiring them or their child to physically interact with a device [11]. Although the spoken information may be unstructured, the system could be designed to identify keywords, intents, and measures to enable practical data storage and information retrieval in a structured database.

Second, digital health tools should provide timely access to information, insights, and patterns specific to the context of the caregivers among whom the information needs to be shared. With the cognitive burden that family caregivers face in accurately sharing information with others, digital tools should support caregivers to access information efficiently and effectively depending on with whom they are interacting and their current working environment. For example, in the clinical setting, design recommendations for digital health technology development to support health care management of pediatric blood marrow transplant patients have been described by Shin et al [42]. Although not explicitly describing how the user would interact with the technology to access insights about the health data, their results similarly point toward the idea of a digital health tool that provides general use in tracking patient symptoms, consult visits, and medications, supporting the caregiver's cognitive load to remember details accurately [42].

Shin et al [42] further recommend providing overviews of the visit to the caregivers in a manner that promotes an accessible understanding of the information to support an engaging clinic visit. Previous recommendations have also been made to design digital health technologies that facilitate document sharing among providers, family caregivers, and educators [45] and automatically send new information to the care team individuals requiring it [39]. To build on these recommendations, developing digital health technologies that center the family caregiver's needs to ensure that the right person receives the correct information at the right time should be prioritized to alleviate cognitive burdens.

Third, digital health tools should allow for flexibility and customization regarding the inputs and outputs of the display to meet the needs of complex home care over time. Adaptation is essential in complex home care when a child's health condition constantly changes over time. In the closely related caregiving domain of child development in educational institutions, similar emerging recommendations have been made—to design digital health technology that supports adaptation for continuously changing caregiving information and communication needs [39]. Recommendations from Mikles et al [39] point toward configurable patient referral reports that provide customization relevant to the relevant stakeholders. The researchers also recommend the inclusion of test results, descriptions and notes, medications, languages, race and ethnicity, care summaries, and health summaries [39].

Finally, any developed digital health tool should offer a shallow learning curve to promote a more intuitive interaction for all caregivers who need to interact with the information. Family caregivers already spend considerable time learning about their children's conditions and the complex medical technologies and medication regimes they require [3,27]. Providing a tool that provides a natural interaction could reduce the learning curve required to use digital health tools and support future engagement by a wider group of users [11]. As a positive consequence, digital health tools that are easier to interact with may subsequently be used as an additional channel to support family caregivers in learning about the conditions of their child and their medical devices in a more effective manner [49].

## Strengths and Limitations

This exploratory study captures the emerging perspectives of family caregivers of CSHCN from a diverse group of participants, including wide-ranging home care contexts and caregiving experiences to represent breadth in caregiving knowledge. Although this research is not explicitly focused on the impact of the COVID-19 pandemic, it did occur during the pandemic, giving important consideration to times when caregiving practice has had to shift rapidly, which is another under-researched area. Caregiver perspectives, the stresses that they have experienced, and their capacity to manage and communicate health information in their homes may have been influenced by the ongoing changes resulting from the pandemic, and there is an opportunity for future research to examine this further.

The participant demographics are limited because of the exploratory nature and practicalities of conducting this study during the COVID-19 pandemic, which affected recruitment because of the time limitations of potential participants caring for children who are medically complex who often require care or other support at all hours. Furthermore, although this study reports on geographical locations and other distinct demographic data for transparency of the sample population, only 2 caregivers were included from the United States. However, this study is guided by the principles of narrative medicine storytelling, where including their data introduces critical perspectives that may identify avenues for future research [24]. Although the data analysis reached saturation, allowing for the development of meaningful themes that provided a rich understanding of the experiences of the family caregivers in this study, a larger sample size would support generalizing these findings to a wider caregiving population. Future work will build on this with broader demographics that include insights on the impacts of

caregivers' financial situations while examining differences between health care systems in Canada and the United States that can inform design. There is also the potential to examine this population more deeply for specific diagnoses and long-term implications of changes in care.

## Conclusions

Our formative research study provides a foundation for some of the emerging challenges related to family caregivers' information management, communication, and caregiving support in complex home care. Furthermore, it begins to identify opportunities for digital health tools to support gaps in the health care system. Digital health solutions may address unmet caregiving needs for access to medical device information and training material, shared situational awareness with other caregivers, and access to caregiving services, including respite care. With the complex information processes that family caregivers of CSHCN are involved in daily, high-level design recommendations for developing future digital health technologies point toward solutions that facilitate intuitive interactions while providing utility through timely access to organized, context-specific data.

Digital health tools for complex home care may also improve the cognitive burden associated with the health care tasks involved with being a family caregiver of a child with complex health care needs—solutions that may lead to safer coordination of care. As digital health tools continue to be developed, future research should focus on designing digital health care tools in close collaboration with the multiple stakeholders involved in care, including diverse family caregivers. Ultimately, the preliminary findings from our study may provide valuable insights for informing the design of digital information management and communication systems in complex home care for family caregivers of CSHCN.

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## Conflicts of Interest

None declared.

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## Abbreviations

**CSHCN:** children with special health care needs

**EHR:** electronic health record

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Original Paper

# Game Plan—a Brief Web-Based Intervention to Improve Uptake and Use of HIV Pre-exposure Prophylaxis (PrEP) and Reduce Alcohol Use Among Gay and Bisexual Men: Content Analysis

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## Abstract

**Background:** HIV pre-exposure prophylaxis (PrEP) has considerable potential for reducing incidence among high-risk groups, such as gay, bisexual, and other men who have sex with men (GBM). However, PrEP's effectiveness is closely linked with consistent use, and a variety of individual-level barriers, including alcohol use, could impede optimal uptake and use. Web-based interventions can encourage medication adherence, HIV prevention behaviors, and responsible drinking and may help support PrEP care, particularly in resource-limited settings.

**Objective:** We previously developed a web application called Game Plan that was designed to encourage heavy drinking GBM to use HIV prevention methods and reduce their alcohol use and was inspired by brief motivational interventions. This paper aims to describe the web-based content we designed for integration into Game Plan to help encourage PrEP uptake and consistent use among GBM. In this paper, we also aim to describe this content and its rationale.

**Methods:** Similar to the original site, these components were developed iteratively, guided by a thorough user-centered design process involving consultation with subject-matter experts, usability interviews and surveys, and user experience surveys.

**Results:** In addition to Game Plan's pre-existing content, the additional PrEP components provide specific, personal, and digestible feedback to users about their level of risk for HIV without PrEP and illustrate how much consistent PrEP use could reduce it; personal feedback about their risk for common sexually transmitted infections to address low-risk perceptions; content challenging common beliefs and misconceptions about PrEP to reduce stigma; content confronting familiar PrEP and alcohol beliefs; and a change planning module that allows users to select specific goals for starting and strategies for consistent PrEP use. Users can opt into a weekly 2-way SMS text messaging program that provides similar feedback over a 12-week period after using Game Plan and follows up on the goals they set.

**Conclusions:** Research preliminarily testing the efficacy of these components in improving PrEP outcomes, including uptake, adherence, sexually transmitted infection rates, and alcohol use, is currently ongoing. If supported, these components could provide a scalable tool that can be used in resource-limited settings in which face-to-face intervention is difficult.

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**KEYWORDS**

HIV; pre-exposure prophylaxis; alcohol use; mHealth; eHealth; intervention; mobile phone

## Introduction

### Background

Although the rates of new HIV infections have declined among most groups in the United States in the recent years, incidence remains consistently high among gay, bisexual, and other men who have sex with men (GBM) [1,2]. Daily oral HIV pre-exposure prophylaxis (PrEP) is an extremely effective HIV prevention option and has the potential to reduce incidence in this group [3,4]. Although the US Food and Drug Administration approved PrEP for adults in 2012 [5], PrEP uptake remains lower than that needed to achieve stable declines in new infections [6,7]. PrEP's efficacy is also closely linked to adherence [8], and although recent demonstration projects and real-world studies have shown high adherence among many GBM [9,10], discontinuation is also common [11]. Young GBM may start PrEP at lower rates, show suboptimal adherence, and have higher rates of discontinuation [10,12]. In some demonstration projects focusing on younger GBM, only 34% of the participants had protective levels of PrEP after 48 weeks [10], far less than the average of about 2 years in which many GBM are at the highest risk for HIV [13]. The rates of other sexually transmitted infections (STIs) are also particularly high among GBM who use PrEP [14]. Efficient, cost-effective interventions are needed that can encourage broader PrEP uptake and consistent use and help reduce STI rates among PrEP users.

Factors such as access and cost have consistently been among the most important barriers to PrEP use among GBM [15,16], but improved coverage among health insurers and national programs providing free PrEP for the uninsured could significantly reduce these barriers [17,18]. However, even with equal access, a number of other important barriers limit PrEP use in GBM. Previous research has shown that low perceived risk for HIV [19,20], low social norms around PrEP (particularly among racial or ethnic minority GBM) [21,22], persistent PrEP stigma [23], and low uptake and adherence self-efficacy [24,25] are among the most important factors determining PrEP use. Unhealthy alcohol use could also make success on PrEP difficult. Alcohol use is a major risk factor for HIV acquisition [26], primarily because intoxication can interfere with condom use during sex in GBM [27,28]. Given this link, it is important to encourage PrEP uptake among GBM who drink heavily. Some evidence suggests that heavy drinking GBM may be less willing to use PrEP and may need increased guidance and support to start PrEP [29]. Low condom use among GBM on PrEP in general also contributes to high rates of STIs [30,31], and heavy drinking GBM could be at even higher risk for STIs when on PrEP [32,33]. For these reasons, interventions to improve PrEP use should provide STI-risk reduction counseling for all PrEP users, and this may be especially helpful for heavy drinking GBM. Finally, although there is little evidence to date that alcohol use interferes with PrEP adherence [34,35], interactive toxicity beliefs are common [29], and lifestyle disruption because of heavy drinking may also confer some risk for suboptimal adherence [34,36].

In clinical settings, interventions to encourage PrEP uptake and optimize PrEP outcomes among those taking PrEP are not

consistently available. Optimizing patient outcomes on PrEP typically requires a high level of ongoing follow-up and support in the form of encouraging uptake, supporting adherence, providing ongoing monitoring, and preventing discontinuation among those who would still benefit from PrEP [37]. Therefore, national guidelines and previous research have underscored the value of providing support or counseling interventions for PrEP patients alongside typical PrEP monitoring and care [38,39]. However, routinely providing this degree of support to PrEP patients in practice is a concern [40], even among dedicated PrEP clinics. Encouraging nonspecialty providers, such as family medicine and primary care clinicians, to provide PrEP has been a key strategy for expanding PrEP access [41,42], but providers in these settings may feel even less equipped to provide an intensive level of ongoing support that is often recommended for optimal PrEP care [40], which may be pronounced in lower resource settings.

A variety of individual-level interventions for improving PrEP outcomes have been designed to date, but nearly all have yet to be rigorously tested [43,44]. Most of these interventions also rely on some form of face-to-face counseling and often require highly trained counselors to meet with patients for several hours [45,46]. These characteristics are resource-intensive and may impede implementation, particularly in low-resource PrEP clinics and nonspecialty settings. A brief intervention that uses evidence-based techniques to address key factors involved in PrEP uptake, adherence, and persistence and is relatively inexpensive and highly feasible across a variety of settings may help provide patients with basic information and support that help them to be more successful on PrEP.

Meta-analyses and systematic reviews have consistently shown that web-based interventions can encourage HIV prevention behaviors [47,48] and could overcome many of the implementation issues of current PrEP support interventions. Web-based interventions are also easy to disseminate and cheaper than individual counseling, making their widespread implementation much more feasible than other approaches [49,50]. They can also standardize content, which is an important benefit given that other interventions delivered by counselors struggle with fidelity and drift as dissemination increases [51]. Web-based interventions are also easier for individual users to access than smartphone apps because they do not require downloading an app and can be used from a variety of devices. Finally, they may also be particularly well-suited to reach young GBM, a key risk group given high rates of HIV and low PrEP uptake and use [1,10,12]. Given these strengths, we designed and built the components of a web application to help improve PrEP outcomes in GBM.

### Objective

Specifically, our goal was to design simple, short features that could help (1) encourage GBM who are not already on PrEP to start using PrEP, (2) urge those already on PrEP to take it consistently for as long as they are at risk, and (3) promote condom use and the use of other forms of prevention to reduce their risk of STIs. Given the conceptual overlap in these goals with Game Plan, a previous web application we built to help GBM reduce their risk for HIV [52], we incorporated the

features we designed for PrEP-related goals into the broader Game Plan web app. This paper describes the features we designed to help improve PrEP outcomes and their theoretical and evidence-based underpinnings.

## Methods

### Background and Overall Design

Game Plan is a web application that was initially developed primarily to help HIV-negative GBM who are *not* on PrEP to reflect on their choices about sex and other potential risks associated with HIV acquisition such as alcohol use and, if interested, consider ways of changing these behaviors to be safer [53]. It is a self-guided application that provides both static and interactive content. It was explicitly designed to be brief (approximately 20-30 minutes, on average) so that it is feasible for use in clinics (eg, in waiting rooms) or at home and to more closely resemble how many people access and use health information on the web: during a few brief visits [54,55]. In our formative work, users spent 20 to 40 minutes interacting with the application in a single visit [53,56]. The site was originally developed using a thorough user-centered design research process [57] conducted among GBM across the United States but concentrated in the northeastern United States. It primarily uses a wizard navigation pattern in which users are guided through a series of sections and activities with progressive disclosure rather than the typical explorative hierarchy of pages. In a small pilot study, the site showed promising effects on both reducing HIV-risk behavior and alcohol use among high-risk, heavy drinking GBM [58]. A full efficacy trial of Game Plan's effects on sexual risk behavior and alcohol use among GBM who are *not* on PrEP is currently ongoing.

Although the initial version of Game Plan suggested that users who were interested in reducing their HIV risk consider PrEP, it included only limited PrEP content. This study focused on designing, developing, and testing additional components that were more explicitly intended to encourage PrEP uptake among GBM at high risk but not currently on PrEP and to encourage consistent PrEP use among those already taking PrEP. Given the notably high burden of STIs among GBM on PrEP [59], we also aim to incorporate content intended to encourage the use of condoms and other prevention strategies among those currently taking PrEP. We also incorporated several overall design and feature updates to all Game Plan content.

### Theoretical Foundation and Design Research

The content of Game Plan is generally informed by the Information-Motivation-Behavior model [60,61] and adopts the basic framework of brief motivational interventions [62] and the *spirit* of motivational interviewing (MI) [63]. It is primarily focused on helping users who are not on PrEP move from the precontemplation or contemplation stages to the preparation and action stages of change [64]. For those already on PrEP, it

is focused on reinforcing their commitment to change during the maintenance stage. However, it is not intended to provide exhaustive or continuous support over time for those in the maintenance stage. We developed the PrEP-specific content that is the focus of this paper to align with these theories and approaches.

To guide the development of these components, we consulted with other PrEP experts to identify the most pressing goals for PrEP care to help prioritize content. Then, we reviewed the available literature to explore key determinants of these goals and potential behavior change techniques with promise in addressing each one. After outlining the basic content, we worked with a professional design team to create a prototype version of the fully redesigned site that incorporated the new PrEP content. We then conducted a thorough usability interview and surveys with 10 heavy drinking GBM who were currently on PrEP and reported taking <80% (24/30 days) of their daily doses of PrEP in the last month. In these interviews, trained interviewers provided participants with a link to the prototype site and asked them to click through each section and *think aloud* as they did so, explicitly encouraging critical feedback [65]. After reviewing each interview and incorporating changes based on the feedback provided, we conducted a user experience survey [66] with 40 additional heavy drinking GBM who were currently on PrEP. These participants completed a baseline survey, received a link to the prototype site, and then completed a follow-up survey to assess their perceptions of the site. The results of these studies have been published elsewhere [56]. In this paper, we describe each component and its theoretical or empirical basis.

## Results

### Flow, Content, and Onboarding

The redesigned Game Plan site with PrEP-specific content generally followed a similar flow to the original Game Plan, which was intended to align approximately with two phases common in MI: (1) content eliciting intrinsic motivation to change and when and if sufficient motivation exists and (2) content intended to help translate that motivation into specific change plans. The overall sequence first discusses HIV and STI topics, followed by alcohol use. Some new PrEP-specific content is presented conditionally based on whether users reported currently using PrEP or not in the About You section, whereas other content is presented to all users because it may benefit PrEP uptake and PrEP use alike (see Table 1 for a brief description of all components). The flow of all the components is presented in Figure 1.

The following sections describe each section of Game Plan and its content in the order in which it is presented to the users and then cite the theoretical and empirical literature that informed content decisions and design.



**Table 1.** Techniques used in each Game Plan section and theoretical constructs or mechanisms they pursue.

Component	Techniques and goals	Theory constructs addressed
Onboarding	<ul style="list-style-type: none"> <li>Set “tone”</li> <li>Express empathy</li> </ul>	— <sup>a</sup>
About you	<ul style="list-style-type: none"> <li>Assess fit for user GBM<sup>b</sup></li> <li>Assess tailoring variables (age and PrEP<sup>c</sup> use)</li> <li>Assess user’s values</li> </ul>	<ul style="list-style-type: none"> <li>Tailoring</li> <li>Grounding guidance in user’s values</li> </ul>
Your sex life	<ul style="list-style-type: none"> <li>Efficiently assess the number of past-year unknown-status partners and number of CAS<sup>d</sup> events as top and bottom</li> </ul>	<ul style="list-style-type: none"> <li>Tailoring</li> </ul>
Your risk	<ul style="list-style-type: none"> <li>Affirm decision to use PrEP</li> <li>Show potential HIV risk over 1 and 5 years based on past-year behavior without PrEP</li> <li>Show how much calculated HIV risk percentages would be reduced with consistent PrEP use</li> <li>Compare past-year HIV risk to all men and gay or bisexual men</li> <li>Show potential risk for chlamydia and gonorrhea in the past year with PrEP use</li> <li>Compare past-year number of partners and CAS with other GBM in age group</li> </ul>	<ul style="list-style-type: none"> <li>Motivation (risk perceptions)</li> <li>Motivation (PrEP use)</li> <li>Motivation (social norms)</li> </ul>
About PrEP	<ul style="list-style-type: none"> <li>Challenge common misconceptions and stigma about PrEP</li> <li>Providing information and instrumental support</li> </ul>	<ul style="list-style-type: none"> <li>Information or PrEP knowledge</li> <li>Challenging PrEP stigma</li> </ul>
Your drinking habits	<ul style="list-style-type: none"> <li>Assess users’ frequency of alcohol use over the past month</li> <li>Assess the quantity users drank during each occasion over the past month</li> <li>Assess regret or remorse after drinking and blackouts</li> </ul>	<ul style="list-style-type: none"> <li>Tailoring</li> <li>Motivation (anticipated regret)</li> </ul>
Alcohol, sex, and PrEP	<ul style="list-style-type: none"> <li>Challenge common beliefs about alcohol facilitating sex based on specific motivations selected by users</li> <li>Provide information about alcohol’s potential effects on PrEP adherence</li> <li>Challenge PrEP-alcohol toxicity beliefs</li> </ul>	<ul style="list-style-type: none"> <li>Information</li> </ul>
Alcohol use profile and norms	<ul style="list-style-type: none"> <li>Provide feedback about level of risk associated with current level of alcohol use</li> <li>Compare past-month alcohol use with other GBM in age group</li> <li>Present HIV and STI<sup>c</sup> risk profile information again to refresh</li> </ul>	<ul style="list-style-type: none"> <li>Motivation (risk perceptions)</li> <li>Motivation (social norms)</li> </ul>
Pros and cons exercise	<ul style="list-style-type: none"> <li>Help users weigh pros and cons of current choices about sex</li> <li>Provide feedback about how these pros and cons stack up</li> <li>Prompt reflection on how these pros and cons align with identified values</li> </ul>	<ul style="list-style-type: none"> <li>Motivation (develop discrepancy)</li> </ul>
Your Game Plan	<ul style="list-style-type: none"> <li>Explore menu of options for ensuring PrEP adherence, reducing STI risk, and reducing alcohol use</li> <li>Identify important reasons for making selected changes</li> <li>Choose specific steps for working toward goal</li> <li>Provide referrals for prevention services (STI testing, PrEP, etc)</li> </ul>	<ul style="list-style-type: none"> <li>Self-efficacy</li> <li>Information (PrEP adherence strategies, instrumental support, and other prevention strategies)</li> <li>Motivation (commitment to change plan)</li> </ul>
Planting a seed	<ul style="list-style-type: none"> <li>Prompt users to consider what would need to happen to consider change</li> <li>Encourage revisiting the site if things change</li> </ul>	<ul style="list-style-type: none"> <li>Self-efficacy</li> </ul>
Local resources	<ul style="list-style-type: none"> <li>Provide information about prevention services (STI testing and PrEP) and other health care services (medical, mental health, and drug or alcohol treatment) tailored to their area</li> <li>Display PrEP or HIV service locator widgets</li> </ul>	<ul style="list-style-type: none"> <li>Self-efficacy</li> <li>Information (instrumental support)</li> </ul>

<sup>a</sup>No theory-based constructs or mechanisms are addressed for this content because it is only intended to help orient the user to the program.

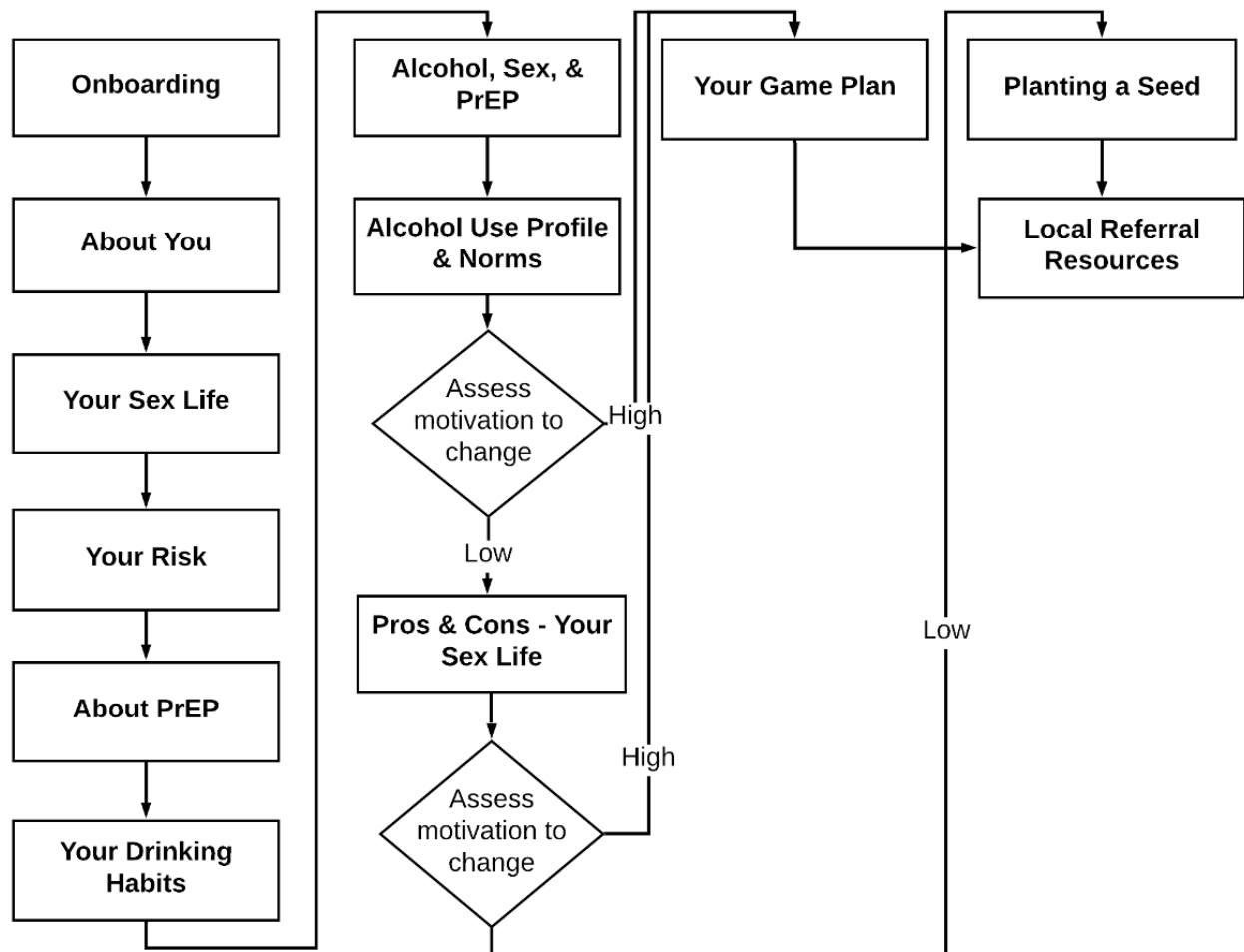
<sup>b</sup>GBM: gay, bisexual, and other men who have sex with men.

<sup>c</sup>PrEP: pre-exposure prophylaxis.

<sup>d</sup>CAS: condomless anal sex.

<sup>e</sup>STI: sexually transmitted infection.

**Figure 1.** Game Plan web application flow for users reporting the use of pre-exposure prophylaxis. PrEP: pre-exposure prophylaxis.



## Onboarding

After the splash screen, users first see a single onboarding screen that explains the purpose of Game Plan and is intended to express empathy and convey other aspects of the MI *spirit*: that the site is nonjudgmental, collaborative, and respects users' autonomy [63]. Next, the *About You* section requests basic information about the user to tailor the content presented throughout the site, including age, gender, sex at birth, sexual orientation, PrEP use, and location [67]. No identifying information is collected, as the site was specifically designed to be anonymous unless the user volunteers to provide their contact information at the end for further follow-up. The *About You* section also asks users to consider a list of values (eg, adventure—having variety, excitement, justice—being fair and accurate, mastery—achievement, challenge, and growth) and asks users to choose up to 4 that they aspire to in their own lives. The goal of this exercise is to encourage users to keep these values in mind as they consider change and whether their current choices align with values that are important to them. Therefore, the user's selected values are summarized for them on the change goals page.

## Your Sex Life

This section was designed to assess variables needed to approximate users' level of risk for HIV and other common STIs (chlamydia, gonorrhea, syphilis, etc) in as few questions as possible. Because condomless anal sex (CAS) with partners of uncertain HIV or STI status confers at least some risk, these questions are focused primarily on helping users report the number of *times* they had CAS as a top and bottom with these partners. These responses are then used to estimate HIV risk over a year and over 5 years, with and without PrEP, and other STI risk in the following sections.

## Your Risk Profile

Users are then presented with a *risk profile* that provides personal, easy-to-digest estimates of their risk based on the data collected in the previous section. As in the original Game Plan, the profile starts by reporting estimates of their risk for HIV over the next year and 5 years if their sex life remains the same, using data from past research [68]. This estimate is calculated using data that the users have entered about the number of condomless, insertive and receptive anal sex events with unknown-HIV-status partners, together with national estimates

of HIV prevalence in GBM and average per-act transmission risks. The goal of this step was to correct any misperceptions of personal risk by providing a credible, personally relevant, and digestible sense of their risk level. Several studies have shown that underestimating one's risk is a key barrier to PrEP uptake in GBM [19,69]. Users are then shown what their HIV risk would be if they used PrEP every day, using estimates drawn from effectiveness studies [70,71]. By presenting credible estimates of a user's personal risk with and without PrEP side by side, our goal was to highlight the significant impact that PrEP could have on their personal risk. One of the key principles of MI suggests that one way to enhance users' intrinsic motivation for change is to draw their attention to discrepancies [63], for example, between an individual's current behavior (not taking PrEP) and desired future states (remaining HIV-negative). Some research in addiction suggests that individuals who experience stronger actual-ideal discrepancies such as these after the intervention show greater change in alcohol or drug use [72,73]. Thus, we hope that highlighting this discrepancy between current risk and much lower potential risk with PrEP might increase users' intrinsic motivation to use PrEP. Finally, using national survey data [74], the risk profile also shows how the users' total number of sex partners and number of CAS events compare with other GBM in the same age group. This step was intended to illustrate the extent to which the user's current risk and behavior deviates from the norms of valued reference groups [73]. Correcting inaccurate perceptions about the social norms of given behaviors may similarly enhance motivation to change by increasing the discrepancy that users experience between current behavior and a desired outcome (avoiding risk behavior that is too extreme compared with that of others) [75,76].

For users already using PrEP, the risk profile starts by affirming their decision to use PrEP. Then, similar to PrEP nonusers, their risk profile displays estimates of HIV risk over a year and 5 years given current behavior if they *did not* use PrEP, followed by the same estimates adjusted for taking PrEP every day. Highlighting this difference in those already using PrEP could similarly boost these users' motivation to continue using PrEP for as long as they are at risk and to continue taking it daily during that time. However, below the risk profile for current PrEP users, the profile emphasizes the importance of continuing to use prevention methods (eg, condoms) while on PrEP because of the continued risk for other STIs and provides estimates of likely past-year personal risk for chlamydia and gonorrhea using

data from past research [77,78]. As with HIV, the goal of this step was to increase motivation to reduce their risk for other STIs by correcting inaccurate risk perceptions. Similar to PrEP nonusers, the risk profile for PrEP users also provides normative comparisons for past-year sexual behavior compared with that of other GBM in their age group to increase motivation to use additional prevention methods. Afterward, the site assesses users' reactions to this information as well as their motivation to change to reduce their risk (Figure 2).

At least one large study has tested the effects of a similar technique using a calculator to give GBM feedback about their risk for HIV based on their recent behavior on PrEP uptake among GBM who were not on PrEP [69]. This risk calculator used participants' responses to 16 questions relevant to risk (eg, CAS over the last 30 days, recent STIs, and drug use) to provide 2 risk scores to participants, which were presented both via iPad and verbally. Results suggested that GBM who were provided with these scores were not more likely to start PrEP after 8 weeks than those who were not, despite a substantial number of participants underestimating their risk at baseline. Although these findings could suggest that providing GBM with more objective information about their risk does not lead to greater PrEP uptake in general, the extent to which the specific scores used in this study increased the accuracy of participants' misperceptions is not clear. It is also possible that the specific type of feedback given, which involved classifying participants into broad low-, medium-, and high-risk categories, may not be as powerful as providing more specific values. Providing feedback such as this could also be more effective when users are also directly linked to options for actions they can take to reduce their risk, and additional content is also dedicated to easing key barriers (eg, PrEP stigma). Although there could be some concern that providing such specific estimates may inadvertently convey certainty about users' risk level, text boxes and footnotes on this page specifically highlight that their risk level is an *estimate* that is calculated using *average* per-act risk and that their true risk also depends on several other unassessed factors (eg, whether either partner had another STI and how recently the HIV-positive partner was infected). If this basic technique proves to be helpful, we intend to revisit it in future versions to tailor this feedback based on other important factors (eg, HIV prevalence in the user's age group and other demographics) and consider how to present this information even more carefully.

**Figure 2.** Game Plan—HIV risk profile. PrEP: pre-exposure prophylaxis.



**About PrEP**

The goal of the About PrEP section is to provide information that primarily addresses common misconceptions about PrEP and challenges beliefs that contribute to stigmas about PrEP use. We included this section given evidence that despite gains in general awareness, there are still gaps in information that may be key barriers to PrEP uptake and persistence, especially among some of those who might benefit most from PrEP (eg, racial and ethnic minority GBM) [79,80]. Similarly, PrEP-related stigma, or a belief that PrEP users are promiscuous

or tainted, may also be a key barrier to PrEP uptake and persistence, particularly among racial and ethnic minority GBM [81,82]. Providing information from a credible source is one technique that can effectively increase knowledge, and specifically, offering information to correct misperceptions about the social consequences of PrEP use may be effective in challenging PrEP stigma [83,84]. In consultation with PrEP providers and past research, we generated a list of five common questions that patients or research participants raise as potential barriers to PrEP uptake, adherence, or persistence: (1) missing a single dose negates protection, (2) side effects are severe, (3)



abandoning PrEP is the only choice if one cannot afford it, (4) HIV treatment medications will not work for those who have taken PrEP, and (5) PrEP is only for promiscuous people. One additional misconception was also included because it has been reported among GBM on PrEP who drink alcohol [29]: (6) drinking and taking PrEP may make them sick or reduce PrEP's efficacy. This section presents each of these misconceptions on an accordion that, when clicked, expands to provide more information and links to helpful sites (eg, links to the US Department of Health and Human Services page for the *Ready, Set, PrEP* program for those who responded consistent with concerns about paying for PrEP). These links are also presented on Game Plan's final page so that users can reference them later. Footnotes for all information in this section are also included to convey its credibility. This information is presented to both PrEP users and nonusers, given that it may be helpful in addressing barriers to both uptake and adherence or persistence alike.

### Your Drinking Habits

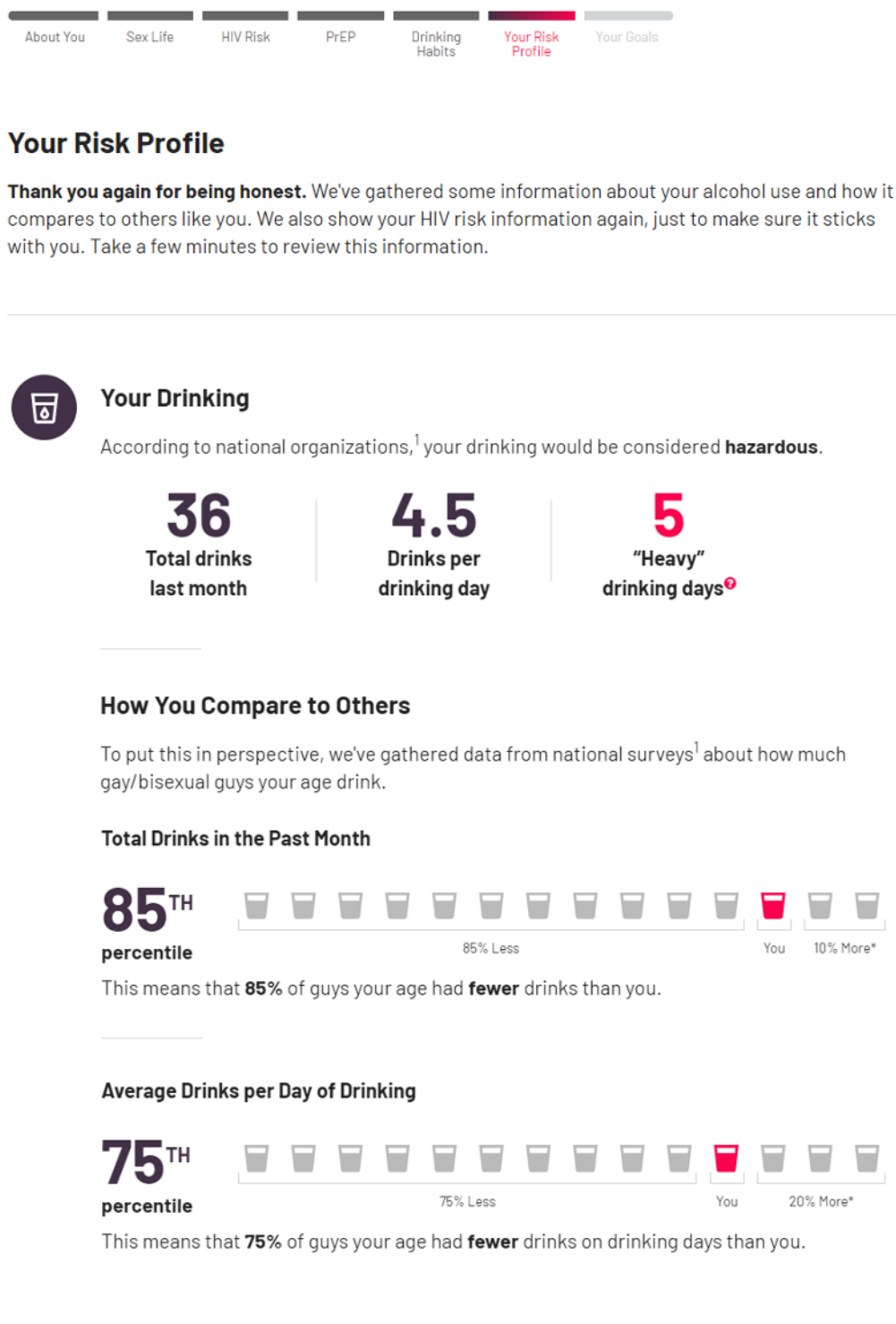
After sections on sexual behavior, risk, and PrEP, a splash page transitions users to focus on alcohol use. This first section collects information about the users' recent drinking pattern (past 30 days) and provides feedback that is similar to many other existing personalized feedback interventions for alcohol use [85,86]. The content of this section is also largely unchanged compared with that of the initial version of Game Plan [52]. Briefly, users report their drinking frequency and quantity over the past 30 days using a graduated-frequency approach [87]. To prompt reflection on some common negative consequences of drinking, they are also asked to report whether they have regretted their drinking or experienced an alcohol-related *blackout* within the last month (Figure 3).

The next screens in this section provide information about the link between alcohol use and sexual risk behavior, including

the specific ways alcohol plays a role in HIV transmission [26,88], in much the same way as the initial version of Game Plan. It also asks users to identify specific reasons for why they often drink before or during sex [89] and provides specific information challenging beliefs about alcohol's effects on sexual or romantic behaviors that may produce those motivations. For those using PrEP, these screens also present conditional content that provides information about the ways in which alcohol might interfere with taking PrEP consistently, such as (1) disrupting their normal routines (eg, going to bed or waking up later than usual), (2) causing hangovers that make them feel too sick or indifferent to take their meds, or (3) believing that taking PrEP with alcohol contributed to feeling sick or having worse hangovers. As in previous sections, references are also shown where necessary to ensure that the information provided is perceived as credible.

At the end of this section, users revisit their earlier risk profile with feedback about their drinking included. Users' overall level of drinking is first classified as *moderate* or *hazardous* according to the National Institute on Alcohol Abuse and Alcoholism guidelines [90]. This screen also provides basic summary feedback about the total number of drinks they consumed, the average number of drinks per drinking day, and the total number of *heavy* drinking days (>5 drinks) they reported in the last month. These data are then compared with those of other GBM in their age group in the United States, highlighting a percentile of GBM that the user drank more than. The goal of this feedback and normative comparison is to again increase intrinsic motivation to change alcohol use by both correcting misperceptions that the user's current alcohol use level is normative and by highlighting the potential discrepancy between their actual behavior (heavy drinking) and ideal behavior (normative drinking) [91,92]. Feedback about HIV or STI risk from the earlier profile is then presented again to ensure that this information is retained.

**Figure 3.** Game Plan—alcohol feedback and social norms. PrEP: pre-exposure prophylaxis.



**Pros and Cons Exercise**

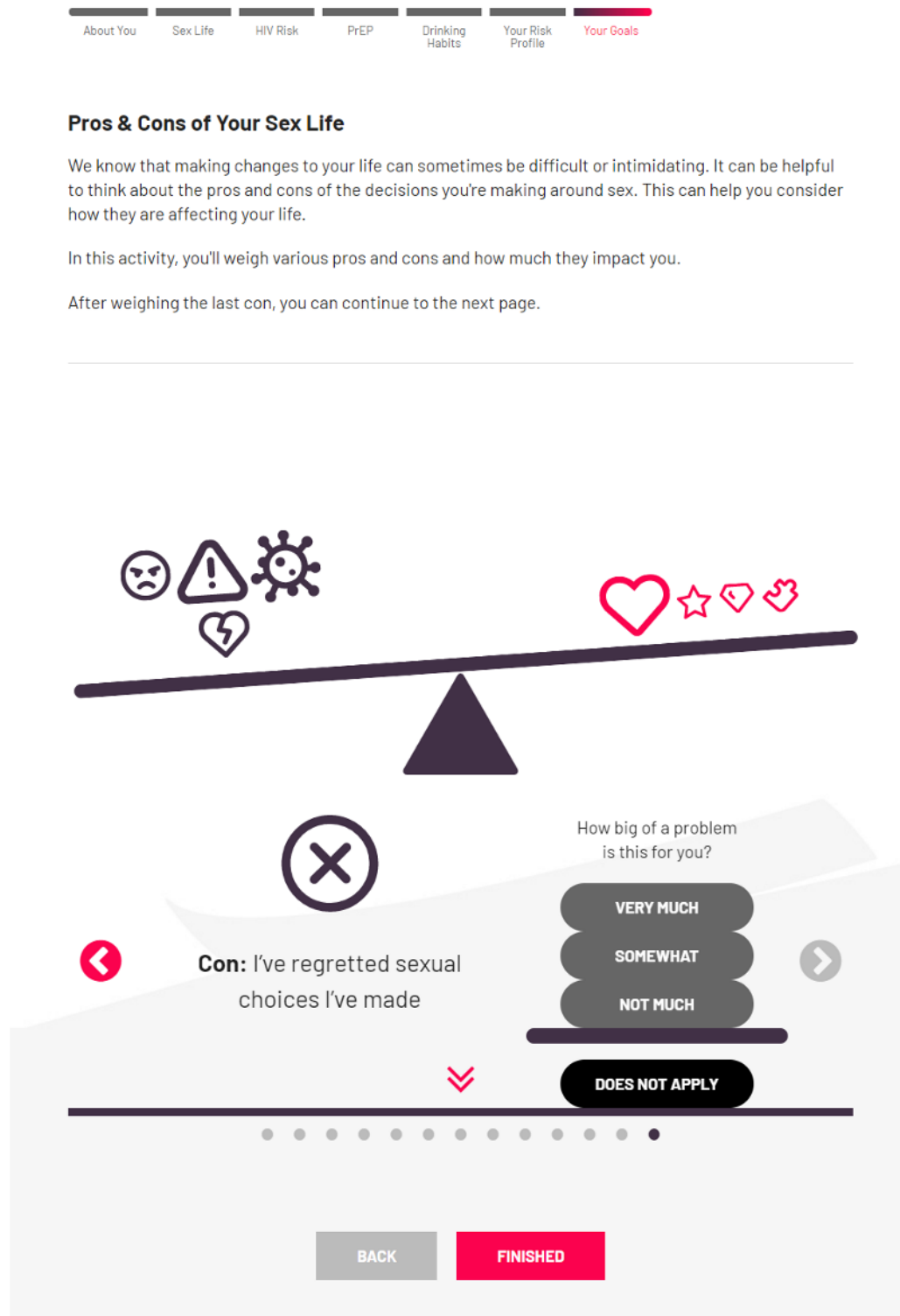
Users' motivation to change their choices about sex or alcohol use is then reassessed in a similar way as earlier in the flow. Users who report they are either *not ready* or *not sure* are then directed to a *pros* and *cons* or *decisional balance* exercise [93] that is similar to that in the original Game Plan site. In this exercise, users are presented with a graphical weighing *scale* and asked to scroll through a carousel of *Things I like about my*

*sex life now*. Users indicate whether each pro presented is relevant to them, and if so, its importance to them. Example pros include *My sex life helps me feel connected to my partner* and *My sex life helps me have a better day/night*. Selecting a given pro adds an icon to the scale, and users' ratings of the importance of each factor determines how much weight the pro adds to the scale. After completing the pros, the users scroll through possible cons. Example cons include *My sex life gets me in trouble with my partner* and *I worry a lot about my choices*

about sex. After all possible pros and cons have been selected and rated, a final screen provides users with a summary of the most important pros and cons they chose and feedback text that is conditional based on the direction that their scale was weighted. If the scale is weighted in the direction of cons, the

feedback reflects that there seem to be many drawbacks regarding their recent choices about sex. For scales noting at least one con, feedback notes that there are at least some drawbacks that the user may be able to avoid by considering some changes (Figure 4).

Figure 4. Game Plan—pros and cons exercise. PrEP: pre-exposure prophylaxis.



**Your Game Plan**

For users who indicate some level of interest in or ambivalence about change, this section presents a menu of options they can

select to help them reduce their sexual risk and alcohol use. In addition to these goals, PrEP users can also select goals to help them take their PrEP more consistently. The section starts by

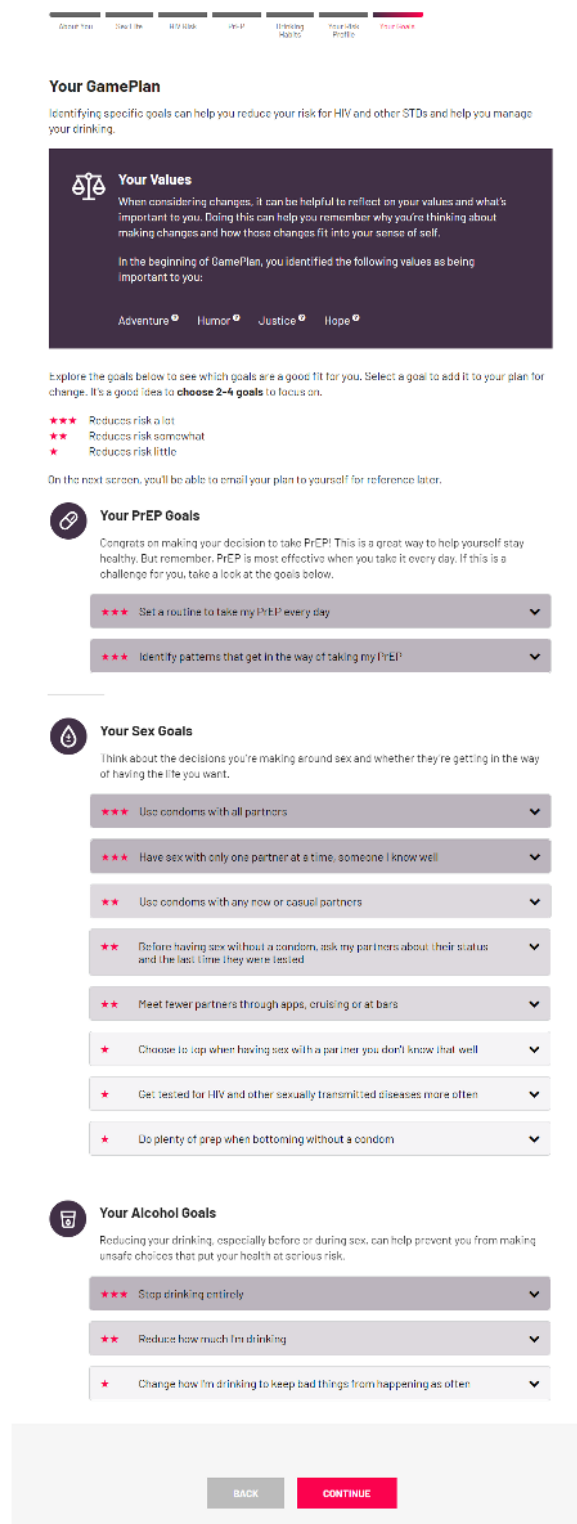
reminding users of the values they selected in the About You section and suggests that keeping them in mind as they consider the possibility of change might help them choose goals that fit them best. All goals shown in this section are prioritized, with those that reduce risk the most presented at the top of each section (Figure 5). Each goal is also assigned a star rating and filled in grayscale, with those that reduce risk considerably given 3 stars and darker gray fill and those that only reduce risk slightly given 1 star and light gray fill. We chose stars and grayscale over other possible color schemes (eg, green, yellow, and orange) to maximize accessibility (eg, for those with colorblindness). Selecting a goal expands an accordion that then asks users to select the most important reasons why they want to make this change and to identify specific steps they will take to achieve this goal. For example, those taking PrEP who choose the goal *Set a routine to take my PrEP every day* can select specific steps such as *Keeping my meds in a prominent place I go every day*, *Set up an alarm or calendar reminder in my phone*, or *Download a medication reminder app*, with links to 2 evidence-based reminder apps provided. For some goals, the available steps are tailored based on the barriers identified by the users. Non-PrEP users are shown goals in two categories: *Your sex goals* and *Your alcohol goals*, with *Take a medication (PrEP) to reduce my risk of HIV* highlighted as a top step. Once

users have selected their desired goals (up to 4), motivations, and steps, they can move on to the next screen. This screen congratulates them on their completion of the Game Plan site and affirms their reflection on their sexual health and allows the users to email the plan they made to themselves and to sign up for weekly text messages to check up on the goals they set. Although users can access local resources from anywhere in the site via a navigation pane (eg, for HIV or STI testing, PrEP, medical care, mental health care, and drug or alcohol treatment), links to a page providing these resources also appear on this page.

This section is similar to the change planning steps in MI [63] and involves eliciting users' potential goals, helping them identify specific steps that can help achieve those goals, and eliciting commitment to that plan [63,94]. Presenting users with several options and encouraging them to choose any that are right for them may also help convey a sense of respect for users' autonomy. Similarly, presenting several practical ideas for ways to achieve each goal supports users' self-efficacy, a factor that past studies have shown is linked to PrEP uptake, consistent use, and condom use [25,95]. Finally, encouraging users to select specific goals may also help produce a sense of commitment that builds motivation for change to help users enact their planned changes (Figure 5).



**Figure 5.** Game Plan—goal setting. PrEP: pre-exposure prophylaxis; STD: sexually transmitted disease.



### SMS Text Messaging

On the final page of the Game Plan site, users can enter their phone number to sign up for weekly SMS messages that check in on the goals they set on the site. If they do, the program involves one interaction per week for 12 weeks. A weekly interval was chosen given that most of the behaviors of interest (PrEP adherence, sex, and alcohol use) are likely to be accurately recalled at weekly intervals [96] and to ensure that

follow-up was as minimally burdensome as possible for users. Each week, a 2-way interaction was initiated on Monday. The goal of this program is to increase or maintain users' motivation to start or adhere to PrEP and reduce their sexual risk and alcohol use by providing them with ongoing feedback about their progress toward the goals they set in Game Plan and how their engagement in these behaviors over time affects their risk. For users on PrEP, the program asks participants how many days in the last week they took their PrEP (0 to 7 days) and then

either praises them if they took  $\geq 5$  doses or offers encouragement if they took less. If users chose goals to increase their PrEP adherence in the Game Plan site, text messages also provide feedback about how well past week adherence aligned with the goals they set, offering praise if it did or encouragement if it did not. For those not on PrEP who set a goal to start PrEP in Game Plan, the program asks whether they started taking PrEP in the last week or not and offers praise if they did and encouragement with a link to the HIV.gov PrEP locator website if they did not.

Next, the program asks a similar set of questions as those in the main site about past week sexual behavior (eg, number of anal sex partners and number of times they had anal sex as bottom and top with and without condoms). The program then provides feedback about how their cumulative *rate* of CAS events reported over each week after completing Game Plan compares with the rate they reported in the year before completing Game Plan. For example, if users report having CAS with an unknown-status partner once each week in the first 2 weeks of the SMS text messaging program and 24 total such events in the past year in the Game Plan, the SMS text messaging program provides feedback that this represents a 117% increase over the previous year. It also provides feedback to users about what this rate would suggest their risk for HIV (if they are not on PrEP) or STIs (if they are on PrEP) might be over the course of a year and how that compares to the rate they were shown on the Game Plan site. If users set goals in Game Plan to reduce their number of sex partners or use condoms with all or status-unknown partners, the SMS text messaging program also gives them feedback about what their *rate* of new partners or CAS events would suggest about their progress toward those goals, praising them if they are reducing these, and encouraging them if they have remained the same or increased.

Finally, the SMS text messaging program asks participants how many standard drinks they consumed over the past week and how many days they drank  $\geq 5$  drinks in a single day. It then gives them feedback on how this level of drinking compares with their level over the 30 days before they completed Game Plan. If users had set a goal to reduce their drinking in Game Plan (either reducing how much they were drinking or quitting alcohol entirely), it also gives them feedback about whether their weekly drinking since completing Game Plan represents progress toward those goals or not, praising them if it does and encouraging them if it does not. The SMS text messaging program provides links to local resources in a link at the end of each interaction.

This interaction is similar to several other previous SMS text message-based interventions developed to address each of these outcomes. For example, Liu et al [97] showed that daily SMS text message-based *check-ins* and reminders to take PrEP increased more than twice the participants' PrEP adherence and follow-up visit attendance. These findings are consistent with a large body of work showing that SMS text message-based interventions also reduce nonadherence to HIV treatment medications and follow-up visits [98]. Fewer such programs have been developed for sexual risk reduction, and evidence of efficacy is mixed [99,100]. However, similar programs developed to help recipients reduce alcohol use show promising

effects [101], although the rigor of studies testing stand-alone SMS text messaging interventions for alcohol has been low to date.

## Discussion

### Principal Findings

Deciding to start and remain on PrEP is a complicated decision that is influenced by several structural, interpersonal, and individual factors. Similarly, for those already using PrEP, taking it every day for as long as one is at risk also depends on a variety of factors, such as the ability to pay for it, logistical gaps in renewing and receiving prescriptions, and the capacity to find and set a routine [34]. A web application is not well-suited for addressing all of these barriers. However, individual-level determinants, such as underestimated risk, low PrEP knowledge, high PrEP stigma, and low self-efficacy, also play important roles in PrEP uptake and use [24,25], and as access to PrEP improves and the cost barrier is reduced, these factors may become even more important in optimizing these outcomes. A growing body of research has clearly shown that web-based interventions can change factors such as these and result in meaningful improvements in health outcomes [102,103]. In this study, we created several components of a web application to address these individual-level factors, with the goal of ultimately increasing PrEP uptake among those not using PrEP and improving PrEP adherence and persistence and reducing STIs among those using PrEP. We designed these components and redesigned the broader Game Plan web application with the goal of creating a simple tool that uses evidence- and theory-based strategies that help some GBM who are ambivalent about PrEP to see its utility and use it. We also designed this tool to be brief and feasible for real-world use so that it aligns with how most people access and use health information on the internet [54,55] and could realistically be implemented in the real world, if it is shown to improve outcomes. We also spent considerable effort ensuring that the site was attractive so that users might *want* to use it, a necessary condition for success with digital interventions in the real world.

To date, few internet-facilitated interventions addressing PrEP outcomes exist and among those that do [104], to our knowledge, all are still in the process of being rigorously tested in large efficacy trials. As such, determining how much internet-facilitated interventions might assist other efforts in improving PrEP uptake and use among GBM in the United States is not yet clear. Many similar self-guided, internet-facilitated interventions for alcohol use have been tested, and meta-analyses have shown that they are effective in reducing drinking [105,106]. Most studies have specifically tested these interventions in samples that include those at high risk for alcohol use disorder [107,108], and although this level of care may intuitively seem insufficient for those with such severe problems, the improvement these interventions initiated was not reduced in samples with a higher percentage of participants with more severe alcohol problems. As such, although interventions like Game Plan alone are unlikely to be sufficient to consistently encourage extensive and durable long-term change, particularly in those with severe alcohol use

disorders, there is reason to expect that it may be helpful for some at highest risk and could play a role in initiating decisions to seek further help.

### Future Directions

Research on these new components of Game Plan is currently in its preliminary phases. Initial design research with GBM suggests that Game Plan is generally engaging and that users believe they would use it if they encounter it in the real world [56]. However, little is known about the effects of these components on PrEP outcomes. We are currently conducting a pilot randomized controlled trial with 50 heavy drinking GBM who currently use PrEP and have taken <80% (24/30 days) of their prescribed doses in the past month. Participants will be randomly assigned 1:1 to either use Game Plan or an attention-matched control (a general health site that discusses diet and sleep) and followed for 6 months. During the 6-month period, participants will complete web-based surveys assessing PrEP use, sexual behavior, alcohol use, and important antecedents of change for each of these outcomes at baseline and 1, 3, and 6 months. They will also provide dried blood spots collected using kits sent to them in the mail for analysis of tenofovir-diphosphate—a biomarker of PrEP adherence—and phosphatidylethanol—a biomarker of recent alcohol use—at baseline and 3 and 6 months. Finally, we will also collect data on STI diagnoses from the participants' medical records throughout the study. The primary outcomes will be (1) PrEP adherence or persistence, (2) STI rates, and (3) alcohol use. If the results of this pilot are promising, we plan to pursue support for a full-scale efficacy trial testing of Game Plan's effects on similar outcomes among GBM in *real-world* PrEP clinics in areas with high HIV incidence. We also recently began a fully powered efficacy trial of Game Plan's effects on PrEP uptake (among other outcomes) in GBM who are testing for HIV and other STIs using kits delivered to them in the mail. This study will recruit 360 GBM from several high HIV incidence areas in the United States (eg, Atlanta, Miami, and Baltimore) from several web-based platforms (eg, social media and gay-oriented dating apps) and randomize them 1:1 to either use Game Plan or standard of care (access to a 24-hour helpline) when they complete their first test kit. Participants will then be followed for a year, completing quarterly web-based surveys and HIV or STI test kits at 6 and 12 months. These studies will be critical for determining whether a tool like Game Plan can help make a plan to start and take PrEP consistently.

We initially designed Game Plan to provide content to help users reflect and *make* a plan about PrEP because relatively few tools have been explicitly designed so far to boost users' motivation to reduce their HIV-risk behavior. Therefore, Game Plan currently contains few tools to help users follow through on or maintain those plans. However, users who set a goal to take their PrEP regularly while completing their change plans are shown links to several smartphone apps that were developed

to help encourage consistent adherence to medications (eg, Mango Health [TrialCard, Inc] and MediSafe). In the near future, we hope to develop additional features to help users maintain their adherence over time that are unique to PrEP.

### Limitations

Although Game Plan has many strengths, several limitations are important to note. First, Game Plan was primarily developed through user-centered design research conducted with GBM. Risk and social norms feedback are also provided in comparison with other GBM. As such, Game Plan is not appropriate for use with other high-priority populations, including transgender individuals. Second, Game Plan was designed primarily to help those for whom individual-level factors are the primary barriers to successfully using PrEP. Although some content provides simple ways for some users who may have difficulty starting or taking PrEP because of financial or structural barriers to overcome them (eg, by learning about the *Ready, Set, PrEP* program and reaching out themselves), Game Plan's content is likely to be insufficient for helping these individuals durably address these barriers. Therefore, Game Plan was not intended to replace other critical services (eg, PrEP navigation and provider panel management) and may be best viewed as a tool that could add to these services or provide at least some support when offering these other services is not possible. Finally, one of our highest priorities in developing Game Plan was to create a tool that users might actually use in the *real world*, which could be easily accessed and used in a variety of settings (eg, at home and in clinics). As such, it was essential that Game Plan deliver its techniques within a timeframe that matched how users typically engage with similar tools in their normal lives: a single, brief interaction rather than multiple sessions over time. Given this timeframe, its support for behavior change over time is limited. Although the weekly text messaging feature may add some support for users after they complete their Game Plan, this degree of support is unlikely to be sufficient for many users with more severe or complicated barriers (eg, substance use disorders).

### Summary and Conclusions

In summary, the redesign of the Game Plan site and addition of new components addressing PrEP uptake and use could help encourage some GBM who are not on PrEP to start it or encourage those who already use PrEP to take it more consistently. By showing users how much PrEP could reduce their risk for HIV with consistent use, challenging common myths, eliciting commitment to starting PrEP or using PrEP consistently, and providing practical steps that users can take to accomplish those goals, Game Plan could be a scalable and far-reaching tool that helps some GBM be successful on PrEP. If ongoing research demonstrates its benefit for PrEP outcomes, Game Plan could be a useful option for helping facilitate PrEP-related change in settings where providing evidence-based, face-to-face interventions is difficult.

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## Conflicts of Interest

None declared.

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## Abbreviations

- CAS:** condomless anal sex
- GBM:** gay, bisexual, and other men who have sex with men
- MI:** motivational interviewing
- PrEP:** pre-exposure prophylaxis
- STI:** sexually transmitted infection

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Original Paper

# The Views and Needs of People With Parkinson Disease Regarding Wearable Devices for Disease Monitoring: Mixed Methods Exploration

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## Abstract

**Background:** Wearable devices can diagnose, monitor, and manage neurological disorders such as Parkinson disease. With a growing number of wearable devices, it is no longer a case of whether a wearable device can measure Parkinson disease motor symptoms, but rather which features suit the user. Concurrent with continued device development, it is important to generate insights on the nuanced needs of the user in the modern era of wearable device capabilities.

**Objective:** This study aims to understand the views and needs of people with Parkinson disease regarding wearable devices for disease monitoring and management.

**Methods:** This study used a mixed method parallel design, wherein survey and focus groups were concurrently conducted with people living with Parkinson disease in Munster, Ireland. Surveys and focus group schedules were developed with input from people with Parkinson disease. The survey included questions about technology use, wearable device knowledge, and Likert items about potential device features and capabilities. The focus group participants were purposively sampled for variation in age (all were aged >50 years) and sex. The discussions concerned user priorities, perceived benefits of wearable devices, and preferred features. Simple descriptive statistics represented the survey data. The focus groups analyzed common themes using a qualitative thematic approach. The survey and focus group analyses occurred separately, and results were evaluated using a narrative approach.

**Results:** Overall, 32 surveys were completed by individuals with Parkinson disease. Four semistructured focus groups were held with 24 people with Parkinson disease. Overall, the participants were positive about wearable devices and their perceived benefits in the management of symptoms, especially those of motor dexterity. Wearable devices should demonstrate clinical usefulness and be user-friendly and comfortable. Participants tended to see wearable devices mainly in providing data for health care professionals rather than providing feedback for themselves, although this was also important. Barriers to use included poor hand function, average technology confidence, and potential costs. It was felt that wearable device design that considered the user would ensure better compliance and adoption.

**Conclusions:** Wearable devices that allow remote monitoring and assessment could improve health care access for patients living remotely or are unable to travel. COVID-19 has increased the use of remotely delivered health care; therefore, future integration of technology with health care will be crucial. Wearable device designers should be aware of the variability in Parkinson disease symptoms and the unique needs of users. Special consideration should be given to Parkinson disease-related health barriers and the users' confidence with technology. In this context, a user-centered design approach that includes people with Parkinson disease in the design of technology will likely be rewarded with improved user engagement and the adoption of and compliance with wearable devices, potentially leading to more accurate disease management, including self-management.

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## KEYWORDS

Parkinson disease; wearable devices; technology; mixed method; focus group; survey; mobile phone

## Introduction

### Background

Parkinson disease is a progressive, chronic neurodegenerative disorder. The disease is characterized by motor symptoms including tremor, rigidity, bradykinesia, dyskinesia, and nonmotor symptoms such as cognitive impairment, fatigue, and pain [1,2]. Globally, Parkinson disease is the second most common neurodegenerative disease, affecting >6 million people worldwide [3], with an estimated prevalence of 1% in people aged  $\geq 60$  years and 2% in people aged  $\geq 80$  years [4]. As the median age increases in many countries, so does the prevalence of Parkinson disease [3]. This increased prevalence carries a personal and societal burden, with an estimated cost to society of US \$22,800 per patient, per year [5].

Owing to the heterogeneity and complexity of Parkinson disease features, its clinical assessment may be challenging, relying on sporadic, subjective clinician assessment and self-evaluation of symptoms by patients [6]. Symptom diaries can be onerous to complete, whereas infrequent clinical examinations offer limited insight into the day-to-day symptom fluctuations [7]. In contrast, wearable devices can collect continuous, accurate, and objective data over a prolonged period. They quantify motor fluctuations, collect key data during critical events (eg, whether dramatic motor decline is due to bradykinesia or hypotension), and continuously monitor motor symptoms [8]. Wearable devices have been used to identify and quantify bradykinesia [9], tremor [10], postural sway [11], motor fluctuations [12], and dyskinesia [13]. They have also been used to measure gait [14], sleep disorders [15], falls [16], and physical activity levels [17]. On the basis of the deliberations of the International Parkinson and Movement Disorders Society Task Force on Technology, Espay et al [8] summarized how technology-based objective measures may decrease clinical visits, engage patients in their own care, and close the loop between clinicians and their patients.

Previous research has identified the general research priorities for people with Parkinson disease, including improving motor and nonmotor symptoms, mental health issues, medication side effects, interventions specific to Parkinson disease, better monitoring systems, and quality health care [18-20]. People with Parkinson disease have already expressed their desire for wearable devices to capture data on a range of symptoms and lifestyle factors. They want the technology to capture data on bradykinesia, tremor, balance, gait, sleep, and cognition [21]. Design interface, usability, and accuracy are important aspects,

and people with Parkinson disease want an unobtrusive design [22-25]. They want to understand which data are collected before, during, and after monitoring. In addition, they want to be assured that the information gathered is worthwhile and clinically relevant to them and that it captures Parkinson disease symptom fluctuations [25]. Additional desirable features include specialized Parkinson disease functions, such as real-time detection of motor fluctuations and medication prompts [26]. The importance of interactive communication and feedback between the devices, patients, and health care professionals is evident [25]. Although many older adults embrace technology, people aged >65 years generally use fewer new technologies and use them less frequently [27]. Older adults use technology for emailing, web-based searching, and web-based shopping, but less so for connected health [28]. Older adults with ability limitations appear to use technology even less frequently [29]. Similarly, poor confidence in handling new technology has been highlighted as an area of concern for people with Parkinson disease; therefore, wearable devices should be easy to learn and use [23].

### Objectives

The aforementioned feedback was derived from a variety of study designs. To our knowledge, much of the previous research in this area has used surveys to solicit feedback from people with Parkinson on specific devices only [22,24,30] or included the views of people with Parkinson disease alongside other populations such as people with epilepsy [25]. With a growing number of wearable devices on the market, it is no longer simply a case of whether a wearable device can measure Parkinson disease motor symptoms but rather of which features best suit the user's needs. Previous research has outlined the motor symptoms that a wearable device should measure [21], and the latest devices can accurately measure these [31]. Thus, concurrent with continued device development, we must generate insights on the nuanced needs of the user in the modern era of wearable device capabilities.

As part of a larger European study on wearable devices for remote rehabilitation of older people (SENDOC [Smart Sensor Devices for Rehabilitation and Connected Health]), we aim to explore, using a mixed method approach, the views and needs of people with Parkinson disease who are aged  $\geq 50$  years, regarding wearable devices for monitoring, treatment decisions, and care-planning.

## Methods

### Study Design

This study used a mixed method parallel design, wherein surveys and focus groups were concurrently conducted with people with Parkinson disease in Munster, Ireland. There have been calls in the technological literature to use a mixed method approach to produce meaningful understanding when studying complex contexts [32]. This approach is quite novel in Parkinson disease wearable device research, where previous mixed method studies have mainly focused on disparate populations or on specific devices only. A mixed method approach combines the advantages of quantitative and qualitative methodologies, enabling the collection of rich data that reflect the participants' perspectives and ensures that the study findings are rooted in their experience [33]. Qualitative research methods are well suited to examine user needs and may offer explanations for unexpected or anomalous findings in quantitative data [34] or uncover usability barriers that quantitative approaches often miss.

Members of a local branch of the Parkinson's Association of Ireland (PAI) formed part of the research team and guided the study design and advised on patient recruitment. These advisers consisted of 2 people with Parkinson disease and a caregiver of a person with Parkinson disease. The advisory group helped identify and prioritize the research questions and shaped the data collection tools. They also assisted in the recruitment of participants for the focus groups and the distributed surveys. Upon completion of the research, the advisers guided the researchers on how best to disseminate the results to people affected by Parkinson disease.

### Participants

The inclusion criteria for the survey and focus groups were as follows: age  $\geq 50$  years and a diagnosis of Parkinson disease. The focus group participants were selected using a criterion theoretical sampling strategy to satisfy the following criteria: inclusion of different age categories (50-60 years, 61-70 years, 71-80 years,  $>80$  years) and the inclusion of men and women.

Participants were excluded if they had significant communication deficits. Ethical approval was obtained from the Clinical Research Ethics Committee of the University College, Cork.

Participants were recruited through local branches of PAI, a not-for-profit advocacy and support group, with researchers or PAI research volunteers attending local branch meetings to inform the attendees (people with Parkinson disease and their families). Those expressing interest were given an information sheet about the study, and a copy of the survey which was to be returned later to the PAI branch if desired.

### Survey

The survey consisted of structured questions in 2 parts. Part A included 8 items including gender, age, experience with technology, and knowledge of wearable devices. Part B contained 18 Likert items that probed the importance of certain wearable device features across 4 thematic categories:

*wearability, user interface, wearer feedback, and clinical accuracy.* This survey was closely based on the survey by Bergmann and McGregor [35], with 5 items unchanged, 8 with minor wording changes to improve understanding, and 5 new or substituted items based on the advisory group's feedback. These included the device being rechargeable, sending alerts, and giving the user ownership of their own health care (see [Multimedia Appendix 1](#) for the full survey, mapped to the original Bergmann survey). The 10-point Likert response format from Bergmann's survey was converted to a 5-point Likert scale to make it easier for older participants to complete. Items were thus presented as *strongly agree, agree, neutral, disagree, and strongly disagree*. By completing the anonymous survey and returning it to the PAI branch, participants gave their consent to participate (signed consent would have removed anonymity).

### Focus Groups

Focus groups took place in local community spaces throughout Munster, Ireland. Written informed consent was obtained from all the patients in advance.

The semistructured topic guide questions explored the priorities of people with Parkinson disease in everyday life; the usefulness of wearable devices, their perceived benefits, and the barriers to use; and the usability and important design features.

Initial drafts of the topic guide were based on existing literature and the purpose of the study. These were iteratively reviewed by the advisory group and the researchers together in terms of the content, focus, and relevance to people with Parkinson disease (see [Multimedia Appendix 2](#) for the final focus group schedule). The focus group guide was used to ensure that all topics were covered, but the groups were informal and interactive to obtain as many insights as possible, lasting from 50 to 70 minutes. During the focus group, participants were shown examples of a wearable smart watch and a glove device. However, the participants did not try on or take these devices to their homes. They were used as tools to demonstrate examples of wearable technology to encourage discussion.

### Data Analysis

Simple descriptive statistics were used to represent the data for the Likert items in part B of the survey. Given that the participants rated all statements positively (no one selected disagree or strongly disagree for any Likert items), the data have been presented as the ratio between the categories of neutral, agree, and strongly agree responses. A higher proportion of strongly agree responses for an item indicated its importance to the participants. No statistical tests were conducted because of the positive skew of the Likert statements and the invalidated status of this survey tool. In part A of the survey, Fisher exact test and the Wilcoxon signed rank test were used to test the difference between men and women for each survey response.

The focus groups were audiotaped and transcribed. Transcripts were analyzed for common themes using a qualitative thematic approach [36]. A lead researcher (highly familiar with this approach) used open coding to collect data from the participants' views. The coding scheme combined an inductive and deductive process, where codes were assigned as appropriate; however, the researcher also deductively decided how these codes fitted



with the categories of the survey (ie, wearability, user interface, wearer feedback, and clinical accuracy). Transcript data were broken down into discrete excerpts, labeled, and described, with the coding remaining tentative and subject to change as it continued in subsequent rounds. A second researcher (SF) reviewed a sample of the transcripts and codes, and both researchers established an agreement on the final codes. Codes were then grouped into provisional subthemes and themes, and key phrases were later assigned according to their content. Themes were designated on the foundation that they echoed the patterns of participant responses in the transcript data and were significant to our research question [36], that is, *what are the views and needs of people with Parkinson disease regarding wearable devices for monitoring, treatment decisions, and care-planning?*

The survey and focus groups were conducted concurrently and analyzed separately. The results were *integrated through narrative*, where the qualitative and quantitative results were described and woven together on a theme-by-theme basis [37]. Findings from each type of data confirmed the results of the other type and provided similar conclusions, which increased their reliability [38]. This representation procedure ensured coherent data integration and allowed a fuller depiction of the views and needs of people with Parkinson disease regarding wearable devices [39].

## Results

### Participants

The people with Parkinson who attended the meetings, and hence participated in the surveys and focus groups, were typically at Hoehn and Yahr stage 1 to 3 (informal impression from a Parkinson disease expert, ST, from attendance at a meeting). There were 32 surveys completed by people with Parkinson disease. Of the respondents, 56% (18/32) were male and 44% (14/32) were female, ranging in age from 50 to 83 years, with a median age of 68 years. The response rate was not captured because the surveys were disseminated by a PAI member volunteer who distributed surveys to group members who had attended meetings over a period of 6 months. The PAI volunteer reported that, to their recollection, every dyad who attended the meetings completed the survey, with no refusals, and that most people with Parkinson disease completed the survey alone and some completed it with their family members' support.

In part A of the survey, the results of the statistical tests showed no significant differences between males and females for any of the responses ( $P > .60$ ). The results for part A have been presented in [Table 1](#). For part B of the survey, statistical tests were not performed. The results have been presented in [Table 2](#) as a percentage selection, grouped by category.

Overall, 4 semistructured focus groups were held with 24 people with Parkinson disease, with 4 to 7 participants in each group. In all, 14 men and 10 women participated, ranging in age from 53 to 84 years with a median age of 70.5 years.

**Table 1.** Technology use among participants.

	All (N=32)	Female (n=14)	Male (n=18)
Age (years), median (range)	68 (46-83)	68.5 (46-78)	66.5 (53-83)
<b>Current technology use, n (%)</b>			
Smartphone	18 (58)	8 (57)	10 (59)
Games console	2 (6)	1 (7)	1 (6)
Desktop computer	25 (81)	11 (79)	14 (82)
Any of the above	27 (87)	12 (86)	15 (83)
Other technology	2 (6)	2 (14)	0 (0)
Missing data	1 (3)	0 (0)	1 (6)
<b>Self-rating of technology skills, n (%)</b>			
No skills	4 (13)	2 (14)	2 (11)
Poor skills	3 (9)	1 (7)	2 (11)
Average skills	10 (31)	5 (36)	5 (28)
Good skills	14 (44)	5 (36)	9 (50)
Excellent skills	1 (3)	1 (7)	0 (0)
Missing data	0 (0)	0 (0)	0 (0)
<b>Frequency of technology use, n (%)</b>			
Every day	24 (77)	11 (79)	13 (76)
Most days	3 (10)	1 (7)	2 (12)
Every week	0 (0)	0 (0)	0 (0)
Rarely	3 (10)	2 (14)	1 (6)
Missing data	1 (3)	0 (0)	1 (6)
<b>Have heard of wearable devices, n (%)</b>			
Yes	20 (65)	7 (50)	13 (76)
Missing data	1 (3)	0 (0)	1 (6)
<b>Have used a wearable device, n (%)</b>			
Yes	11 (35)	3 (21)	8 (47)
Missing data	1 (3)	0 (0)	1 (6)
<b>Currently using store-bought wearable device, n (%)</b>			
Yes	2 (6)	1 (7)	1 (6)
Missing data	1 (3)	0 (0)	1 (6)

**Table 2.** Responses to Likert statements about wearable device features and capabilities<sup>a</sup>.

Statement	Strongly agree, n (%)	Agree, n (%)	Neutral, n (%)	Missing, n (%)
<b>Wearability of a medical sensing device (n=180)</b>	116 (64)	58 (33)	6 (3)	N/A <sup>b</sup>
Should be comfortable to wear <sup>c</sup>	17 (53)	11 (34)	2 (6)	2 (6)
Should be compact (light and small) <sup>c</sup>	17 (53)	12 (38)	1 (3)	2 (6)
Should be discrete <sup>c</sup>	17 (53)	12 (38)	1 (3)	2 (6)
Should be easy to attach to the body <sup>c</sup>	22 (69)	8 (25)	0 (0)	2 (6)
Should not affect your normal daily routine <sup>c</sup>	21 (66)	8 (25)	1 (3)	2 (6)
Should not detach accidentally <sup>c</sup>	22 (69)	7 (22)	1 (3)	2 (6)
<b>User interface (n=90)</b>	60 (67)	30 (33)	0 (0)	N/A
Should be rechargeable <sup>c</sup>	19 (59)	11 (34)	0 (0)	2 (6)
Should be simple to operate (and maintain) <sup>c</sup>	20 (63)	10 (31)	0 (0)	2 (6)
Should be accompanied by clear and readable instructions for use <sup>c</sup>	21 (66)	9 (28)	0 (0)	2 (6)
<b>Wearer feedback (n=90)</b>	52 (58)	37 (40)	1 (1)	N/A
Should give instant feedback to you	17 (53)	12 (38)	1 (3)	2 (6)
Should send alerts to the user	20 (63)	10 (31)	0 (0)	2 (6)
Should provide you with alerts, that is, performance versus target (eg, step count)	15 (45)	15 (45)	0 (0)	3 (9)
<b>Clinical accuracy (n=175)</b>	143 (82)	32 (18)	0 (0)	N/A
Should be reliable	24 (75)	6 (19)	0 (0)	2 (6)
Should increase the accuracy of current clinical assessment	24 (75)	5 (16)	0 (0)	3 (9)
Should reduce your requirement to travel for clinical assessment	23 (72)	6 (19)	0 (0)	3 (9)
Should form part of your clinical assessment	24 (75)	5 (16)	0 (0)	3 (9)
Should give you a sense of ownership of your own health care	24 (75)	5 (16)	0 (0)	3 (9)
Should work alongside your medical care team, instead of replacing them	24 (75)	5 (16)	0 (0)	3 (9)

<sup>a</sup>No participant selected *Disagree* or *Strongly Disagree* for any Likert item.

<sup>b</sup>N/A: not applicable.

<sup>c</sup>n=30.

## Survey and Focus Group Results

The first major theme below was not addressed in the survey. For all other themes, the survey data have been first presented, followed by the relevant subthemes from the focus group.

### Living With Parkinson Disease

At the beginning of the focus group, participants shared what they felt were important aspects of daily life for people with Parkinson disease. The participants valued their independence and wanted to remain independent for as long as possible:

*Independence. That is my goal. Hits it on the head. I'd love to be independent.*

*It's trying to live as normal a life, as close to it as possible, and adapting where necessary and that's the other thing, you're having to develop a whole set of different skills.*

Participants discussed a range of different challenges they faced with Parkinson disease, including motor function and tremor. They described their problems with bradykinesia and the resulting frustration:

*The slowness I find, I gets angry now and frustrated. It takes maybe half an hour to do what I can do in five minutes.*

*It takes me a long time, you know. The dogs aged another dog year by the time I'm finished. It's that type of thing. That's the slowing down which I've struggled with myself.*

Falls, and the risk of falling was also a common concern expressed by the participants: "People with Parkinson's tend to get falls, quite a lot of falls, and means that basically [falls] take them out of circulation for months." Participants described how *normal day to day things and continuing the routine are essential* in managing the condition effectively, especially for

medication regimes, daily activities, exercise, and sleep. The benefits of exercise on Parkinson disease symptoms were viewed as an important part of maintaining health, and participants shared personal experiences of how various exercise regimes helped improve both motor and nonmotor symptoms. The group felt that *exercise really is essential* and physical activity should be encouraged for people with Parkinson disease:

*I have to maintain a certain level of activity to keep going as in walking or some form of exercise, and even this past week now I haven't been as consistent or as regular and I find that I'm stiffening a little bit first thing in the morning...I have to do it because otherwise I won't be able to keep going or it'll slow me down that bit more.*

Sleep was suggested as another vital element for overall health and well-being, but obtaining adequate rest was often challenging for the participants, as many experienced difficulty sleeping: "If I've a bad night, I'd be completely thrown all the next day." The positive impact of good quality, accessible, and timely health care was discussed. The participants highlighted the importance of regular access to quality health care to alleviate Parkinson disease symptom deterioration:

*It's really important to me to see my GP and consultant regularly. My GP is great cause she's always linking in with the consultant to make sure we're on the right track with medication and treatment. As we all know it's key to get the right support.*

However, many experienced difficulties in accessing appropriate specialized Parkinson disease health care in Ireland, including long waiting times to see a consultant:

*It's the lack of the go to person, this lack of the proper support nurse. You have your GP who doesn't seem to understand it that well. Or that he refers you onto your consultant who is not easily accessible. There's that gap in the middle.*

*You could be waiting months for an appointment with a consultant and it's just not good enough.*

It was also felt that geographic barriers existed within certain areas:

*We're in a very black hole in this area. In fact, XX generally is very poorly serviced...Consultants seem to be drifting away, retiring or going to the private sector and oh you can get good care here, but it'll cost you. That's what you've got here. Generally, there is very little and what there is a long time coming, you know.*

### Technology Use

The technology use of survey participants has been summarized in [Table 1](#). Most participants used at least one form of technology daily and rated their skills as average or good. However, although many participants had heard of wearable devices, only a fraction were currently using a purchased wearable device.

The focus groups mirrored this, with technology use most commonly being in the form of desktop computers and smartphones. People used technology to set personal alarms for medication reminders:

*The phone is handy. I set alarms. In a half an hour, this phone will go and I'll know to take the tablets.*

*I use it [technology] for medication. I have alarms set to take medication and it reminds me then when to take the next dose.*

Two participants in the focus group used medical devices such as medication-administration pumps: "I wasn't [independent] up to five weeks ago but I am now again, with the help of a machine, a pump." In addition to mechanical aids in the kitchen, such as a *kettle cradle* or adapted cutlery, a few participants used technology aids for daily living, such as for writing or typing difficulties: "I do and I find now I'm trying to make use of voice to text apps and voice apps from documents." Such technologies were considered to have improved users' lives, and it was felt that *health technology can be good for protecting the well-being of older people and making just your everyday things a little bit better and a little more comfortable*.

Generally, participants saw a role for technology; however, they felt it should be supplementary to appropriate health care delivery, not a replacement for it:

*Personally I think quality primary services are the first things to get right, then you look at what you can do then afterwards with technology. That's what I think anyway.*

Similar to the survey respondents, participants from the focus groups were familiar with wearable monitoring technology; however, no participant was currently using a purchased wearable device. Nevertheless, the participants identified that wearable devices may be conceivably beneficial and acceptable for people with Parkinson disease: "There's no sense that in the main those with Parkinson's may be technophobes that they may not like using that technology cause many do use it often and competently." Participants suggested that wearable devices may provide the opportunity to measure and monitor the individual variability of motor and nonmotor symptoms of Parkinson disease and could provide opportunities for collecting clinical parameters such as medication, balance, tremor, gait, sleep, and exercise:

*I'm all for technology and anything that may aid me to walk. If there was a device that could help do that or if there's any kind of device that through monitoring could help me improve, that would really help me.*

### Clinical Usefulness

Clinical usefulness was the highest rated thematic category in the survey ([Table 2](#)). People with Parkinson disease felt strongly that a device should increase clinical accuracy, reduce travel, and integrate as part of their care team. In the focus groups, participants emphasized that technology should objectively monitor their symptoms, and it was deemed beneficial if this information could be relayed to their medical care team:



*Something that could monitor your symptoms perhaps and even if there was a way that this could be sent to your doctor or whoever. That would be helpful.*

*It can be hard to describe symptoms to your consultant, so something that offers an independent evaluation of how you are would be great.*

A wearable device that captures Parkinson disease data could provide richer health information to clinicians, which may aid in the improved assessment of Parkinson disease:

*We try and write what's happening in advance because the clinicians time is precious, your cash is precious cause you're paying him a fee to assess you, and if you don't have the information he can't judge.*

The capturing of individual health parameters would eliminate the need for diary-based recording of symptoms, which was believed to be problematic at times:

*But I think if you got an overall, if you got to know yourself. I write things down at night, but at night I'm wrecked. We all are, and you forget half of it. It would be your individual information.*

Supporting medication dosing or timing was highlighted as a main area of focus:

*I think even listening to the accounts here this morning that patients are experiencing times when they have inadequate medication and when they're over medicated. And if the [device] can level that out in some way, that would be ideal.*

*Some mechanism of determining what your dopamine level is in your brain. As regards telling you what should you be taking; maybe an inhaler that you could use. Or something along those lines that you could have a kind of monitoring of your dopamine level and an appropriate response process to it. Because sometimes, when I get a bit of heaviness in my head, I think is I because I haven't taken enough medicine or because I've taken too much. Like right now, I've taken enough, but sometimes I couldn't actually say whether or which.*

Although it was important for health care teams to have access to the data, people also wanted a sense of ownership over their own health care:

*Knowledge is power. The more you know the more you can meet it and anticipate it.*

One focus group included a discussion on whether medical professionals would like technology that could alter the dosage of medicines they prescribe and that this may require a change in attitude from some health professionals:

*But the way medicine is controlled in the sense the pharmacist gives out what the prescription is. If you were to have medication that you could adjust accordingly that requires a completely different mind-set and I don't know would the professionals go for it.*

## **Wearability and User Interface**

Survey respondents highly rated a small, easy-to-use device that would not interfere with their routine; they responded strongly agree, with 64.4% (116/180) and 67% (60/90) overall score, to the categories for wearability and user interface, respectively (Table 2).

The wearability and usability of wearable devices for Parkinson disease similarly emerged in the focus groups, and it was felt that wearable device design should consider the user needs to ensure compliance and adoption. Although the size and weight of the device were important, the esthetics of the device appeared less significant: "I don't care how it looks but if something is hard to use for a person with PD then they're not going to use it." Participants felt that wearable device design should consider the complexity of Parkinson disease symptoms, especially motor dexterity: "I don't know if that technology can be adapted for people with Parkinson's who have these issues with making precise movements." Participants also discussed the importance of ease of use, device weight, and a design which reflected the needs of people with Parkinson disease:

*Now it would matter if it was easy to take on and off, that sort of thing, or that it wasn't heavy or getting in the way.*

*It needs to be developed...to have things that are liveable. You don't want it bulky, you don't want anything that's too small. It's got to be suitable for a person with Parkinson's.*

In addition, a participant described that given Parkinson disease variability, "technology for us needs to be multifactorial."

Participants felt that although most participants felt comfortable with technology, some may feel intimidated:

*There are some very confident people around, but there is clearly a large cohort of people who feel excluded by technology. They find it a bit impenetrable.*

Designs should make allowances for a person's possible lack of knowledge or exposure to a specific technology. It was discussed how some would need general guidance to feel more comfortable, which would also enable greater user adoption of the device:

*Another thing for me is having someone help me to understand technology or whatever the technology is. Like a step by step, on how to use it properly. That way we'd all get a lot more out of it.*

Another possible barrier was the cost of technology; wearable devices should not be expensive, as this may exclude some people with Parkinson disease: "The cost of something would be important cause that might mean some people can get access but others couldn't."

## **Feedback From the Device**

Wearer feedback was the least highly rated category in the survey. Most participants selected strongly agree 58% (52/90) of the time with statements about the device providing alerts and instant feedback (Table 2).

The importance of wearable device feedback similarly emerged in the focus groups, where one participant detailed how they wanted to receive as much feedback as possible from a device that captured their data: "...in relation to everything really, to the dyskinesia, to the memory, to whether I'm upright or not." This would not only be useful for the user but would also be valuable for their health care team: "I would see improvement in the trend or if I was getting worse and my doctor would also see that." Motor symptom fluctuations resulting from medication wearing off was seen as an important area where feedback from a wearable device would be useful: "There could be things that could help to let you know when something is escalating, shuffle at a particular time and you could get information on that to feedback in terms of stuff wearing off." In addition, prevention and detection of falls and feedback on balance and coordination were highlighted:

*I find with balance that's the big problem with me. This sounds funny now but I'd love something to tell me what way I'm facing, you know. My head is sideways or up or down and I kind of go sideways when I'm walking, you know. If there's some kind of thing that would tell you that whether you're walking straight or not. Some kind of feedback mechanism.*

Monitoring and feedback of blood pressure was also a desirable feature: "The blood pressure yes because once the blood pressure goes down that's when you could fall." Participants suggested that data collected could be used to activate a response or intervention. For example, a device that could activate an alarm in case of a fall and automatically call for assistance would be advantageous: "There are certain ways it could maybe detect a fall and send you an alarm and call somebody then you know attached to the patient." The automatic recording of data from a wearable device (as opposed to a user-triggered device) was considered important: "Maybe everybody might not be so alert that they could monitor everything so that the automatic option would be good." However, people would also like to have the option to interact with or input specific information to the wearable device, if desired:

*I think there could be a stage 1 and stage 2, I suppose. Stage 1 could just be the monitoring and stage 2 would be manipulate it.*

The ability of a wearable device to alert the person to nonmotor symptoms, such as mood, stress, and sleep, was stated as important:

*Mood, if you're getting stressed and you don't realise it. Suddenly you're having a panic attack. Kind of like a warning sign that you might be. I wonder can technology look at that kind of stuff, mood, sleep and so on.*

People were especially interested in being able to know how their data compared with the data of other people with Parkinson disease and the potential solidarity that it could bring through knowing they were not alone in a certain symptom:

*There are times where I'd like to know where I'm at on the scale, to see the measurement of where I am.*

*So if you go to the nurse specialist...and you think that you've just got something that's pertinent to you, and only you feel it, and then she says oh yeah but somebody else had it. Because she maybe has a catalogue live and suddenly you don't feel so isolated and then you can compare it maybe...rather than you just trying plough a lonely furrow.*

## Discussion

### Principal Findings

This study explored the views of people with Parkinson disease regarding wearable devices for the management of Parkinson disease. The participants highlighted the challenges of living with a progressive disease, difficulties accessing quality health care, difficulty maintaining independence, and the importance of exercise and sleep. They discussed ways in which wearable devices could benefit their lives and the priorities for future research.

This study suggests that wearing a device is both feasible and acceptable to people with Parkinson disease, as most participants frequently used technology and were receptive of and familiar with health technology. Some participants already used medication reminders, medication-administration pumps, and fall-detection devices. Provided a wearable device is user-friendly, the technical skills required should not be a barrier for the current generation of people with Parkinson disease who are older or soon to be older.

One of the main findings of this study is that technology was perceived to be supplementary to appropriate health care, and it should not replace clinician involvement. In line with previous research [25], our participants prioritized information exchange between the patients and health care workers. Similarly, in another study [40], people with Parkinson disease saw the use of exergames in physiotherapy as being supplemental to physiotherapy sessions, not as their replacement.

Notwithstanding this, and in line with previous research [8], our study participants perceived that information from wearable devices could provide a better understanding of Parkinson disease and improve their symptoms. In addition, objective data may allow for more accurate management of Parkinson disease; specifically, symptom monitoring wearable devices could replace paper symptom diaries, which our participants cited as burdensome and limited. In line with studies by Ozanne et al [25] and AlMahadin et al [41], assessment methods are needed to increase the chance of effective treatment. As people with Parkinson disease experience symptom fluctuations as the day progresses, our participants, along with those in Ozanne et al [25], both identified the value of instant feedback. Prompt, real-time feedback on *switch on* or *switch off* states could help tailor their medication doses. Warnings about stress, lack of sleep, and falls would support their quality of life. Feedback from wearable devices could be tailored to individual preferences and used to trigger an intervention.

The survey demonstrated that people with Parkinson disease are more concerned with the functionality of a wearable device than its appearance. The focus group added a more nuanced

viewpoint—the size and weight of the device were important but the esthetics were less significant. Other studies of people with Parkinson disease reported similar findings; usability, accuracy, unobtrusive design, and functionality were important aspects of device design [24,25]. However, in the research by Botros et al [22], participants did not feel fully at ease wearing sensors in public, which contrasts with the results in this study where participants reported no such issues. Nevertheless, participants did emphasize that wearable device design needs to consider Parkinson disease–related barriers such as poor hand motor function that may hinder donning and doffing and device interaction, a finding that was also illuminated in a previous wearable device trial by Fisher et al [24].

Our results demonstrated that special considerations should be given to Parkinson disease–related health barriers, cost of wearable devices, and user confidence with technology. The lack of motivation to use a wearable device should not be underestimated, as previous evidence suggests that user preference influences utility and sustained use [35]. Although people with Parkinson disease may have more medical needs than other older adults, both populations are more inclined to use a wearable device when they are motivated by the medical benefits of the device [42]. When a wearable device offers tangible improvements to their lives, older adults and people with Parkinson disease may be willing to sacrifice esthetic features in favor of useful device functions.

Many Parkinson disease–monitoring wearable devices exist [31]. Although none are all-encompassing, some devices accurately monitor certain Parkinson disease symptoms [12,43,44]. The symptoms of Parkinson disease manifest in various regions of the body, so it follows that the tools to measure these symptoms must be widely located. For example, gait speed is best measured near the center of mass, whereas dyskinesia is best measured by a wrist-worn device [31]. Our participants discussed the importance of ease of use, particularly for individuals lacking confidence in technology; consequently, use of multiple devices may be cumbersome for these individuals. Future designs should strive for a simple device that can measure multiple Parkinson disease symptoms.

In the timeline of device development, our study is a useful resource for the initial blueprint stage of wearable device design. Designers could search qualitative exploratory papers, such as ours, for inspiration and a framework to structure their design goals. User-centered design (UCD) is a broad philosophy that spans methodologies [45] and can help ensure wearable device usability, accessibility, affordability, and reliability, all of which can impact the quality of interaction of older adults with wearable devices [46]. The central tenet of UCD is end user participation [45]. A UCD approach is particularly beneficial when end users require a variety of features, such as for people with Parkinson disease. UCD, especially when health care is focused, can respond to people with Parkinson disease through an integrative and iterative development procedure focused on understanding the end users' needs [47]. Many previous studies have used focus groups and surveys to evaluate existing devices as part of a UCD approach [48-50]. However, the participants in these studies were confined to discussions on predetermined devices. The variability of Parkinson disease severity,

presentations, and symptoms means that a one-size-fits-all approach to device design is not appropriate for this population of patients. Living with Parkinson disease is a unique experience for each person, so consideration should be given to tailoring devices to individual needs, or at least designing a set of devices that can measure different symptoms.

The World Health Organization defines healthy aging as “the process of developing and maintaining the functional ability that enables wellbeing in older age” [51]. Individuals with chronic conditions, such as Parkinson disease, must manage a range of factors that contribute to their health. Self-management support acknowledges this and aids people in developing the knowledge, confidence, and skills they need to make optimal decisions about their health [52]. However, the health and social needs of people with Parkinson disease are often complex and change over time, with a wide range of functional abilities, where some individuals will maintain their independence and others will need help with their activities of daily living. Wearable devices will not cure Parkinson disease but they can add value to the user's life by supporting them as they live with their disease. As defined by the World Health Organization, intrinsic capacity describes the composite of all the abilities of individuals and how those abilities develop over time [51]. This can be supported by wearable devices but each user's intrinsic capacity will differ, and the wearable devices should also differ in their features. For example, if a wearable device can accurately track symptom fluctuations, the user may be able to fine-tune their medication regime and retain more of their intrinsic capacity. A device with multiple features will add value to users, ensuring a more effective person-centered device based on an individual's intrinsic capacity. Considering intrinsic capacity may identify novel opportunities for disease management and has the potential to help wearable device designers better understand chronic conditions such as Parkinson disease and to design individualized technology to improve the health of their users.

Wearable devices that allow remote monitoring could improve health care access for rural patients or those unable to travel, resulting in a positive impact on health care outcomes and costs. Preceding the COVID-19 pandemic, the application of telehealth was more of an exception in health care, but the pandemic saw rapid implementation of remote health care across all disciplines [53]. This may continue in part after travel restrictions end, as health care professionals and patients become more familiar with and appreciate the advantages of telemedicine. Therefore, the future integration of technology with health care is crucial. As per Fasano et al [53], the COVID-19 pandemic is challenging the health care system to reflect on the modes of traditional access to care and to facilitate the remote management of people with Parkinson disease where needed to improve patient care. Remote care models, in which a person with Parkinson disease is not face-to-face in a clinical setting with their health care team, are enhanced by using wearable devices together with communication-based technologies such as videoconferencing [54]. Wearable devices allow remote monitoring of patient health data, which can then be fed to a database that can be accessed by the patient and their health care team [55]. These data may more accurately capture the symptoms of Parkinson



disease in daily life, which may not be reflected in controlled clinical assessments. The pandemic motivated a notable shift to telemedicine within the Parkinson community and in a recent survey it was found that most respondents were satisfied with the experience, and a near majority expressed interest in continuing to use telemedicine after the COVID-19 outbreak had ended [56]. Although these technologies are not new, they are gaining greater application through the realization that telehealth and wearable monitoring can provide comparable and innovative levels of care [54].

### Limitations

Our study is one of a few that did not confine itself to focusing on gathering perspectives on a predetermined device and focused solely on a Parkinson disease population. It involved a mixed method approach to gain rich, in-depth data about the monitoring needs, values, and preferences of people with Parkinson disease. However, this study has several limitations. This is a small study of a geographically limited population, and the study design may have had a positive bias in attracting participants more familiar with technology. As participants were recruited from the same geographic region, it is possible that some individuals participated in both the survey and focus groups. The survey was anonymous and the response rate was unknown. An unspecified number of surveys were distributed by volunteers at PAI meetings and surveys were passively returned to the researchers. However, the survey participants represented a broad range of ages and were split between genders. Owing to their positive wording, the results from the Likert items must be interpreted with caution. They provide a slight indication that clinical usefulness is prioritized by people with Parkinson disease, but this result does not support a rigorous survey design. Our survey design was modified from Bergmann and McGregor [35]. However, an alternative study design, such as a discrete choice experiment, might better elicit participant preferences

[57]. It could be argued that the sample was relatively homogenous as patients were recruited through a Parkinson disease support group, which may not be representative of all people with Parkinson disease. Moreover, because of the limited number of individuals involved, it was not possible to differentiate by ethnicity, educational level, background, and digital literacy. Future studies expanding on this work should aim to include people with Parkinson disease across a range of backgrounds and stages of Parkinson disease and recruit from a variety of settings.

### Conclusions

This study aimed to understand the views and needs of people with Parkinson disease regarding wearable devices for monitoring the disease and assisting in its management. People with Parkinson disease provided useful information about living with the disease, their current use of technology, and the desirable features of wearable devices, which designers and clinicians should consider. Although the participants were positive about wearable technology, they tended to see the use of wearable devices more for providing data for health care professionals than for providing feedback for themselves. They sacrifice esthetics for ease of use, function, and accuracy. Barriers to using wearable devices include poor hand function, average technology confidence, and potential costs. Considering intrinsic capacity can identify opportunities for disease management and has the potential to help wearable device designers better understand chronic conditions such as Parkinson disease, and in designing individualized technology to improve the health of its users. A UCD approach that includes people with Parkinson disease in the design of technology is likely to be rewarded with improved user engagement and adoption of wearable devices. This could result in better Parkinson disease symptoms and function data, leading to more accurate Parkinson disease management.

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### Conflicts of Interest

None declared.

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#### Multimedia Appendix 1

Survey including Bergmann mapping.

[\[DOCX File, 17 KB - formative\\_v6i1e27418\\_app1.docx \]](#)

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#### Multimedia Appendix 2

Interview schedule for focus group.

[\[PDF File \(Adobe PDF File\), 384 KB - formative\\_v6i1e27418\\_app2.pdf \]](#)

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## Abbreviations

**PAI:** Parkinson's Association of Ireland

**SENDOC:** Smart Sensor Devices for Rehabilitation and Connected Health

**UCD:** user-centered design

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Original Paper

# Feasibility of Monitoring Health and Well-being in Emerging Adults: Pilot Longitudinal Cohort Study

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## Abstract

**Background:** Emerging adulthood is a distinct segment of an individual's life course. The defining features of this transitional period include identity exploration, instability, future possibilities, self-focus, and feeling in-between, all of which are thought to affect quality of life, health, and well-being. A longitudinal cohort study with a comprehensive set of measures would be a valuable resource for improving the understanding of the multifaceted elements and unique challenges that contribute to the health and well-being of emerging adults.

**Objective:** The main aim of this pilot study was to evaluate the feasibility and acceptability of recruiting university graduates to establish a longitudinal cohort study to inform the understanding of emerging adulthood.

**Methods:** This pilot study was conducted among graduates at a large university. It involved collecting web-based survey data at baseline (ie, graduation) and 12 months post baseline, and linking survey responses to health records from administrative data collections. The feasibility outcome measures of interest included the recruitment rate, response rate, retention rate, data linkage opt-out rate, and availability of linked health records. Descriptive statistics were used to evaluate the representativeness of the sample, completeness of the survey responses, and data linkage characteristics.

**Results:** Only 2.8% of invited graduates (238/8532) agreed to participate in this pilot cohort study, of whom 59.7% (142/238) responded to the baseline survey. The retention rate between the baseline and follow-up surveys was 69.7% (99/142). The completeness of the surveys was excellent, with the proportion of answered questions in each survey domain ranging from 87.3% to 100% in both the baseline and follow-up surveys. The data linkage opt-out rate was 32.4% (77/238).

**Conclusions:** The overall recruitment rate was poor, while the completeness of survey responses among respondents ranged from good to excellent. There was reasonable acceptability for conducting data linkage of health records from administrative data collections and survey responses. This pilot study offers insights and recommendations for future research aiming to establish a longitudinal cohort study to investigate health and well-being in emerging adults.

**Trial Registration:** Australian New Zealand Clinical Trials Registry number ACTRN12618001364268; <https://tinyurl.com/teec8wh>

**International Registered Report Identifier (IRRID):** RR2-10.2196/16108



**KEYWORDS**

young adult; emerging adulthood; health; well-being; health-related quality of life; feasibility; monitoring; pilot study; longitudinal; cohort; youth; acceptability; survey; quality of life

## Introduction

Emerging adulthood is the life stage between adolescence and young adulthood, lasting approximately from ages 18 to 25 years [1,2]. There are many events and factors that can impact the life course of emerging adults [1,2]. Changing health states, different lived experiences, exposure to diverse opportunities, education, and influences from cultural and socioeconomic circumstances can challenge the transition from late adolescence to adulthood, and they have a significant impact on the health and well-being of emerging adults [2-5].

Few longitudinal studies have investigated aspects of health-related quality of life (HRQoL) and well-being in emerging adults. In the United States, 2 university cohorts were established at Harvard University to investigate risk factors for chronic diseases and long-term health in nurses and health professionals [6,7]. In Spain, a prospective university graduate cohort was established at Seguimiento Universidad de Navarra (SUN) to examine dietary habits in the Mediterranean region [8,9]. The scope of the SUN study was subsequently broadened to examine other risk factors and health conditions and expanded to include graduates from 5 other Spanish universities [9]. No longitudinal cohort study comprehensively investigating HRQoL and well-being in emerging adults has been undertaken in Australia. In Australia, Eisenberg et al [10] examined phase transitions of emerging adults, but did not report on any HRQoL or well-being measures. Landstedt et al [11] investigated mental health in a cohort of young Australian adults, but the participants were only asked a single question (ie, "How healthy have you felt mentally during the past 12 months?"), which was not included at baseline.

Conducting a large, prospective longitudinal cohort study of emerging adults using a comprehensive set of measures (eg, physical and mental health, risk factors, life events, resilience, education and employment factors, and social connectedness) would be a unique and valuable resource for improving our understanding of the determinants of healthy and resilient individuals in our society. However, because large, prospective longitudinal cohort studies can be very costly and resource-consuming undertakings, it is essential to first determine the feasibility of conducting such studies.

This pilot study, therefore, aimed to establish the feasibility of recruiting university graduates to establish a large, prospective longitudinal cohort study to inform our understanding of emerging adulthood. Specifically, this pilot study evaluated the following: (1) the feasibility of research methods to recruit university graduates at a large Australian university, including determination of the opt-out rate for data linkage of health records and survey responses; (2) the representativeness of the recruited participants; (3) the ability to obtain baseline survey data, including completion of individual survey instruments;

(4) the ability to retain participants and collect follow-up survey data 12 months post baseline, including the completion of individual survey instruments; and (5) opportunities for improving the design of future studies.

## Methods

### Registration

This study was registered with the Australian New Zealand Clinical Trials Registry (ACTRN) on August 14, 2018 (ACTRN12618001364268). The study protocol was published on April 23, 2020 (international registered report identifier: DERR1-10.2196/16108) [12].

### Study Design

This pilot longitudinal cohort study was conducted at Macquarie University in Sydney, Australia. It involved collecting information via web-based surveys (ie, at baseline and 12 months post baseline) and health data record linkage.

### Recruitment

All students graduating from Macquarie University in 2018 (N=8532) were eligible to participate in this study. Macquarie University is a large public university located in a suburban area of Sydney, Australia. At the time of participant recruitment, the university comprised five faculties (ie, Faculty of Arts, Faculty of Business and Economics, Faculty of Human Sciences, Faculty of Medicine and Health Sciences, and Faculty of Science and Engineering), which collectively hosted approximately 45,000 students, including 33,000 undergraduate students, 9000 postgraduate students, and 1500 higher-degree research students.

The graduates were invited to participate via email during the autumn (ie, April) and spring (ie, September) graduation periods. Email invitations included a unique link to a purpose-made website where the graduates were informed about the study before consenting to participate. The initial invitation was followed by 3 reminder emails over a 6-week period. After completing the web-based registration form, participants received an email with an individualized link to the baseline survey.

An incentive to participate was introduced for the second (ie, September) graduation period. The incentive to participate was an entry into a random draw to win 1 of 3 prizes, namely an iPad mini (Apple Inc, first prize) or movie tickets (second and third prizes).

### Survey Data Collection

Surveys were administered via the web-based Qualtrics XM platform (Qualtrics International Inc) at baseline and 12 months post baseline. The baseline and 12-month follow-up surveys comprised the same battery of validated questionnaires and instruments designed to capture data regarding

sociodemographic factors, education, employment, job satisfaction, mentoring, self-perceived physical and mental health status, work-life balance, connectedness, resilience, injury, risk behaviors, and life events, as well as social media and technology use. For a detailed overview of the domains and specific questionnaires included in the web-based surveys, see the published study protocol [12].

### Health Record Linkage

Survey responses were linked to personal health information from administrative data collections (ie, ambulance dispatches, emergency department presentations, hospital admissions, cancer registry, and mortality records) in New South Wales (NSW) from April 1, 2018, to 12 months after the completion of the baseline survey. Participants had an opportunity to opt out of having their survey responses linked to their health records during the web-based registration process. The secure health data linkage was conducted by the Centre for Health Record Linkage (CHeReL).

### Outcome Measures

The specific feasibility outcome measures for this pilot study were as follows:

1. Recruitment rate: Calculated as the number of graduates who registered to participate in the pilot study, divided by the total number of graduates.
2. Response rate: Calculated as the number of registered participants who completed the baseline survey, divided by the total number of registered participants.
3. Representativeness: Evaluated by comparing the distribution of graduates and responding participants by faculty and level of qualification.
4. Retention rate: Calculated as the number of participants who completed both the baseline and 12-month follow-up surveys, divided by the number of participants who completed the baseline survey only.
5. Completeness: Calculated as the proportion of missing data for each survey item separately for the baseline and

follow-up surveys. For the purpose of this study, survey completeness was categorized as poor (<50%), average (50% to <75%), good (75% to <95%), or excellent ( $\geq 95\%$ ).

6. Data linkage opt-out rate: Calculated as the number of registered participants who opted out of having their survey responses linked to their health records, divided by the total number of registered participants.
7. Data linkage rate: Calculated as the number of participants who did not opt out of having their survey responses linked to their health records and had one or more health records identified in the Master Linkage Key, divided by the number of registered participants who did not opt out of having their survey responses linked to their health records.
8. Linked record availability: Calculated as the number of available linked health records in each administrative data collection.

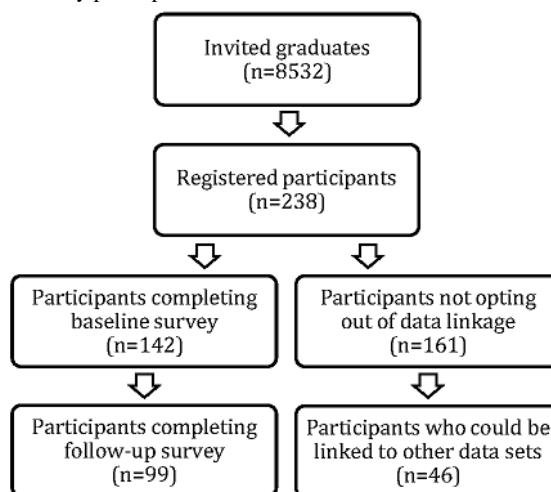
### Data Analysis

All data were analyzed using SAS, version 9.4 (SAS Institute). The recruitment rate, response rate, retention rate, data linkage opt-out rate, data linkage rate, and linked record availability rate were calculated as described above and presented as proportions. Descriptive statistics were used to evaluate the representativeness of the sample and completeness of the baseline and follow-up surveys.

### Results

A total of 8532 graduates were invited to participate in this pilot study, of whom 238 agreed to participate (Figure 1). This equated to a recruitment rate of 2.8%. Of the 238 graduates who registered to participate in this study, 142 answered the baseline survey. This equated to a response rate of 59.7%. The majority of respondents were female (100/142, 70.4%), single (79/142, 55.6%), and born in Australia (95/142, 66.9%) (Table 1). Compared to the invited graduates, the sample of responding participants was significantly different in its distribution by gender ( $P < .001$ ), but not by level of award ( $P = .14$ ) or graduation time ( $P = .08$ ) (Table 2).

**Figure 1.** Flow diagram of the selection of the study participants.



**Table 1.** Demographic characteristics of responding participants.

Characteristic	Respondents (n=142), n (%)
<b>Gender</b>	
Female	100 (70.4)
Male	41 (28.9)
Other or unspecified	1 (0.7)
<b>Marital status</b>	
Single	79 (55.6)
In relationship, not living with partner	5 (3.5)
In relationship, living with partner	24 (16.9)
Married	32 (22.5)
Divorced	2 (1.4)
<b>Country of birth</b>	
Australia	95 (66.9)
Other specified country	46 (32.4)
Unspecified	1 (0.7)
<b>Primary language spoken at home</b>	
English	101 (71.1)
Other specified language	41 (28.9)
<b>Household income (Aus \$)<sup>a</sup></b>	
Less than \$50,000 per year	38 (26.8)
\$50,001-\$100,000 per year	33 (23.2)
More than \$100,000 per year	52 (36.6)
Unsure or unspecified	19 (13.4)

<sup>a</sup>Aus \$1=US \$0.70.

**Table 2.** Representativeness of responding participants.

Characteristic	Graduates (N=8532), n (%)	Respondents (n=142), n (%)	<i>P</i> value <sup>a</sup>
<b>Gender<sup>b</sup></b>			<.001
Female	4758 (55.8)	100 (70.9)	
Male	3774 (44.2)	41 (29.1)	
<b>Level of award<sup>c</sup></b>			.14
Undergraduate	5480 (64.2)	82 (58.2)	
Postgraduate	3052 (35.8)	59 (41.8)	
<b>Graduation time</b>			.08
April	5308 (62.2)	78 (54.9)	
September	3224 (37.8)	64 (45.1)	

<sup>a</sup>Chi-square test for difference in proportions.

<sup>b</sup>Gender was missing for n=1 responding participant, who was omitted from the chi-square test.

<sup>c</sup>Level of award was missing for n=1 responding participant, who was omitted from the chi-square test.

Of the 142 participants who answered the baseline questionnaire, 99 also completed the 12-month follow-up survey. This equated to a retention rate of 69.7%. The completeness of the baseline and 12-month follow-up surveys is shown in [Table 3](#).

Of the 238 graduates who registered to participate in this study, 161 consented to having their survey responses linked to their health records, while 77 opted out of the data linkage component of this study. Thus, the data linkage opt-out rate was 32.4%. Of

the 161 registered participants who consented having their survey responses linked to their health records, 46 had used health services and were linked to health records in the CHeReL Master Linkage Key. This equated to a data linkage rate of 28.6%. The most commonly available linked health records

were hospital episodes of care and emergency department presentations (Table 4). Unsurprisingly, there were no linked mortality data for this study period. Linkage with cancer registry records was not possible because the most recent cancer registry update preceded the follow-up period for the present study.

**Table 3.** Completeness of survey components at baseline and 12-month follow-up. Completeness was calculated as the number of survey items within a specific survey domain that had missing data, divided by the cross product of the total number of survey items within the specific survey domain and the number of participants not lost to follow-up when the survey was administered.

Domain/Instrument	Baseline (%)	Follow-up (%)
<b>Sociodemographic factors</b>		
Questions about personal status	99.8	99.7
Questions about tertiary education	98.8	100.0
Questions about employment status	97.9	99.0
<b>Working life</b>		
Questions about job satisfaction	97.5	96.5
Questions about career mentoring	97.3	98.0
Role Balance Scale (RBS)	97.1	98.0
<b>Health and lifestyle</b>		
Questions about physical activity	96.4	96.8
Questions about health risk factors	91.5	94.6
Short Form Health Survey (SF-12)	95.6	95.8
EuroQoL 5-dimension (EQ-5D)	94.8	95.8
General Anxiety Disorder scale (GAD-7)	94.5	95.1
Social Interaction Anxiety Scale (SIAS-6)	95.1	94.6
Kessler Psychological Distress Scale (K10)	94.3	94.6
Questions about injury	92.3	94.9
<b>Social support and resilience</b>		
Questions about social connectedness	93.0	94.9
Brief Resilience Scale (BRS)	92.8	94.9
Multidimensional Scale of Perceived Social Support (MSPSS)	92.2	94.8
Social Readjustment Rating Scale (SRRS)	89.4	93.9
<b>Caregiver activities</b>		
Questions about caregiver responsibilities and activities	89.4	92.9
<b>Social media and technology</b>		
Questions about use of social networking sites	89.1	89.5
Questions about social media experiences	87.3	89.9



**Table 4.** Availability of linked records.

Data source	Respondents (n=46), n (%)
NSW <sup>a</sup> Emergency Department Data Collection	37 (80)
NSW Admitted Patient Data Collection	31 (67)
NSW Ambulance – electronic medical record	6 (13)
NSW Registry of Births, Deaths and Marriages – Death registrations	0 (0)
NSW Cause of Death – Unit Record File	0 (0)
NSW Central Cancer Registry <sup>b</sup>	N/A <sup>c</sup>

<sup>a</sup>NSW: New South Wales.

<sup>b</sup>Linkage not possible because most recent records preceded the follow-up period for this study.

<sup>c</sup>N/A: not applicable. At the time of linkage, the NSW Central Cancer Registry data for the study period were not yet available in the Master Linkage Key.

## Discussion

This pilot study examined the feasibility of recruiting university graduates to establish a longitudinal cohort study to inform our understanding of emerging adulthood. It found that the overall recruitment rate was poor, while the completeness of survey responses among respondents was good to excellent. There was moderate acceptability for conducting data linkage of health records from administrative data collections and survey responses.

### Survey Recruitment and Response Rates

Of the 2.8% (238/8532) of invited graduates who agreed to participate in this pilot cohort study, 59.7% (142/238) responded to the baseline survey. This is considerably lower than the response rate for, for instance, the pilot SUN study (11%) [13] and the Australian arm of the World Health Organization's World Mental Health Surveys International College Student initiative (7%) [14]. Although the overall recruitment and response rates are disappointing, they are perhaps unsurprising given the general decline in survey participation observed in recent decades [15-17]. Superimposed on this general decline, there is a myriad of factors that may have contributed to the relatively poor recruitment and response rates observed in this pilot cohort study. Dillman's extension of social exchange theory, the tailored design method, is a theoretical framework that seeks to explain why individuals are motivated to engage in certain social behaviors such as survey participation [18]. This framework suggests that survey response rates depend on reward, cost, and trust. For instance, survey participation is typically more rewarding when participants have a vested interest in the topic [19]. The time spent completing a survey is an important cost consideration for survey participants [19], with longer stated survey length resulting in fewer respondents [20]. In addition to survey length, poor survey structure and design can increase the perceived cost of responding to surveys [19]. In regard to trust, perceived trustworthiness of the organization or institution responsible for administering the survey, confidential use of data, and adequate privacy protections are key elements for reassuring survey participants and improving response rates [19].

It is difficult to determine to which extent each of the abovementioned factors have influenced the recruitment and response rates in this pilot cohort study. Although one might expect recent university graduates to have a vested interest in the topic of health and well-being in emerging adults, perhaps the relative absence of health problems in this age group resulted in a lower interest in the topic and thus lower perceived reward and motivation for participation. For instance, there is evidence suggesting that emerging adults are less motivated by long-term health concerns and lifestyle interventions than older counterparts [21-24]. Additionally, perhaps graduating from university is accompanied by a sense of separation and decreased interest in participating in university-based research surveys. There is also the potential issue of different surveys competing for graduates' attention and motivation. For instance, Australian university graduates are regularly invited to complete the nationwide Graduate Outcomes Survey, which is one component of the Quality Indicators for Learning and Teaching suite of surveys conducted for the Australian Government Department of Education, Skills and Employment [25]. Competition for attention and motivation becomes a particularly important consideration in the context of emerging adults' perceived scarcity of time [26]. The graduates invited to participate in this pilot study were informed that it would take approximately 40 minutes to complete each survey (ie, baseline and follow-up). It is conceivable that many potential participants considered the perceived costs of participation in this study to be too high.

Although there is conflicting evidence, some studies have demonstrated that incentives such as monetary rewards or lotteries can positively impact response rates [27,28]. In an attempt to improve the recruitment rate in this pilot study, an incentive to participate was introduced for the second (ie, September) graduation period. Consequently, the recruitment rate increased from 2% for the first (ie, April) graduation cohort to 3.8% for the second graduation cohort. The improvement after introducing incentives notwithstanding, the recruitment rate remained disappointingly low. This suggests that the incentives to participate in this pilot study were insufficient to counteract the perceived costs of participation for the vast majority of invited graduates. Perhaps the proliferation and ubiquity of mobile devices in modern society means that the main incentive

used in this pilot study (ie, a chance to win an iPad mini) is not perceived as an attractive reward for participating in research.

Previous research has demonstrated that multiple reminders are an effective way to increase response rates [29-31]. However, studies have also shown that the recruitment yield typically declines rapidly with each subsequent reminder [32-34]. This rapidly diminishing marginal return suggests that increasing the number of reminders beyond a small number may not be a cost-effective measure [35]. Hence, Saleh and Bista [19] recommended sending at least 1 reminder, but not more than 3. Furthermore, the desire for increased survey response rates also needs to be balanced with the concern among human research ethics committees that multiple reminders may result in potential survey participants feeling harassed or coerced into participating in the research [36,37].

### Survey Completeness

Survey completeness can be used to refer to 3 different concepts: (1) completeness of the achieved sample with respect to the original one, (2) participation of the respondents throughout all the phases predicted by a research design, and (3) respondents' propensity to answer all the questions within the questionnaire [29]. The latter 2 concepts were considered in this pilot study. The first of which corresponds to the retention rate between the baseline and follow-up surveys, which was found to be 69.7% (99/142). In regard to the propensity to answer all the questions within a survey, the completeness was excellent, with the proportion of questions answered in each survey domain ranging from 87% to 100% in both the baseline and follow-up surveys. This suggests that the participants did not consider the survey length to be excessive in the pilot study. This is important because previous research has shown that longer survey length can result in both poorer completeness and quality of responses [26].

### Data Linkage

Approximately two-thirds (161/238, 67.6%) of the participants in this pilot study did not opt out of having their survey responses linked to their health records. This suggests that the acceptability of data linkage in the present study was very similar to that in previous Australian studies. For instance, one study reported that 66% of older Australians found it acceptable to have their health data accessed and linked in a registry [38]. Another study of young Australian parents reported, unsurprisingly, that privacy protection was an important consideration for most participants [39]. However, it also was noted that protection measures adopted in best practice health data linkage studies were viewed by most participants as adequate protection for data linkage to proceed without specific individual consent.

### Recommendations

This pilot study offers insights into the feasibility of recruiting recent university graduates to establish a longitudinal cohort study to investigate health and well-being in emerging adults. It is unrealistic to expect a reversal of the general decline in survey response rates. However, it has been suggested that reducing nonresponse rates is less important than minimizing bias in estimates. That is, despite preconceived notions of a good response rate, neither a 5% response rate nor even a 75% response rate necessarily provides unbiased estimates [40,41]. Nonresponse bias occurs when subgroups respond at different rates. In this pilot study, female graduates were more likely to respond to the baseline survey. Overrepresentation of females is common in health-related survey research. Although postsurvey adjustment techniques can be implemented to help reduce nonresponse biases, it is often preferable to prevent nonresponse bias by designing surveys that are more acceptable to the target population in the first instance [42].

In the context of this pilot study, future cohort studies of emerging adults should target populations that are more likely to hold interest in the research. For instance, it might be more useful to target populations at an earlier stage, such as at first enrollment at university or before leaving high school. There are potentially more opportunities for targeted engagement with a student cohort who are commencing postsecondary education. Only a subset of emerging adults undertakes postsecondary education. In Australia, 39.7% of people aged 25 to 34 years had a bachelor's degree or higher in 2018 [43]. Thus, a cohort of high school graduates offers a less biased sample.

Apart from the choice of specific target populations, future studies should consider the need for personalizing invitations, reducing survey length, crafting surveys that are simple to complete, administering surveys via smartphone apps, and incentivizing participation (eg, through gamification). Lastly, future studies are strongly encouraged to use research codesign to optimize survey parameters. Incorporating the lived experiences of emerging adults into the development and implementation of future research will increase its likelihood of success and impact [44,45].

### Conclusions

The overall recruitment rate was poor, while the completeness of survey responses among respondents was good to excellent. There was reasonable acceptability for conducting data linkage of health records from administrative data collections and survey responses. Future research aiming to establish a longitudinal cohort study to investigate health and well-being in emerging adults should carefully consider the target population as well as how best to obtain an unbiased sample and craft surveys to maximize participation.

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### Authors' Contributions

All authors contributed to the conception and design of the study. DFP and RPL were responsible for drafting the first version of the manuscript. JA, JB, CMC, RJM, and VW were responsible for supervising the project. All authors contributed to or edited the manuscript. All authors read and approved the final version of the manuscript.

### Conflicts of Interest

None declared.

#### Multimedia Appendix 1

Multiple regression analysis for socioeconomic and clinical factors affecting anxiety and depressive disorders in the local community group.

[[DOCX File, 16 KB - formative\\_v6i1e30027\\_app1.docx](#)]

#### Multimedia Appendix 2

Multiple regression analysis for socioeconomic and clinical factors affecting anxiety and depressive disorders in the foreign community group.

[[DOCX File, 16 KB - formative\\_v6i1e30027\\_app2.docx](#)]

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## Abbreviations

**ACTRN:** Australian New Zealand Clinical Trials Registry

**CHeReL:** Centre for Health Record Linkage

**HRQoL:** health-related quality of life

**NSW:** New South Wales

**SUN:** Seguimiento Universidad de Navarra

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Original Paper

# Continuous Monitoring of Vital Signs With Wearable Sensors During Daily Life Activities: Validation Study

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## Abstract

**Background:** Continuous telemonitoring of vital signs in a clinical or home setting may lead to improved knowledge of patients' baseline vital signs and earlier detection of patient deterioration, and it may also facilitate the migration of care toward home. Little is known about the performance of available wearable sensors, especially during daily life activities, although accurate technology is critical for clinical decision-making.

**Objective:** The aim of this study is to assess the data availability, accuracy, and concurrent validity of vital sign data measured with wearable sensors in volunteers during various daily life activities in a simulated free-living environment.

**Methods:** Volunteers were equipped with 4 wearable sensors (Everion placed on the left and right arms, VitalPatch, and Fitbit Charge 3) and 2 reference devices (Oxycon Mobile and iButton) to obtain continuous measurements of heart rate (HR), respiratory rate (RR), oxygen saturation (SpO<sub>2</sub>), and temperature. Participants performed standardized activities, including resting, walking, metronome breathing, chores, stationary cycling, and recovery afterward. Data availability was measured as the percentage of missing data. Accuracy was evaluated by the median absolute percentage error (MAPE) and concurrent validity using the Bland-Altman plot with mean difference and 95% limits of agreement (LoA).

**Results:** A total of 20 volunteers (median age 64 years, range 20-74 years) were included. Data availability was high for all vital signs measured by VitalPatch and for HR and temperature measured by Everion. Data availability for HR was the lowest for Fitbit (4807/13,680, 35.14% missing data points). For SpO<sub>2</sub> measured by Everion, median percentages of missing data of up to 100% were noted. The overall accuracy of HR was high for all wearable sensors, except during walking. For RR, an overall MAPE of 8.6% was noted for VitalPatch and that of 18.9% for Everion, with a higher MAPE noted during physical activity (up to 27.1%) for both sensors. The accuracy of temperature was high for VitalPatch (MAPE up to 1.7%), and it decreased for Everion (MAPE from 6.3% to 9%). Bland-Altman analyses showed small mean differences of VitalPatch for HR (0.1 beats/min [bpm]), RR (-0.1 breaths/min), and temperature (0.5 °C). Everion and Fitbit underestimated HR up to 5.3 (LoA of -39.0 to 28.3) bpm and 11.4 (LoA of -53.8 to 30.9) bpm, respectively. Everion had a small mean difference with large LoA (-10.8 to 10.4 breaths/min) for RR, underestimated SpO<sub>2</sub> (>1%), and overestimated temperature up to 2.9 °C.

**Conclusions:** Data availability, accuracy, and concurrent validity of the studied wearable sensors varied and differed according to activity. In this study, the accuracy of all sensors decreased with physical activity. Of the tested sensors, VitalPatch was found to be the most accurate and valid for vital signs monitoring.

**KEYWORDS**

wearable sensors; telemonitoring; continuous monitoring; vital signs; mHealth; wearable; biosensor; validity; accuracy

## Introduction

### Background

Continuous telemonitoring of vital signs in daily life may lead to earlier detection of patient deterioration [1-3] and facilitate the migration of care toward home. In chronic diseases, telemonitoring is associated with improved clinical outcomes and cost-effectiveness of care [4,5]. It is expected that telemonitoring may also be of added value in other settings, such as the perioperative trajectory to monitor postoperative recovery in a ward or home setting. Preoperative monitoring at home may improve the knowledge of patients' baseline vital signs. Especially since the COVID-19 pandemic, the demand for remote monitoring of vital signs has grown [6].

Several wearable sensors are available for telemonitoring of patients both in hospital and at home [1,7], which mainly differ in the location of placement, being reusable or disposable, battery life, and data transmission. According to legislation, sensors must be certified as a medical device and be safe and beneficial in their intended use. However, wearable sensors should be accurate and reliable as well before implementation in health care [1]. Accurate technology for telemonitoring is essential when used for clinical decision-making, although little is known about the accuracy and reliability of current generation wearable sensors, especially during daily life activities. Wearable sensors for continuous monitoring of vital signs are often evaluated in the in-patient setting [7] using patches (ie, Sensium Vitals, Sensium), mattress sensors (ie, EarlySense, EarlySense Inc), or more extensive sensors worn on the arm (ie, Radius-7, Masimo) [8]. Results from in-patient settings cannot directly be translated to the home environment when performing daily activities with less supervision, and research using wearable sensors for vital sign monitoring at home is lacking.

### Objectives

Information about the performance of wearable sensors in daily life is scarce and should be available before using these sensors for clinical decision-making. The aim of this study is to assess the data availability, accuracy, and concurrent validity of vital signs measured with currently available wearable sensors during daily life activities in a simulated living environment. We

selected 3 types of recently available wearable sensors: arm-worn, chest-worn, and wrist-worn. This study investigates the technical performance of wearable sensors during daily life activities in volunteers to gain insight into their potential for telemonitoring.

## Methods

### Design

For this prospective observational validation study, experiments were performed at the eHealth House of the University of Twente, a simulated living environment (furnished apartment) used for research purposes [9]. The protocol was approved by the ethical committee of the University Medical Center Groningen and was executed according to the Declaration of Helsinki. Written consent was received from all participants for study participation and data use.

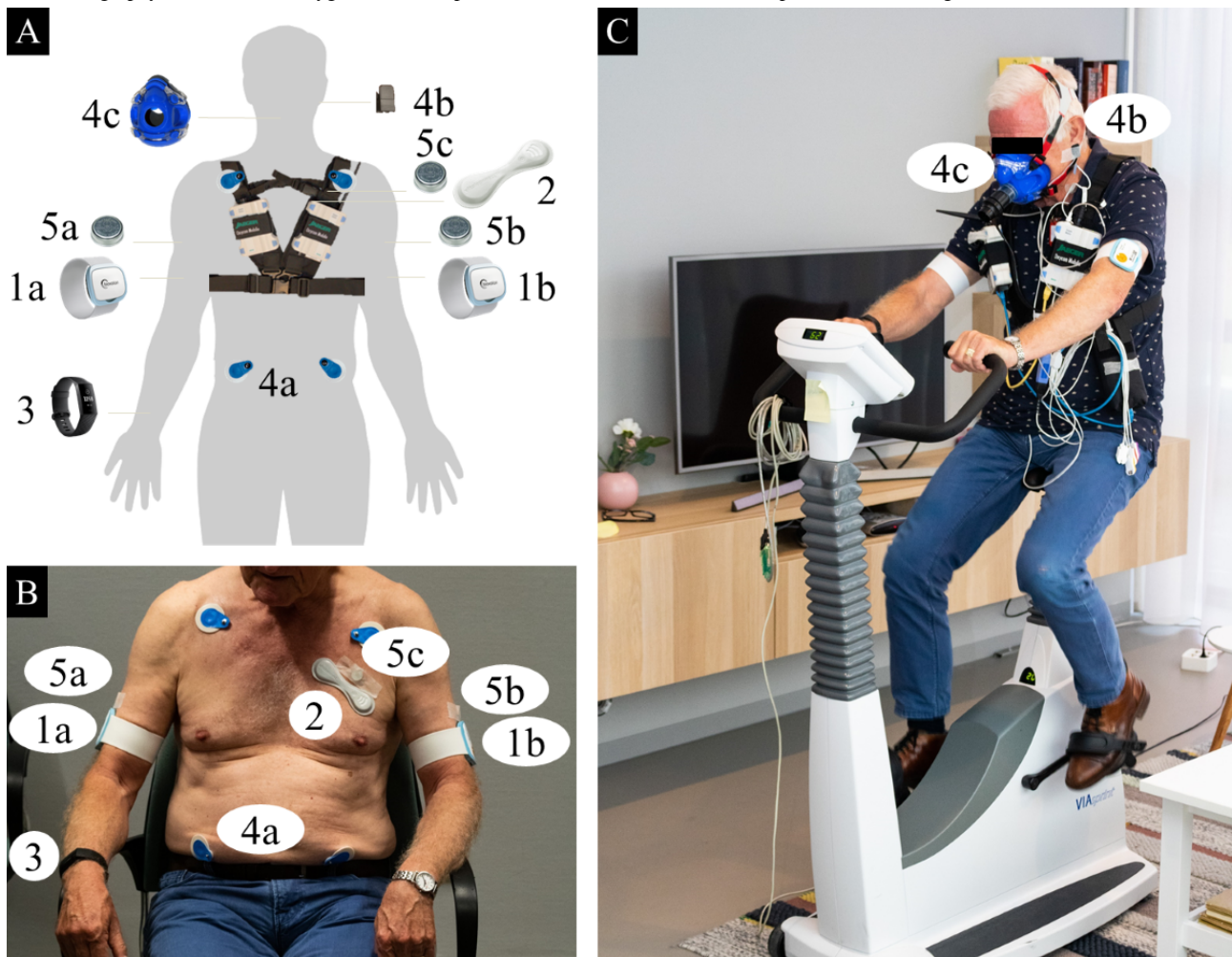
### Participants

Volunteers aged >18 years were included, with at least half of the participants aged >60 years, to reflect a general patient population. Interested volunteers were contacted by one of the researchers (RV) to assess their eligibility for study participation. The exclusion criteria were having a medical condition uncontrolled with medication that interferes with the execution of the protocol (ie, cardiovascular diseases, neuromuscular diseases, immobility, or cognitive disorders), pacemaker, or plaster allergy. Because of the lack of preliminary data for power calculation, a sample size of 20 was chosen on the basis of previous experience in quite similar validation studies for wearable devices associated with vital sign monitoring in volunteers [10-13].

### Devices

A total of 3 wearable sensors of interest for continuous and noninvasive measurement of vital signs were used: Everion (Biovotion AG), VitalPatch (MediBioSense), and Fitbit Charge 3 (Fitbit Inc). The VitalPatch is intended for the collection of physiological data in a health care setting, whereas Everion and Fitbit are intended to monitor fitness and general wellness only. These sensors differ in measurement location and techniques and have the potential to be used in clinical settings. All the used sensors are depicted in [Figure 1](#).

**Figure 1.** (A) Schematic overview of wearable sensors and reference devices and their placement on the participant's body (B) during application and (C) during the experiment. Details: (1) Everion placed on the (a) right arm and (b) left arm; (2) VitalPatch; (3) Fitbit Charge 3; (4) Oxycon Mobile (a) 4 electrocardiography electrodes, (b) oxygen saturation probe, and (c) face mask; (5) iButton placed on the (a) right arm, (b) left arm, and (c) chest.



Everion is a Conformity European (CE) class 2a–certified sensor worn on the upper arm that measures heart rate (HR), respiratory rate (RR), and blood oxygen saturation ( $SpO_2$ ) by photoplethysmography (PPG) and skin temperature using a negative temperature coefficient thermistor. The vital signs were stored every 10 seconds. VitalPatch is a CE class 2a–certified and Food and Drug Administration 510(k)–cleared disposable patch worn on the chest to measure HR and RR by electrocardiography (ECG) and temperature by a thermistor with a sample storage frequency of once per 4 seconds. The Fitbit Charge 3 is a commercially available activity tracker worn at the wrist and measures HR using PPG with a sample storage frequency of once per second during exercise and once per 5 seconds at all other times [14].

A total of 2 devices were used as gold standard reference devices. Oxycon Mobile (CareFusion Germany 234 GmbH) is a portable metabolic measurement system certified as a CE class 2a medical product and has been used as the gold standard in several studies [15,16]. Oxycon Mobile used ECG and expired volume measurements to monitor HR and RR, respectively. Volume measurement is a reliable method for RR calculation compared with other measurement principles that derive RR from impedance, ECG, or waveform modulation, such as in other wearable devices. In addition,  $SpO_2$  was measured using

a PPG sensor that was positioned using an ear probe instead of a finger probe to enable free hand movement during the experiment. If ECG was missing, HR was determined from the  $SpO_2$  curve as reference. For all vital signs, a storage frequency of once per 5 seconds was used. The ThermoChron iButton (Maxim Integrated), a validated wireless skin temperature logger [17], was used as a reference device for monitoring temperature with a sample storage frequency of once per 10 seconds and a resolution of 0.5 °C. The iButtons enabled wireless temperature measurements right above the relevant wearable sensors.

### Protocol

Before the start of the experiment, the protocol was explained and demographic data of participants were obtained and stored in Research Electronic Data Capture (REDCap; Vanderbilt University) version 10.0.23, including age, gender, BMI, occupation, physical activity lifestyle [18], and relevant medical history. The standardized protocol existed for 17 different tasks subsequently performed by participants with a total duration of 57 minutes. The detailed protocol, including task descriptions and durations, is provided in [Multimedia Appendix 1](#). The task durations varied from 2 to 10 minutes and were performed in 6 activity clusters: resting, walking, metronome breathing, daily household activities (chores), stationary cycling on an exercise



bike, and recovery. Transition periods were present between all tasks, which were not included in the data analysis. For more intensive tasks, a transition period of several minutes was included in the protocol for physiological stabilization between tasks. Resting included lying in several positions, sitting, and standing. Walking included walking at normal and slow speeds and stair climbing. Metronome breathing comprised breathing at 6, 15, 20, and 24 breaths per minute (brpm) and was guided by a metronome app. Chores were performed in the kitchen, where the participant was instructed to do various household tasks such as preparing food and cleaning. Cycling was performed on an ergometer with increasing load and rotation until a HR of at least 120 beats per minute (bpm) was reached. Thereafter, the participants recovered in an armchair or on a

couch. During each experiment, 2 researchers were present, of whom 1 instructed the participant, and the other logged the start time of each task.

All sensors were synchronized with the computer time before the start of the experiment. During the experiment, vital signs were simultaneously recorded by the 4 wearable sensors and 2 reference devices. The placement of all the sensors is shown in [Figure 1](#) and [Table 1](#). A total of 2 Everion sensors were placed on the left and right arm, respectively, aiming to investigate the performance for different sensor placements. The data availability of real-time measurements was monitored regularly during the protocol, and technical issues were dissolved if needed.

**Table 1.** The 12 combinations of wearable sensors and reference devices to measure vital signs and their location on the participants' body.

Vital sign and wearable sensor (location)	Reference device (location)
<b>Heart rate</b>	
Everion (right upper arm)	Oxycon Mobile (4-lead ECG <sup>a</sup> /left ear lobe)
Everion (left upper arm)	Oxycon Mobile (4-lead ECG/left ear lobe)
VitalPatch (below left clavicular bone)	Oxycon Mobile (4-lead ECG/left ear lobe)
Fitbit (right wrist)	Oxycon Mobile (4-lead ECG/left ear lobe)
<b>Respiratory rate</b>	
Everion (right upper arm)	Oxycon Mobile (facemask)
Everion (left upper arm)	Oxycon Mobile (facemask)
VitalPatch (below left clavicular bone)	Oxycon Mobile (facemask)
<b>Oxygen saturation</b>	
Everion (right upper arm)	Oxycon Mobile (left ear lobe)
Everion (left upper arm)	Oxycon Mobile (left ear lobe)
<b>Skin temperature</b>	
Everion (right upper arm)	iButton (right upper arm)
Everion (left upper arm)	iButton (left upper arm)
VitalPatch (below left clavicular bone)	iButton (below left clavicular bone)

<sup>a</sup>ECG: electrocardiography.

## Data Collection and Analysis

Data from all devices were exported from separate databases and processed in MATLAB R2018b (MathWorks, Inc) and SPSS Statistics 23 (IBM Corp). The logged start time and predefined duration of the respective tasks were used to select the data-recording windows for each task. Subsequently, nearest-neighbor resampling was used to pair wearable sensor data with the nearest data of reference devices for the combinations of sensors, as shown in [Table 1](#). As the lowest data storage frequency was once per 10 seconds (for Everion and iButton), the maximum time shift between data points of the wearable sensor and reference device was 5 seconds. Data analysis was performed for each activity cluster and over the complete experiment (for all tasks).

## Statistical Analysis

### Data Availability

The data availability of each sensor was assessed by the percentage of missing data points out of the expected data points per activity cluster and over all tasks per vital sign. In addition, the number and duration of missing data periods (epochs), for example, where the time between subsequent data points exceeded the expected sample period, was assessed.

### Vital Sign Agreement

Agreement in vital sign data between wearable sensors and reference devices was inspected visually over all tasks. The measured values and variability of each sensor were described using the median and median absolute deviation (MAD) calculated per minute for all sensors and all participants. The median and IQR of the median and MAD of all participants were calculated per activity cluster and over all tasks to compare

the (differences in) measured values and variability between activities and sensors. Furthermore, the median absolute percentage error (MAPE) was calculated per minute per vital sign to evaluate the accuracy of each wearable sensor.

### Concurrent Validity

Concurrent validity was assessed using the data samples in a preselected activity cluster, with the aim of obtaining a large range of physiological variation with the least variation in position or task to minimize movement artifacts. Accordingly, the concurrent validity of HR was obtained in the cycling cluster, RR in the breathing cluster, and SpO<sub>2</sub> and temperature in the recovery cluster after cycling. As the VitalPatch and Everion had an averaging duration of 45 and 60 seconds, respectively, to compute RR, measurements during the first minute of each breathing activity were not considered in the validity analysis. Before data selection, data of reference devices during the selected activity clusters were visually analyzed per participant to exclude physiologically implausible reference data by 2 researchers (MEH and MCVR). If needed, periods with unexpected scattering, variation, or drops were excluded from

further analysis. Concurrent validity was assessed using Bland-Altman analyses to evaluate the mean differences (bias) and 95% limits of agreement (LoA). Bland-Altman analyses were corrected for repeated measurements, where the variance between measurement pairs was the sum of between- and within-subject variances [19,20]. The root mean square error (RMSE) was calculated to obtain insights into the amplitude of deviations. Bland-Altman plots, mean differences, LoA, and RMSEs were also assessed using median values per minute during the same predefined activity cluster. The results of both Bland-Altman analyses were compared to evaluate the influence of averaging on the concurrent validity of the wearable sensors.

## Results

### Overview

Between September 2020 and October 2020, 20 volunteers were included in the study. A total of 2 experiments were redone because of incomplete data from the reference devices because of recording failure. Data from 20 participants were analyzed, and the participant characteristics are shown in [Table 2](#).

**Table 2.** Participant characteristics (N=20).

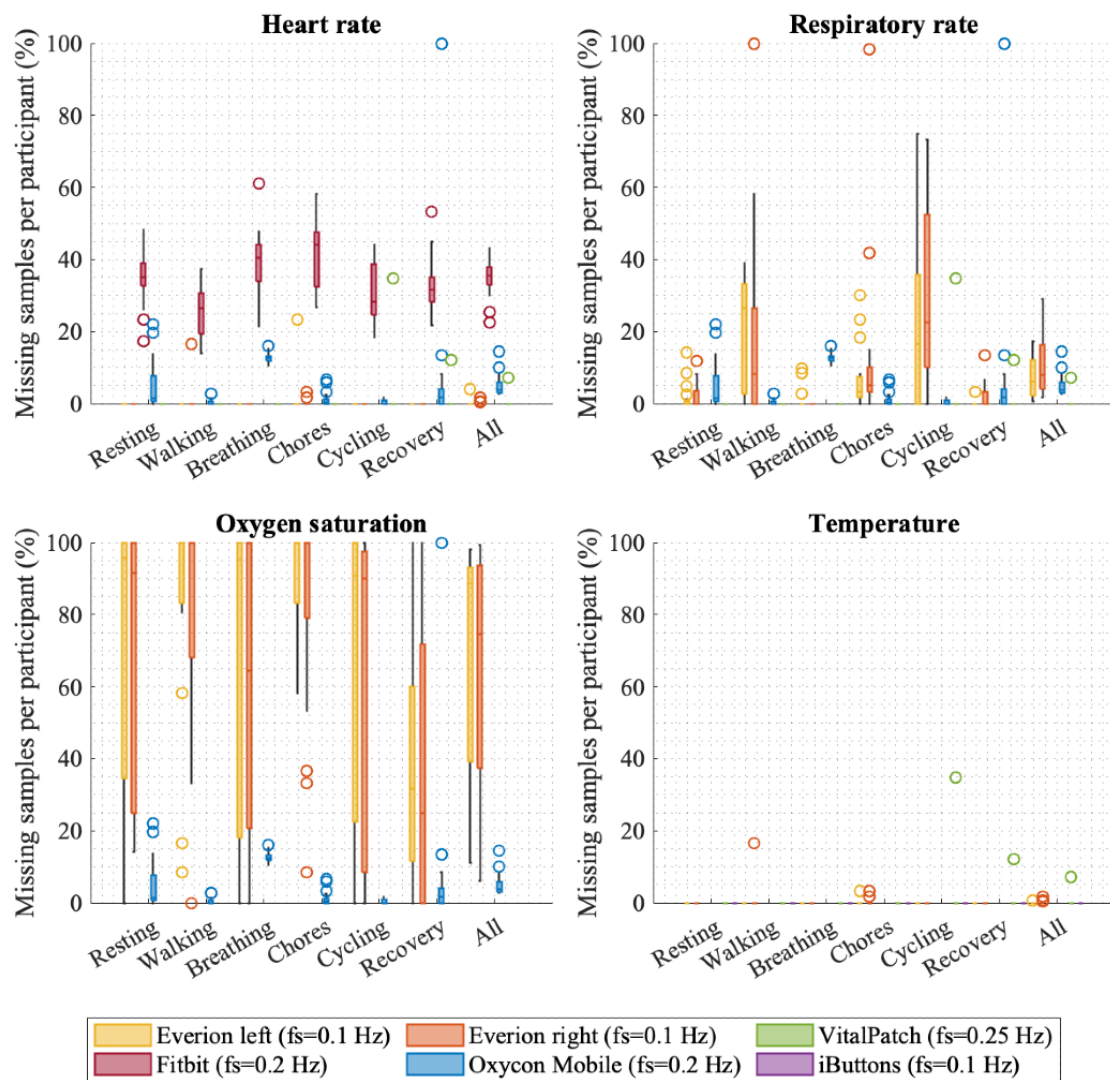
Characteristics	Values
Age (years), median (range)	64 (20-74)
<b>Age (years), n (%)</b>	
20-40	4 (20)
40-60	4 (20)
60-70	7 (35)
70-80	5 (25)
<b>Gender, n (%)</b>	
Male	11 (55)
Female	9 (45)
BMI (kg/m <sup>2</sup> ), median (range)	23.4 (20.1-28.4)
<b>Physical activity lifestyle, n (%)</b>	
Sedentary or light activity	10 (50)
Active or moderately active	10 (50)
<b>Relevant medical history, n (%)</b>	
No relevant medical history	14 (70)
Chronic obstructive pulmonary disease	2 (10)
Atrial fibrillation	1 (5)
Orthopedic surgery	3 (15)

### Data Availability

Percentages of missing samples are shown in boxplots per vital sign for the different activity clusters and all tasks in [Figure 2](#). HR data measured by Everion was available 99.83% (13,657/13,680) of the time, where only 4% (1/23) of missing epochs was >30 seconds. VitalPatch measured HR 99.64% (17,039/17,100) of the time, with a maximum duration for

missing epochs of 24 seconds. Data availability for VitalPatch was the same for all measured parameters; for example, data of all vital signs were available or none at all. Fitbit had the most missing data samples for HR based on the minimum-sample-storage frequency of once per 5 seconds; the median percentage of missing samples per participant was 35.7%. However, in 99.93% (2918/2920) of the missing epochs, the duration was ≤10 seconds.

**Figure 2.** Boxplot (median, IQR, range, and outliers) of the percentages of missing samples per participant per activity cluster and over all tasks for each sensor based on its expected storage frequency per vital sign.



For RR, Everion had the most available data during the breathing activity (2865/2880, 99.48%) and most missing data points during the more active clusters, walking and cycling, with median percentages of missing data of 8.3% to 26.4%. Of the missing RR epochs for both Everions, 51.4% (95/185) lasted >10 seconds, and 15.1% (28/185) lasted >1 minute up to 4 minutes.

SpO<sub>2</sub> data by Everion were available 31.44% (4301/13,680) of the time (1960/6840, 28.66% at the left arm and 2341/6840, 34.23% at the right arm). Most SpO<sub>2</sub> data of the Everions were recorded during recovery (753/1200, 62.75% of the time) and least during walking and chores activities, with a median percentage of missing data of 100%. Of all the missing SpO<sub>2</sub> epochs for both Everions, 83% (93/112) lasted >10 seconds, and 16.1% (18/112) lasted >1 minute up to 9 minutes.

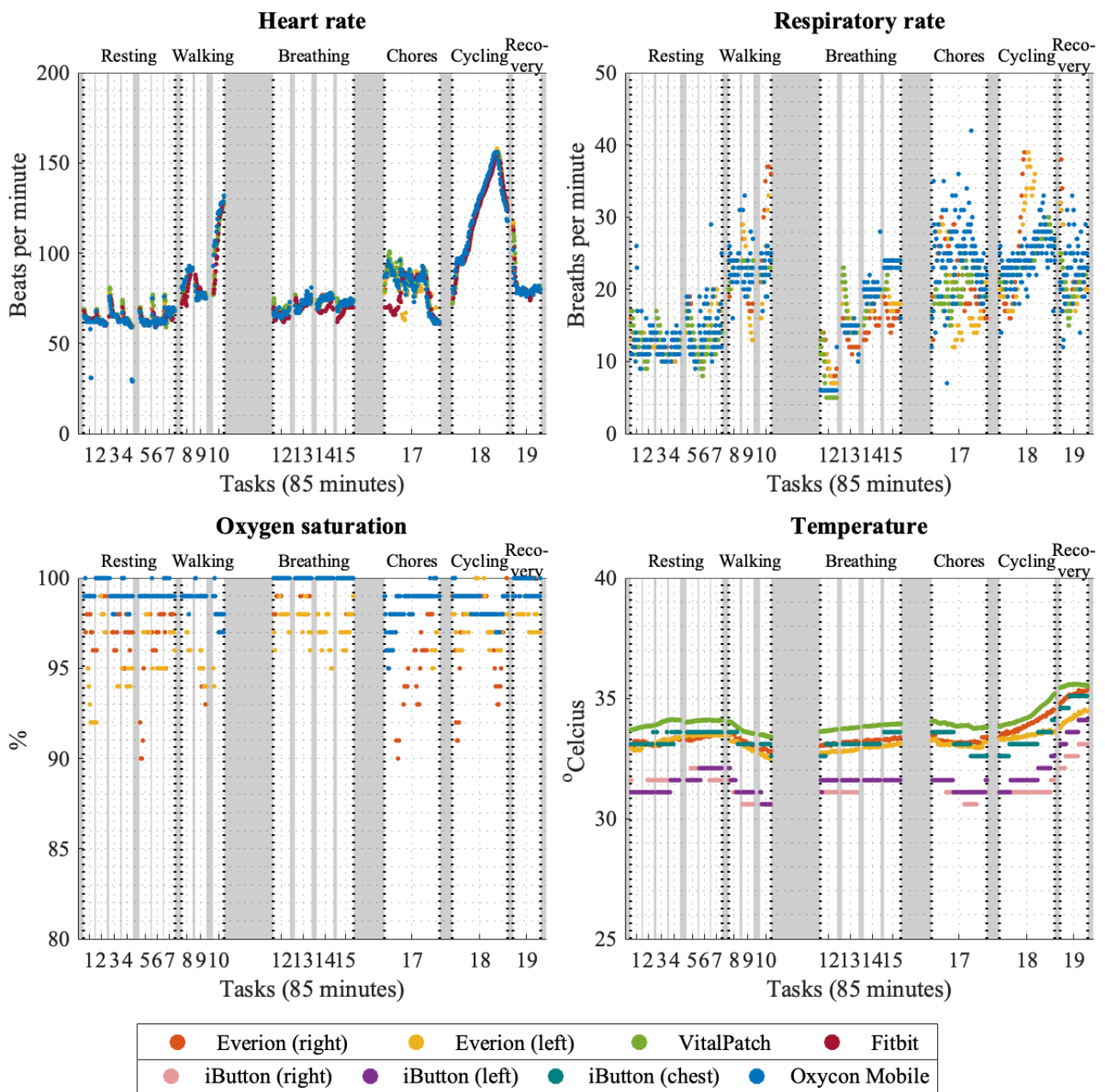
Temperature measurements of Everion were present 99.9% (13,669/13,680) of the time.

### Vital Sign Agreement

In most cases, wearable sensors showed similar trends compared with those of reference devices when measuring HR, RR, and temperature. Trends in vital signs during the complete experiment are shown in [Figure 3](#) for 1 participant as an example. In half of the participants (10/20, 50%), an unexpected drop or low agreement in HR during cycling could be seen for Fitbit (9/10, 90%) and Everion (3/10, 30%), as illustrated in [Multimedia Appendix 2](#), and also in the Oxycon Mobile (1/10, 10%).

The median values and MAD per minute for each vital sign and sensor over all tasks are shown in [Table 3](#). Variability in terms of MAD per minute was generally low for all devices and vital signs.

**Figure 3.** Measured data of all sensors for one study participant, classified by vital sign. White boxes represent the tasks, and the grey boxes the transition periods between tasks.





**Table 3.** Median and median absolute deviation (MAD) per minute values of all participants for all sensors per vital sign over all tasks.

Parameters	Sensor, median (IQR)							
	Everion (right)	Everion (left)	VitalPatch	Fitbit	Oxycon Mobile	iButton (right)	iButton (left)	iButton (chest)
<b>Median</b>								
HR <sup>a</sup> (bpm <sup>b</sup> )	78.5 (68-94)	78.5 (68-93)	79 (68-96)	76 (67-90)	80.5 (67.4-101.1)	N/A <sup>c</sup>	N/A	N/A
RR <sup>d</sup> (brpm <sup>e</sup> )	17.5 (14-22)	18 (14.0-22.5)	18 (15-22)	N/A	19.5 (15.0-23.5)	N/A	N/A	N/A
SpO <sub>2</sub> <sup>f</sup> (%)	98 (96-99)	98 (96.9-99)	N/A	N/A	99 (99-100)	N/A	N/A	N/A
Temperature (°C)	32.8 (31.9-33.8)	33 (32.2-33.9)	34 (33.4-34.6)	N/A	N/A	30.6 (29.6-31.6)	30.6 (29.6-31.6)	33.6 (33.1-34.1)
<b>MAD</b>								
HR (bpm)	1 (0.5-2.0)	1 (0.5-2.0)	1 (1-2)	1 (1-2)	1.5 (1.0-3.5)	N/A	N/A	N/A
RR (brpm)	0.5 (0-1)	0.5 (0-1)	1 (0-1)	N/A	1 (0.5-2.0)	N/A	N/A	N/A
SpO <sub>2</sub> (%)	0 (0-0.5)	0 (0-0.5)	N/A	N/A	0 (0-0)	N/A	N/A	N/A
Temperature (°C)	0 (0-0)	0 (0-0)	0 (0-0)	N/A	N/A	0 (0-0)	0 (0-0)	0 (0-0)

<sup>a</sup>HR: heart rate.<sup>b</sup>bpm: beats per minute.<sup>c</sup>N/A: not applicable.<sup>d</sup>RR: respiratory rate.<sup>e</sup>brpm: breaths per minute.<sup>f</sup>SpO<sub>2</sub>: oxygen saturation.

The median MAPE of each wearable sensor as compared with the reference device per activity cluster per vital sign is shown in Table 4. For HR, all wearable sensors had an overall low median MAPE (2.3%-3.9%), with the highest MAPE for Fitbit. All sensors had the highest median MAPE during the walking cluster for HR (13.4%-23.4%). For RR, VitalPatch had the lowest median MAPE during the breathing and cycling cluster,

whereas the Everion median MAPE was higher, especially during walking and cycling. The median MAPE of SpO<sub>2</sub> measured by Everion was maximally 3.8% (during walking). The median MAPE for temperature of VitalPatch was very low (1%-1.7%). The lowest median MAPE for temperature of Everion was during the first activity cluster (resting: mean 6.3%) and the highest during the last cluster (recovery: mean 9%).

**Table 4.** Median absolute percentage error (MAPE) with IQR of all participants for all wearable sensors as compared with reference devices per vital sign during each activity cluster and overall tasks<sup>a</sup>.

Vital signs	Sensor (%), MAPE (IQR)			
	Everion (right)	Everion (left)	VitalPatch	Fitbit
<b>HR<sup>b</sup></b>				
Resting	1.6 (0.7-4)	1.6 (0.7-4.4)	1.6 (0.7-4.8)	1.6 (0.6-4.1)
Walking	16 (2.8-33.3)	23.4 (3.1-35.2)	13.4 (3-32.6)	20.2 (8-34.4)
Breathing	2.1 (0.7-8.2)	2.2 (0.7-8.2)	2.7 (0.9-8.9)	3.2 (1.4-10.9)
Chores	2.1 (0.7-5.6)	2.6 (0.7-6.7)	1.7 (0.8-5.8)	6.2 (2.4-11.2)
Cycling	3 (1-6.2)	2.9 (0.8-6.7)	2.3 (1-4.9)	6.1 (2.4-14.8)
Recovery	1.1 (0.6-3.1)	1.1 (0.6-2.9)	1.3 (0-3.2)	1.6 (0.1-3.4)
All	2.3 (0.7-6.8)	2.3 (0.7-7.4)	2.3 (0.8-6.7)	3.9 (1.3-12)
<b>RR<sup>c</sup></b>				
Resting	12.5 (6.1-21.9)	13.6 (6.5-22.6)	8.3 (4.8-14.3)	N/A <sup>d</sup>
Walking	22.9 (10-46.7)	22.7 (9.7-41.7)	8.3 (4.2-15.7)	
Breathing	20 (7.5-41.7)	20 (6.7-43.3)	6.7 (2.6-19.5)	
Chores	19 (8.3-38.1)	22 (11.9-34.6)	15.9 (6.8-23.5)	
Cycling	27.1 (13.2-42.8)	26.8 (13.2-42.6)	6.7 (3.6-11.9)	
Recovery	12.5 (5.7-27.6)	14.6 (4.9-27.4)	7.7 (4.1-17.2)	
All	17.5 (7.7-35.1)	18.9 (7.7-35)	8.6 (4.2-17.3)	
<b>SpO<sub>2</sub><sup>e</sup></b>				
Resting	2 (1-3.8)	2 (1-4)	N/A	N/A
Walking	3.8 (2.5-6)	3 (1.5-4.5)		
Breathing	2 (1-2)	2 (1-3)		
Chores	2.5 (1-3)	1 (1-2)		
Cycling	1.5 (0.5-3)	1.3 (0.5-2)		
Recovery	1 (0.5-2.5)	1 (0.5-2.1)		
All	2 (1-3)	2 (1-3)		
<b>Temperature</b>				
Resting	5.9 (4.3-8)	6.7 (5.8-8.2)	1.1 (0.6-2)	N/A
Walking	7.8 (6.2-9.9)	8.8 (7.6-9.9)	1.2 (0.5-2.5)	
Breathing	7.1 (5.9-9.5)	7.9 (6.2-9.6)	1 (0.5-1.7)	
Chores	8.4 (6.5-10)	8.7 (6.9-10.4)	1.2 (0.7-2)	
Cycling	8.2 (6.5-10.3)	9.1 (7-10.3)	1.7 (0.8-2.6)	
Recovery	8.6 (6.7-10.7)	9.4 (7.6-11.4)	1.7 (0.7-3.1)	
All	7.3 (5.9-9.6)	8.1 (6.5-9.9)	1.2 (0.6-2.3)	

<sup>a</sup>Median values per minute are used to calculate median absolute percentage error.

<sup>b</sup>HR: heart rate.

<sup>c</sup>RR: respiratory rate.

<sup>d</sup>N/A: not applicable.

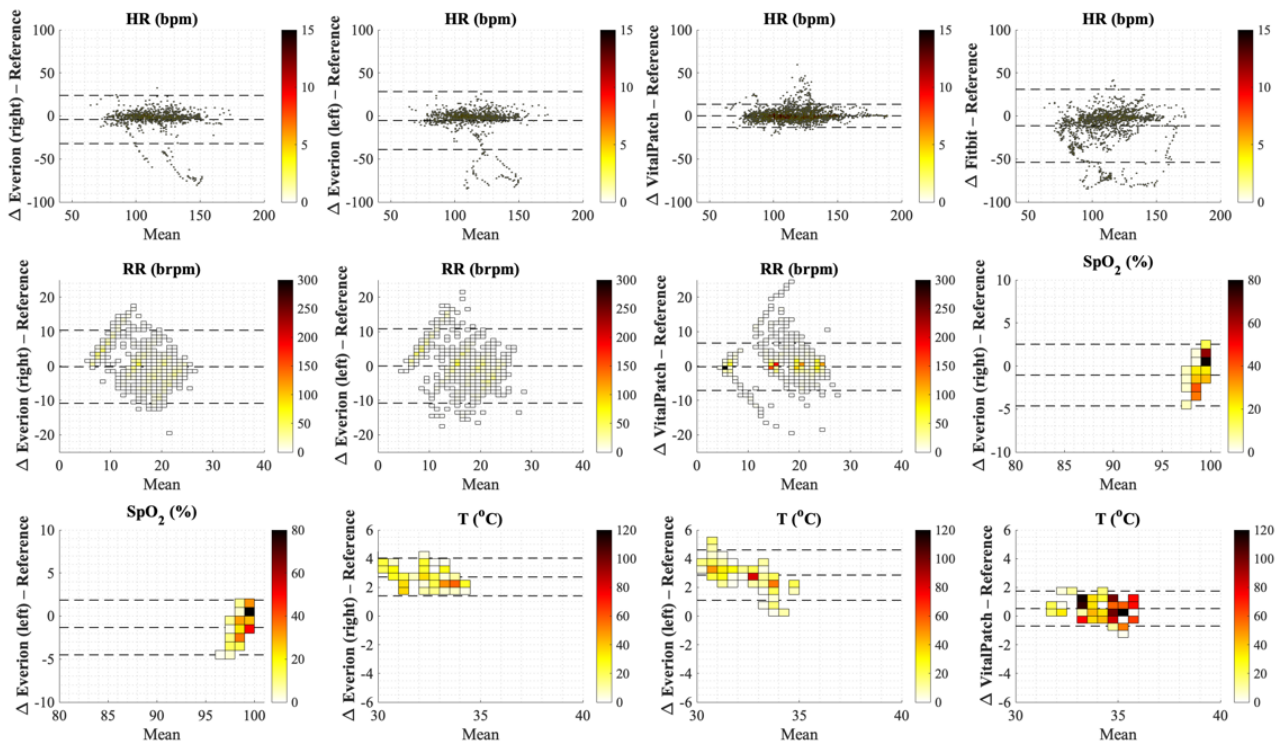
<sup>e</sup>SpO<sub>2</sub>: oxygen saturation.

### Concurrent Validity

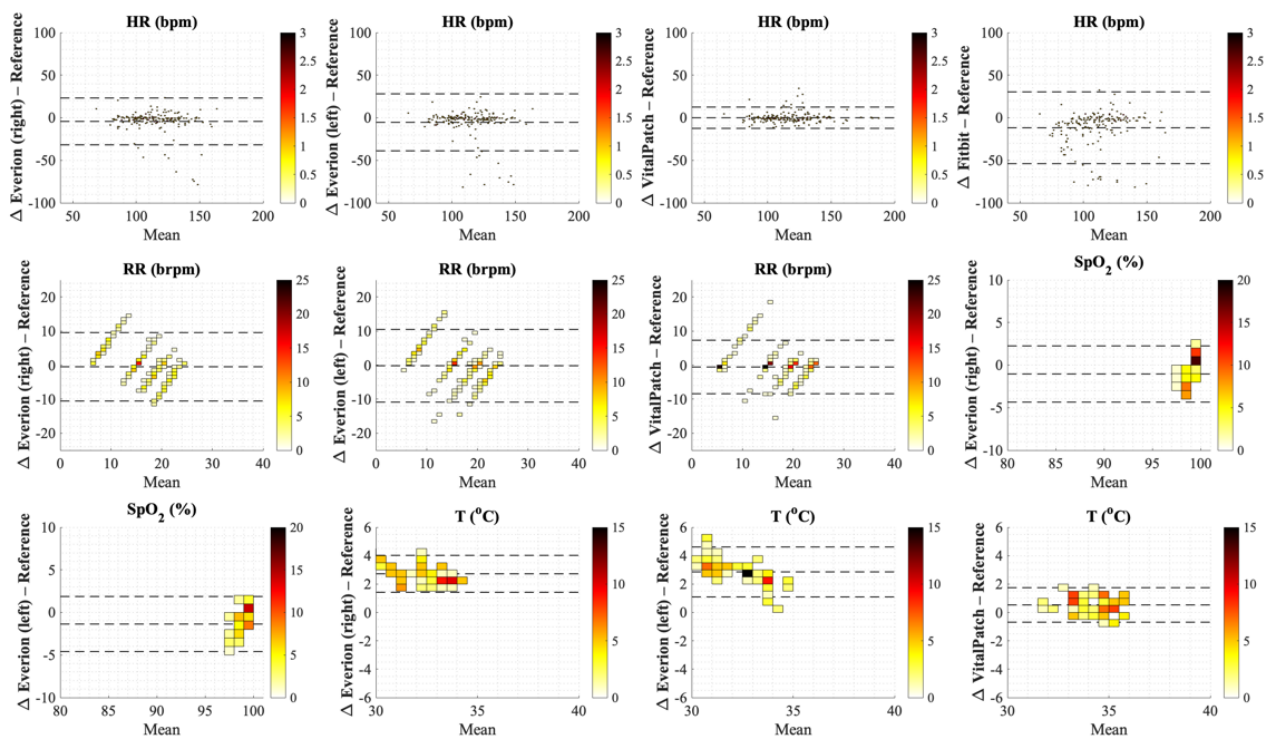
Figure 4 shows Bland-Altman plots for individual samples, whereas plots for median values per minute are shown in Figure

5. Table 5 shows mean differences and LoA from Bland-Altman analyses and RMSE per vital sign for the 2 methods for each wearable sensor compared with their reference devices.

**Figure 4.** Bland-Altman plots for the 12 combinations of vital signs measured by the wearable sensors and reference devices for individual samples during the preselected activity cluster, where the x-axis represents the mean of and the y-axis the difference ( $\Delta$ ) between both sensors. Dotted lines represent the mean difference and limits of agreement for repeated measurements. bpm: beats per minute; brpm: breaths per minute; HR: heart rate; RR: respiratory rate; SpO<sub>2</sub>: oxygen saturation; T: temperature.



**Figure 5.** Bland-Altman plots for the 12 combinations of vital signs measured by the wearable sensors and reference devices of median data per minute during the preselected activity cluster, where the x-axis represents the mean of and the y-axis represents the difference ( $\Delta$ ) between both sensors. Dotted lines represent the bias and limits of agreement for the repeated measurements. bpm: beats per minute; brpm: breaths per minute; HR: heart rate; RR: respiratory rate; SpO<sub>2</sub>: oxygen saturation; T: temperature.



**Table 5.** Mean differences and 95% limits of agreement (LoA) from Bland-Altman analysis for repeated measurements of each wearable sensor compared with its reference device per vital sign using both individual samples and median values per minute during the preselected activity cluster.

Vital signs	Everion (right)		Everion (left)		VitalPatch		Fitbit	
	Samples	Minute	Samples	Minute	Samples	Minute	Samples	Minute
<b>HR<sup>a</sup> (activity cluster: cycling)</b>								
Number of data pairs	1077	180	1076	180	2639	180	1490	179
Number of participants	18	18	18	18	18	18	18	18
Mean difference (LoA; bpm <sup>b</sup> )	-4.2 (-32.2 to 23.9)	-4.3 (-31.8 to 23.2)	-5.3 (-39 to 28.3)	-5.4 (-38.9 to 28.1)	0.1 (-13.3 to 13.5)	0 (-12.4 to 12.5)	-11.4 (-53.8 to 30.9)	-11.8 (-53.9 to 30.4)
RMSE <sup>c</sup> (bpm)	14.7	14.5	17.7	17.6	6.8	6.3	24.1	24.1
							N/A <sup>e</sup>	N/A
<b>RR<sup>d</sup> (activity cluster: breathing)</b>								
Number of data pairs	2220	160	2102	160	3720	160		
Number of participants	20	20	20	20	20	20		
Mean difference (LoA; brpm <sup>f</sup> )	-0.4 (-10.6 to 9.8)	-0.5 (-9.1 to 8.0)	0.1 (-9.3 to 9.4)	-0.3 (-9.1 to 8.6)	-0.1 (-7.6 to 7.3)	-0.5 (-5 to 4.1)		
RMSE (brpm)	5.5	5.1	5.6	5.4	3.5	4.0		
					N/A	N/A	N/A	N/A
<b>SpO<sub>2</sub><sup>g</sup> (activity cluster: recovery)</b>								
Number of data pairs	354	69	351	65				
Number of participants	17	17	17	17				
Mean difference (LoA; %)	-1.1 (-4.6 to 2.5)	-1 (-4.3 to 2.3)	-1.3 (-4.5 to 1.9)	-1.4 (-4.6 to 1.9)				
RMSE (%)	2.1	2.0	2.1	2.1				
							N/A	N/A
<b>Temperature (activity cluster: recovery)</b>								
Number of data pairs	598	100	595	100	1478	100		
Number of participants	20	20	20	20	20	20		
Mean difference (LoA; °C)	2.7 (1.4 to 4.0)	2.7 (1.4 to 4.0)	2.9 (1.1 to 4.6)	2.9 (1.1 to 4.6)	0.5 (-0.7 to 1.7)	0.5 (-0.7 to 1.7)		
RMSE (°C)	2.8	2.8	3.0	3.0	0.8	0.8		

<sup>a</sup>HR: heart rate.<sup>b</sup>bpm: beats per minute.<sup>c</sup>RMSE: root mean square error.<sup>d</sup>RR: respiratory rate.<sup>e</sup>N/A: not applicable.<sup>f</sup>brpm: breaths per minute.<sup>g</sup>SpO<sub>2</sub>: oxygen saturation.

For HR measured by VitalPatch, the mean difference was 0 bpm (LoA -13.3 to 13.5 bpm). Everion worn at the right or left arm underestimated HR with 4.2 bpm and 5.3 bpm (overall LoA -39.0 bpm to 28.3 bpm), and Fitbit underestimated HR with 11.4 bpm (LoA -53.8 bpm to 30.9 bpm).

Mean differences for RR were low with large LoA for both VitalPatch (LoA -7.6 brpm to 7.3 brpm) and Everion (LoA -10.6 brpm to 9.8 brpm). In addition, [Figures 4 and 5](#) show higher differences for RR by Everion at the lowest breathing frequency (overestimation) and highest breathing frequency (underestimation).



SpO<sub>2</sub> was underestimated, with mean differences of over 1% by Everion and LoA of -4.6% to 2.5%. For temperature, VitalPatch had a small overestimation of 0.5 °C. Everion overestimated temperature with a mean difference of 2.8 °C, with slightly higher differences at lower temperature and vice versa. The mean differences and LoA for median values per minute were similar to those for the individual samples.

## Discussion

### Principal Findings

Telemonitoring requires vital sign data from wearable sensors to be available, accurate, and valid when used for clinical decision-making, as well as during daily activities. Our results showed variable data availability and accuracy of vital signs measured for the evaluated wearable sensors during different daily life activities in a simulated free-living environment. VitalPatch is accurate and the least vulnerable to movement during daily activities. With regard to Everion, the mean difference, lower accuracy during physical activity, and limited data availability for RR and SpO<sub>2</sub> must be considered when interpreting its measurements for diagnostic aims. Our results showed no relevant differences in performance between the left and right Everion because of sensor placement. Fitbit had a large mean difference and an activity-dependent storage frequency for HR.

Different results for the tested wearable sensors may be explained by differences in the underlying measurement technologies, processing algorithms, and sensor placement sites. Relevant findings and points of consideration will be discussed in the context of each sensor.

Our study showed low availability of Everion RR during the more active clusters and SpO<sub>2</sub> data, which might be because of the placement site of the Everions. The upper arm is a nontraditional and uncommon site for measuring PPG signals, for which its accuracy has not yet been established [21,22]. Everion calculates an accuracy metric per vital sign, which prevents data with an accuracy <50% from being stored. This accuracy metric could be low when the measurement of vital signs is affected by movement, which is a general limitation of PPG signals [22,23]. On the other hand, the fact that Everion is PPG-based creates the ability to monitor multiple vital signs (HR, RR, and SpO<sub>2</sub>) with only 1 sensor [24]. There is an increasing demand for such devices, as patients are becoming multimorbid.

We reported an underestimation of HR by Everion. Only Barrios et al [13] evaluated HR measured by Everion in 6 healthy volunteers compared with ECG Holter measurements during different activities and found a mean difference for HR of -0.2 bpm (LoA of -6.3 bpm to 6.0 bpm) during cycling. These results imply better accuracy compared with those of our study, which could be related to the small number and young age of their participants. Finally, our study showed unexpected drops in HR by Everion during the rapid increase of HR while cycling without extensive arm movement, which is expected to be because of the algorithms of the sensors.

In our study, VitalPatch measured all vital signs with the highest accuracy and validity. No previous studies have been reported on the performance of VitalPatch. Only similar patches have been studied previously, including the Sensium Vitals patch (Sensium) [25] and HealthPatch (VitalConnect) [26].

For Fitbit, our study showed the lowest data availability of HR, which might be related to its irregular storage frequency. Although the sensor specification [14] stated that the sample storage frequency should be once per second to once per 5 seconds, depending on the level of activity, data were collected at much lower frequencies between once per 5 seconds and once per 15 seconds in our study.

Our results showed high errors and mean differences for Fitbit compared with the reference device. Earlier validation of the Fitbit Charge HR (Fitbit Inc) for HR showed higher accuracy during walking or running on a treadmill and lower accuracy during daily activities, with a MAPE of 8.4% and 10.1%, respectively [27]. A second validation study using Fitbit Charge HR showed an even higher underestimation of HR of 16 bpm during moderate-to-vigorous physical activity compared with Polar H6 HR monitor in 10 healthy participants during daily life activities [28].

In general, our results showed that the mean difference and LoA did not improve using median values per minute instead of individual data samples. This was unexpected, as using median values minimizes the influence of potential outliers. Bretelet et al [26] found an improvement in the mean difference and LoA of HR and RR when applying a median filter per 15 minutes, although this might be more relevant for long-term measurements. In addition, averaging rigorously decreases the number of data points.

### Strengths and Limitations

A strength of this study is that we evaluated the sensor performance during daily life activities in a general population with mixed characteristics. In addition, the study was performed in a simulated home environment, which is as close as possible to the target setting while enabling well-controlled study measurements. Accordingly, the current results give more insight into the sensor performance as compared with typically performed validation protocols that only include young, healthy participants and measurements at rest.

A limitation is that we assessed the wearable sensor performance over a relatively short period. A second limitation is the limited translatability of our results to patients because of the measurement of vital signs in volunteers without pathophysiological abnormalities. Other limitations are related to the reference devices; we had to redo 1 volunteer because of the recording failure of Oxycon Mobile, and the resolution of the iButtons was set at 0.5 °C. This might have influenced the bias of Everion and VitalPatch in temperature. Although Oxycon Mobile has been used as the gold standard for portable monitoring of vital signs before [15,16], validation studies have so far focused on its measurement of metabolic capacity [29-33].

## Implications

Wearable sensors could assist in various areas of health care, such as detection of deviant values of vital signs to alarm health care professionals, trend analysis to monitor recovery or deterioration, and decision-making to operate or visit the hospital. Applications of vital sign telemonitoring are diverse, from trend monitoring to acute alarms, based on the clinical goal and which medical actions follow. The required accuracy of the sensor measurements depends on this. Sensor performance for patient monitoring still needs evaluation in specific patient groups, at home or in hospital, during longer periods, and on its diagnostic ability, which are the next steps toward clinical applicability. Patient acceptance and actual use (adherence) are important for clinical use [34]. Therefore, this should be the subject of future work. However, the potential of our tested wearable sensors for patient monitoring will be discussed in the context of the following technical factors to consider: (1) the vital signs to monitor, (2) a sensors' accuracy and trending ability, (3) data storage frequency or filtering, and (4) confounding factors such as movement during daily activities.

First, the vital signs that need to be monitored depend on the aforementioned application. For example, for in-hospital monitoring, detection of cardiac events might require ECG monitoring [35], whereas for detection of postoperative deterioration, all vital signs used in the modified early warning score might be preferred [2], which are HR, RR, temperature, SpO<sub>2</sub>, and blood pressure. In many cases, it is still unknown which parameters to monitor at home and how to interpret long-term measurements obtained in a remote setting, as current common practice is often that a patient returns to or contacts the hospital in case of (increasing) symptoms without further monitoring [7,36]. The ability of the tested sensors to measure the available parameters is discussed per vital sign.

VitalPatch and Everion both monitor multiple vital signs, whereas VitalPatch can also monitor raw ECG. HR is the most commonly measured vital sign and is often measured accurately [7,8,13]. Owing to its large mean difference and unexpected drops during rapidly increasing HR, Fitbit is the least suitable for HR monitoring in patients.

Everion measurements for RR were less accurate <15 brpm or >20 brpm, according to our Bland-Altman analyses. However, these ranges are especially important for the detection of deterioration and predicting cardiac arrest [37,38]. Algorithms for ECG and PPG can use the same techniques to derive RR, such as amplitude and frequency modulation, although algorithms based on ECG perform better than those based on PPG [39]. Respiratory-synchronized variations are subtle, and proximity to the chest improves the measurement of RR (less susceptible to vasoconstriction) [40,41]. Therefore, VitalPatch may be preferred for monitoring RR.

SpO<sub>2</sub> is less commonly measured [7,8,13]. Available wearable SpO<sub>2</sub> sensors are generally commercially available fingertip

sensors, and few meet the International Organization for Standardization 80601-2-61 accuracy standards [42]. Fingertip probes are not ideal for long-term monitoring of SpO<sub>2</sub> at home, although this enables transmission mode PPG with higher perfusion compared with more convenient measurement sites that require reflection mode PPG [41,42]. The low variability in SpO<sub>2</sub> levels of volunteers precludes insight into the accuracy of Everion for monitoring SpO<sub>2</sub> levels in patients. However, because of its limited data availability and underestimation of SpO<sub>2</sub>, our results indicate that Everion is not suitable for (high-frequency) clinical monitoring of SpO<sub>2</sub>.

Most available wearable sensors measure skin temperature (including Everion and VitalPatch), whereas core temperature may be clinically more relevant because of its current use in clinical practice. Nevertheless, the clinical relevance of skin temperature monitoring should be evaluated in future research [2].

Second, it is important to define what performance and trending ability are acceptable for clinical use. Currently, no criteria are available for MAPE, mean differences, and LoA of wearable sensors. Although all wearable sensors in our study followed similar trends compared with those followed by the reference devices for HR, RR, and temperature, their trending ability and diagnostic ability to detect clinically relevant changes should be assessed during longer assessments in patients.

A challenge for validation studies for vital sign monitoring is choosing the right reference devices to use as gold standard devices [43]. We experienced that ECG cables and electrodes used for the HR reference measurements are susceptible to movement as well, as also described by Barrios et al [13] using ECG Holter. The Oxycon Mobile reference device enabled ambulatory expired volume analysis, which is the best available solution to monitor RR wireless and continuously. Accordingly, the RR validation results are expected to be more accurate as compared with those of clinical validation studies that use intermittent nurse assessments as reference, which is often poorly reported or inaccurate [1].

Third, optimal filtering strategies and data storage frequencies should be investigated. Fourth, further reduction of movement artifacts, for example, using information from the present accelerometer [42], is essential for optimizing measurements at sites that enable long-term monitoring, such as the upper arm.

## Conclusions

To use wearable sensors for clinical decision-making, information about their performance in daily life is needed. Of the tested sensors, VitalPatch was found to be the most accurate and valid for vital sign monitoring. For all sensors, movement during daily activities should be considered. Longer assessments of wearable sensors are needed to evaluate the technical performance and trending ability to work toward the clinical applicability of wearable sensors in patients.

## Conflicts of Interest

None declared.

## Multimedia Appendix 1

Measurement protocol with the activity clusters, task descriptions and task durations and cumulative time of the 17 tasks included in the analysis.

[[PDF File \(Adobe PDF File\), 195 KB - formative\\_v6i1e30863\\_app1.pdf](#) ]

## Multimedia Appendix 2

Measured data of all sensors for one study participant, classified by vital sign. White boxes represent the tasks, and the grey boxes the transition periods between tasks.

[[PNG File , 224 KB - formative\\_v6i1e30863\\_app2.png](#) ]

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## Abbreviations

**bpm:** beats per minute  
**brpm:** breaths per minute  
**CE:** Conformity European  
**ECG:** electrocardiography  
**HR:** heart rate  
**LoA:** limits of agreement  
**MAD:** median absolute deviation  
**MAPE:** median absolute percentage error  
**PPG:** photoplethysmography  
**REDCap:** Research Electronic Data Capture  
**RMSE:** root mean square error  
**RR:** respiratory rate  
**SpO<sub>2</sub>:** oxygen saturation

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Original Paper

# Development of a Web-Based, Guided Self-help, Acceptance and Commitment Therapy–Based Intervention for Weight Loss Maintenance: Evidence-, Theory-, and Person-Based Approach

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## Abstract

**Background:** The long-term impact and cost-effectiveness of weight management programs depend on posttreatment weight maintenance. There is growing evidence that interventions based on third-wave cognitive behavioral therapy, particularly acceptance and commitment therapy (ACT), could improve long-term weight management; however, these interventions are typically delivered face-to-face by psychologists, which limits the scalability of these types of intervention.

**Objective:** The aim of this study is to use an evidence-, theory-, and person-based approach to develop an ACT-based intervention for weight loss maintenance that uses digital technology and nonspecialist guidance to minimize the resources needed for delivery at scale.

**Methods:** Intervention development was guided by the Medical Research Council framework for the development of complex interventions in health care, Intervention Mapping Protocol, and a person-based approach for enhancing the acceptability and feasibility of interventions. Work was conducted in two phases: phase 1 consisted of collating and analyzing existing and new primary evidence and phase 2 consisted of theoretical modeling and intervention development. Phase 1 included a synthesis of existing evidence on weight loss maintenance from previous research, a systematic review and network meta-analysis of third-wave cognitive behavioral therapy interventions for weight management, a qualitative interview study of experiences of weight loss maintenance, and the modeling of a justifiable cost for a weight loss maintenance program. Phase 2 included the iterative development of guiding principles, a logic model, and the intervention design and content. Target user and stakeholder panels were established to inform each phase of development, and user testing of successive iterations of the prototype intervention was conducted.

**Results:** This process resulted in a guided self-help ACT-based intervention called SWiM (Supporting Weight Management). SWiM is a 4-month program consisting of weekly web-based sessions for 13 consecutive weeks followed by a 4-week break for participants to reflect and practice their new skills and a final session at week 18. Each session consists of psychoeducational content, reflective exercises, and behavioral experiments. SWiM includes specific sessions on key determinants of weight loss maintenance, including developing skills to manage high-risk situations for lapses, creating new helpful habits, breaking old unhelpful habits, and learning to manage interpersonal relationships and their impact on weight management. A trained, nonspecialist

coach provides guidance for the participants through the program with 4 scheduled 30-minute telephone calls and 3 further optional calls.

**Conclusions:** This comprehensive approach facilitated the development of an intervention that is based on scientific theory and evidence for supporting people with weight loss maintenance and is grounded in the experiences of the target users and the context in which it is intended to be delivered. The intervention will be refined based on the findings of a planned pilot randomized controlled trial.

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## KEYWORDS

weight management; eHealth; acceptance and commitment therapy; third-wave cognitive behavioral therapy; guided self-help

## Introduction

### Background

About 33% of UK adults are overweight, and a further 28% live with obesity [1]. Behavioral weight management programs (BWMPs) are the most commonly used treatment for overweight and obesity and typically use behavior change techniques (BCTs), such as self-monitoring, goal setting, stimulus control, and social support, to facilitate energy restriction and increase physical activity [2]. BWMPs can support initial weight loss of approximately 5% to 10% of body weight and are associated with improvements in the risk of diabetes, cardiovascular diseases, and related metabolic disorders [3,4]. However, systematic reviews have shown that even after a gold standard specialist-led BWMPs, most individuals regain weight within 3-5 years [5,6]. The cost-effectiveness and long-term health impact of these programs depend on the maintenance of posttreatment weight loss [7]. Although the extended use of traditional behavioral strategies can improve weight loss maintenance to some extent [8], alternative approaches are needed to better support weight loss maintenance and maximize the long-term health benefits of BWMPs.

There is growing evidence that third-wave cognitive behavioral therapies (3wCBTs) have better long-term outcomes for weight management than standard behavioral therapy (SBT) [9] and thus may be a more effective approach to support weight loss maintenance. The term 3wCBT refers to a set of behavioral and cognitive approaches that focus on a person's *relationship* with their thoughts, rather than the *content*, as in traditional cognitive behavioral therapy, and centers on concepts such as mindfulness, acceptance, values, and goals, among others [10]. Such approaches include acceptance and commitment therapy (ACT), mindfulness-based cognitive therapy, compassion-focused therapy, and dialectical behavioral therapy. These approaches encourage the acceptance and tolerance of aversive internal experiences (eg, food cravings and physical discomfort) using strategies such as present-moment awareness and cognitive defusion. In relation to weight management, it is hypothesized that developing these skills facilitates improved recognition of internal and external cues to overeat and behavioral responses that move a person toward their value-based goals [10]. In addition, 3wCBT encourages compassion toward the self, which may help prevent discouragement following minor lapses. Systematic reviews have also shown that 3wCBT interventions can improve psychological determinants of weight loss maintenance that have been identified in previous qualitative

and quantitative studies, such as self-regulation, autonomous motivation, dietary restraint, disinhibition, negative mood, and emotional eating [9,11-13]. Despite growing evidence that shows that 3wCBT interventions may improve long-term weight management, there is uncertainty regarding their scalability and affordability. These interventions are usually psychologist-led, and psychologists specializing in obesity are scarce and costly. Following the success of cognitive behavioral therapy delivered using technology and trained nonspecialists [14,15], recent, early-phase studies have shown that 3wCBT for weight management can also be delivered remotely, with findings highlighting improvements in weight management and determinants of weight loss maintenance, including experiential avoidance, psychological flexibility, and binge eating [16-18]. Furthermore, a systematic review of 3wCBT eHealth interventions to improve mental health outcomes reported that these programs were feasible and acceptable to participants in practice [19].

### Objectives

This study aims to develop an ACT-based intervention to be delivered using digital technology and nonspecialists to support adults with overweight and obesity to maintain their weight loss following completion of a BWMP. To develop a relevant, engaging, and effective intervention, careful planning and a design process are required, particularly when translating health care interventions into a digital format [20]. Such a process facilitates the development of interventions that are designed to address the identified needs of the target users which are grounded in their experiences, and provides an opportunity to minimize potential barriers to successful implementation. This paper reports the evidence-, theory-, and person-based approach that was used to develop this intervention and the findings of this approach.

## Methods

### Overview

We used a systematic and iterative intervention development process guided by 3 frameworks: the Medical Research Council (MRC) framework for the development of complex interventions in health care [21], the Intervention Mapping Protocol (IMP) [22], and a person-based approach for enhancing the acceptability and feasibility of interventions [23]. The MRC framework encourages a 4-phase approach including development, feasibility and piloting, evaluation, and implementation, with each phase requiring a body of work to

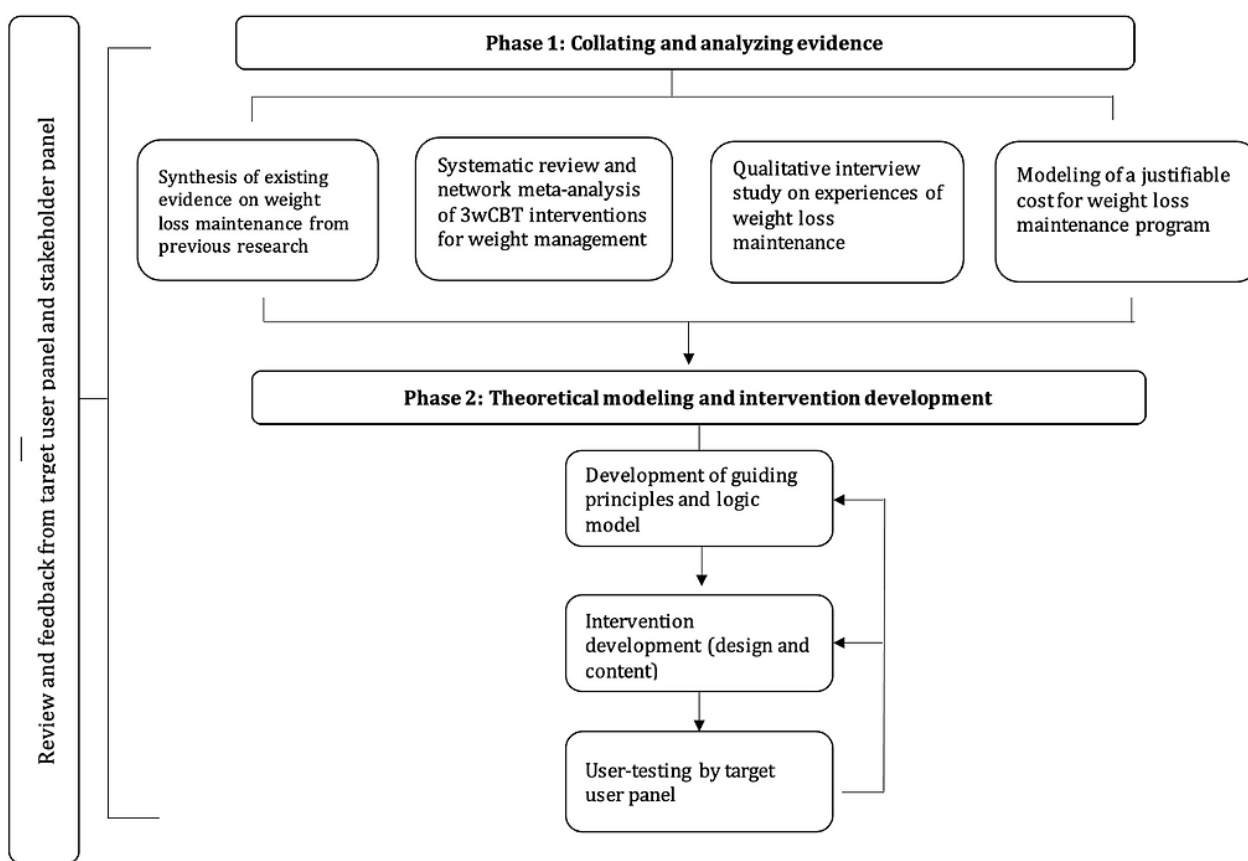
be conducted [21]. Similarly, the IMP sets out 6 steps for intervention development, which broadly include the consideration of the target behavior from an ecological perspective, the participation of stakeholders in all phases of development, and the integrated use of theory and evidence [22]. Finally, a person-based approach, which advocates for in-depth exploration of the target users and their context, was used to complement these frameworks to facilitate the development of a relevant and engaging intervention [23].

In line with these frameworks, we conducted an initial needs assessment through workshops and focus groups with a panel of key stakeholders (including local commissioners and providers of weight management and diabetes services in the United Kingdom National Health Service [NHS] and local authority) and a panel of target user representatives (16 adults who had lost weight and attempted weight loss maintenance and were independent of the research study, 9 of whom regularly responded and attended meetings). Workshops and focus groups took place before the first COVID-19 lockdown in the United Kingdom. Both panels expressed a need for a weight loss maintenance program to support adults who have completed a BWMP (including NHS, local authority and commercial weight management, and diabetes prevention programs) within the last 3 months. Adults who use insulin, have undergone bariatric surgery in the past 2 years or have planned a surgery, are pregnant or planning a pregnancy, or have a current diagnosis of an eating disorder will not be eligible for this weight loss maintenance program based on expert stakeholders advise that the specific support needs of these groups are beyond the remit of this intervention. The stakeholder panel reported that there were insufficient resources for a program to be psychologist-led

and thus required a program that could be delivered to a large number of adults from the target population at low cost. The locality of these meetings (East Anglia) has both rural areas and poor transport links. Accordingly, the target user and stakeholder panels favored a remotely delivered intervention comprising a web-based platform with telephone support.

We conducted two phases of work to plan and design the intervention: phase 1 consisted of collating and analyzing existing and new primary evidence, and phase 2 consisted of theoretical modeling and iterative intervention development, including repeated cycles of user testing and refinement (Figure 1). The target user and stakeholder panels were involved in each of the work phases to maximize the feasibility and acceptability of the intervention from the perspectives of the target users, practitioners, and service commissioners. The members of the research team regularly met with both panels. The patient and public involvement representative on the research team (JB) chaired the target user panel meetings to facilitate a dynamic and informal environment, whereby members felt empowered to provide critical feedback. Findings and materials from both phases of work, including the theoretical modeling and intervention content, were presented to each panel at key stages of development for review and feedback. Panel members who could not attend meetings were sent materials via email and were able to provide feedback via email or telephone. Feedback was discussed with the research team and incorporated into revised materials, where appropriate. During each panel meeting, we discussed any changes we had made to the intervention, and if changes recommended by the panels had not been implemented, we discussed the reasons for this.



**Figure 1.** Flowchart outlining each phase of work. 3wCBT: third-wave cognitive behavioral therapies.

## Phase 1: Collating and Analyzing Evidence

### Overview

We collated evidence on weight loss maintenance from previous research, including a systematic review and synthesis of qualitative studies of weight loss maintenance [24] and systematic reviews of theories of behavior-change maintenance [25], the determinants of weight loss maintenance [26], and the effectiveness of weight loss maintenance interventions [27], as well as our knowledge of the wider literature. In addition, we conducted primary research to fill several evidence gaps that we identified. Full reports of each of these primary studies have been published elsewhere [9,28]. The key methods and findings relevant to the intervention development are briefly described below.

### Systematic Review and Network Meta-analysis of Evidence on 3wCBT-Based Interventions for Weight Management

#### Purpose

Previous systematic reviews of 3wCBT interventions were not comprehensive and had several methodological limitations. We conducted a systematic review and network meta-analysis of evidence on 3wCBT interventions for weight management to examine the relative effectiveness of different approaches (eg, ACT vs mindfulness-based cognitive therapy) and to identify

whether specific intervention characteristics were associated with better outcomes.

#### Methods

This systematic review and network meta-analysis evaluated the effects of 3wCBT for weight management on body weight and psychological and physical health outcomes in adults with overweight and obesity [9]. A total of 21 randomized controlled trials that included participants with a BMI  $\geq 25$  kg/m<sup>2</sup>, a 3wCBT intervention for weight management, and measurement of body weight or BMI before intervention and  $\geq 3$  months after baseline were identified through database searches and included in the meta-analyses. Pairwise random-effects meta-analysis compared 3wCBT with SBT or no or minimal intervention. A network meta-analysis was conducted to investigate whether specific types of 3wCBT were more effective than others. Meta-regression was conducted to identify whether specific intervention characteristics were associated with better outcomes.

#### Results

We found moderate to high quality evidence suggesting that 3wCBT interventions result in greater weight loss compared with SBT and no or minimal interventions after intervention and at the 12- and 24-month follow-up. The network meta-analysis found that ACT-based interventions had the most consistent evidence of effectiveness, indicating greater weight loss compared with SBT after intervention and at the 12- and

24-month follow-up. ACT was ranked as the best intervention for up to 12 months and was the only 3wCBT to report weight outcomes at 24 and 36 months. Meta-regression did not identify any specific intervention characteristics associated with better outcomes. The overall findings of this review support our decision to develop an ACT-based intervention to support the long-term maintenance of weight loss. The findings of our review also confirmed that to date, there is no available evidence on the effectiveness of ACT-based interventions that are designed to support weight loss maintenance and delivered remotely using digital technology and nonspecialists.

### ***Qualitative Interview Study on Experiences of Weight Loss Maintenance***

#### **Purpose**

A recent systematic review and qualitative synthesis identified a dearth of qualitative studies that directly compared the experiences of people who had maintained their weight loss following a BWMP with the experiences of those who had regained the weight [24]. No studies have explored the experiences of weight loss maintenance beyond 1 year. We conducted a qualitative study to identify cognitive and behavioral strategies used to overcome lapses and prevent relapse among weight loss *maintainers* and *regainers*, who had lost weight several years previously.

#### **Methods**

We conducted semistructured interviews [28] with 26 participants (15/26, 58% female) from the Weight loss program Referrals for Adults in Primary care (WRAP) trial [8]. Participants randomized to the intervention arms of the WRAP trial (referral to 12 or 52 weeks of a commercial weight loss program) and who had lost  $\geq 5\%$  baseline weight during the active intervention (year 0-1) were recruited at the 5-year follow-up. Interview participants were purposively sampled for a split of postintervention weight trajectories (maintainers vs regainers) and a range of demographic characteristics. Interview questions focused on postprogram experiences, including identifying the cognitive and behavioral strategies employed in efforts to maintain weight loss over time. Thematic analyses explored the differences in experiences of weight loss maintenance between participants who had maintained their weight over 5 years and those who had regained weight.

#### **Results**

Maintainers reported using more self-regulation techniques (eg, self-monitoring and planning), anticipated lapses (particularly for social occasions), and made conscious plans to compensate for lapses and continue to manage their weight. In contrast, although regainers made some efforts to self-regulate their behavior, they did not tend to make plans to avoid or overcome lapses, used relaxed dietary monitoring, and had particular difficulty navigating the role of food within interpersonal relationships. The findings of this study highlighted that behavioral monitoring, planning, and managing interpersonal relationships were important skills for overcoming lapses and preventing relapse after participating in a weight management program. This study suggests that creating a weight maintenance plan and making specific plans for high-risk situations should

be a key focus of our weight loss maintenance intervention. In addition, the findings highlighted that skills in managing interpersonal relationships with regard to food should also be included.

### ***Modeling of a Justifiable Cost for Weight Loss Maintenance Program***

#### **Purpose**

In the absence of data on the cost-effectiveness of the proposed intervention, we modeled the maximum justifiable cost of a weight loss maintenance intervention, given an estimated intervention effect and a specified incremental cost-effectiveness ratio (ICER).

#### **Methods**

We estimated the initial weight loss and the difference between intervention and control at 12 months by meta-analyzing data from previous studies of behavioral weight loss maintenance interventions identified from 2 recent systematic reviews [27,29]. We then used the School for Public Health Research Diabetes prevention model [30] to estimate the long-term quality-adjusted life year (QALY) gains and health care costs associated with this intervention effect in 1) individuals with a BMI of  $\geq 28$  kg/m<sup>2</sup> without diabetes, and 2) individuals with a diagnosis of type 2 diabetes. A sensitivity analysis was conducted around the rate of regain, duration of effect, and initial weight loss. We set the ICER at £20,000 (US \$26,477.30) per QALY (UK NHS benchmark).

#### **Results**

The estimated intervention effect from the meta-analysis was a 1.5 kg difference at 12 months. The justifiable cost for an intervention achieving this effect at an ICER of £20,000 (US \$26,477.30) per QALY varied from £29.98 (US \$39.69) to £203.77 (US \$269.76). We set a budget for our intervention of approximately £100 (US \$132.39).

### **Phase 2: Theoretical Modeling and Intervention Development**

#### ***Guiding Principles and Logic Model***

#### **Purpose**

To guide the intervention development, we developed a logic model and guiding principles to summarize how the intervention would support behavior change.

#### **Methods**

Following the person-based approach [23], we developed a set of guiding principles to specify the intervention design objectives (what the intervention must do to meet the needs of the target user and enhance engagement with the intervention) and the intervention features required to achieve the design objectives in practice. In keeping with the IMP [22], we developed a logic model to describe the hypothesized mechanisms of change. We used the evidence collated in phase 1 to develop the initial logic model and guiding principles. These were presented to the target user and stakeholder panels at each meeting and revised accordingly to incorporate feedback and

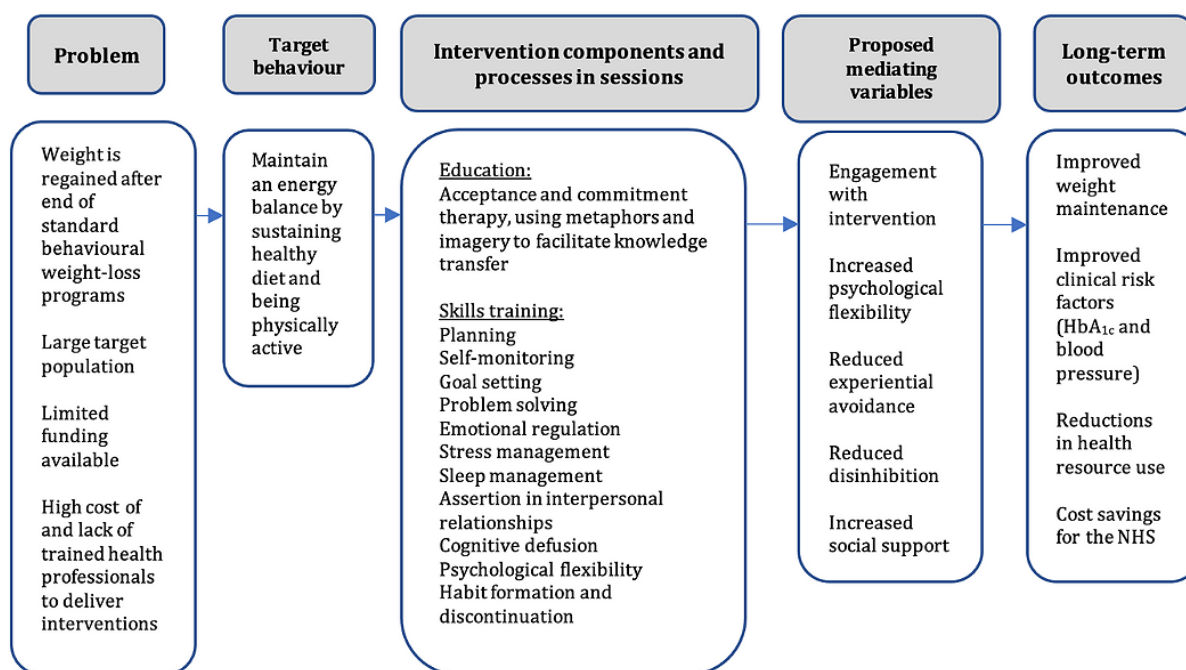
any additional needs that were identified during the development process.

**Results**

The key intervention objectives and design features of the guiding principles and supporting evidence are listed in [Multimedia Appendix 1](#) [9,14,15,19,24,28,31]. The logic model of the hypothesized mechanisms of change in the intervention is presented in [Figure 2](#). The intervention objectives identified from synthesized quantitative and qualitative primary evidence, existing literature, and input from the target user and stakeholder panels included the following:

1. to deliver an effective ACT-based intervention that can be delivered remotely and at scale at a cost of approximately £100 (US \$132.39) per participant;
2. to build on the participants’ existing knowledge and experience of weight management and what works for them;
3. to encourage participants to take ownership of their weight management in the long term;
4. to support participants in planning to navigate factors that commonly derail weight loss maintenance, such as high-risk social situations and old unhelpful habits.

**Figure 2.** Logic model. HbA<sub>1c</sub>: glycated hemoglobin A<sub>1c</sub>; NHS: National Health Service.



**Intervention Development (Design and Content)**

**Purpose**

The purpose was to develop a prototype web-based, guided self-help, ACT-based intervention, including format, content, design, and function.

**Methods**

We used the guiding principles ([Multimedia Appendix 1](#)) to develop an outline of the intervention structure and then worked with a team of software developers (Cauldron Inc) to design the wireframe of the web-based platform. Each stage was reviewed by the target user and stakeholder panels, and feedback was incorporated. The core content was ACT-based; publicly available treatment protocols, behavioral experiments, and reflective exercises were obtained for ACT-based weight management interventions and more generic ACT-based interventions [11,17,18,32-35] and reviewed in the light of our guiding principles and evidence syntheses to identify key skills and strategies to include. SBT behaviour change techniques (eg, goal setting and planning) were also considered for inclusion

when these were supported by our phase 1 work and could be implemented in a manner consistent with an ACT-based approach. We then drafted the intervention content materials, which were reviewed by the target user and stakeholder panels and revised accordingly. We worked with the target user panel and a graphic designer to create images to illustrate important concepts and metaphors from ACT. We chose a cartoon style with bold colors that were engaging and added a light-hearted touch to the content. The images were reviewed by the research team and target user panel, and refined accordingly. The software developers created a wireframe for the intervention platform and released an alpha version to which we added the content.

The prototype of the website platform was tested using multiple rounds of think-aloud protocols in line with the person-based approach [23]. Common themes in user experience were identified, and a focus group was held with the target user panel, software developers, and research team to discuss and agree on what could or should be changed. Examples of feedback and changes are listed in [Table 1](#). The proposed changes were reviewed to determine the extent to which they were important

for behavior change, consistent with the guiding principles, uncontroversial, technically feasible to implement, and repeated by more than one person [36]. A beta version of the website platform was then released for a wider group of target users to test remotely. Further feedback was incorporated into the final version of the platform, which will be used in a planned feasibility trial. Semistructured scripts for the coach telephone calls and a coach training manual were developed by the research team.

The Behavior Change Wheel, COM-B model, Theoretical Domains Framework (TDF), and behavior change taxonomy [37] were used to code the theoretical determinants, intervention functions, and BCTs of the intervention. This behavioral analysis was conducted using the full intervention content and coach training manual. Specifying interventions using this formal and reliable classification of behavior-change components facilitates the evaluation of behavior-change interventions and their mechanisms of action. In addition, coding for BCTs facilitates the comparison among behavior change interventions and evaluation of technique efficacy in systematic reviews [38-40].

**Table 1.** Examples of feedback from the target user panel through the development process and changes that we made.

Target user feedback on intervention components	Changes we made
<b>Content</b>	
Want more focus on action with instructions and less on theory.	Some theory is important for this intervention; however, we altered the balance of text and theory and highlighted action-oriented content within the pages.
Some of the language and terminology is difficult to understand.	We revised the wording of session content to use more lay terms and added clear examples to facilitate understanding, and images were used throughout to illustrate abstract ideas.
Users found the concept of values difficult to understand, and some felt that it could have moral or pejorative undertones.	The session on values was rewritten based on target user feedback, and we worked with the target user panel to find ways of describing the concept of values in a more salient and acceptable way.
Sessions contain too much block text; users want more color and visuals to break this up.	We worked with a graphic designer to create over 30 illustrations to help break large sessions and illustrate key metaphors and learning points.
<b>Presentation</b>	
Some blocks of text are too long.	We edited all content to be more concise and increased the number of pages within a session so that there were fewer words on each page.
Too much white space makes the session pages feel dull. The text should be centered, as it can be difficult to read if the text runs across the screen.	The background artwork from the home page was copied across to form a border around a smaller content box, centered on the page.
Referring to Chris the Supporting Weight Management character with gender neutral pronouns sounds unusual and the text sounds grammatically incorrect.	We revised the text so that it referred to Chris as male. Future iterations of Supporting Weight Management may have different options for the character, including its name and pronouns.
Font size is too small, and some participants (particularly those in the older age group) may struggle to read the text.	The standard font size was increased across the platform. The website was built dynamically to enable browser level zoom function without distorting the page view.
<b>Function</b>	
When a session starts, it would be good to have an idea of how long it takes to complete it and an indicator of how far you are through the session.	A progress bar was included at the top of each page to indicate each progress through the session.
When tables (or other exercises) are populated with data, this is not reflected when the same data are used later on in other exercises.	When data are entered into tables (or exercises), this automatically populates other corresponding tables (or exercises) that appear later on.

## Intervention

The outline of the final intervention structure is shown in [Multimedia Appendix 2](#). To achieve the intervention objectives, a guided self-help, ACT-based intervention was created, which will be delivered remotely via a web-based platform. We named the intervention SWiM (Supporting Weight Management). The ethos of SWiM is to use ACT-based skills and strategies to help people with overweight and obesity who have lost weight to reflect on what has worked (and not worked) in the past, build on what works for them, and learn new strategies to overcome challenges that typically derail weight loss maintenance.

[Multimedia Appendix 3](#) outlines how the intervention components addressed each of the core ACT processes.

To enhance engagement and ensure understanding of the intervention content, participants will receive telephone support from a coach. To ensure that the intervention costs remain within the justifiable costs calculated (estimated cost of approximately £100 [US \$132.39] per participant) and emulate delivery in a pragmatic setting, nonspecialists will be recruited and trained for this role and will work remotely across a large geographic area, effectively using a *call center* approach. The intervention will start by encouraging participants to reflect on their previous experiences and develop a personalized weight loss maintenance



plan. SWiM is diet agnostic, which means that participants may follow a diet that is consistent with their previous positive experiences of weight management. SWiM is a 4-month program, which consists of weekly web-based *SWiM Sessions* for the first 13 weeks, followed by a 4-week break for reflection and practicing of new skills, with a final session at week 18. Each session consists of psychoeducational content, reflective exercises, and behavioral experiments. Between sessions, participants are asked to complete further reflective exercises and behavioral experiments, called *SWiM Practice*. The program content will include specific sessions on important determinants of weight loss maintenance, including developing skills to identify and manage high-risk situations for lapses, creating new helpful habits, breaking old unhelpful habits, and learning to manage interpersonal relationships and their impact on weight management.

Participants will receive 4 scheduled 30-minute telephone calls from a coach over the course of the intervention (after sessions 1, 3, 8, and 14), with an increasing amount of time between telephone calls as the intervention progresses to encourage autonomous motivation. Verbal contracting will occur at the end of the first coach call, where the participant commits to completing the intervention and what it involves. The remaining 3 coach calls will focus on reviewing exercises, troubleshooting, and transition planning (particularly for the gradual withdrawal of coach support). Participants may have up to 3 additional telephone calls with the coach if they require further support over the course of the intervention. The ethos for the coach support is that the participant is the *expert*, with the coach facilitating them to take ownership of their weight management by creating a collaborative relationship, drawing from the principles of motivational interviewing [41].

The website platform was designed to be simple and interactive. Intervention content is divided into *SWiM Sessions*, each of which is subdivided into sections with activities. Progress

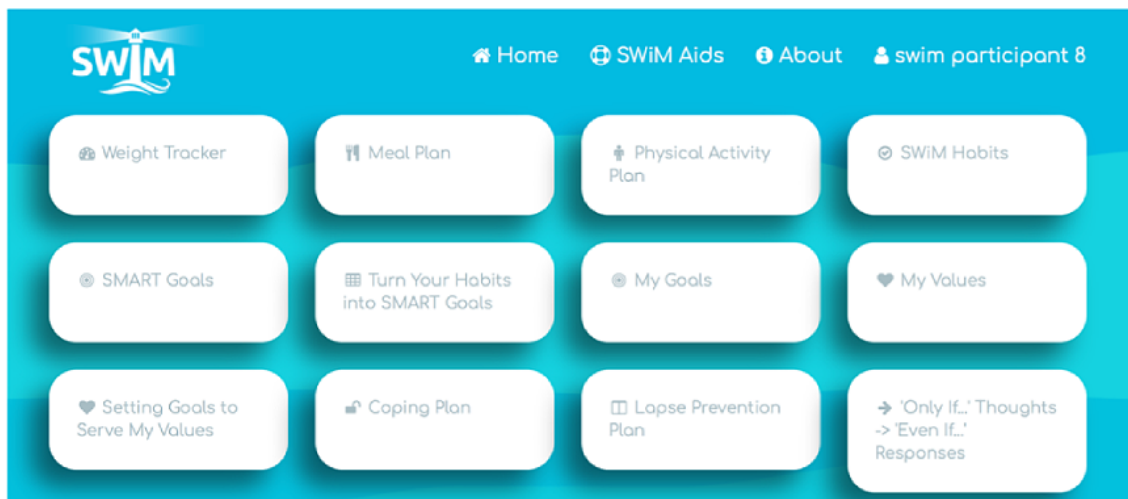
through the sessions is presented as a *journey* using a map-like graphic down the center of the home page, and star icons light up when sessions (and subsections) are completed (Figure 3). Sessions can be exited at any point, and participants can easily return to the place they exited. Sessions and subsections are unlocked when the previous session or subsection is completed. Reflective exercises and behavioral experiments related to core skills and strategies are saved in a separate section of the website, called *SWiM Aids*, for easy access and use (Figure 4). The website also includes a visual weight tracker, which tracks weekly weight over time. The weight tracker generates a line graph as data are inputted by the participant and automatically sets a weight loss maintenance target *buffer* range with boundaries of +3 kg to -3 kg within which participants are encouraged to remain. The buffer range is adjustable as their weight changes; for example, if they continue to lose more weight or if they have regained weight and are finding it discouraging. Each session contains several cartoon-style images to illustrate the important concepts and metaphors drawn from ACT (Figure 5). Finally, session 13 includes an audio-video feature on self-acceptance.

Behavioral analysis revealed that all 3 components of the COM-B model (capability, opportunity, and motivation) will be targeted by the intervention to facilitate long-term weight management. The TDF was used to further elaborate on the COM-B components. Multimedia Appendix 4 outlines how each of the 3 components of the Behavior Change Wheel, their subcomponents, and corresponding TDF domains map onto elements of the intervention, with examples outlined. A total of 5 intervention functions and 27 BCTs were identified. Multimedia Appendix 5 outlines the intervention functions and their definitions, and indicates which program components correspond to each function. Multimedia Appendix 6 includes the BCTs included in the intervention and examples of how each is implemented.

**Figure 3.** Screenshot of the SWiM (Supporting Weight Management) website showing the journey tracker. SMART: Specific Measured Active Realistic Time limited.



**Figure 4.** Screenshot of the SWiM (Supporting Weight Management) Aids tab. SMART: Specific Measured Active Realistic Time limited.



**Figure 5.** Examples of the graphic images created for SWiM (Supporting Weight Management).



## Discussion

### Principal Findings

The long-term impact and cost-effectiveness of weight management programs depend on posttreatment weight loss maintenance [7]. There is growing evidence that interventions based on 3wCBT, particularly ACT, could improve long-term weight management; however, these interventions are typically delivered face-to-face by psychologists, which limits the scalability of these types of interventions [9,12,42,43]. This paper describes an evidence-, theory-, and person-based approach to the development of an ACT-based intervention to support adults with overweight and obesity to maintain their weight loss in the long term. A key aim of the development was to design an intervention that could be delivered using digital technology and nonspecialists to minimize the resources needed for delivery at scale.

By drawing on a series of robust evidence syntheses [24-27], including a network meta-analysis conducted specifically for this project [9], we ensured that our intervention was informed by the latest scientific research on the determinants of weight loss maintenance, the behavioral interventions that are most effective for long-term weight management, and the experiences of people who have attempted to maintain weight loss. In-depth qualitative research provided additional insights into the specific needs of this target population, particularly the cognitive and behavioral strategies used by individuals who maintain their weight loss [28]. In addition, by modeling a justifiable cost for a weight loss maintenance program based on a hypothesized effect size, we were able to design an intervention within a set of specific resource parameters and increase the probability of the intervention being cost-effective.

We used the person-based approach to develop clear guiding principles based on collated evidence, including key intervention objectives and design features [23]. We then undertook an iterative cycle of intervention design and user testing to refine the content, design, and function. This facilitates the development of an intervention that is engaging for and relevant to target users. The involvement of a target user panel in the review and refinement of each intervention iteration helped ensure that target user feedback was given full consideration. Regular meetings with a stakeholder panel also ensured that any changes were considered within the context of existing care pathways and the experiences of health care practitioners and weight management service commissioners.

We have developed all the materials needed to deliver the web-based, guided self-help, ACT-based intervention, including the website platform, coach manual, and associated coach training materials. We have also finalized the logic model that specifies the hypothesized mechanisms of change of the intervention. In line with the MRC framework for the development of complex interventions in health care [21], the next phase for the development of the SWiM intervention will involve conducting a mixed methods feasibility study to evaluate the acceptability of the intervention from the perspectives of participants and the coaches who deliver the intervention and the feasibility of the intervention and study, including testing procedures, estimating recruitment and retention, and determining sample size for a randomized controlled trial. A protocol for a feasibility study was completed, and received ethical approval (ISRCTN12685964; March 5, 2021), with participant recruitment anticipated to begin in June 2021.

The systematic and theoretical development of the SWiM intervention outlined in this paper builds on the current evidence base of advanced intervention development methodology for

digital weight management interventions [44-46]. By using this systematic, evidence- and theory-based development process, including the formal coding of BCTs and identification of hypothesized mechanisms of change [38,40], this emerging body of cutting-edge research will help us move forward the investigation of which BCTs work for whom, in which contexts, and delivered by what means, for effective long-term weight management [47].

## Conclusions

This paper highlights how an evidence-, theory-, and person-based approach can be applied to the development of a

complex intervention to support weight loss maintenance for adults with overweight and obesity. The integrated, comprehensive, and iterative approach has facilitated the development of an intervention that is based on scientific theory and evidence but grounded in the experiences of the target users, stakeholders, and the context in which the intervention is intended to be delivered. Future intervention refinement will be guided by the findings of the planned feasibility study, which will evaluate the acceptability and feasibility of the intervention, and will inform a future trial of clinical and cost-effectiveness.

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## Acknowledgments

We would like to thank our target user panel (Frances Amrani, Holly Anderson, Rosemary Bentley, Ron Clifton, Tony Morris, Gill Pountain, Iain Smith, Nick Timmings, Mike Willis, Josette Brook, Susan Harrison, Kirsty Keegan, Ann Morley, Christina Norman, and Aidan Ward), stakeholder panel (Joanne Fallon, Mary Hall, Colin Lainson, Angie Lucas, Imogen Gray, and Caroline McArthur) for helping shape and review the intervention content, and the participants in our previous primary research that contributed to the development of the SWiM (Supporting Weight Management) program. We also thank the participants of the wider studies that contributed to the development of SWiM. This project was funded by the National Institute for Health Research Program Grants for Applied Research Programme (Reference Number RP-PG-0216-20010). The views expressed are those of the authors and not necessarily those of the National Institute for Health Research or the Department of Health and Social Care. ALA, RAJ, and SJG are funded by the Medical Research Council through grant MC\_UU\_00006/6.

JB is a Patient and Public Involvement Representative in Kent, United Kingdom.

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## Conflicts of Interest

ALA is the principal investigator of 2 publicly funded trials in which the intervention is provided by WW (formerly Weight Watchers). SJG reports grants from the Medical Research Council, personal fees from Eli Lilly, and personal fees from Janssen. AJH has received payment as an adviser to the Slimming World. Other authors declare no conflicts of interest.

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### Multimedia Appendix 1

Guiding principles for the intervention.

[DOCX File, 22 KB - [formative\\_v6i1e31801\\_app1.docx](#) ]

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### Multimedia Appendix 2

The SWiM (Supporting Weight Management) intervention structure and content.

[DOCX File, 25 KB - [formative\\_v6i1e31801\\_app2.docx](#) ]

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### Multimedia Appendix 3

Outline of how the SWiM (Supporting Weight Management) intervention addresses each of the core acceptance and commitment therapy processes.

[DOCX File, 22 KB - [formative\\_v6i1e31801\\_app3.docx](#) ]

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### Multimedia Appendix 4

The COM-B model components targeted by the SWiM (Supporting Weight Management) intervention.

[DOCX File, 20 KB - [formative\\_v6i1e31801\\_app4.docx](#) ]

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### Multimedia Appendix 5

Outline of the SWiM (Supporting Weight Management) intervention components and corresponding intervention functions.

[DOCX File, 14 KB - [formative\\_v6i1e31801\\_app5.docx](#) ]

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### Multimedia Appendix 6

Behaviour change techniques included in the SWiM (Supporting Weight Management) intervention, numbered according to the BCTTV1.

[DOCX File, 23 KB - [formative\\_v6i1e31801\\_app6.docx](#) ]



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## Abbreviations

**3wCBT:** third-wave cognitive behavioral therapies  
**ACT:** acceptance and commitment therapy  
**BCT:** behavior change technique  
**BWMP:** behavioral weight management program  
**ICER:** incremental cost-effectiveness ratio  
**IMP:** Intervention Mapping Protocol  
**MRC:** Medical Research Council  
**NHS:** National Health Service  
**QALY:** quality-adjusted life year  
**SBT:** standard behavioral therapy  
**SWiM:** Supporting Weight Management  
**TDF:** Theoretical Domains Framework  
**WRAP:** Weight loss program Referrals for Adults in Primary care

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Original Paper

# Use of a Mobile Peer Support App Among Young People With Nonsuicidal Self-injury: Small-scale Randomized Controlled Trial

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## Abstract

**Background:** Nonsuicidal self-injury (NSSI) is a widespread behavior among adolescents and young adults. Although many individuals who self-injure do not seek treatment, there is evidence for web-based help-seeking through web-based communities and mobile peer support networks. However, few studies have rigorously tested the efficacy of such platforms on outcomes relevant for NSSI recovery.

**Objective:** The aim of this small-scale preregistered randomized controlled trial is to provide preliminary insight into the shorter- and longer-term efficacy of the use of a peer support app, TalkLife, in reducing NSSI frequency and urges and increasing readiness to change. In addition, we explore contact with informal support, interest in therapy, and attitudes toward professional help-seeking.

**Methods:** Individuals aged 16-25 years with current (within 3 months) and chronic (>6 episodes in the past year) NSSI history were eligible to participate in this study. After baseline assessments, the intervention group was instructed to use the app actively (eg, post or comment at least three times per week) and the control group received weekly psychoeducational materials through email, for 8 weeks. Follow-up was assessed at 1 month and 2 months. Linear mixed modeling was used to evaluate condition and time point effects for the primary outcomes of NSSI frequency and urges, readiness to change, contact with informal support, interest in therapy, and attitudes toward professional help-seeking.

**Results:** A total of 131 participants were included in the analysis. We evidenced a significant effect of condition on NSSI frequency such that the participants using the peer support app self-injured less over the course of the study (mean 1.30, SE 0.18) than those in the control condition (mean 1.62, SE 0.18;  $P=.02$ ;  $\eta^2=0.02$ ). We also evidenced a significant condition effect of readiness to change such that the treatment participants reported greater confidence in their ability to change their NSSI behavior (mean 6.28, SE 0.41) than the control participants (mean 5.67, SE 0.41;  $P=.04$ ;  $\eta^2=0.02$ ). No significant differences were observed for contact with informal support, interest in therapy, or attitudes toward professional help-seeking.

**Conclusions:** Use of the peer support app was related to reduced NSSI frequency and greater confidence in one's ability to change NSSI behavior over the course of the study period, but no effects on NSSI urges, contact with informal support, interest in therapy, or attitudes toward professional help-seeking were observed. The findings provide preliminary support for considering the use of mobile peer support apps as a supplement to NSSI intervention and point to the need for larger-scale trials.

**Trial Registration:** Open Science Foundation; <https://osf.io/3uay9>

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**KEYWORDS**

nonsuicidal self-injury; randomized controlled trial; mobile app; peer support; urges; digital intervention



## Introduction

### Overview

Nonsuicidal self-injury (NSSI)—“the deliberate damage of body tissue without suicidal intent” [1]—is estimated to affect 17%-18% of young people [2]. Although NSSI often signals significant underlying distress and is a risk factor for future suicidal ideation and attempts [3-5], it can be a relatively invisible condition. Approximately half of the young people who self-injure do not disclose their NSSI thoughts or behaviors to anyone, [6] and those who choose to disclose them often do so only to close peers or parents [7-9]. Research has also shown similar rates of disclosure among those engaged in therapy, with approximately half discussing NSSI with their providers [9]. Thus, many young people who engage in NSSI do not access, or benefit from, resources to support NSSI behavior change. However, there is a rich exchange of information and social support related to NSSI on the web [10-12], and research suggests that many individuals who self-injure are receptive to web-based and mobile interventions [13-15]. Mobile apps that include elements of social support may thus be a promising direction for NSSI intervention.

### Background

#### *Web-Based Communities and NSSI*

Web-based peer-to-peer communication regarding NSSI on social media websites and social support forums is highly prevalent. A robust body of work demonstrates the exchange of informational support, such as strategies to cope with symptoms, resources, advice on help-seeking, as well as emotional support, such as validation of shared struggles and empathetic responses on web-based NSSI forums [16,17]. Commonly, benefits to participation in web-based communities for NSSI include an increased sense of belonging and social connection in a space that is free of the stigmas that may be encountered and inhibit help-seeking in day-to-day life. Indeed, a primary benefit of web-based spaces where individuals discuss NSSI seems to be the exchange of experiential knowledge and the sense of community this exchange affords [18]. Relationships in these web-based spaces are often cited as being destigmatizing and have been associated with decreased feelings of isolation, greater sense of purpose, and feelings of acceptance and belonging [19]. As web-based communication regarding NSSI has been linked to components deemed important for NSSI recovery (eg, sense of belonging and social connection) [20], it is possible that participation may increase one's readiness to change NSSI behavior and contribute to the recovery process.

At the same time, there are noted risks to participation on such web-based forums for individuals with a history of NSSI behavior. The types of information exchanged on the web are not always reliable or congruent with existing therapeutic or clinical recommendations [21]. Moreover, participation in web-based communities can lead to the normalization of NSSI behavior [22-24] or expose individuals to triggering graphic or emotional images or text [17,25,26].

Although qualitative work has set a foundation for understanding the likely effects of the exchange of peer support on NSSI

behavior, few studies have examined this relationship in a controlled trial. Some social media research suggests that high levels of use of [27], and exposure to, NSSI content may be related to increased odds of NSSI behavior over time [28]. Preliminary evidence from survey research suggests that engagement in peer support communities may be linked to reductions in NSSI behavior [29], and positive interpersonal relationships are protective against both NSSI behavior and worsening symptoms [30-32], as well as a facilitator of NSSI recovery [20]. Given the high rates of web-based activity related to NSSI, particularly among young people who are otherwise unlikely to engage in treatment, there is a need for further empirical tests of the relationship between web-based peer support and NSSI outcomes.

#### *Utility of Mobile Apps for NSSI*

A growing body of research provides support for the efficacy of web-based and mobile apps in reducing various mental health symptoms [33-36]. Although the structure and goals of these digital interventions vary (eg, symptom tracking, therapy, coaching, assessment, and peer support) [37], support for the benefits of mobile apps over no-treatment controls is consistent [38], making them a useful alternative for individuals who face barriers to traditional in-person treatment, such as stigma, cost, and accessibility [39,40].

For individuals who have unaddressed NSSI behaviors, web-based and mobile apps may provide some relief and serve as gateways for additional help. Young people report interest in, and acceptability of, digital interventions for NSSI [41-44]. However, as in the case of peer support forums, there are few efficacy trials of digital interventions for NSSI. A recent review of the effectiveness of web-based and mobile apps for self-injurious thoughts and behaviors broadly conceived (with and without suicidal intent) showed limited evidence for their efficacy in reducing NSSI [13,45]. However, several apps have been associated with encouraging preliminary findings.

Franklin et al [46] conducted 3 randomized controlled trials on a mobile intervention that used an aversive conditioning approach with images related to NSSI. The intervention was associated with fewer self-cutting episodes over the treatment period, but there were no effects on other outcomes (eg, suicidal ideation or dysregulated emotion) and treatment effects were not retained at 1-month follow-up. The mobile app Blue Ice was designed as an adjunct to face-to-face therapy, and its primary function is to link users to coping strategies rooted in cognitive behavioral therapy (CBT) and dialectical behavior therapy, including a mood diary, mood-lifting activities, and safety checks to prevent self-harm [47]. A preliminary trial showed postuse improvement in depression and anxiety symptoms, and 73% of the users reported having stopped or decreased self-injury over the course of the study. Similarly, pilot trials of another adjunctive skills-based app (DBT Coach) demonstrated reductions in urges to self-harm, NSSI frequency, and subjective distress [48], as well as increases in self-efficacy and emotion regulation among individuals with borderline personality disorder [49].

Although extant research suggests the feasibility and acceptability of mobile apps for treating NSSI behaviors, few

publicly available apps have been evaluated through efficacy trials. Most of the apps reviewed have focused on internet-based CBT, psychoeducation, or elements of *third wave* CBT, including mindfulness and acceptance [45]. Despite the prevalence of web-based peer-to-peer communication regarding NSSI, none of these studies of apps included or evaluated a peer support component. In sum, there have been no trials, to our knowledge, that examine the relationship between web-based peer support exchange and NSSI outcomes.

## Objectives

This study explores the efficacy of a mobile peer support app, TalkLife, in improving NSSI outcomes and informal support and formal help-seeking outcomes. This app is free and publicly available and designed to provide young people with immediate and informal mental health support. Preliminary research on this app shows that many young people use it to discuss NSSI and related mental health conditions [11,50]. A recent longitudinal study connecting app-related activity to NSSI behaviors and thoughts found that greater engagement on this app was associated with decreased likelihood of NSSI thoughts and fewer intentions to injure within a week's time, whereas posting triggering content was related to increased likelihood of both NSSI thoughts and behaviors [50]. However, to date, there has not been a test of this platform's efficacy in improving outcomes relevant to NSSI recovery. This trial is designed to meet this need.

Given the lack of prior work testing the effects of publicly available web-based and mobile platforms as resources for NSSI recovery, we sought to provide preliminary evidence of a treatment effect pursuant to future research and larger-scale trials. The broad aims of this small-scale trial are to assess the shorter- and longer-term efficacy of using the peer support app in mitigating NSSI frequency and urges, increasing contact with informal support and interest in therapy, and improving attitudes toward professional help-seeking. We present several hypotheses and research questions related to these primary outcomes. Please note that the hypotheses and research questions presented in this manuscript are part of a larger preregistered set. Because of power constraints, we did not include planned tests of mediation and reduced the number of variables explored in some cases (eg, H2). In addition, the ordering of these hypotheses differs from the study preregistration to assist in the logical flow of the results.

Specifically, we hypothesized that participation on this app would be associated with improvements in NSSI outcomes, readiness to change, and attitudes and behaviors related to support and help-seeking. Our hypotheses were guided by theory and existing literature—largely on perceived effects of web-based communities (from the vantage point of individuals with lived NSSI experience) and prior empirical support for the role of social support in NSSI recovery:

- H1: Participation on the peer support app would lead to reductions in NSSI (i) frequency and (ii) urges, as well as increases in (iii) readiness to change compared with the control group.
- H2: Participation on the peer support app would lead to increases in (i) informal conversations, (ii) satisfaction

derived from these conversations, (iii) interest in therapy, and (iv) improved attitudes toward formal help-seeking compared with the control group.

We pose an exploratory research question of secondary outcomes that may be associated with participation on a web-based peer support platform based on prior qualitative research:

- RQ1: Will participation on the peer support app lead to increases in (i) sense of belonging and (ii) social connectedness, as well as reductions in (iii) internalized stigma?

We also hypothesized a dose–response relationship among those in the peer support app treatment group, wherein greater engagement (sessions per week) would strengthen treatment effects:

- H3: There would be a dose–response relationship between app use and the magnitude and durability of the effect of use on NSSI (i) frequency and (ii) urges.

Given that the peer support app is a relatively lightweight and nonprofessional intervention, we explored the durability of the postintervention effects:

- RQ2: Will the effect of participation on the peer support app on NSSI (i) frequency and (ii) urges as well as (iii) readiness to change be maintained at 1-month and 2-month follow-up?

## Methods

### Trial Design and Procedure

This study was supported by a small pilot program grant and was intended to serve as a small-scale trial that would allow us to explore the feasibility and necessary parameters required for a larger outcome trial. All study procedures were approved by the institutional review board at our university and the trial was preregistered at the Open Science Foundation. This was a 2-arm randomized controlled trial. Participants in the treatment group were invited to use the peer support app platform for a duration of 8 weeks. They were instructed to engage with the platform (publish posts or comments) at least three times per week. Although the trial was not deemed to elevate participant risk and was, in fact, intended to reduce risk, we were careful to minimize the likelihood of participant discomfort through careful consideration of inclusion and exclusion criteria, using a platform with strong in-app user protections, regularly reminding participants of available resources, and following up on anyone who expressed discomfort through communication with the research team.

To inform our decision regarding the amount of engagement that would be appropriate for participants using the app, we conducted preliminary analysis on a large sample of existing app users. A latent profile analysis of 105,504 users who had been flagged by self-injury classifiers or had posted within the self-injury thread suggested that moderate in-app engagement was associated with 3.35 posts and comments (combined) per week. These analyses also suggested that a 6–8-week trial

duration would be ideal because this was well within the range of natural use.

Participants in the control group received weekly psychoeducational materials regarding NSSI through email. Psychoeducation is commonly a component of digital mental health interventions [51-53] and was chosen as an appropriate control because it was not participative or interpersonal and could easily be delivered electronically. The decision to use an active versus waitlist control was largely to keep participants engaged through the intervention period. Both groups were asked to complete a survey at baseline and weekly for the duration of the intervention period (8 weeks) and at 1 month and 2 months after the intervention period.

### Participant Eligibility

Participants aged 16-25 years with current (within 3 months) and chronic (>6 episodes in the past year) NSSI history were eligible to participate in this study. The exclusion criteria included recent history of psychosis (>2 weeks' institutionalization in the past year) or current suicidality (operationalized as suicidal thoughts or plans at baseline). Potential participants were screened in a web-based eligibility survey. Upon completion of this eligibility survey, all eligible participants received an email from the research team providing them with key information regarding their participation and a web-based consent document. Participants were randomly assigned to the treatment or control condition upon consent, using a random number generator to avoid bias. The consent document for participants in the treatment condition informed them that the research team would have access to their use data on the mobile app for the duration of the study and follow-up period. All participants then received a welcome email containing several videos explaining expectations per week, how to register for the platform (where applicable), and details regarding how and when they would receive compensation.

### Recruitment

Recruitment occurred through solicitations posted on (1) self-injury information clearing house websites and (2) through affiliated professional networks, social media outlets (such as Facebook or Twitter), and listservs, as well as (3) through the university recruitment system. Participants were eligible to receive a total of US \$90 in the form of Amazon gift cards for completion of the study components (weekly surveys) throughout the study. Participants were compensated based on the number of weekly surveys they submitted. The trial ran from April 2019 to April 2020, with the last follow-up in June 2020.

### Outcome Measures

The primary outcome variables were assessed at each time point throughout the study—a total of 8 time points (week 1-8) were considered, with the addition of 2 time points (1 month and 2 months after the intervention period) in follow-up analysis. Baseline measures on primary outcomes were controlled for in their respective analysis, as were demographics: gender and country of origin. On the basis of high comorbidity among individuals who engage in NSSI and the potential for this to affect the engagement and efficacy of treatment [54,55], lifetime NSSI frequency (assessed with the NSSI Assessment Tool

[NSSI-AT]; [56]) and mental health and trauma histories were also controlled for. Mental health history was assessed with a self-report checklist of 13 mental health conditions wherein participants were asked the following question: "To the best of your knowledge, have you ever suffered from any of the following?" Trauma history was assessed through the Stressful Life Events Screening Questionnaire [57]. Both variables were operationalized as counts of the number of mental health conditions or traumas (eg, death of a parent and sexual abuse) that participants reported at baseline (see Table 1 for details on participant characteristics).

### Primary Outcomes

#### *NSSI Frequency*

Participants completed a self-injury form checklist from the NSSI-AT [56]: "In the past week, have you ever done any of the following with the purpose of intentionally hurting yourself?" Response options were *Yes* or *No*. Participants who responded *Yes* were then asked the number of times they intentionally hurt themselves. Response options were on an 8-point scale, 0-7, with 0 reflecting no NSSI, 1 reflecting *Only once* and 7 reflecting *More than 50 times*.

#### *NSSI Urges*

Urges to self-injure were measured with two items adapted from the Alexian Brothers Urge to Self-Injure Scale [58]: "How often have you thought about injuring yourself in the last week?" and "How difficult was it to resist injuring yourself in the last week?" The first item was measured on a continuous scale from 1=*Never* to 100=*Nearly all of the time*, with a midpoint of *Sometimes (1-2 times per day or 5-10 times per week)*. The second item—"How difficult was it to resist injuring yourself in the last week?"—was measured on a 7-point scale ranging from 1=*Not at all difficult* to 7=*Was not able to resist*.

#### *Readiness to Change*

Readiness to change was assessed with the Readiness Ruler—a simple tool used to help patients visualize their readiness to change. Participants indicated where they fell regarding their readiness to change, confidence in their ability to change, and importance of change on a scale of 1=*Absolutely not true* to 10=*Absolutely true*. The items included: "Taking steps toward stopping self-injury is important to me," "I am ready to take steps toward stopping self-injury," and "I am confident I can take steps toward stopping self-injury." This measure is typically used in clinical contexts, but its use in studies with constraints—such as field or lengthy surveys—has been suggested [59,60].

#### *Contact With Informal Support*

Informal support was operationalized as both (1) the number of conversations a participant reported having about self-injury and (2) the number of conversations that participants perceived as helpful. These were assessed through disclosure items from the NSSI-AT. Specifically, participants were asked if someone knew about their self-injury at baseline and if they had had a conversation about their self-injury in weekly surveys. If yes was selected, participants were asked to check boxes for the categories of people with whom they had had these



conversations (eg, parent or guardian and friend). The number of boxes selected (or categories represented) were then summed weekly. If participants indicated that they had had a conversation with someone, they were also asked, "Have the conversations you've had with this person been helpful?" The response options were *Yes*, *No*, and *I don't know*. As in the number-of-conversations measure, the number of helpful conversations was summed weekly.

### **Interest in Therapy**

NSSI-AT Treatment Experiences items were used to assess interest in therapy. Participants responded to "How interested are you in attending therapy in the next month?" at baseline and weekly. The response options were assessed on a 5-point scale ranging from 1=*Not at all interested* to 5=*Very interested*.

### **Attitudes Toward Professional Help-Seeking**

Attitudes toward professional help-seeking were assessed through the Attitudes Toward Seeking Professional Psychological Help Scale [61]. Participants were asked to rate the extent to which they agreed with 5 items meant to assess their attitudes toward help-seeking. These items were assessed on a 5-point scale ranging from 1=*Disagree* to 5=*Agree* (Cronbach  $\alpha=.70$ ).

### **Secondary Variables**

#### **Internalized Stigma**

Mental health stigma was measured through the Internalized Stigma of Mental Illness Scale [62]. This measure consists of 3 subscales (alienation, withdrawal, and stereotype) with 4 items each. Participants indicated the extent to which they agreed with statements on a 5-point Likert scale (from 1=*Strongly disagree* to 5=*Strongly agree*). Higher values indicate greater internalized stigma. All scales demonstrated acceptable factor structure—alienation: Cronbach  $\alpha=.78$ , withdrawal: Cronbach  $\alpha=.84$ , and stereotype: Cronbach  $\alpha=.70$ .

#### **Sense of Belonging**

Sense of belonging was measured through the belonging subscale of the short form version of the Interpersonal Support Evaluation checklist [63]. Participants rated the extent to which they agreed with 4 statements on a 7-point scale from 1=*Strongly disagree* to 7=*Strongly agree*. Higher values indicate a greater sense of belonging (Cronbach  $\alpha=.75$ ).

#### **Social Connectedness**

Participants responded to the Social Connectedness Scale developed by Lee and Robbins [64] and rated the extent to which they agreed with 8 statements reflecting their sense of social connection on a 7-point scale from 1=*Strongly disagree* to 7=*Strongly agree*. Factor structure was acceptable (Cronbach  $\alpha=.88$ ).

#### **Mobile App Activity**

Data on participants' mobile app activity were supplied with license from the platform and consent from participants. These data included the number of posts and comments participants

published weekly over the course of the trial and follow-up periods and were used for a dose-response analysis.

### **Statistical Analysis**

Primary analyses were run on an intention-to-treat basis, with all participants randomized regardless of level of adherence. The relationship between survey completion as a continuous variable and demographics (gender, age, and region), indicators of mental health severity that may affect one's ability to engage with the intervention (mental health diagnosis and trauma history), and attitudinal and motivational factors (eg, readiness to change, confidence in change, and importance of change) was also investigated through 1-way analysis of variance, where these predictors were independently regressed on survey completion. Missingness was not related to any of these variables. Finally, because some participants completed their week 8 and follow-up surveys during the COVID-19 pandemic, we ran parallel analyses that included and excluded data points that fell within the period in which most countries and states had formalized stay-at-home orders. Only 6.9% (9/131) of the participants completed their final intervention week (week 8) during the COVID-19 pandemic period (treatment=2 and control=7). Given this small sample, we observed no significant differences in the main analyses.

Linear mixed models (LMMs) were used to examine each of our primary outcome variables. Several estimators (maximum likelihood and restricted maximum likelihood) and covariance structures (first-order autoregressive process, compound symmetry, and unstructured) were compared before arriving at a combination that best fit our data: a maximum likelihood estimator with a first-order autoregressive covariance structure. All models included a random intercept for participant, fixed effects of condition, time point, a condition by time point interaction term, and relevant covariates. Models controlled for demographics (gender and country of origin), mental health history (trauma, mental health diagnoses, and lifetime NSSI), and the primary outcome variable at baseline. When the time point by condition interaction effect was not significant, it was removed from the final model before interpreting significant main effects. All analyses were performed using SPSS software (versions 25 and 27; IBM Corp).

## **Results**

### **Participant Characteristics**

A total of 131 participants were randomized into treatment and control conditions and completed baseline surveys. The flow of participants through the study is depicted in Figure 1. Participants completed a mean of 6.48 (SD 2.36) of the 8 total surveys during the treatment period on average. Completion rates were not statistically different by condition:  $t_{129}=-0.65$ ;  $P=.51$ ; Cohen  $d=-0.11$  (intervention: mean 6.36, SD 2.45; control: mean 6.63, SD 2.24). In terms of engagement with the app among those in the treatment arm, the mean number of posts and comments published per week was 3.13 (SD 2.46), with an average of 8.43 (SD 9.36) sessions per week over the study period.



Figure 1. Flow of participants.

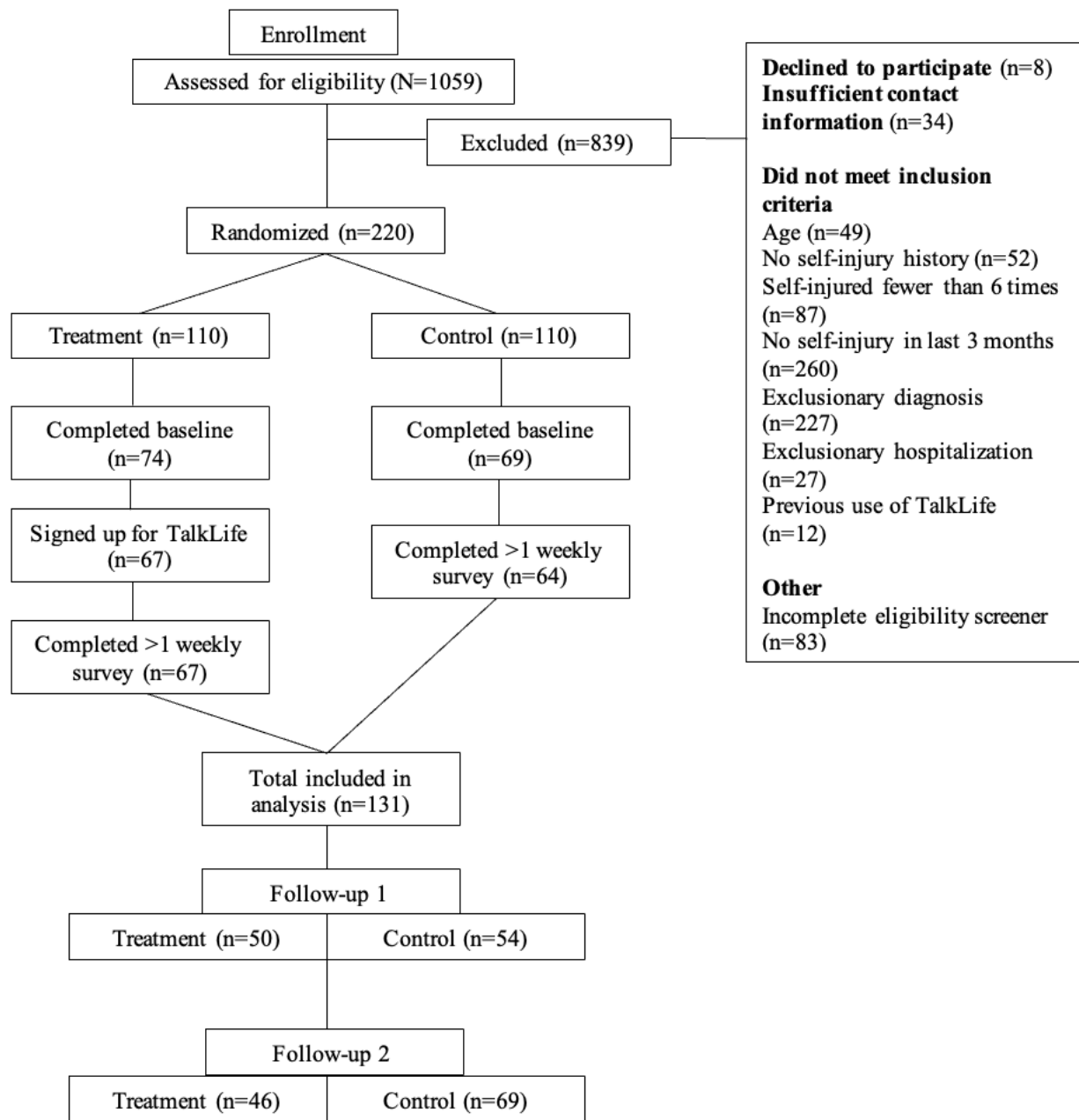


Table 1 depicts the basic demographics, comorbidities, and key variables in these groups at baseline. The groups differed significantly at baseline on self-reported interest in therapy

( $P=.01$ ), attitudes toward professional help-seeking ( $P<.001$ ), and social connectedness ( $P<.001$ ).

**Table 1.** Participant characteristics and key variables at baseline based on condition (N=131).

	Full sample (N=131)	Treatment (n=67)	Control (n=64)	Significance test		P value
				<i>t</i> test ( <i>df</i> )	Chi-square ( <i>df</i> )	
<b>Demographics</b>						
Age (years), mean (SD)	20.32 (2.52)	20.04 (2.24)	20.61 (2.76)	-1.29 (129)	N/A <sup>a</sup>	.20
<b>Gender, n (%)</b>				N/A	2.4 (3)	.49
Male	24 (18.3)	13 (19.4)	11 (17.2)			
Female	89 (67.9)	42 (62.7)	47 (73.4)			
Nonbinary	15 (11.5)	10 (14.9)	5 (7.8)			
Other	3 (2.3)	2 (3)	1 (1.6)			
<b>Region, n (%)</b>				N/A	0.5 (2)	.78
North America	82 (62.6)	40 (59.7)	42 (65.6)			
European Union	24 (18.3)	13 (19.4)	11 (17.2)			
United Kingdom	25 (19.1)	14 (20.9)	11 (17.2)			
<b>NSSI<sup>b</sup> characteristics</b>						
<b>Age at first NSSI (years), n (%)</b>				N/A	7.6 (4)	.11
≤10	19 (14.5)	11 (16.4)	8 (12.5)			
11-12	35 (26.7)	11 (16.4)	24 (37.5)			
13-14	43 (32.8)	25 (37.3)	18 (28.1)			
15-16	18 (13.7)	10 (14.9)	8 (12.5)			
≥17	16 (12.2)	10 (14.9)	6 (9.4)			
<b>NSSI frequency<sup>c</sup>, n (%)</b>				N/A	1.3 (2)	.53
2-3 times per week	112 (85.7)	59 (88.1)	53 (82.8)			
1 time per week	10 (7.6)	5 (7.5)	5 (7.8)			
1-3 times per month or less	9 (6.9)	3 (4.5)	6 (9.4)			
<b>Lifetime NSSI (NSSI total)<sup>d</sup></b>				N/A	1.9 (2)	.40
4-20 times, n (%)	8 (6.1)	3 (4.5)	5 (7.8)			
21-50 times, n (%)	28 (21.4)	12 (17.9)	16 (25)			
More than 50 times, n (%)	95 (72.5)	52 (77.6)	43 (67.2)			
Urges: thoughts, mean (SD)	50.43 (23.74)	50.91 (26.81)	49.93 (20.24)	0.24 (130)	N/A	.81
Urges: difficulty resisting, mean (SD)	4.52 (1.46)	4.37 (1.48)	4.67 (1.43)	-1.17 (129)	N/A	.24
<b>Informal and formal support</b>						
Conversations (yes or no), n (%)	112 (85.5)	60 (89.6)	52 (81.3)	N/A	1.8 (1)	.18
Number of roles, mean (SD)	4.26 (2.17)	4.07 (2.07)	4.48 (2.27)	0.32 (110)	N/A	.32
Number of helpful conversations with roles, mean (SD)	2.03 (1.42)	2.03 (1.46)	2.01 (1.39)	0.05 (111)	N/A	.96
Therapy (yes or no), n (%)	105 (80.2)	56 (83.6)	59 (76.6)	N/A	1.0 (1)	.38
NSSI in therapy (yes or no) <sup>e</sup> , n (%)	90 (85.7)	49 (73.1)	41 (83.7)	N/A	0.3 (1)	.58
Helpfulness of therapy overall (1=not at all helpful; 10=very helpful), mean (SD)	5.89 (2.51)	6.16 (2.59)	5.60 (2.41)	1.13 (102)	N/A	.26
Helpfulness of therapy in stopping NSSI (1=not at all helpful; 5=very helpful), mean (SD)	2.52 (1.43)	2.35 (1.14)	2.18 (1.34)	0.76 (94)	N/A	.45
Interest in therapy (scale: 1-5), mean (SD)	2.84 (1.77)	1.63 (1.43)	3.04 (1.74)	-2.53 (72)	N/A	.01

	Full sample (N=131)	Treatment (n=67)	Control (n=64)	Significance test		P value
				<i>t</i> test ( <i>df</i> )	Chi-square ( <i>df</i> )	
ATSPPH <sup>f</sup> (scale: 5-35), mean (SD)	21.09 (7.36)	25.53 (5.70)	16.45 (5.91)	8.95 (129)	N/A	<.001
<b>Other characteristics, mean (SD)</b>					N/A	
Importance of change	7.14 (2.49)	7.05 (2.54)	7.22 (2.44)	-0.36 (129)		.72
Readiness to change	6.64 (2.68)	6.49 (2.78)	6.79 (2.58)	-0.65 (129)		.52
Confidence in change	5.68 (2.59)	5.51 (2.52)	5.85 (2.67)	-0.78 (129)		.44
Internalized stigma, total	2.88 (0.61)	2.89 (0.523)	2.86 (0.70)	0.29 (129)		.83
Stigma: stereotype	2.20 (0.72)	2.09 (0.633)	2.33 (0.79)	-1.94 (129)		.05
Stigma: alienation	3.59 (0.74)	3.68 (0.668)	3.49 (0.80)	1.45 (129)		.15
Stigma: withdrawal	2.83 (0.93)	2.89 (0.843)	2.77 (1.01)	0.78 (129)		.44
Belongingness	14.40 (5.72)	14.60 (6.03)	14.19 (5.43)	0.41 (129)		.68
Social connectedness	27.56 (10.82)	31.21 (10.92)	23.73 (9.37)	4.19 (129)		<.001
Trauma history (total traumatic events)	3.52 (2.01)	3.28 (1.93)	3.77 (2.08)	-1.37 (129)		.17
Mental health history (total mental health conditions)	3.24 (1.82)	3.24 (1.83)	3.23 (1.92)	0.014 (129)		.99

<sup>a</sup>N/A: not applicable.

<sup>b</sup>NSSI: nonsuicidal self-injury.

<sup>c</sup>The last 2 categories were collapsed for nonsuicidal self-injury frequency 1-3 times per month and 1 time every month because of low cell sizes.

<sup>d</sup>The first 3 categories were collapsed for lifetime nonsuicidal self-injury (4-5 times, 6-10 times, and 11-20 times) because of low cell sizes.

<sup>e</sup>Of those who reported attending therapy (n=105).

<sup>f</sup>ATSPPH: Attitudes Toward Seeking Professional Psychological Help.

## Primary Outcomes

### Overview

No significant time point by condition effects were observed in our analysis of primary outcomes, suggesting that patterns

of change were not linear or equivalent across groups (see [Multimedia Appendix 1](#) for line graphs of primary outcomes over the course of the trial and follow-up periods). We thus report on the results of LMM models after the interaction effect was removed. Condition effects, marginal means, and effect sizes are presented in [Table 2](#).

**Table 2.** Differences in outcomes by condition<sup>a</sup>.

	Full sample, mean (SE)	Treatment, mean (SE)	Control, mean (SE)	F test (df)	P value	$\eta^2$ <sup>b</sup>
<b>Primary outcomes<sup>c</sup></b>						
<b>NSSI<sup>d</sup></b>						
NSSI frequency	1.46 (0.17)	1.30 (0.18)	1.62 (0.18)	5.78 (1,129.91)	.02	0.02
Urges: thoughts	44.53 (3.79)	42.69 (4.06)	46.37 (4.09)	1.53 (1,124.63)	.22	0.001
Urges: difficulty resisting	3.36 (0.24)	3.31 (0.26)	3.42 (0.26)	0.314 (1,121.39)	.58	0.001
<b>Readiness to change</b>						
Importance of change	7.80 (0.35)	8.03 (0.37)	7.57 (0.38)	3.21 (1,112.70)	.08	0.006
Readiness to change	6.69 (0.39)	6.96 (0.43)	6.42 (0.42)	2.91 (1,126.20)	.09	0.01
Confidence in change	5.97 (0.38)	6.28 (0.41)	5.67 (0.41)	4.27 (1,127.33)	.04	0.02
<b>Informal and formal support</b>						
Weekly informal conversations	0.31 (0.12)	0.28 (0.13)	0.33 (0.13)	0.35 (1,107.76)	.55	0.05
Satisfaction derived from weekly conversations	0.72 (0.24)	0.73 (0.26)	0.71 (0.26)	0.02 (1,88.54)	.88	0.06
Interest in therapy (scale: 1-5)	2.93 (0.32)	2.93 (0.38)	2.94 (0.32)	0.002 (1,63.31)	.97	0.03
Attitudes toward professional help-seeking (scale: 5-35)	25.95 (1.36)	26.34 (1.48)	25.56 (1.53)	0.36 (1,127.06)	.55	0.01
<b>Secondary outcomes</b>						
Internalized stigma: stereotype	2.27 (0.13)	2.30 (0.14)	2.23 (0.14)	0.39 (1,129.49)	.53	0.01
Internalized stigma: alienation	3.51 (0.16)	3.40 (0.17)	3.62 (0.18)	2.94 (1,128.81)	.09	0.08
Internalized stigma: withdrawal	2.62 (0.16)	2.55 (0.16)	2.69 (0.17)	1.68 (1,122.39)	.19	0.01
Sense of belonging	15.19 (0.71)	15.91 (0.75)	14.44 (0.77)	7.45 (1,128.83)	.007	0.06
Social connectedness	29.21 (1.87)	28.65 (2.08)	29.77 (2.01)	0.47 (1,121.12)	.49	0.02

<sup>a</sup>All means reflect estimated marginal means from adjusted models.

<sup>b</sup>For effect size  $\eta^2$ , 0.01 corresponds to a small effect, 0.06 corresponds to a medium effect, and 0.14 corresponds to a large effect [65].

<sup>c</sup>Covariates include gender, region, trauma and mental health history, nonsuicidal self-injury frequency and lifetime nonsuicidal self-injury, and tested outcome at baseline. In addition, models control for time point and random effect of participant.

<sup>d</sup>NSSI: nonsuicidal self-injury.

### **NSSI Frequency and Urges**

Significant effects were observed for NSSI frequency (H1i) such that on average, participants in the peer support app condition injured themselves less over the course of the study (mean 1.30, SE 0.18) than participants in the control condition (mean 1.62, SE 0.18;  $P=.02$ ; H1i). We did not observe any differences by condition for NSSI urges (H1ii) (see Table 2 for full results).

### **Readiness to Change**

A significant effect of treatment on confidence in one's ability to change NSSI behaviors was observed (H1iii). Specifically, participants using the peer support app reported greater confidence in their ability to change their NSSI behavior (mean 6.28, SE 0.41) compared with control participants (mean 5.67, SE 0.41;  $P=.04$ ). No significant effects were found for importance of changing NSSI behavior or readiness to change (see Table 2 for full results).

### **Informal Support, Interest in Therapy, and Attitudes Toward Professional Help-Seeking**

No significant differences were evidenced between the groups or across time for any informal support or help-seeking outcomes (H2) including (i) informal conversations, (ii) satisfaction derived from these conversations, (iii) interest in therapy, and (iv) attitudes toward professional help-seeking (see Table 2 for full results).

### **Secondary Outcomes**

Exploratory analyses of internalized stigma, sense of belonging, and social connectedness as secondary variables (RQ1) revealed a significant condition effect for sense of belonging such that participants in the peer support app group reported greater sense of belonging (mean 15.91, SE 0.75) compared with those in the control group (mean 14.44, SE 0.77;  $P<.007$ ). Time point was also significant for sense of belonging ( $P<.001$ ), but the interaction between time point and condition did not reach significance ( $F_{7,732.87}=1.89$ ;  $P=.07$ ). There were no other



significant effects for internalized stigma or social connectedness (see Table 2 for full results).

### Dose–Response Relationship

To explore the potential for a dose–response relationship between app use and NSSI frequency and urges, log data from the platform were used (H3). Specifically, all participants' posts and comments were summed at the week level. Several data points were observed at 3 times the IQR (21 data points from 10 participants). After inspection of participant trends and confirming normality in their responses on other study measures, they were deemed outliers. Winsorizing was selected to reduce the pull of these significant outliers while retaining their data [66].

The dose variable was entered as a predictor in the main LMMs, as described previously. No significant effects of dose were found for NSSI frequency (H3i;  $F_{1,403.96}=2.17$ ;  $P=.14$ ;  $\eta^2=0.04$ ) or urges (H3ii; NSSI thoughts:  $F_{1,390.14}=1.02$ ;  $P=.31$ ;  $\eta^2=0.002$ ; difficulty resisting:  $F_{1,309.36}=0.39$ ;  $P=.53$ ;  $\eta^2=0.005$ ). A test of sensitivity was run by comparing the results with the raw, nonwinsorized values, and the results remained insignificant: NSSI frequency (H3i):  $F_{1,292.19}=0.79$ ;  $P=.38$ ;  $\eta^2=0.03$ ; NSSI thoughts (H3ii):  $F_{1,258.37}=0.02$ ;  $P=.89$ ;  $\eta^2=0.003$ ; and difficulty resisting (H2ii):  $F_{1,157.75}=0.44$ ;  $P=.51$ ;  $\eta^2=0.005$ .

### Follow-Up Analyses

Follow-up analyses (RQ2i–iii) were conducted to explore the durability of effects at 1 month and 2 months after the intervention period. We ran 2 LMMs that included all data during the intervention period (weeks 1–8) in addition to data at first follow-up (1 month) or all data during the intervention period in addition to data at first and second follow-up (1 month and 2 months). The results showed a decay in intervention effects at both follow-up periods. Given the similarities across both follow-up periods, we report statistics for the 2-month follow-up here.

At 2 months after the intervention period, the condition effect of NSSI frequency (H1i) remained significant ( $F_{1,130.16}=5.49$ ;  $P=.02$ ;  $\eta^2=0.02$ ) such that participants using the peer support app continued to report lower mean NSSI frequency (mean 1.24, SE 0.17) compared with the control participants (mean 1.54, SE 0.18). The effect of condition on NSSI urges (RQ2ii) remained insignificant (thoughts:  $F_{1,117.29}=1.62$ ;  $P=.21$ ;  $\eta^2=0.001$ ; difficulty resisting:  $F_{1,121.99}=0.98$ ;  $P=.32$ ;  $\eta^2=0.01$ ). In terms of readiness to change (RQ2iii), the effect on confidence in ability to change was not sustained ( $F_{1,130.32}=3.63$ ;  $P=.06$ ;  $\eta^2=0.02$ ), and importance of change ( $F_{1,133.83}=1.59$ ;  $P=.21$ ;  $\eta^2=0.02$ ) and readiness to change ( $F_{1,128.37}=2.13$ ;  $P=.15$ ;  $\eta^2=0.01$ ) continued to be insignificant.

## Discussion

### Principal Findings

Overall, our findings suggest that when compared with provision of web-based psychoeducational materials, use of the peer support platform was associated with reduced NSSI frequency over the course of the 8-week study period (H1i). Significance was sustained at both 1- and 2-month follow-up periods (RQ2i), with slight reductions in the magnitude of the effect at each reporting period. We also found a treatment effect for confidence in one's ability to change NSSI behaviors. Participants in the treatment group reported greater confidence in their ability to change behaviors over the course of the study (H1iii) compared with those receiving psychoeducational materials. However, this effect was not sustained at the follow-up periods (RQ2iii).

Given that effect sizes were small for both treatment effects and this study was not fully powered to detect small effects, the results should be interpreted with appropriate caution. Digital interventions targeting mental health outcomes are often characterized by small to moderate treatment effects [36,67,68], and even highly structured and time-intensive clinical treatments for NSSI result in small treatment effects [69]. Although trials of web-based support groups and peer-to-peer interventions vary in their efficacy on mental health outcomes, it is not uncommon for effect sizes to be small to moderate in powered trials [70–74]. This is a factor worth considering in future research because rolling recruitment for this study endured for more than one year. Notwithstanding these limitations, evidence of sustained effects of low-intensity engagement in the treatment group over 2 months is promising. These findings suggest the potential of lightweight interventions—such as peer support apps—as among the resources that may benefit young people engaging in NSSI and as worthy of future investigation.

Counter to our expectations, there were no treatment effects on NSSI urges, contact with informal support, interest in therapy, or attitudes toward professional help-seeking. Urges are an important clinical feature of NSSI; however, not all individuals who engage in NSSI report urges [58], and research suggests that those with more severe NSSI behaviors are more likely to report urges [75]. Future work may wish to consider other measures that may be more sensitive to change across subgroups.

Use of the peer support platform was not associated with increased offline conversations regarding their NSSI behaviors. Although models of web-based disclosure [76–78] often assume that increased comfort in making disclosures and reductions in stigma can result from web-based discourse and supportive exchange and subsequently prompt offline, in-person disclosures, there is not strong empirical support for this in the NSSI literature. In fact, one of the noted risks to web-based communication regarding NSSI is the potential for overidentification with the community and the potential for this to stunt alternative help-seeking [79,80]. Future research should follow up on this relationship through the inclusion of behavioral and attitudinal measures. Exploring the addition of specific guidance or interventions aimed at broadening help-seeking knowledge and increasing intentions to seek help, within these

peer support spaces, is another worthy line for future work. We also feel the need to acknowledge the potential limitations of the measurements used to assess this construct and the limited variability we observed within and across participants. Informal conversations were computed by summing the number of roles (eg, parents, coaches, and peers) reflected in the weekly conversations regarding NSSI. Although this measure captures the types of individuals with whom the participants communicated over the course of the study, it was not capable of capturing who initiated the conversation (eg, self or other), the quantity of disclosures over time (eg, the number of friends), or the quality of conversations that ensued after disclosure. Each of these aspects of informal conversations and disclosure are important to consider in future work.

There was no evidence of a dose–response relationship in app use on any of the NSSI outcomes. Participants were instructed to engage on the platform at least three times (eg, publish 3 posts or comments) weekly. Although all participants engaged at this level for at least one week during the trial, we note variation in individual engagement across weeks. The mean number of posts and comments per week was 3.13 (SD 2.46), with an average of 8.43 (SD 9.36) sessions (log-ins) per week over the study period. The decision to prescribe 3 times of participative use per week was made to ensure that there was meaningful engagement beyond scrolling and based on past work suggesting that active use is more beneficial than passive use [81,82]. The fact that so many participants engaged at the prescribed level suggests that it is an appropriate baseline for future work. However, the range of this value also suggests that it may have diverged from what would have been natural or normal use patterns for some. A lower threshold of engaged use or natural nonprescribed use may be warranted in future studies.

In terms of secondary variables, we did not find significant differences between the groups on internalized stigma or social connectedness; however, we did note a significant treatment effect for sense of belonging. Participants using the platform reported higher levels of belonging compared with the control group, and changes in sense of belonging were also trending toward significance over time. These findings are largely in line with research documenting sense of belonging and reduced loneliness as benefits of engagement in web-based communities [5,10]. These findings also align with open-ended user experience data that were collected as part of the week 8 survey in this trial, wherein the treatment group reported feeling less alone and expressed that a sense of shared experience as well as the destigmatizing nature of the exchanges were among the positive qualities of the platform (Kruzan et al, unpublished data, 2022). In brief, the participants' qualitative responses showed a pattern of stronger positive and negative associations with the peer support platform compared with the participants in the control or psychoeducation condition who largely reported positive experiences. This dual harmful and helpful nature of the peer support app indicates that the relationship between app use and NSSI behaviors may not be as straightforward as our quantitative results suggest. For example, some participants suggested that the peer support app would have been helpful if they had been at a different (earlier) stage in their recovery

process, underscoring the need to consider both readiness to change and stage of change in tailoring interventions, even in app-based settings [20,83]. We speculate that the differences observed among the participant outcomes reported in this paper and the self-reported experience may be in part due to the relative complexity and dynamic nature of interacting on a platform with other humans and the static quality of the psychoeducational materials.

Another lens that may explain some of the observed treatment effects but which was not explored in this study is social comparison. Prior work suggests that social comparison processes can play a negative role on peer-to-peer support platforms such that exposure to graphic content can trigger young people and drive competitiveness by making them feel as though their own NSSI behavior is not *severe* enough [25,26,84]. Less attention has been given to the possibility that certain comparisons (eg, downward social comparisons) may have a positive impact on NSSI by drawing individuals' attention to the progress that they have made in their recovery, or by bringing increased awareness to current behaviors for those ready to contemplate change [12]. Engaging on a peer support platform and being exposed to NSSI content may uniquely position participants to see the need for change and to feel capable of changing with the support of others. In this sense, exposure to negative and graphic content may be an additional motivator influencing both readiness and frequency over the course of the study. In any case, the possibility of complex interactions between readiness to change and social comparison processes on these platforms should be further explored. Follow-up work is needed to disentangle the specific qualities of web-based spaces that may lead to incongruence in one's subjective experience of the platform and outcome data.

Finally, although this was a small-scale trial with power limitations, we note that some of the small effects observed may be because the psychoeducational materials provided to the control participants were also regarded as efficacious (Kruzan et al, unpublished data, 2022) and seemed to exert some positive influence on several key outcome variables in this study (see [Multimedia Appendix 1](#) for line graphs). Understanding the intervention utility of psychoeducational materials merits further empirical investigation because many publicly available web-based communities for NSSI do not currently include active psychoeducational components, but they may be a relatively easy and cost-effective addition for increasing access to such resources. Offering psychoeducational materials directly from a platform, either as a static resource or through a prompt (such as email), with some regularity may also reduce common motivational or attitudinal barriers to seeking such information independently. The findings from this trial also highlight a need to better understand the interaction of time and both study conditions. Although there were overall treatment effects or positive trends for both conditions, there were no meaningful linear trends from time point to time point, suggesting that the effects were not accrued through accumulation over time.

## Limitations

When interpreting the results, several limitations should be considered. First, the findings from this trial should be

interpreted with appropriate caution, given that the study is underpowered to detect small effect sizes. There were few prior studies upon which we could base a priori assumptions and necessary parameters for sample size. Our study contributes some of these parameters for use in future research. Second, given the length of the trial and level of involvement requested of the participants, our sample may have been more motivated to engage in research (and thus with the intervention) than the average individual engaging in NSSI. Furthermore, we prescribed use of the platform, but natural use patterns may differ and this could affect outcomes. Future trials may wish to compare natural use to prescribed use. In addition, although we see an effect of app use on NSSI behavior, we were unable to explore possible mediators in this study. Future work should explore which elements of the experience on the platform drive the observed effect on NSSI frequency. Our findings suggest that sense of belonging may play an important role in this relationship. This trial did not control for a variety of other factors that may influence individuals' NSSI behaviors over time, such as user expectancies, natural periodicity or the cyclical nature of NSSI, and other study procedures. We also note that our exclusion criteria affect the generalizability of our findings to individuals with more severe suicidality. Finally, although the need for this trial was in part informed by our prior work on the importance of social support in NSSI recovery [20],

we did not directly involve individuals with lived experience in the trial design and must note this as a limitation and an important addition to future work.

## Conclusions

To date, there are few studies that have formally explored the role of web-based peer support in reducing NSSI behaviors and other factors that may support NSSI recovery. The prevalence of NSSI among young people and the tendency for them to disclose it and seek help in web-based spaces such as mobile apps and social media highlight a need for research exploring efficacy and disentangling key mechanisms. This small-scale trial explored the potential efficacy of a mobile peer support app in reducing NSSI behaviors and urges, increasing readiness to change, and increasing contact with support. Although we found only small effects of the platform on NSSI frequency and confidence in one's ability to change NSSI behaviors over the course of the study, we did find evidence for increased supportive conversations and interest in therapy, as well as improved attitudes toward help-seeking behaviors. Furthermore, we found suggestive evidence that sense of belongingness may play a critical role in benefits derived from platform use. Future work investigating the key mechanisms underlying the efficacy of this app and other platforms where individuals exchange peer support in reducing NSSI behaviors through fully powered randomized controlled trials is warranted.

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## Conflicts of Interest

None declared.

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### Multimedia Appendix 1

Line graphs of primary outcomes over time.

[PDF File (Adobe PDF File), 509 KB - [formative\\_v6i1e26526\\_app1.pdf](#) ]

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### Multimedia Appendix 2

CONSORT-eHEALTH checklist (V 1.6.1).

[PDF File (Adobe PDF File), 339 KB - [formative\\_v6i1e26526\\_app2.pdf](#) ]

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## Abbreviations

- CBT:** cognitive behavioral therapy  
**LMM:** linear mixed model  
**NSSI:** nonsuicidal self-injury  
**NSSI-AT:** Nonsuicidal Self-injury Assessment Tool

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Original Paper

# Developing a Web-Based App to Assess Mental Health Difficulties in Secondary School Pupils: Qualitative User-Centered Design Study

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## Abstract

**Background:** Secondary schools are an ideal setting to identify young people experiencing mental health difficulties such as anxiety or depression. However, current methods of identification rely on cumbersome paper-based assessments, which are lengthy and time-consuming to complete and resource-intensive for schools to manage. Artemis-A is a prototype web app that uses computerized adaptive testing technology to shorten the length of the assessment and provides schools with a simple and feasible solution for mental health assessment.

**Objective:** The objectives of this study are to coproduce the main components of the Artemis-A app with stakeholders to enhance the user interface, to carry out usability testing and finalize the interface design and functionality, and to explore the acceptability and feasibility of using Artemis-A in schools.

**Methods:** This study involved 2 iterative design feedback cycles—an initial stakeholder consultation to inform the app design and user testing. Using a user-centered design approach, qualitative data were collected through focus groups and interviews with secondary school pupils, parents, school staff, and mental health professionals (N=48). All transcripts were thematically analyzed.

**Results:** Initial stakeholder consultations provided feedback on preferences for the user interface design, school administration of the assessment, and outcome reporting. The findings informed the second iteration of the app design and development. The unmoderated usability assessment indicated that young people found the app easy to use and visually appealing. However, school staff suggested that additional features should be added to the school administration panel, which would provide them with more flexibility for data visualization. The analysis identified four themes relating to the implementation of the Artemis-A in schools, including the anticipated benefits and drawbacks of the app. Actionable suggestions for designing mental health assessment apps are also provided.

**Conclusions:** Artemis-A is a potentially useful tool for secondary schools to assess the mental health of their pupils that requires minimal staff input and training. Future research will evaluate the feasibility and effectiveness of Artemis-A in a range of UK secondary schools.

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**KEYWORDS**

mental health; assessment; young people; youth; schools; computerized adaptive testing; mobile apps; user-centered design; coproduction; qualitative study



## Introduction

### Background

Mental and substance use disorders are the leading causes of disability in children and young people worldwide [1]. In the United Kingdom, 1 in 7 secondary school pupils meets the diagnostic criteria for at least one mental health disorder [2]; however, <25% of young people with a diagnosable mental health condition are identified and offered support [2]. Mental health difficulties in adolescence predict a number of negative outcomes, including lower educational attainment, school dropout, substance abuse, delinquency, self-harm, and suicide [3]. Many mental health difficulties with onset in adolescence will persist into adulthood, negatively affecting an individual's quality of life, productivity, and physical health [3] and resulting in high societal costs from increased health care use, unemployment, and criminal behaviors [4,5].

Schools have been championed as an optimal setting for the early identification of mental health difficulties in young people [6]. Young people identified in school settings are more likely to receive in school and specialist mental health support and have better long-term mental health outcomes compared with those identified in the community [7-10]. School-wide screening programs have been shown to be the most effective method for detecting mental health difficulties in young people compared with less systematic approaches [11]. However, schools are often reluctant to use this form of identification because of concerns regarding potential harms [11,12], adverse events [13,14], stigmatization of identified pupils [15], and increased demand for mental health services that exceeds available service provision [12,16]. There is also concern regarding the burden placed on schools, as universal methods of identification rely on cumbersome, costly, and time-consuming paper-based assessments, which teachers then need to score, interpret, and act upon [17,18].

The growing use of mobile technologies has accelerated the development and use of technology-based mental health interventions, particularly in younger age groups [19]. Studies focusing on young people's perceptions of digital mental health interventions suggest that most youth feel comfortable using them [20], and almost 40% prefer web-based support to face-to-face therapy [21]. Web-based interventions are highly acceptable and viewed by young people as a way to avoid stigma associated with seeking and accessing help for mental health problems [21]. Some findings also indicate that digital mental health interventions reach young people who would otherwise delay help-seeking or not access support at all if face-to-face therapy were the only available option [20,22]. Research has identified a number of factors that predict young people's engagement with digital mental health interventions. Level of detail and relevance of the content, acceptability, user-centeredness, personalization, and positive user experience (UX) contribute to continuous engagement [23,24], whereas concerns around privacy, validity, and credibility are likely to preclude young people from using digital mental health interventions [24,25]. These findings highlight the importance of involving end users in the design and development of mental

health apps to maximize uptake, adherence, and effectiveness [23-25].

In recent years, technology-based mental health assessments using computerized adaptive testing (CAT) have gained traction because of their conciseness and accuracy and minimal burden on both patients and clinicians [26]. Adaptive tests for screening a range of mental health difficulties, including anxiety, depression, substance misuse, and suicidality, are now available in cloud-based environments and are being introduced in emergency departments, primary and secondary health care settings, student health clinics, child welfare, and justice systems [26]. Numerous simulation and evaluation studies have confirmed that CAT is a highly accurate method for assessing mental health difficulties in different populations [26-30]. However, very little is known about the feasibility and user perceptions of technology-based mental health assessments, particularly in the younger population.

In this study, we applied a user-centered design approach to develop Artemis-A, a web app that offers a rapid, practical, and feasible solution to mental health assessment in school settings. This paper describes the refinement of the app's user interface (UI) and user testing to illustrate how coproduction is likely to improve functionality and ease of implementation.

### ARTEMIS: CAT Platform

The Artemis-A app for early identification of mental health difficulties in secondary school pupils was developed through an adaptation of an existing CAT platform (ARTEMIS) [28]. The application of CAT technology offers a personalized assessment by selecting each item based on the respondent's answer to the preceding one [28]. CAT reduces the length of the assessment without compromising the accuracy of the results [26,28], enabling automated scoring and preparation of tailored reports [31]. In simulations [32], our testing in secondary schools and a real app pilot study [33] showed that users can complete the assessment in 7 questions (median 7, IQR 5-10) or 1-7 minutes depending on the age of the respondents.

The ARTEMIS platform incorporates a bank of 106 items derived from standardized psychological measures covering the most prevalent mental health difficulties. The measures are the Moods and Feelings Questionnaire [34], Revised Children's Manifest Anxiety Scale [35], Leyton Obsessional Inventory [36], Rosenberg Self-Esteem Scale [37], Warwick-Edinburgh Mental Wellbeing Scale [38], and Schizotypal Personality Questionnaire [39], and there are an additional 8 items asking about symptoms of antisocial behaviors. For each assessment question, users choose a response (eg, *never*, *sometimes*, *mostly*, or *all the time*).

### This Study

The Artemis-A app is an adaptation of the root ARTEMIS platform. It was developed specifically for use in secondary schools to assess students' mental health. As a screening tool, Artemis-A is intended for assessing the mental health of pupils with already identified mental health difficulties as well as those who have never had or currently do not have mental health concerns. We needed to design a UI that would be engaging for end users (particularly young people for whom web apps are

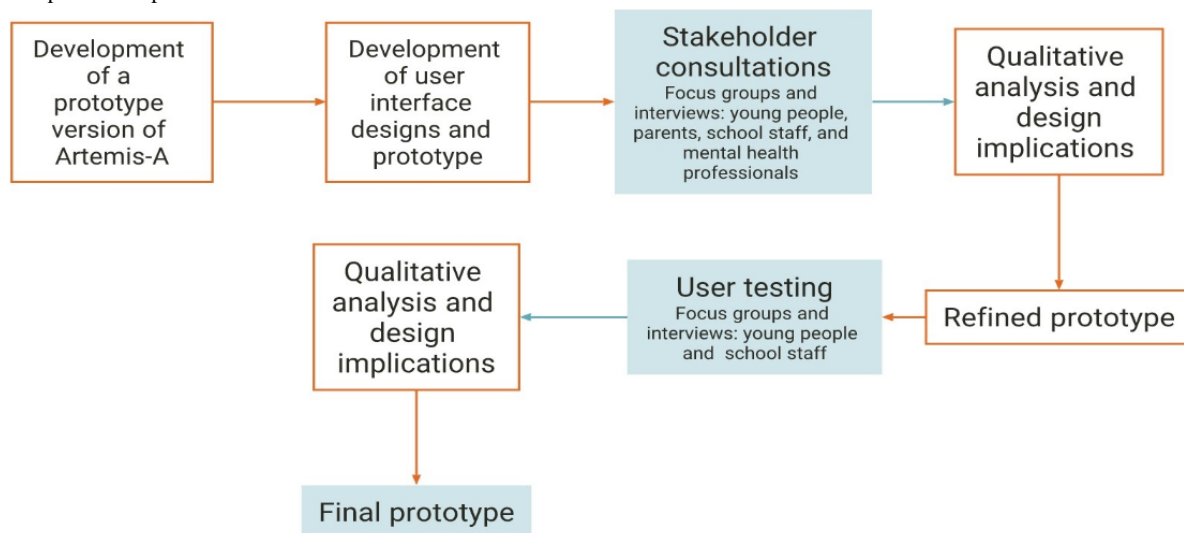
an essential part of everyday life) and enhance the overall experience of those using the app across desktop and mobile platforms, as well as include a user-friendly administration panel for school staff to manage the assessments. We also wanted to explore whether the app would be acceptable in principle for stakeholders. The key objectives of this study are as follows: (1) to coproduce the main components of the app with young people and school staff to enhance the UI; (2) to carry out user testing, finalize the interface design, and explore the UX; and (3) to explore stakeholders' views on acceptability and feasibility of web-based mental health assessments in schools.

## Methods

### Study Design and Setting

The study took place from February 2020 to December 2020 and over 2 iterative design feedback cycles (Figure 1). We

**Figure 1.** Coproduction process for Artemis-A.



### Ethics Approval

Ethical approval was granted by the University of Cambridge Department of Psychology Ethics Committee (ref: PRE.2019.081). Before the focus groups and interviews, signed consent was obtained from all participants (including parental consent for pupils aged <16 years).

### Participant Recruitment

We approached 4 secondary schools in the county of Cambridgeshire, United Kingdom to participate in the study. Key members of staff at each school assisted in the recruitment of pupils and parents and arranging the focus groups. Through existing networks, we purposively sampled school staff who were involved in mental health provision in their respective schools. In addition, we contacted mental health professionals who worked in local voluntary sector organizations specializing in children and young people's mental health. Pupils were not selected based on their mental health, as we envisaged the app to be applied universally rather than on selected groups. Those who expressed an interest in taking part were contacted by a member of the research team and provided with an information

commissioned a digital design company to design and develop a high-fidelity prototype and a linked promotional website. The development of the app was underpinned by a user-centered design approach [40,41]. The initial coproduction work involved a stakeholder consultation with school pupils, parents, school staff, and mental health professionals to understand their needs and preferences. Feedback from the stakeholder consultation informed the design of the next iteration of the prototype. Unmoderated usability testing was conducted with pupils and school staff to gather feedback on the interface design and identify usability problems. In addition, participants' views were sought regarding the use of web-based mental health assessments in schools.

sheet about the study. Participants were offered a £20 (US \$26) web-based voucher as a thank you for their time.

For the stakeholder consultation, we recruited 32 participants, including 15 (47%) pupils (aged 11-15 years; 10/15, 67% female and 5/15, 33% male), 9 (28%) parents, and 8 (25%) school staff and mental health professionals. For the user testing iteration, we recruited 16 participants, which exceeded the recommended number for identifying 80%-85% of usability problems [42-44]. These 16 participants included 11 (69%) pupils (aged 11-15 years; 7/11, 64% female and 4/11, 36% male) and 5 (31%) school staff. Most pupils (across both iterations) attended a state-funded school (21/26, 81%), and 5 (5/26, 19%) attended a private fee-paying school. School staff had a range of roles, for example, school counselor, mental health lead, and director of welfare and inclusion. The mental health professionals worked in 3 voluntary sector organizations, and their roles were program director, a charity project worker, and a counselor who worked across schools.

### Procedures

For both design iterations, semistructured topic guides were developed for each stakeholder group. All participants completed a demographics form at the start of each session.

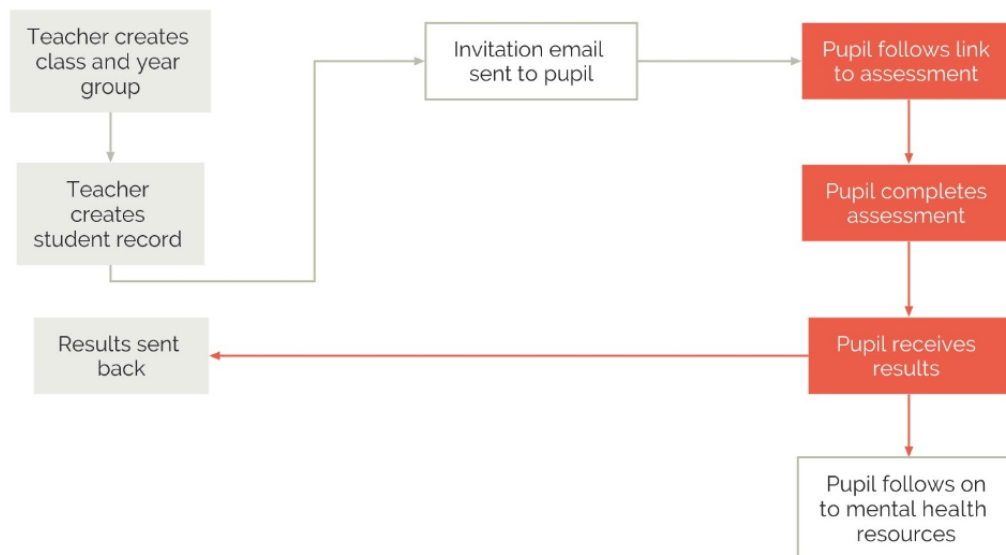
### Iteration 1: Stakeholder Consultation Procedure

We held 5 focus groups: 2 sessions with pupils (7/15, 47% and 8/15, 53%, respectively), 2 sessions with parents (5/9, 56% and 4/9, 44%, respectively), and 1 session with school staff and mental health professionals combined (6/8, 75%). Groups took place on university and school premises and lasted between 1 and 2 hours. Key staff at participating schools assisted in arranging the time and location of the focus groups. In total, 25% (2/8) of school staff members were unable to attend the focus groups; therefore, we arranged to interview them

individually over the phone. Each interview lasted approximately 45 minutes.

Members of the app development team attended the focus group sessions to collect feedback on the design and navigation preferences. At the start of each session, the participants were given a demonstration of the CAT platform to show how items were selected from the bank of measures. The presentation included an outline of the Artemis-A architecture and assessment flow (see the workflow map in [Figure 2](#)).

**Figure 2.** Artemis-A architecture and assessment workflow.



Following this, the app development team presented 3 visual mock-ups for both mobile and desktop platforms using an initial prototype and print assets. The 3 designs shared a visual identity to reflect the following overarching keywords—*positive, digital, modern, mental health orientated, and innovative*—but differed in terms of typeface, text information, and supporting graphical elements. The demonstration of the prototype gave participants a walkthrough of the various app pages based on different UI designs (ie, log-in, introduction page, assessment screen, feedback reports, and mental health resources). The participants were prompted to give feedback on the look and feel of the app, select the best design and functionality features, and suggest additional improvements. The participants were also asked about their general views regarding web-based mental health assessments in schools. User feedback was incorporated into the next version of the prototype and piloted by the members of the research team.

### Iteration 2: User Testing Procedure

Feedback gathered during the stakeholder consultation was incorporated into the new version of the Artemis-A prototype, and a linked website was developed [45]. User testing took place in December 2020 and because of the UK COVID-19 pandemic restrictions at the time, these sessions were held remotely. School staff and pupils took part in an unmoderated usability assessment over a 2-week period. We asked pupils to complete the assessment several times at a time and place where they felt comfortable and to explore the functionality and take note of their UI and navigation experience. We also asked the

pupils to check the privacy policy to see if they found the wording clear or confusing. School staff members were asked to complete several tasks, including using the administration panel to set up assessment groups, adding pupil details, sending invitation emails to participating pupils, and reviewing school outcome reports. We conducted 6 web-based feedback sessions—2 with staff (2/5, 40% and 3/5, 60%, respectively) and 4 with pupils (5/11, 46%; 3/11, 27%; 2/11, 18%; and 1/11, 9%, respectively). During the web-based sessions, we demonstrated the app using a videoconferencing software and a retrospective think-aloud technique and asked the participants to comment on the graphic design, usability, and navigability of the app and suggest improvements. Similar to the previous iteration, the participants were asked about their general views on implementing web-based mental health assessments in schools.

### Data Analysis

Audio recordings of the focus groups and interviews were transcribed, anonymized, and entered into NVivo version 12 (QSR International). The approach to analysis was both inductive and deductive. Initially, 2 team members (A-MB and JKA) independently read and coded a subset of the transcripts and then met to compare coding and discuss discrepancies. Both team members are experienced researchers in children and young people's mental health. An initial coding framework was developed inductively from the data and deductively from the study research questions [46], including human factor elements (eg, design, content, and ease of use) [47]. All transcripts were

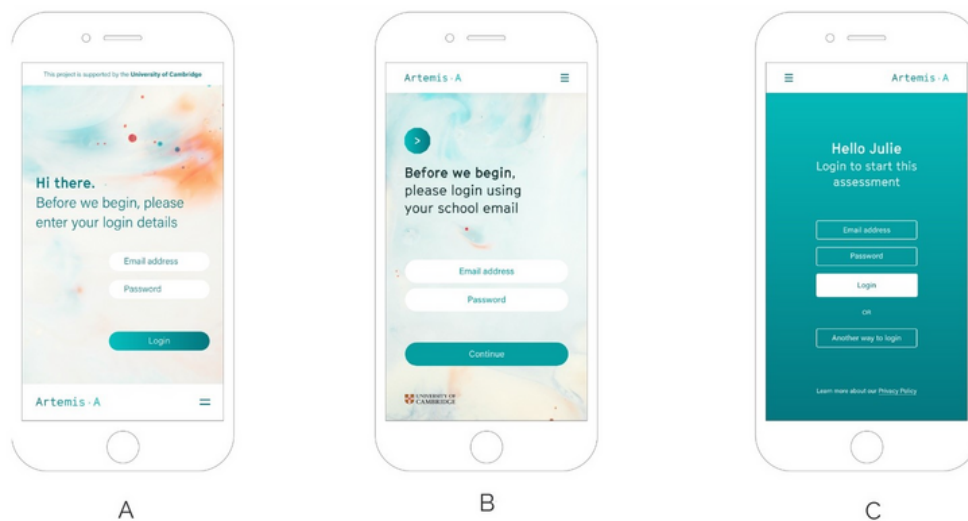
then coded by A-MB, and 50% were coded by JKA. Throughout the analysis stage, both researchers met regularly to discuss and compare the coding, and the findings were discussed with the wider team. The researchers analyzed and interpreted the data and finalized the themes.

## Results

### User Preferences Identified Through Stakeholder Consultation

This section reports the results from the initial consultation with stakeholders. As young people would be the principal users of

**Figure 3.** Schematic representations of the log-in page.



Most young people preferred option B because the design and color scheme were “calming” and “relaxing,” and they favored the large, bolder font as it was easier to read. It was important to young people that the design projected a professional feel because mental health was viewed as a serious matter. The inclusion of the University of Cambridge logo was liked because it carried weight and was seen as a trusted organization. Staff suggested adding the school’s logo to provide reassurance to pupils and parents.

The participants found the Artemis-A logo confusing because the arrow-shaped design suggested it was a clickable icon and would move the user to the next page (which it did not). This highlighted the need to redesign the logo:

*It looks like it’s the going to do something-it’s an arrow, people will click on an arrow. [Young person 4, focus group 2]*

The 3-line burger menu was useful for orientation on the landing and introductory pages, but the consensus was that it should be positioned at the top of the UI to match convention and ease of access:

*I think the menu should be at the top; they’re at the top on most websites, so most people would instinctively go to the top. [Young person 3, focus group 3]*

The participants thought the UI design should be as simple as possible, as other features may distract the user when completing

the web-based assessment, their choices about the UI design were prioritized over staff preferences. Example quotes from participants are provided in the text.

### Preference for Simple, Minimal, and Consistent UI Design

The participants were presented with three schematic representations via an initial prototype (see examples of the log-in page in [Figure 3](#)) and provided feedback regarding components of the UI, including the burger menu, logo, color scheme, and typography.

the assessment. It was agreed that the burger menu was superfluous once the user started the assessment and could temporarily disappear while the users answered the questions.

The introductory pages on each schematic representation provided some background information describing what the assessment involved and what would happen to their results. Both young people and school staff said that the language used should be friendly and informal in tone and liked the personalization of option C, which included the pupil’s name on the log-in screen. However, several young people said that using the term *test* may cause young people to feel anxious and suggested *mental health assessment* or *quiz* as alternatives. Most participants preferred the text information presented in options B and C because it was clear, concise, and broken down into *bite-sized chunks*, which they found easier to read and digest. The vertical scroll felt more fluid to the participants for navigation rather than moving from page to page.

### Young People’s Preference for Navigating the Assessment

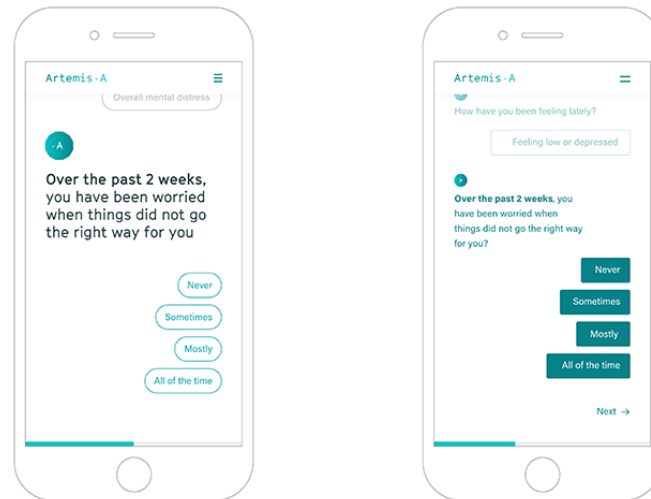
Young people were given a walkthrough of the assessment to demonstrate two potential navigation methods. The first method moved the users seamlessly to the next question once they selected their response. Young people preferred the second method, whereby users selected a response to the assessment question and then needed to validate their response before moving on to the next item. This 2-step process would provide the opportunity to pause and provide an error recovery before



moving to the next question (Figure 4). This feature was particularly important to the younger participants who were concerned about accidentally pressing the wrong answer and biasing their results:

*I'd press next 'cause if you accidentally click a button and you just can't go back then you might have to start it all over again. [Young person 1, focus group 1]*

**Figure 4.** Options to navigate the assessment with and without a “next” command.



### ***Staff Requirements for School Administration of the Assessments***

Using a workflow diagram as a guide (Figure 2), we asked staff what was the most feasible and secure way to distribute the assessment to young people and how they would like to administer the assessment within their schools. There was a clear consensus among staff that sending a link to individual pupils via the school email system would be the most secure method. They recommended that the link should be time-sensitive and remain active for up to 2 weeks.

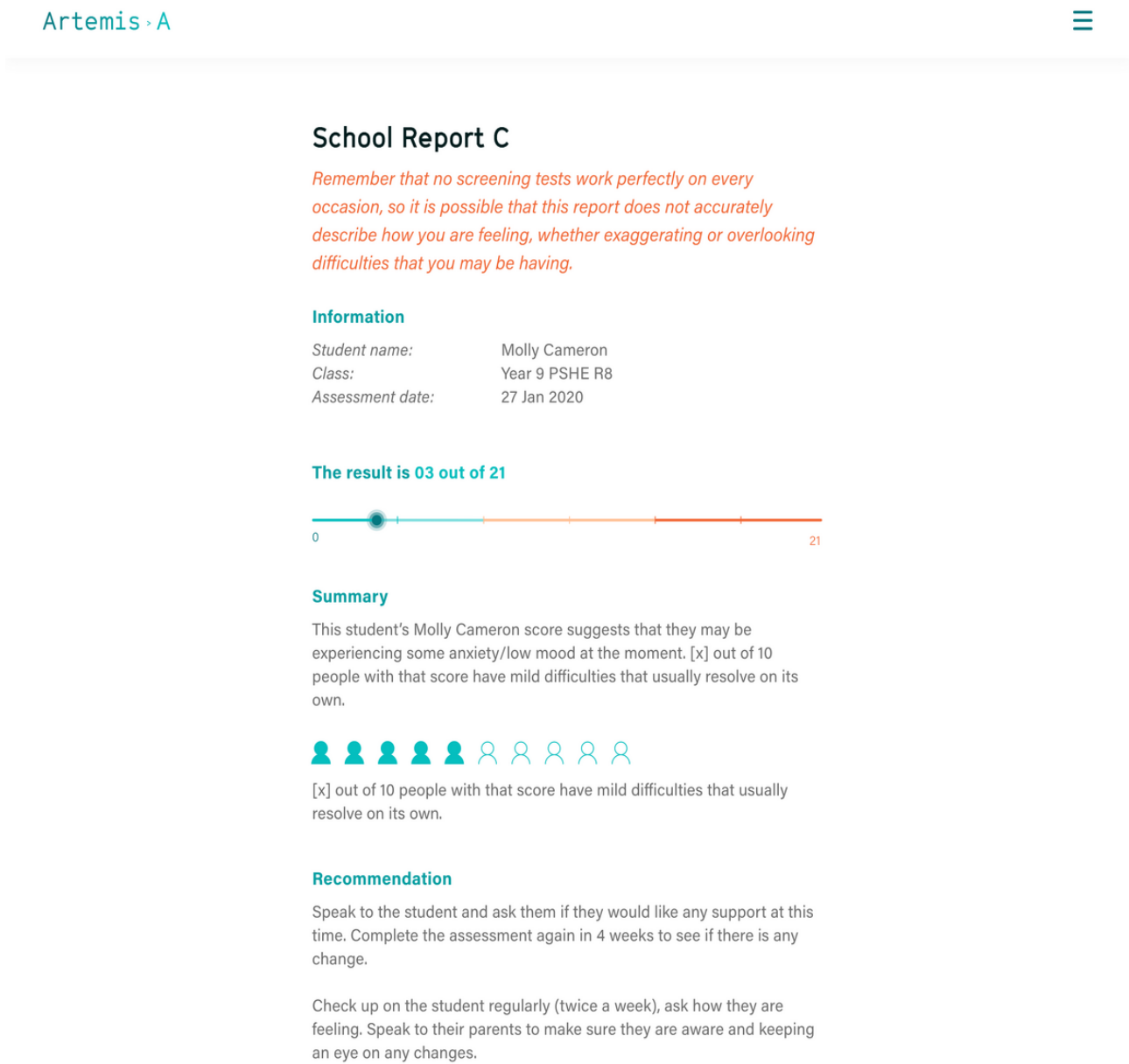
Multilevel access to the administration panel was not seen as an important feature. The general view was that only a small team of school staff would need administration rights to distribute the assessment and access the results:

*I would be tempted to keep that very closed in my school to a very selected group that have full access. [Staff 3, focus group 1]*

However, some staff requested that flexibility be built into the administration panel, which would allow for bespoke-level customization to create specific group distribution emails. For example, some requested the option to set up automatic emails so that the assessment could be sent at regular time points or to be able to resend the assessment to select groups of pupils on specific dates.

In total, 3 exemplar school reports with differing designs and layouts were presented to staff and mental health professionals. High scores in the report were highlighted in red and listed at the top of the report page to indicate a cause for concern (Figure 5). Staff particularly liked that the report flagged pupils who were at risk. However, they requested more features for data visualization of pupils' results organized by school, year, class, or time. The use of color to convey the results was seen as particularly useful for school staff who may have low levels of mental health knowledge when interpreting the results:

*I quite like the traffic light system because for people who aren't trained it's quite a simple way of seeing. [Mental health professional 1, focus group 1]*

**Figure 5.** An example of a school report.

### ***Reports for Young People Need to Be Visual and User-friendly***

Receiving an immediate assessment result was very important to young people. However, they suggested a number of features to make the report more user-friendly (eg, adding resources and helplines to the report page for ease of access).

Both staff and young people felt strongly that a visual representation of the result with a supporting explanation and recommendation would help young people understand the implications of their results better than a solitary numerical score:

*I like the traffic light idea, I think young people are quite visual, but then I think we also need to be mindful that if it is red, they then need to know what the next steps are they can take within school as well as out of school. [Staff 6, interview 1]*

School staff were generally in favor of a traffic light method to convey results to pupils, but some were concerned that, if pupils saw their result falling in the red zone of the bar, this may increase their anxiety and distress. They suggested removing the visual presentation in high-scoring red zone reports. Importantly, reports should include supplementary advice and resources for young people and their parents, and pupils need to be informed about support from a member of staff if the assessment result is high:

*I think there's a lot of scope to personalise this for each school so you could even have the name of a member of staff in there, say, Mr Smith will be in touch with you. [Staff 8, interview 2]*

### ***Schools Need to Customize the Mental Health Resource Pages***

School staff requested bespoke-customization regarding the resource and support pages to tailor them specifically to the school population and to link to the school website. Although

it was important to include national and local helplines, they wanted a section specifically for parents that provided information and resources on how to support their child. Staff suggested that a website should accompany the app, providing background information about the project and app development.

A total of three options for a resource page were presented to the young people. Young people preferred concise paragraphs where the text was broken up with subheadings because it was easier to navigate:

*I like the paragraphs because they're separated with the headers on option B. [Young person 8, focus group 2]*

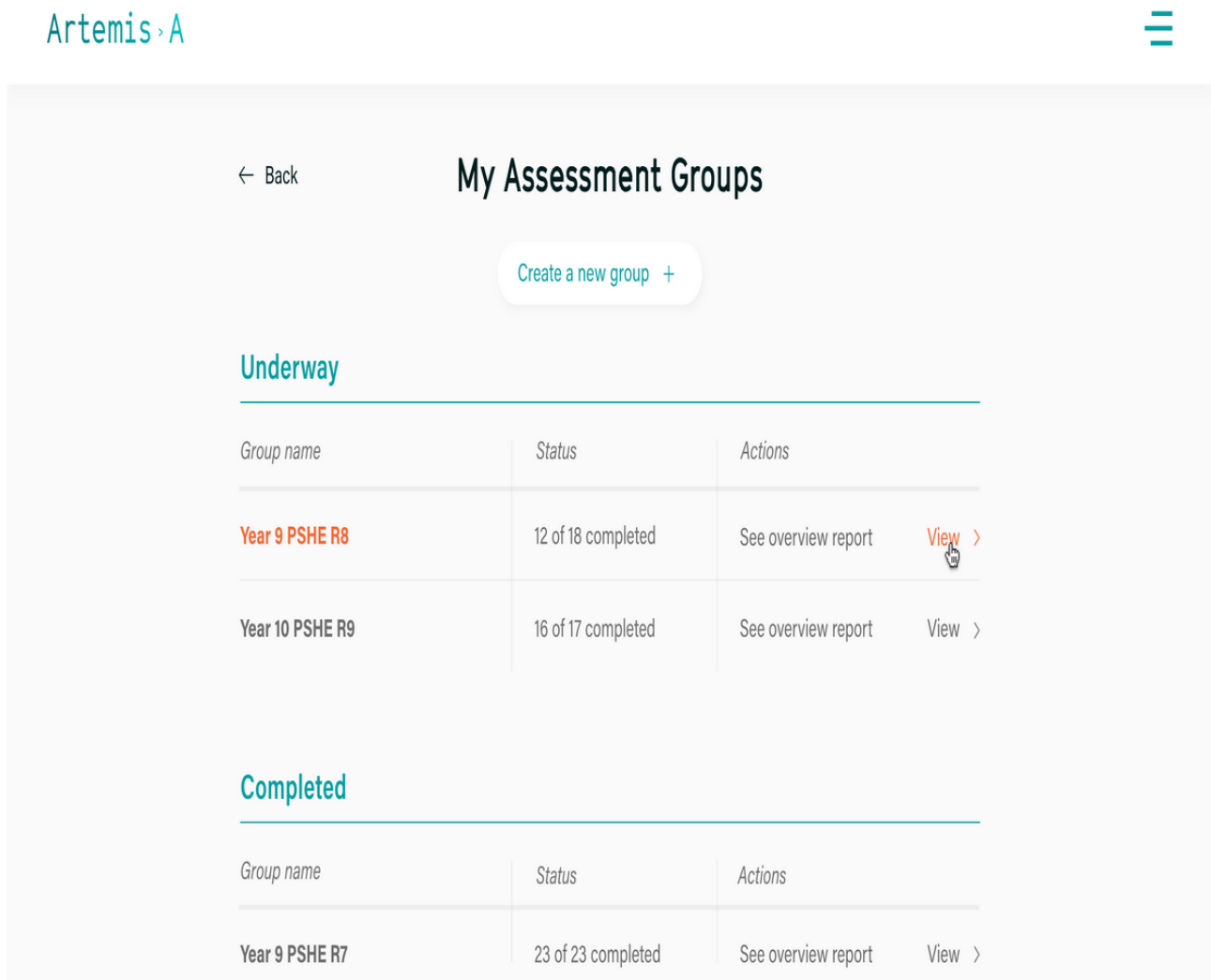
## Findings From the User Testing

The results from the previous stakeholder consultations informed further design of the app. The prototype was tested over a 2-week period (11/16, 69% pupils and 5/16, 31% school staff). Below is the feedback from the user testing. Quotes are integrated into the text.

### ***School Administration Panel Was Easy to Navigate but Lacked Flexibility***

To test the administration panel, staff members were asked to complete a number of tasks, including setting up student groups, adding individual pupil profiles, sending out invitation emails to the participating students, and generating group or individual reports (Figure 6).

**Figure 6.** Administration panel for school staff.



Overall, the school staff found the administration panel easy to navigate; however, they reported some issues with finding particular functions. Setting up assessment groups and adding pupils was generally easy; however, staff preferred to add pupils' details using a comma-separated values data file rather than manually uploading pupil information, and the upload function was difficult to find in the app. The staff members wanted a way of searching for an individual without needing to scroll through the list of all pupils; as they pointed out, in some schools, it may include >1000 names. In addition, they

wanted more functionality to merge all year groups together to create the whole school report or separate year groups into subgroups (classes). Sending out invitations was generally easy to do at the "push of a button," but they found that the emails went into the recipients' spam folders. This involved staff needing to resend the invites and notify the pupils:

*I think it's fairly intuitive. I mean, it's not an option-rich programme, is it, so it's not like you're getting lost in kind of different burger menus here,*

*there and everywhere, it seems fairly straightforward to do it.* [Staff 2, user testing dyad]

Staff reported that the administration panel lacked flexibility in terms of selecting groups of pupils when sending the email invitation. Although these options existed, respondents pointed out that they could not find an option to select specific pupils (eg, those who were currently on the well-being team's radar or receiving an intervention) to only send invites to. They asked that additional functionality be provided so that they could select a few pupils at a time or send invitations to all at once as school staff do not have the capacity to send separate emails:

*What I think I struggled with the assessment group was, even if I were to put in a year eleven, we can only filter by one of those three things; I'd like to be able to just pinpoint, like, three students.* [Staff 1, user testing triad]

Reporting the results turned out to be the most challenging aspect of the administration panel. Many respondents reported having problems creating group reports, and those that did create them did not find them particularly informative. There was confusion regarding how to generate a pupil report and an overview report, and what the difference was between the two. Staff expressed the need for an administration panel feature that would enable them to visually present pupil data in different configurations; that is, for the whole school, year group, or class, as well as generate reports only for a certain period to be able to track fluctuations in pupils' mental health (eg, before and after exams and every school term or semester). They requested some features for the individual pupil reports to enable them to track changes in pupils' mental health, particularly if there were some concerns or if a pupil had received extra support or an intervention to see if it led to improvements. They also wanted to be able to see how an individual compared with other pupils in their class or year group and to have an option to access all individual reports for each pupil, not only the most recent one. Moreover, they wanted to know how long a pupil took to complete an assessment, as they were concerned that those who finished it very quickly might have selected responses randomly. It would be helpful if these pupils were flagged in the administration panel alongside those with extremely low scores so they could ensure that they answered truthfully. Finally, respondents agreed that it would be helpful if flags following the traffic light system were displayed next to each pupil's name rather than only having red flags for pupils at risk:

*If it could have little flags like it does on the other report, and colour coded so it shows who's fine, so just at a glance you can see.* [Staff 3, user testing triad]

### **Young People Valued the App Design and Ease of Use**

All young people completed the assessment several times during the testing period. Most pupils chose to complete it at home, citing privacy and lack of distractions as the main reasons for their choice; 1 young person completed the assessment on their bus journey home from school. Pupils generally found the app easy and simple to use and had a clear understanding of how it worked. As with the stakeholder consultation, several young people described the app as relaxing. Being provided with an

immediate result was reassuring for pupils, and 1 described it as a huge "weight off their shoulders" (Young person 2, user testing 2).

Of the 11 pupils, 6 (55%) tested the app on both mobile and desktop platforms, 3 (27%) tested it on a desktop computer, and 2 (18%) tested it on a mobile device. For those who tried both, there was a strong preference for using the app on a desktop computer rather than on a mobile phone. A young person said it was easier to select a wrong response when completing the assessment on a phone.

Overall, young people liked the simplicity of the design and found the app easy to navigate. They liked the color scheme, although 1 said they thought it looked slightly clinical, and 1 suggested that there could be an option to personalize the color scheme. Several pupils asked for a progress bar to be added even though there was a progress bar at the bottom of the screen, which clearly indicated that it was not prominent on the interface.

### **Young People Valued Simple, Clear, and Informative Text Content**

Young people liked that the assessment was called a mental health quiz rather than a test. They found the text information on the introductory pages easy to understand and said that the tone of the language used was calm and not forceful. They suggested changing *mental health problems* to *mental well-being* as it sounded more positive and encompassed the range of difficulties experienced by pupils. On the basis of the previous feedback, information was presented in smaller units that the participants found acceptable:

*I think it's quite good that you've sectioned it into paragraphs. I think if it was a big chunk of text then it would be quite overwhelming.* [Young person 5, user testing 3]

Most young people found the assessment questions easy to understand, although 1 young person suggested adding a box to say "I don't understand the question" as a response option.

We provided a simple summary using age-appropriate language to help pupils understand the privacy and confidentiality of their data. The lay summary was intended to be used in addition to a comprehensive legal privacy policy. Pupils found the summary to be clear, and they felt reassured that *no other teachers will be able to see your results*. This statement was particularly important to some pupils, and they asked to have this as a stand-alone sentence so it would be more prominent and repeated separately on the introductory pages of the app. They said it would be useful if their school could include the name of the staff member who would manage the assessment and have access to the information.

### **School Reports Were Easy to Understand but Needed More Information**

Most pupils received a report indicating a low to medium score (Figure 7). Following the suggestion made by the school staff in the first iteration, we removed the visual presentation of the results from the high score reports. However, during the user testing, pupils discussed their results with each other, and those



who did not see a bar found it quite concerning. Those with a high score said they would still like the graphical presentation of their results. Pupils suggested that, instead of having a red zone on the graph for the highest score, having a green gradient going into gradually darkening amber would be less alarming. Young people also found the 0 and 100 marks on the graph unclear and suggested replacing them with text (eg, 0 replaced with “you are doing well” and 100 replaced with “you might be having some difficulties at this time”).

In addition, pupils wanted a more detailed explanation of what their particular score meant and, if it was high, more reassurance and suggestions about what they could do to improve their mental well-being. Finally, some young people suggested including the link to mental health resources on the results page together with a 1-button access to crisis support. School staff echoed the points made by the pupils, saying that the report should start with reassurance and that individual scores required more explanation.

**Figure 7.** Example of pupil report with visual representation of score.

Artemis · A



## Your results

Thank you, you have now completed the assessment.

*Remember that no screening quiz works perfectly every time. They give a snap shot, and like a photo can be misleadingly good or bad at times.*

The result is 82 out of 100



## Summary

Your score suggests that you may be having some difficulties. Some people with similar scores would do better if they had some support to help them deal with their difficulties.

## Recommendation

Someone at the school [insert person's name if possible] will check in with you about this quiz. They may offer you some support at the school, or recommend that you talk to an expert.

If at any point you feel things are getting difficult, talk to your parents, someone at the school, or contact your GP. If you prefer to speak to someone you do not know, [here](#) [link to MH resources] is who you can contact.

## Mental Health Resources Need to Be Tailored

Pupils suggested including local organizations (eg, charities providing mental health support) to give young people the option of having face-to-face contact with mental health practitioners and young people who were experiencing similar difficulties (eg, through attending group therapy sessions), as well as including information and support tools concerning how to cope at that moment (eg, cognitive behavioral therapy techniques and mindfulness). Links to websites should go directly to the web-based or counseling pages rather than the general home page. Staff wanted to be able to customize the list of mental health resources to include support offered within the school and add contact details of staff members who are involved in school mental health provision. A young person suggested expanding the list to include organizations providing support to lesbian, gay, bisexual, transgender, and queer (LGBTQ+) youth, and 1 suggested including the organizations' logos as that would make them more recognizable.

## Themes on Acceptability and Feasibility of Web-Based Mental Health Assessments in Schools

Analysis of transcripts across both design iterations identified four themes relating to participants' views regarding the acceptability and feasibility of the Artemis-A app: (1) schools as appropriate settings for web-based mental health assessments, (2) anticipated benefits of the app, (3) anticipated drawbacks of the app, and (4) suggestions for implementation.

### Schools as Appropriate Settings for Web-Based Mental Health Assessments

Most parents and professionals viewed schools as an appropriate setting to assess young people's mental health and for connecting identified pupils to local care and support. Professionals emphasized the value of third sector service provision integrating with schools.

Parents perceived high levels of self-harm within their children's schools, particularly among the younger age groups and hoped that mental health assessments would identify those pupils in need. They valued the role that staff play in fostering good

relationships with pupils, spotting those in distress, and providing good pastoral care. These relationships were seen as crucial for those pupils with difficult home lives (eg, those experiencing domestic abuse). Schools were described as stable and structured environments where vulnerable young people feel safe to seek help:

*A lot of these young people find that schools are the most structured part of the day, the most stable part of their day.* [Mental health professional 3, focus group 1]

### **Anticipated Benefits of the App**

Young people said that regular mental health checkups would give them reassurance and “peace of mind.” Parents echoed this and valued knowing how their children were doing. They hoped that, over time, regular web-based assessments would help normalize conversations about mental health and reduce stigma. An important finding was that young people said the app would provide a useful means for them to communicate their distress to adults without having embarrassing and awkward conversations with staff or parents:

*I feel like this is a less scary way of talking about your mental health and letting people know than having to go face to face with someone.* [Young person 2, user testing 3]

Professionals thought Artemis-A was a useful and feasible tool that would provide schools with a quick, simple, and reliable method for mental health identification. They anticipated that it would be easy to administer and fit well with existing school structures and processes:

*I think this is where it's really exciting, the fact that you're drawing lots of different standardized tests to get there, and the number of questions that they're being asked is really minimal rather than going through a whole questionnaire.* [Mental health professional 1, focus group 1]

Professionals and parents discussed how the app could be used for systematic universal screening, where all pupils are assessed and monitored over time. They noted that universal screening would avoid some pupils feeling singled out and harms associated with stigma. Moreover, the app would capture young people who may be struggling with their mental health and may otherwise go unnoticed:

*This app then may kind of sweep up those that aren't maybe showing major signs of issues.* [Mental health professional 2, focus group 1]

### **Anticipated Drawbacks of the App**

The potential adverse effects of using Artemis-A in schools were raised during both parts of the study. Parents voiced concerns that using the app may exacerbate young people's anxiety about their mental health or lead to bullying, stigma, and feelings of shame:

*When they're filling in the app they might be ashamed of it.* [Parent 3, focus group 4]

Some participants thought screening all pupils with the app would “open a can of worms” by identifying large numbers of pupils which in turn could potentially overwhelm schools. The long waiting times for specialist services could leave schools needing to fill the gap in provision, but staff may not be equipped with the skills or training to do this.

A consistent theme was identified across both study iterations, which showed a high level of concern among young people regarding their privacy and the confidentiality of their data. Young people wanted privacy when completing the assessment and did not want their friends to know about their problems. This influenced their preference for completing the assessment at home away from others, rather than at school:

*I would much prefer to do it at home because I'd feel a lot safer.* [Young person 3, user testing 5]

Young people were also concerned about the confidentiality of their data within the school and clearly articulated that they would want to know which staff members would have access to their results. They suggested that there should be a designated staff member administering and managing the assessment so they would be aware of who they could speak to about their results:

*You might not want them to know about it, you might just want to keep it private.* [Young person 1, user testing 4]

### **Suggestions for Implementation**

During discussions, the participants made clear suggestions for implementing Artemis-A in schools. Staff felt that Artemis-A should be managed by a small team of trained staff to ensure that pupils' confidential data would not be accessible by the wider staff. Comparisons were made with existing school safeguarding systems, which have restricted access. It was seen to be important that young people are given a sense of agency about where and when they complete the assessment and that they feel in control of what happens to their data. It was suggested that pupils be provided with information explaining that their data are private and protected and be made aware of the designated members of staff who will have access to their data. Moreover, staff should have conversations with pupils before sharing their information with others (eg, parents or form tutors).

Across all participant groups, there was a strong view that parental involvement should be kept to a minimum, unless young people were at crisis points and then safeguarding protocols would be followed. Parental consent (opt-in) could be obtained when pupils join the school or at the beginning of each academic year as this would not require significant resources.

Staff and mental health professionals expected that schools would use Artemis-A for both universal and selective mental health screening, but schools should be made aware of the benefits and drawbacks of each approach. Although Artemis-A was perceived to be a useful tool for mental health assessment, the participants noted the lack of specialist support available for those identified. They felt strongly that schools should

include mental health education in the curriculum, training for staff to increase their knowledge and skills regarding mental health, and improved accessibility to effective interventions:

*So I think is this fantastic but it has to be a part of something bigger. [Mental health professional 2, focus group 1]*

## Discussion

### Principal Findings

This study describes the coproduction work with school pupils, parents, school staff, and mental health professionals to ensure their needs and preferences were incorporated into the app design. The participants were enthusiastic to be part of the design process and had clear views regarding the design and how it should work. Incorporating the views of multiple stakeholders increases the acceptability and feasibility of the app and also boosts uptake and retention [40,48]. A number of suggestions made by the users are likely to improve the overall functionality of the app as well as facilitate its implementation and adoption in schools.

Initial stakeholder consultations with pupils and school staff directed the UI design, including color scheme, typography, text content, graphical elements, and preferred navigation features. Pupils specified a minimalist design, a personalized UI, and user-friendly text content presented in small units with clear subheadings. They favored a 2-step process to minimize user error when selecting an assessment response and the removal of the burger menu during the assessment process. School staff and mental health professionals provided valuable insights relating to the features for assessment distribution, administration, and outcome reporting for schools. They highlighted the need for schools to customize the administration panel and mental health resource pages. Although the outcome reports were liked and easy to understand, the staff expressed concerns about reports increasing distress in high-scoring pupils.

In subsequent user testing, staff found it easy to add individual profiles, set up groups, and send out invitation emails to pupils. However, staff reported that some features of the administration panel were not intuitive and that there was a lack of functionality for generating group or individual reports. They required more flexibility for searching through pupil records and for data visualization to track fluctuations in pupils' mental health by cohort at particular times of the year (eg, before and during exams). An important design change would be to have flags next to the names of at-risk pupils and move these pupils to the top of the list.

During user testing, young people liked the design of the UI and found the text content easy to read when presented in smaller units with subheadings. The lay privacy summary was particularly useful to young people because it reassured them of their privacy and confidentiality. They found the app easy to navigate and comfortable to use, but they asked for the progress bar to be more prominent. They valued the resource page but suggested more local third sector organization support should also be included.

It is important to note that different stakeholders sometimes had conflicting expectations regarding the content of the app. Initially, school staff expressed a concern that providing a visual representation of the results to students who achieved high scores in the red zone (indicating significant mental health risks) could be distressing for young people. In response to this, we removed the graph from reports for students who achieved the highest scores; however, in the user testing feedback sessions, young people admitted that, although seeing their score being in the red zone may be worrying, they were more concerned about why the format of their feedback was different from that of their peers. They suggested replacing the red zone with an amber color gradient that darkens as the score increases. This is an important finding showing the importance of testing an intervention with different user groups as well as finding a balance when addressing conflicting expectations to ensure wider acceptability.

School staff viewed the app as useful, feasible, and congruent with existing school structures and processes. Pupils and parents considered it a useful tool to monitor young people's mental health over time and ensure that those who may be struggling are identified. They were also convinced that regular mental health checkups would normalize conversations about mental health and help reduce stigma. However, pupils, parents, and staff all voiced concerns that using the app may exacerbate young people's anxiety about mental health or instigate bullying, stigma, and feelings of shame. Pupils were also concerned about the confidentiality of their data and who within the school would be made aware of their results.

School staff thought the app would be relatively easy to implement in schools; however, they stressed the importance of young people being given a sense of agency about where and when they completed the assessment and being informed about what happens to their data, as well as the importance of the availability of resources to address the mental health needs of young people identified by the app.

### Comparison With Previous Work

Although CAT has previously been applied to facilitate mental health assessments in different patient groups [26,27,49,50], the use of CAT to assess children and young people's mental health is relatively new [30]. In contrast, early prototyping, the involvement of users, and continuous iteration are key principles of a user-centered design approach [40,51], which in recent years has become more prominent in the development of mental health web apps [52-56]. Ospina-Pinillos et al [52,53] applied user-centered design methodologies with young people, their carers, and health professionals in Colombia [52] and Australia to culturally adapt a Spanish version of a web-based Mental Health eClinic. The design process involved four iterative phases: co-design workshops, knowledge translation, tailoring to cultural context, and one-on-one user-testing sessions. Similar to our findings, young people valued flexibility and personalization of the app and stressed the importance of privacy and data protection. The color palette users selected in co-design workshops was blue-green with orange, very similar to the preferences of our study participants [52]. Interestingly, in both countries, all young people agreed that assessment results should

be displayed immediately, whereas in Colombia, some mental health professionals were concerned that the pertinence of the results could be a source of distress. Their proposed solution was to give users a choice of whether they wanted to view their results straight away or wait to review them with a professional present [52]. In Australia, young people liked the traffic light system (similar to the one proposed for our app) used in the reports [53]. In our study, school staff suggested the inclusion of measures of eating disorders and suicide risk, whereas in Colombia, practitioners and young people wanted to include measures of poverty level, exposure to violence, and posttraumatic stress disorder because of the specific context.

A review of existing mental health apps conducted by Bakker et al [57] resulted in a number of evidence-based recommendations for app development. The authors highlighted the importance of automated, seamless tailoring; the simplicity of the interface and ease of navigation; short sentences; and simple, concrete language. Our study identified key areas of improvement to the UI and UX that are consistent with the usability heuristics by Nielsen [58] and reflect the above recommendations. The findings from this study indicated that the interface needed a minimalist design without unnecessary elements that may distract users. Textual information needed to be presented in short paragraphs, which is consistent with the recommendations for developing web apps whereby textual information is chunked to support users' capacity for working memory [59] and to account for slower readability on screens [60,61]. The 2-step process incorporated into the assessment aided in error prevention [62]. We found that the Artemis-A icon usability was poor and did not successfully communicate meaning [59]. Regarding content, Bakker et al [57] stressed the importance of including quick-access links to crisis support, something that was also highlighted by our study participants.

Our findings on the potential benefits and drawbacks associated with using the app in schools are in line with findings from other studies on mental health assessments in schools. Systematic, universal screening correctly identifies more at-risk pupils, including those with internalizing disorders who are often missed, than any other identification method currently used in schools [11]. Moreover, pupils identified in school are more likely to receive support from mental health services [7-9] and have better long-term mental health outcomes compared with those identified in community health care settings [63,64]. Studies examining the iatrogenic effects of mental health assessments in schools are scarce. To our knowledge, there are no studies focusing specifically on harms associated with general mental health assessments in schools; however, a recent systematic review and meta-analysis found no evidence of adverse events following screening for self-harm and suicide-related behaviors [65]. In our study, the participants thought the app would be relatively easy to implement in schools. School staff generally prefer mental health programs delivered on the web over those delivered face to face [66], mainly because of the flexibility and cost-effectiveness of web-based interventions [59]. Although there are no studies examining pupils' views on web-based mental health assessments, evidence shows that young people are happy to

engage with digital mental health programs and perceive them as less stigmatizing and more accessible [21,67,68].

### Study Limitations

Participants were recruited from a small number of schools in the East of England, and their views may not be representative of pupils and staff from other schools or regions. The app features and design preferences may not be applicable or practicable for other schools and staff members. To ensure a range of views, we included young people from different types of schools (ie, state-funded and privately funded). However, we acknowledge that our sample lacked diversity, and further work should ensure the participation of pupils from a broad range of backgrounds, including young people from marginalized groups such as LGBTQ+ and young people with disabilities. Therefore, the app design may not be acceptable or accessible to all pupils.

### Implications for Practice

The findings from our study suggest that using apps for the identification of mental health difficulties is a feasible and acceptable alternative to paper-based mental health assessments. The application of CAT technology had a positive impact on the willingness of both pupils and school staff to use the proposed app because of its rapidity and minimal user burden.

Our study highlighted the importance of involving the end users in the design process from the early stages. Young people who participated in the focus groups stressed the importance of particular app features, including privacy and data protection, instant feedback, and access to crisis support, which our team had not considered as vital. End users also made important suggestions about the language (ie, making it positive and unthreatening and presenting text in bite-sized chunks). Involving users and allowing them to take the lead during the design process ensured that the final product was highly acceptable to young people and that the assessment invoked positive feelings rather than anxiety about one's mental health.

It is also important that participants are given a small number of design options to choose from rather than being asked to generate new ideas. We found that limiting options helped maintain the focus during group discussions, promoted a better use of time, and made participants' suggestions easier to actualize.

Our study also highlights the importance of involving a range of stakeholders before implementing school-based interventions. The participants provided important information that will guide future implementation strategies (ie, how Artemis-A will be put into practice in schools). The participants identified a number of issues that could affect acceptability (eg, stigma, data confidentiality, and privacy) and feasibility (eg, designated staff to manage the app and access data). This information is crucial for promoting the successful implementation of web-based mental health assessments in school settings.

### Future Work

Future work will include item calibration and validation with a younger secondary school population, which will enable us to further refine the CAT algorithm. We will test the usability



of Artemis-A with more diverse populations to ensure that it is acceptable to young people with a range of backgrounds and accessible by pupils with disabilities. Furthermore, we will evaluate the feasibility and effectiveness of Artemis-A in a range of UK secondary schools and explore barriers to and facilitators of implementation.

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## Authors' Contributions

JKA, TJF, JS, and PBJ conceived the study design and wrote the protocol. A-MB and JKA were responsible for the study design, development of study materials, recruitment, data collection, and analysis. A-MB and JKA wrote the first draft of this paper. All authors reviewed and commented on the draft manuscript and approved the final version.

## Conflicts of Interest

JS and PBJ are cofounders of Cambridge Adaptive Testing.

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## Abbreviations

- CAT:** computerized adaptive testing  
**NIHR:** National Institute for Health Research  
**UI:** user interface  
**UX:** user experience

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Original Paper

# Nutrient and Food Group Prediction as Orchestrated by an Automated Image Recognition System in a Smartphone App (CALO mama): Validation Study

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## Abstract

**Background:** A smartphone image recognition app is expected to be a novel tool for measuring nutrients and food intake, but its performance has not been well evaluated.

**Objective:** We assessed the accuracy of the performance of an image recognition app called *CALO mama* in terms of the nutrient and food group contents automatically estimated by the app.

**Methods:** We prepared 120 meal samples for which the nutrients and food groups were calculated. Next, we predicted the nutrients and food groups included in the meals from their photographs by using (1) automated image recognition only and (2) manual modification after automatic identification.

**Results:** Predictions generated using only image recognition were similar to the actual data on the weight of meals and were accurate for 11 out of 30 nutrients and 4 out of 15 food groups. The app underestimated energy, 19 nutrients, and 9 food groups, while it overestimated dairy products and confectioneries. After manual modification, the predictions were similar for energy, accurately capturing the nutrients for 29 out of 30 of meals and the food groups for 10 out of 15 meals. The app underestimated pulses, fruits, and meats, while it overestimated weight, vitamin C, vegetables, and confectioneries.

**Conclusions:** The results of this study suggest that manual modification after prediction using image recognition improves the performance of the app in assessing the nutrients and food groups of meals. Our findings suggest that image recognition has the potential to achieve a description of the dietary intakes of populations by using “precision nutrition” (a comprehensive and dynamic approach to developing tailored nutritional recommendations) for individuals.

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**KEYWORDS**

health app; image recognition; automatic calculation; nutrient and food contents; validity; mobile phone; mHealth; validation; nutrition; diet; food

## Introduction

Noncommunicable diseases such as cardiovascular disease, diabetes, and some forms of cancer pose severe public health problems and constitute serious global social welfare issues [1]. Diet is a key modifiable factor related to health [1,2]. National strategies to improve diet and physical activity patterns at the

population level have been implemented worldwide [1], and Japan has a national healthy diet goal for improving public health [3]. To plan and evaluate the achievement of these goals, the development of effective and adequate dietary assessment tools at the population level has long been a focus in the public health field.

In the research field, dietary recalls, dietary records, and food frequency questionnaires have been widely used as general dietary assessment tools [4]. Each of these methods has its strengths and limitations such as placing a burden on participants and researchers or limited accuracy. These tools are strongly dependent on researcher training and competency for dietary recalls, participant literacy, high motivation to maintain dietary records, and participant literacy and memory for questionnaires. New dietary assessment tools that utilize computers, internet, telecommunications, and imaging analysis technology have been developed and advanced [5]. Some of these new tools do not involve self-reporting or a dietitian's entry of data, but instead employ automated image recognition for food photographs taken by a smartphone and an automated calculation system of nutrient intake [6-11]. Some of these tools provide automatic feedback on the nutrient intake of individuals, which may improve dietary outcomes and promote behavioral changes among users [6,12]. Advancements in these new technological tools will allow users to monitor their daily dietary habits and enable researchers to assess dietary intake at the population level more easily than ever before.

These comprehensive dietary assessment tools, which use image recognition systems to evaluate nutrient and food contents, have not yet had their validity experimentally evaluated. Previous experimental studies have examined the validity of the estimated quantities of energy and protein [11] or carbohydrates [13] in samples assessed using new dietary assessment tools, and other studies have examined the validity of food portion sizes [14,15]. In the epidemiological field, some validation studies have examined the validity of these apps but only for energy intake [16,17]. Two studies have evaluated the validity of these apps in assessing selected nutrient intakes [18,19], and 1 validation study has examined efficacy at monitoring the intake of the 4 food groups [20]. These new dietary assessment tools have already been used in many weight-loss intervention studies [21], and yet, their validity regarding comprehensive nutrients and food groups has not yet been assessed.

In this study, we examined the validity of nutrient and food group content assessed using an image recognition app called *CALO mama*. This study explored the potential of a smartphone app to estimate dietary intake at the population level in daily life.

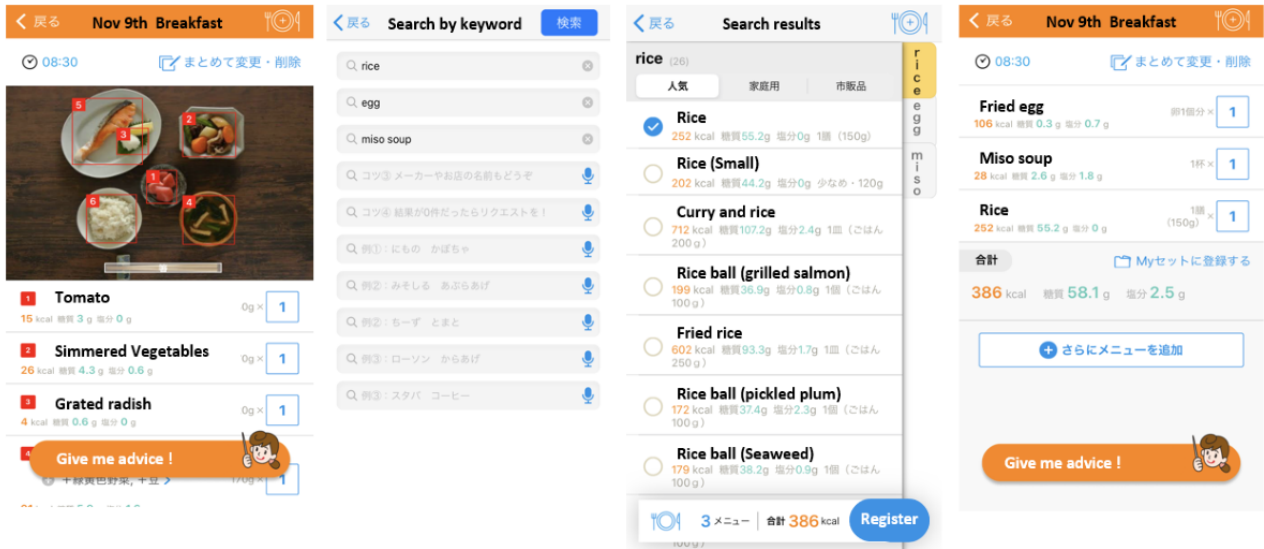
## Methods

### A Smartphone App With an Image Recognition System

Link & Communication Inc (Tokyo, Japan) recently developed a health app for smartphones called *CALO mama*. Users of *CALO mama* can register their diet, exercise, mood, and quality of sleep on a daily basis. *CALO mama* offers the automated image recognition of meals and can automatically calculate nutrient and food content based on photographs taken by users. Additionally, artificial intelligence creates specific dietary recommendations for users based on their registered meals. For example, it warns users with nutrient deficiencies or an excess intake of fat, sugar, and salt, and indicates what they ought to watch out for in their next meal.

Figure 1 shows screenshots of this app illustrating how to identify and record meals. This app has a built-in list of approximately 150,000 food items, including fresh food, self-made meals, ready meals, and commercial products. Nationally registered dietitians developed a list of food items by referring to several recipe books and their standard energy and nutrient contents based on the Standard Tables of Food Composition in Japan [22]. Ready meals and commercial products were also registered from approximately 450 manufacturers and restaurants by dietitians. First, photographs of the meals taken by users are sent to a cloud server. An automated image recognition system involving deep learning predicts food items from a list of the standard 215 items and identifies ingredients in each item and portion size. Next, another system calculates the nutritional values of the items based on the predictions made by the image recognition system. Finally, the predicted names of the items, their portion sizes, and corresponding nutrition values are displayed on users' smartphones. If the outputs appear imprecise, users can manually search for appropriate food items from the full list of approximately 150,000 items, modify the name and portion size of each item, and record them. For example, automated image recognition can distinguish coffee with milk and without milk based on the color of the liquid. In contrast, it is difficult to detect the difference between foods that cannot be determined from their external shape or color. If, for example, the app imprecisely recognizes diet coke and low-fat yogurt as a sugar-sweetened beverage and full-fat yogurt, respectively, based on the list of the standard 215 items, users can select the correct items from the full list and modify their records.

Figure 1. Screenshots of meal recording using the CALO mama app.



Study Protocol

Figure 2 shows how the results of our study data were obtained. A total of 120 sample meals, including 3-9 food dishes, were prepared by cooking staff (Table 1); 97 out of 120 (80.8%) sample meals had 4-6 dishes. Basically, the sample meals were

cooked following standard recipes, but the cooking staff were allowed to remove or add ingredients while cooking. Dietitians observed the cooking process and recorded the nutrient and food group contents of the 120 sample meals as the gold standard (data G).

Figure 2. The study protocol using the CALO mama app.

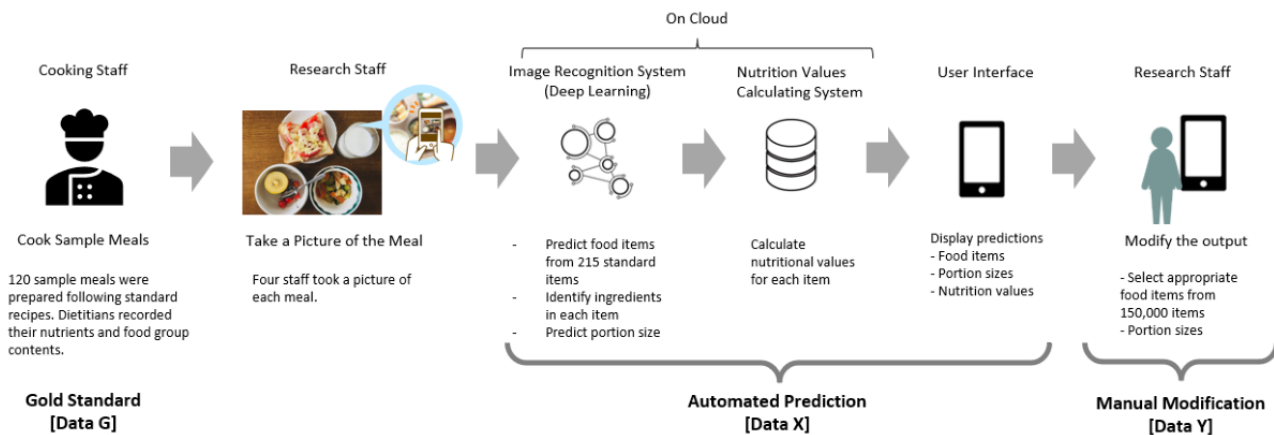


Table 1. The number of dishes included in a sample meal (N=120 sample meals).<sup>a</sup>

Dishes (n)	Sample meals, n (%)
3	12 (10)
4	35 (29.2)
5	44 (36.7)
6	18 (15)
7	9 (7.5)
8	1 (0.8)
9	1 (0.8)

<sup>a</sup>“Dishes” means dishes including multiple ingredients and foods such as a glass of milk or an apple, which can be regarded as 1 item in a meal.

The data of the 120 sample meals were registered in the app by 20 research staff who were recruited by Link & Communication Inc and blinded to the cooking process. First, the research staff

took photographs of the sample meals and uploaded them to the app. Subsequently, we obtained the data regarding the nutrition and food content of the meals automatically predicted

by the app (data X). In the next step, the staff were allowed to manually modify the name and portion size of each item based on their visual inspection. If the staff found that some ingredients needed to be added or removed, they modified the outputs from the app and recorded them (data Y). For every sample meal, 4 research staff registered data X and Y. We calculated the means of the 4 entries of data X and Y and compared them with data G as the gold standard.

### Statistical Analysis

Weight, energy, nutrient, and food group contents derived from data G, X, and Y are presented as means and standard

deviations. The food groups used in this study are shown in [Table 2](#). The means of the difference between data X or Y and data G were also calculated. Statistically significant differences between data X or Y and data G in each of the dietary variables were determined with the paired *t* test using 2-sided values. Statistical significance was set at  $P < .05$ . Further, we evaluated the agreement for the energy and macronutrients of data X and Y compared with data G by using Bland-Altman plots [23]. All statistical analyses were conducted using the SPSS statistical software package version 36 (IBM Corp).

**Table 2.** Definition of the food groups.

Food group	Item number in the Standard Tables of Food Composition in Japan [22] and definition <sup>a</sup>
Cereals	1001-1166
Potatoes	2001, 2006-2027, 2041, 2045-2055
Pulses	4001-4094 and % energy of carbohydrate <51%
Nuts	5001-5037 and dietary fiber >6.1 g/100 g and polyunsaturated fat >12 g/100 g
Vegetables	6001-6362
Green and yellow vegetables	6001-6362 and $\beta$ -carotene $\geq 600$ $\mu\text{g}/100$ g, or 6182, 6007-6011, 6020, 6021, 6093, 6094, 6157, 6158, 6245, 6246, 6237
Fruits	7001-7176 and carbohydrate <39 g, salt=0 g, and not included beverages, canned, or preserved in syrup
Mushrooms	8001-8052
Seaweed	9001-9055, Korean-style laver (ie, dried, edible seaweed)
Fish and shellfish	10001-10362, 10389-10423
Meats	11001-11197, 11199-11293
Eggs	12020-12016, 12020
Dairy products	13001-13041, 13048-13058 and calcium $\geq 100$ mg/100 g
Confectioneries	15001-15141
Alcoholic beverages	16001-16024, 16027-16032, tequila, liqueur, <i>shochu</i> mixed with carbonated beverage, <i>makgeolli</i>

<sup>a</sup>Food items not given an item number in the Standard Tables of Food Composition in Japan are described with food names.

## Results

The means and standard deviations of meal weight and energy, nutrients, and food group contents derived from data G, X, and Y are shown in [Table 3](#). Data X were similar to data G in weight, accurately capturing 11 out of 30 nutrients and 4 out of 15 food groups; it underestimated energy, capturing only 19 nutrients and 9 food groups, while it overestimated dairy products and confectioneries. After manual modification, data Y were similar to data G in energy, accurately capturing 29 out of 30 nutrients and 10 out of 15 food groups; it underestimated pulses, fruits,

and meats, while it overestimated weight, vitamin C, vegetables, and confectioneries.

[Figure 3](#) also depicts the proportions of the mean contents of data X or Y to that of data G for selected nutrient and food groups that are often employed in dietary counseling. The contents of data Y were relatively well estimated for sample meals compared to those of data X. We depicted the Bland-Altman plots for energy ([Figure 4](#)) and macronutrients ([Multimedia Appendix 1](#)) to evaluate the agreement of the values estimated by the app and the gold standards. Both data X and Y showed acceptable agreement with data G.



**Table 3.** Nutrient and food group contents in sample meals (G), automatically estimated meals (X), and manually adjusted meals (Y) from the *CALO mama* app.

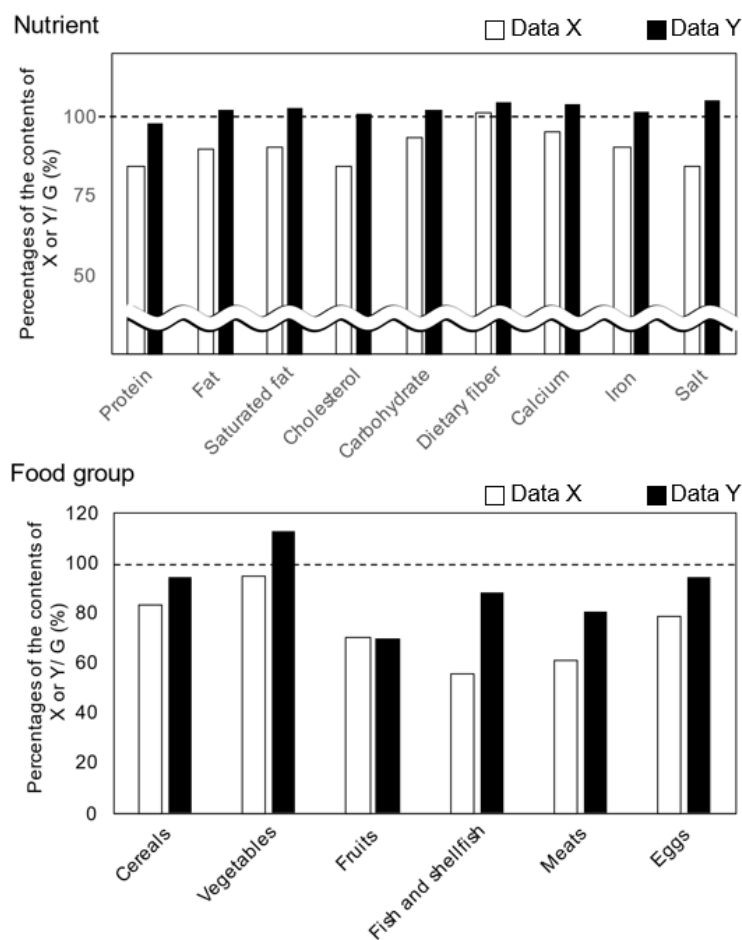
Dietary variables	Unit	Sample meals (N=120)	Automatically estimated meals (N=120)			Manually adjusted meals (N=120)		
		Mean (SD)	Mean (SD)	Difference <sup>a</sup>	P <sup>b</sup> value	Mean (SD)	Difference <sup>a</sup>	P <sup>b</sup> value
Weight	g	524 (129)	521 (156)	-4	.72	572 (169)	48	<.001
Energy	kcal	562 (191)	505 (189)	-57	<.001	571 (185)	9	.40
<b>Nutrient</b>								
Protein	g	23.1 (8.9)	19.5 (8.9)	-3.5	<.001	22.6 (9.0)	-0.4	.40
Fat	g	18.6 (11.3)	16.7 (10.9)	-1.9	.02	19.1 (10.9)	0.5	.43
Saturated fat	g	5.41 (3.93)	4.91 (3.84)	-0.50	.10	5.56 (4.03)	0.16	.50
n-6 polyunsaturated fat	g	3.22 (1.84)	2.49 (1.66)	-0.73	<.001	3.15 (1.88)	-0.07	.55
n-3 polyunsaturated fat	g	0.60 (0.56)	0.48 (0.43)	-0.13	.01	0.62 (0.50)	0.01	.68
Cholesterol	mg	126 (97)	106 (91)	-20	.001	128 (107)	2	.74
Carbohydrate	g	68.9 (23.4)	64.6 (24.5)	-4.3	.02	70.4 (23.2)	1.5	.27
Dietary fiber	g	4.5 (1.9)	4.5 (1.8)	0.1	.60	4.7 (1.9)	0.2	.07
Vitamin A	µg RAE	169 (235)	140 (142)	-29	.12	173 (228)	4	.65
Vitamin D	µg	2.4 (5.5)	1.8 (5.5)	-0.6	.19	2.1 (5.7)	-0.3	.47
α-tocopherol	mg	2.3 (1.3)	2.0 (1.2)	-0.3	.001	2.4 (1.3)	0.1	.24
Vitamin K	µg	76 (62)	75 (55)	-2	.65	80 (56)	4	.29
Vitamin B1	mg	0.35 (0.23)	0.29 (0.17)	-0.06	<.001	0.35 (0.22)	0.00004	>.99
Vitamin B2	mg	0.4 (0.21)	0.3 (0.16)	-0.03	.08	0.4 (0.17)	0.01	.52
Niacin	mg NE	4.8 (3.2)	4.2 (2.9)	-0.6	.007	5.0 (3.1)	0.1	.44
Vitamin B6	mg	0.40 (0.20)	0.35 (0.21)	-0.05	<.001	0.42 (0.21)	0.02	.18
Vitamin B12	µg	1.8 (3.3)	1.4 (2.4)	-0.4	.12	1.8 (2.5)	-0.03	.86
Folate	µg	113 (79)	105 (64)	-8	.09	118 (65)	5	.29
Pantothenic acid	mg	1.87 (0.68)	1.63 (0.64)	-0.24	<.001	1.89 (0.63)	0.02	.66
Vitamin C	mg	34 (26)	36 (29)	1	.37	39 (29)	5	<.001
Sodium	mg	1166 (629)	1008 (582)	-157	.003	1241 (707)	76	.06
Potassium	mg	734 (258)	674 (253)	-60	<.001	764 (266)	30	.08
Calcium	mg	143 (94)	136 (95)	-6	.38	149 (92)	6	.24
Magnesium	mg	81 (42)	70 (29)	-11	<.001	79 (34)	-2	.32
Phosphorus	mg	323 (114)	288 (128)	-35	<.001	329 (123)	7	.38
Iron	mg	2.3 (1.0)	2.1 (0.8)	-0.2	<.001	2.4 (0.9)	0.04	.42
Zinc	mg	2.6 (1.0)	2.3 (1.0)	-0.3	<.001	2.6 (0.9)	-0.01	.85
Copper	mg	0.37 (0.28)	0.30 (0.13)	-0.06	.001	0.35 (0.16)	-0.02	.23
Manganese	mg	0.79 (0.38)	0.75 (0.34)	-0.04	.14	0.83 (0.35)	0.04	.08
Salt	g	3.0 (1.6)	2.5 (1.5)	-0.5	<.001	3.1 (1.8)	0.2	.14
<b>Food group</b>								
Cereals	g	132.0 (79.5)	110.2 (80.6)	-21.8	<.001	125.2 (81.0)	-6.8	.12
Potatoes	g	9.2 (25.9)	6.1 (19.9)	-3.1	.02	9.1 (23.2)	-0.1	.95
Pulses	g	14.8 (37.9)	9.7 (24.6)	-5.1	.01	11.1 (28.6)	-3.7	.009
Nuts	g	0.1 (0.5)	0.04 (0.5)	-0.008	.32	0.1 (0.5)	0.02	.18
Vegetables	g	88.8 (57.8)	84.0 (59.9)	-4.8	.29	100.1 (68.6)	11.3	.02

Dietary variables	Unit	Sample meals (N=120)	Automatically estimated meals (N=120)			Manually adjusted meals (N=120)		
		Mean (SD)	Mean (SD)	Difference <sup>a</sup>	<i>p</i> <sup>b</sup> value	Mean (SD)	Difference <sup>a</sup>	<i>p</i> <sup>b</sup> value
Green and yellow vegetables	g	30.9 (35.5)	31.6 (41.1)	0.7	.64	33.5 (39.5)	2.6	.08
Fruits	g	21.8 (41.1)	15.3 (26.6)	-6.5	.003	15.3 (27.0)	-6.5	<.001
Mushrooms	g	3.1 (10.1)	2.0 (9.6)	-1.1	.03	2.5 (9.8)	-0.6	.23
Seaweeds	g	4.9 (11.6)	3.5 (9.5)	-1.4	.02	4.3 (10.5)	-0.6	.13
Fish and shellfish	g	17.9 (38.5)	10.1 (26.1)	-7.9	.005	15.9 (34.0)	-2.0	.18
Meats	g	30.8 (39.5)	18.9 (29.9)	-11.9	<.001	24.8 (31.3)	-6.1	.001
Eggs	g	16.4 (22.8)	12.9 (18.9)	-3.5	.007	15.6 (23.3)	-0.9	.41
Dairy products	g	26.5 (54.0)	31.9 (62.4)	5.4	.03	28.4 (59.5)	1.9	.24
Confectioneries	g	7.8 (23.8)	24.3 (83.3)	16.6	.02	19.0 (66.2)	11.2	.03
Alcoholic beverages	g	2.5 (5.8)	1.6 (4.5)	-0.9	.08	2.5 (5.9)	0.0	.95

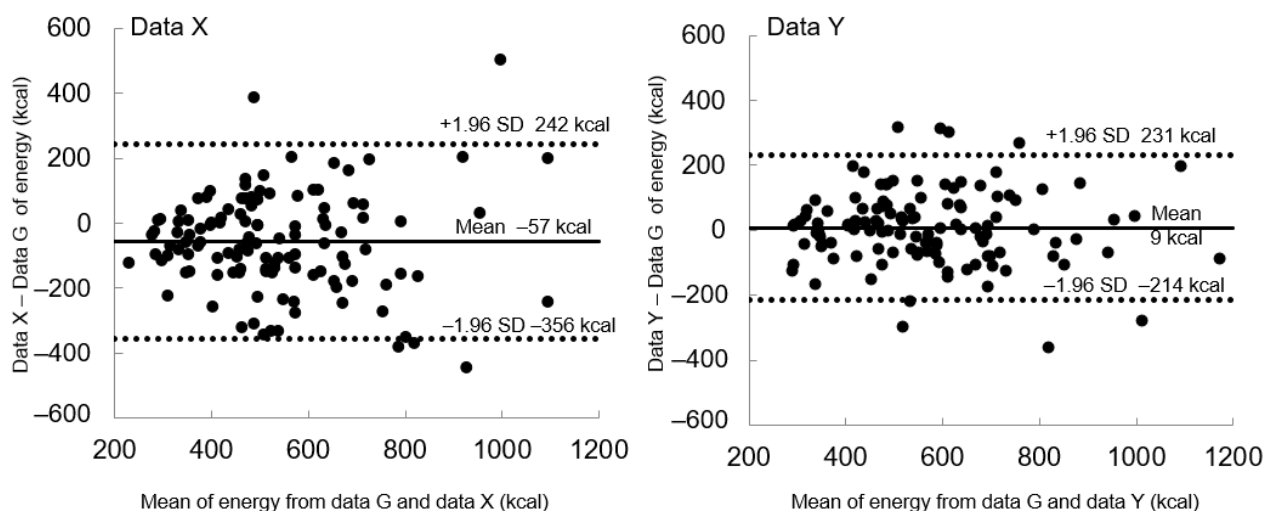
<sup>a</sup>Mean values of X-G or Y-G.

<sup>b</sup>Paired 2-sided *t* test.

**Figure 3.** Proportions of the selected nutrient and food group contents of automatically recognized meals (data X) and manually adjusted meals (data Y) from *CALO mama* to the gold standard of sample meals (data G).



**Figure 4.** The Bland-Altman plots for energy. Data X are automatically recognized, data Y are manually adjusted, and data G are the gold standard.



## Discussion

This study examined the validity of weight, energy, 30 nutrients, and 15 food group contents estimated by the *CALO mama* app by comparing sample meals as a reference. The mean nutrient and food group contents estimated by *CALO mama* using manually adjusted data were close to those of sample meals. Most of the mean nutrient and food group contents that *CALO mama* automatically estimated were significantly lower than those of the sample meals. Nevertheless, the automatically estimated data hit the reference data in 11 out of 30 cases for nutrients and in 4 out of 15 cases for food groups without manual adjustment. These results may indicate that *CALO mama* has the potential to estimate representative intakes among populations by using an automated picture recognition system. Further, the manually adjusted data matched the reference data in 29 out of 30 cases for nutrients and 10 out of 15 cases for food groups. The estimation was even more accurate when the automatically calculated data were manually adjusted.

Many new dietary assessment tools using new technology, such as smartphones and image analysis systems, have recently been developed [6,24,25]. Although these new tools offer a wide range of feasible options to enable dietary assessment to be incorporated into daily routines [24], adequate validation studies have not yet been conducted with regard to the estimation of comprehensive nutrient and food intake. Furthermore, a study design for examining the validity of these new tools has not yet been established. Some experimental studies have evaluated the validity of predictions by using image recognition technologies embedded in mobile devices and examined whether they precisely estimate energy or a single nutrient content for sample meals. Six et al [11] examined the accuracy of the energy and protein content of prepared meals and snacks estimated by a mobile phone food recording system in 1 day among 15 adolescents by comparing duplicated meals and snacks. For many of the full-meal items, the energy and protein values estimated by the tool were accurate within  $\pm 10\%$  of the gold standard. In terms of the intake of each participant on a single research day, many of the participants had energy values within  $\pm 10\%$  errors and values for protein within  $\pm 20\%$  errors. Rhyner

et al [13] examined the difference between the carbohydrate content of prepared meals in a hospital and the values estimated by the mobile phone-based system over 10 days in the cases of 19 adult volunteers with type 1 diabetes. The mean error was 26.2%. Other studies have examined the accuracy of the portion size of dish items [14,15]. Although all of these experimental validation studies concluded that these new dietary assessment tools are useful and can assist in dietary assessments, the validity of nutrient or food content estimations as concluded by automated image recognition systems has not yet been examined.

Some epidemiological studies have examined the validity of dietary intakes estimated by the new tools by using a traditional study design, in which dietary intakes estimated from the new assessment tools were compared with those from a doubly labeled water method or 24-hour recall. Some studies have examined the validity of energy intake alone [16,17,19], and 1 study examined the validity of energy intake and 4 types of food [20]. Other studies have examined the validity of the intake of energy and some selected nutrients [18,19]. Many of these epidemiological validation studies showed that the dietary values from the new tools in 3- to 7-day assessments were acceptable [17-19] for assessing dietary habits among individual participants, although 1 study concluded that a 1-day assessment was inadequate [20]. The validity of these tools for estimating nutrient and food intake at the population level has not yet been adequately examined.

To the best of our knowledge, this study is the first validation study to evaluate the ability of a smartphone app with an image recognition system to estimate comprehensive nutrient and food group contents in terms of the ability to estimate mean dietary contents in over 100 meals. Five commercial diet-tracking mobile apps were recently evaluated in Japan with regard to their ability to estimate energy and nutrient intake. Only the nutrition calculation software aspect was evaluated; however, the validity, including the discrimination between dishes and the estimation of portion size by automatic image recognition, was not evaluated [26]. Our research is novel in this respect. Although the validity of nutrient and food group contents at the individual level was not adequately explored, as this study is

experimental, the mean dietary values of 120 meals estimated from the *CALO mama* app were close to those included in the sample meals for many nutrients and foods.

Misreporting is inevitable in traditional self-reporting dietary assessment methods, such as dietary records, 24-hour recalls, and food frequency questionnaires. Many studies have shown that the energy intake of populations assessed by self-reporting dietary assessment methods was misreported in the range of approximately -40% to 20% compared to the doubly labeled water method [2]. Other nutrients are also assumed to be underreported or overreported to a similar extent in self-reported dietary assessments. This study showed that the proportion of the difference in nutrient contents from data X to the sample meals was -25% to 4% and that from data Y was -11% to 13%. Although we could not compare our results to those of previous traditional validation studies because of the differing study designs, our results indicate that the image recognition system may have the potential to estimate nutrient intakes among populations to the same extent as traditional dietary assessment tools. In addition, *CALO mama* immediately provides individuals with data on their dietary intake, which can be used as is or easily adjusted if needed. Compared to traditional self-reporting methods, registration, and assessments for dietary intake, the app is much lower in cost and reduces the burden on both those who make assessments and those who need to be assessed. These findings support the idea that, for many nutrients and food groups, apps with an image recognition system have great potential to estimate dietary intake. Further validation studies at both the individual and population levels are needed to confirm the accuracy of the estimations as a dietary assessment tool in large-scale epidemiological studies.

The major strength of this study is that this validity assessment examined comprehensive nutrient and food group contents, and the estimation of nutrients and food groups was made by a health app that employed an image recognition system that enables the automatic calculation of the nutrient and food content in a meal.

Several limitations of this study require mentioning. First, the generalizability of our findings is lacking because we examined the performance of a specific app, *CALO mama*. The performance of image recognition could be better or worse than our findings, depending on the app. Nevertheless, we found that manual modification can improve the accuracy of predictions carried out using image recognition. Second, not all research staff were familiar with the *CALO mama* app. Furthermore, in the protocol of this study, the research staff could modify the outputs from the app only once without eating or tasting the

sample meals. However, the app has a function allowing users to modify meals after the initial registry, and they can thus correct and register their meals more precisely after eating. In this study, meal registration correction may have been inadequate. However, the results showed that most of the mean nutrient and food group contents estimated by the image recognition system were similar to the reference, especially when manually adjusted. This result may indicate that even users who are unfamiliar with the app with image recognition can have their diets assessed correctly. If users are familiar with the app and register their meals after eating, the estimation may be more precise. Third, the image recognition system has difficulty distinguishing foods with similar shapes and colors. However, it was improved by updating its prediction model and expanding the training data. There is also a plan for implementing collaborative filtering into the system; collaborative filtering will help the system to provide more precise predictions based on the combination of food items (for instance, brown liquid that comes with a Japanese meal is more likely to be miso soup rather than coffee with milk). Finally, this study examined the ability to estimate the mean values of the nutrient and food group contents of 120 meals by using the *CALO mama* app. Although the estimated values were acceptable, it cannot be concluded from the results that *CALO mama* can estimate dietary intake at the population level in daily life. Further validation studies at both the population and individual levels are needed in the epidemiological field that uses *CALO mama* as a health administration app for individuals or as a dietary assessment tool.

In conclusion, this study showed that the mean values of the nutrient and food group contents of 120 meals derived from the image recognition system in the *CALO mama* app were well estimated compared to those of the sample meals. Automatically estimated data have a certain amount of accuracy with regard to estimating nutrient and food group contents, but this accuracy is enhanced when these data are manually adjusted. Health apps embedding image recognition have the potential to contribute to "precision nutrition," a comprehensive and dynamic approach to developing tailored nutritional recommendations in consideration of genetics, dietary habits, eating patterns, and physical activity [27,28]. They can overcome the limitations of conventional measurements, and real-time data from them will enable researchers to study how diet affects health and diseases more accurately and provide helpful dietary recommendations. Further validation studies at both the population and individual levels are essential if we are to utilize image recognition as a health administration app for individuals or as a dietary assessment tool in research.

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## Authors' Contributions

YS and KA conceived the study design. YS conducted the experiments and data collection. SK conducted the statistical analysis. YS, KS, and SK were involved in the writing of the manuscript. KA directed the study. All authors provided input for the final draft of the manuscript.

## Conflicts of Interest

This work was conducted using research expenditures from Link & Communication Inc. YS and SK are employees of Link & Communication, Inc. KS has an advisory contract with a company for research. KA declares no competing interest.

## Multimedia Appendix 1

The Bland-Altman plots for macronutrients. Data X are automatically recognized, data Y are manually adjusted, and data G are the gold standard.

[[DOCX File, 109 KB - formative\\_v6i1e31875\\_app1.docx](#) ]

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Original Paper

# An Open-Source Privacy-Preserving Large-Scale Mobile Framework for Cardiovascular Health Monitoring and Intervention Planning With an Urban African American Population of Young Adults: User-Centered Design Approach

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## Abstract

**Background:** Cardiovascular diseases (CVDs) are the leading cause of death worldwide and are increasingly affecting younger populations, particularly African Americans in the southern United States. Access to preventive and therapeutic services, biological factors, and social determinants of health (ie, structural racism, resource limitation, residential segregation, and discriminatory practices) all combine to exacerbate health inequities and their resultant disparities in morbidity and mortality. These factors manifest early in life and have been shown to impact health trajectories into adulthood. Early detection of and intervention in emerging risk offers the best hope for preventing race-based differences in adult diseases. However, young-adult populations are notoriously difficult to recruit and retain, often because of a lack of knowledge of personal risk and a low level of concern for long-term health outcomes.

**Objective:** This study aims to develop a system design for the MOYO mobile platform. Further, we seek to address the challenge of primordial prevention in a young, at-risk population (ie, Southern-urban African Americans).

**Methods:** Urban African Americans, aged 18 to 29 years (n=505), participated in a series of co-design sessions to develop MOYO prototypes (ie, HealthTech Events). During the sessions, participants were orientated to the issues of CVD risk health disparities and then tasked with wireframing prototype screens depicting app features that they considered desirable. All 297 prototype screens were subsequently analyzed using NVivo 12 (QSR International), a qualitative analysis software. Using the grounded theory approach, an open-coding method was applied to a subset of data, approximately 20% (5/25), or 5 complete prototypes, to identify the dominant themes among the prototypes. To ensure intercoder reliability, 2 research team members analyzed the same subset of data.

**Results:** Overall, 9 dominant design requirements emerged from the qualitative analysis: customization, incentive motivation, social engagement, awareness, education, or recommendations, behavior tracking, location services, access to health professionals, data user agreements, and health assessment. This led to the development of a cross-platform app through an agile design process to collect standardized health surveys, narratives, geolocated pollution, weather, food desert exposure data, physical activity, social networks, and physiology through point-of-care devices. A Health Insurance Portability and Accountability Act-compliant

cloud infrastructure was developed to collect, process, and review data, as well as generate alerts to allow automated signal processing and machine learning on the data to produce critical alerts. Integration with wearables and electronic health records via fast health care interoperability resources was implemented.

**Conclusions:** The MOYO mobile platform provides a comprehensive health and exposure monitoring system that allows for a broad range of compliance, from passive background monitoring to active self-reporting. These study findings support the notion that African Americans should be meaningfully involved in designing technologies that are developed to improve CVD outcomes in African American communities.

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## KEYWORDS

agile design; cardiovascular disease; community-based participatory research; exposome; user-centered design; minority health; African American; mobile phone

## Introduction

### Background

Longitudinal cohort studies require significant resources to track patients over long periods, particularly for chronic diseases. Portable digital identities, such as phone numbers and emails, however, can often persist for many years, with almost half of adults living in urban areas in the United States possessing a cellphone number from elsewhere [1]. This provides an exciting possibility for recruiting and retaining electronic cohorts. The rise of mobile phone use and the complexity of sensors they possess further stretch the options of the type of data we might gather concerning a person's health, particularly beyond standard metrics such as symptoms, weight, and blood pressure. Moreover, society is becoming increasingly aware that the environment or *exposure* of an individual will significantly influence their health trajectory [2]. However, measuring environmental exposures and behaviors over long periods is cumbersome and costly. Smartphone apps, with geolocation and intuitive interfaces for rapid ecological momentary assessment, provide a scalable and straightforward way to capture exposure data through application programming interfaces (APIs) to a more extensive infrastructure, such as weather and pollution monitoring stations, as well as wirelessly connected wearables and point-of-care devices.

Although consumer wearables have generated much excitement over the last decade, they have from 2 fundamental problems. First, they do not provide access to the raw data. Conversely, wearables provide access to some undisclosed, and often evolving, proprietary metrics or nonstandard measures such as *steps*. Mobile phones, particularly Android-based ones, do in fact provide such access and can allow a user to extract deep, actionable insights from their data [3,4]. Second, the lack of *stickiness* among wearables is a significant problem, with over half of the wearable consumer base ceasing to wear a fitness tracker after 6 months [5]. However, mobile phones do not have the same fate, with phone upgrades occurring approximately every 3 years, perhaps less frequently among lower-resourced communities [6]. Moreover, users can automatically port apps between phone upgrades, allowing long-term tracking for multiple years if there is a reason to want to use the app. Therein lies the final barrier, with the vast majority of apps not being used after just a few months, with the exception of entertainment-based apps [7]. Therefore, gamification of

personal data has been lauded as a possible solution [8]. In this work, we present the process of designing a system for and with low socioeconomic status disparity populations through an agile approach, with a particular focus on cardiovascular diseases (CVDs).

CVDs, including coronary heart disease and stroke, remain the leading causes of death, disability, and economic burden globally [9,10]. In 2016, an estimated 17.9 million people died of CVDs, representing 31% of all global deaths [8]. Approximately 85% of CVD-related deaths are attributed to heart attacks or strokes, and Americans experience 1.5 million heart attacks and strokes per year [11]. In these numbers, an alarmingly disproportionate rate of heart-disease incidence is seen among the African American community. Although the national age-adjusted rates of heart attacks and strokes have declined, the rates for African Americans remain 20% higher for heart attacks and 40% higher for strokes, compared with White people [12]. In fact, in the United States, the age-adjusted mortality rate for CVDs is the highest among African Americans compared with all racial and ethnic groups [13]. Modifying behavior and lifestyle choices surrounding physical activity, diet, smoking, sleep quality, and alcohol consumption can significantly reduce the likelihood of developing CVD risk factors such as hypertension, diabetes mellitus, and obesity. Although the improved understanding and control of behaviors associated with CVD risk factors have led to a decline in CVD-related mortality rates in the United States, CVD risk factors manifest earlier in African Americans than in other subgroups, leading to higher mortality rates in the African American community [14].

Advancements in digital technology have changed how people interact with the world and present an opportunity to monitor and modify behaviors that are directly associated with CVD risk factors. Innovations in mobile health (mHealth) technologies and technologies for information and communication technologies have shown promise and evidence for the support of behavior change. For instance, several studies have assessed the impact of mHealth technologies and technology-based (eg, websites, SMS text messaging, telemonitoring, and telemedicine) approaches on chronic disease management (secondary prevention). In recent years, there has been a proliferation of apps and technology-based interventions that promote physical activity [15], smoking cessation [15,16], monitoring caloric intake [17], and providing education on



health risk factors, with the primary focus being the prevention of disease advancement [18]. However, there is limited research on leveraging technology-based or mHealth interventions to prevent disease, specifically in younger ethnic minority demographics. As CVD mortality rates are higher among African Americans, and CVD risk factors are evident earlier, engaging young-adult members of the African American community in the development of an mHealth platform that shows promise for primordial prevention (ie, to avoid the development of the initial risk factors) is the next step to improving outcomes. Owing to the disproportionately high prevalence of CVDs in African American communities, the risk factors of CVDs and the ubiquity of mobile phones, young African Americans need to be engaged in the system design of a CVD risk-reduction mobile data collection platform.

## Objectives

This study aims to develop a system design for the MOYO mobile data collection platform using the design requirements for an urban African American population. The function of the MOYO mobile platform is to gather longitudinal and granular environmental, psychosocial, behavioral, and clinical data from a population of young African American adults to reduce CVD risk factors.

## Methods

### Overview

Developed initially for psychiatric populations [19-21], this new platform was developed as a generalized extension to address both psychiatric and physiological health, with an augmented user interface to address these issues, with a particular focus on extending to cardiovascular health.

The study design was an electronic cohort study. The study procedures were approved by the institutional review board of the Morehouse School of Medicine.

### Community-Based Participatory Research and User-Centered Design

Community-based participatory research (CBPR) values community-academic partnership and shared leadership in the planning, implementation, evaluation, and dissemination of initiatives. The 9 key principles of CBPR are recognizing the community as a unit of identity; building on strength and resources with the community; facilitating collaborative, equitable involvement of all partners in all phases of the research; integrating knowledge and action for the mutual benefit of all partners; promoting a colearning and empowering process that attends to social inequalities; involving a cyclical and iterative process; addressing health from both positive and ecological perspectives; disseminating findings and knowledge gained to all partners; and involving a long-term commitment [22]. The research team implemented the principles of CBPR in the recruitment and development of MOYO prototypes that addressed community-identified social, structural, physical, environmental, and policy priorities that impact CVD risk factors.

Similar to CBPR, the user-centered design (UCD) approach explicitly engages end users (ie, community) in the development process. The 2 theories depart in applicability: CBPR is focused on the planning and implementation of community-focused research, and UCD is primarily leveraged to develop consumer-oriented products and applications. By combining CBPR principles and a UCD approach, the research team wanted to ensure that the end user would engage in every phase of development, influence the design, and ultimately increase the usability of MOYO.

### Co-design Sessions

A series of event-based recruitment events (ie, HealthTech Events), similar to coding hack-a-thons, were designed and implemented to extract the design requirements from the target population by (1) leveraging community-based participatory and UCD approaches to engage the end user in identifying environmental factors that contribute to behaviors associated with CVD risk factors, (2) leveraging the Health Belief Model to increase the understanding and ownership of the disparity that exists, (3) use design-thinking to explore solutions to problems associated with the sustained use of mHealth technologies (eg, declining retention rates), and (4) aligning identified requirements with the social cognitive theory of mass communication to ensure that the incorporated design requirements produced a prototype that would ensure behavior change.

The Health Belief Model suggests that a personal belief in the threat of an adverse health outcome and the effectiveness of the recommended intervention will predict the likelihood that the person will adopt the behavior. Conversely, the social cognitive theory of mass communication provides an agentic conceptual framework to analyze the determinants and psychosocial mechanisms through which symbolic communication influences human thought, affect, and action. Although the theories have overlapping constructs, these theories do not serve to assess behavior change equally.

### Participants and Mentors

MOYO was initially conceived as a tool to collect CVD primordial prevention data and to monitor the health behaviors of urban African Americans, aged 18 to 29 years. Participants who self-reported the inclusion criteria were invited to participate in the HealthTech Events and subsequently join the study. The inclusion criteria were (1) self-identification as Black or African American, (2) aged between 18 and 29 years, and (3) own an iPhone operating system or Android-based smartphone. Informed consent was obtained electronically from the study participants.

### Settings

Owing to convenience sampling, some HealthTech Events were hosted at Atlanta-based colleges and summer enrichment programs that target ethnic minorities and underserved communities.

The HealthTech Events took place at academic institutions and community sites where non-African Americans had access to the facility. The research team did not want to exclude

community members from learning about the lived experiences of those at the greatest risk of CVD because of ethnicity. Furthermore, non-Black or African Americans were not assigned to a design team nor were they permitted to enroll in the study, unless they self-identified as Black or African American. Subsequently, neither the data nor the design concepts of non-Black or African Americans were included in the analysis. However, non-Black or African Americans were not prevented from attending the training sessions, in which the study participants discussed their design concepts.

Participants were recruited to participate in 1 of the 3 health-related events over the course of 18 months. The research team hosted one event every 4 to 5 months.

### Mentors

Public health graduate students and user experience and user interface designers serve as volunteer mentors for HealthTech Events. Each team was assigned 1 to 2 mentors with diverse expertise (eg, user experience or public health and user interface or public health). To ensure that each member had a foundational understanding of public health and the design process, mentors received a 1-hour training before each event. The mentors guided the end user (ie, HealthTech Event participants) through the 6 phases of the design-thinking process to create and pitch prototypes. Each event included 35 to 50 participants, separated into design teams composed of 5 members each, forming a combined total of 25 teams. Although 25 teams existed, 25 prototypes were not created. Prototypes were not completed as teams were not able to complete the design process because of schedule conflicts. Furthermore, several prototypes were lost because of data loss.

### A Cloud-Enabled Health Insurance Portability and Accountability Act-Compliant mHealth Sensing Infrastructure

Through an agile design process [23,24], the development team created the following superset of components for the Android-based version of the app:

1. High-resolution actigraphy from the movement sensor (with sampling frequency varying based on the Android operating system version and phone model).
2. The deidentified location indicates the distance from the most frequented location at which the least movement occurred (eg, home, work, or school).
3. The social network size was assessed from the calls and SMS text messages. The thinking behind this was that most people who are ill use more traditional communication channels. By hashing each phone number, it is possible to look at the variety and consistency of communication, both incoming and outgoing, to identify changes in social dynamics.
4. The type of establishment in which the user dwells (or probability of this activity) is given by the Android API [25].
5. Place names from the Android place API (deidentified using a white list of major consumer chains).
6. Mode of transport (from Google Fit API).
7. Battery recharging behavior (times at which phone was plugged in).
8. Weather, pollution, and food desert levels are based on the user's geolocation from a cloud-based bespoke server that consumes the DarkSky API (for weather) and AirNow (for pollution).

We also included several self-administered standardized scales, including:

1. *The Patient Health Questionnaire-9*: The 9-item Patient Health Questionnaire is a 9-question self-report tool used to screen, diagnose, monitor, and measure the severity of depression [26,27].
2. *The Kansas City Cardiomyopathy Questionnaire-12*: The 12-item Kansas City Cardiomyopathy Questionnaire is a 12-item heart failure-specific health status questionnaire. It has 4 domains: physical limitations, symptom frequency, social limitations, and quality of life, as well as a summary score that combines the 4 domain scores [28].
3. *The Patient-Reported Outcomes Measurement Information System Global-10*: The 10-item Patient-Reported Outcomes Measurement Information System is a publicly available global health assessment tool that allows the measurement of symptoms, functioning, and health-related quality of life in a wide variety of chronic diseases and conditions [29].
4. *Quality of life, enjoyment, and satisfaction questionnaire*: The quality of life, enjoyment, and satisfaction questionnaire (Q-LES-Q) is a self-report measure designed to enable investigators to quickly obtain sensitive measurements of the degree of enjoyment and satisfaction experienced by subjects in various areas of daily functioning [30].
5. *Subjective Units of the Distress Scale*: The subjective units of the distress scale is a self-administered scale for the emotional intensity of disturbance or distress experienced by an individual [31].
6. *The Posttraumatic Stress Disorder Checklist* [32].

The posttraumatic stress disorder checklist was included to capture the influence of trauma on the study population, which has been shown to be associated with an increased likelihood of cardiovascular events [33], with a disproportionate effect on African Americans [34]. The research team also included the *MoodZoom* survey from the original Automated Monitoring of Severity of Symptoms app and *Mood Swipe*, a 5-point Likert emoticon-based scale of frowny and smiley faces (☹️). The latter was implemented as a low friction way of expressing mood in an almost universally accepted manner. Notifications to take the surveys are programmable, with a default to pop up in the morning (between 10 AM and noon depending on the study) and repeated at 2-hour intervals until taken and repeated if ignored for a maximum of 4 times. The start time, frequency, and the maximum number of repeat pop-ups are all programmable. In addition, the user can click on a standard *cog* symbol to alter the types of data collected to adjust the app (as often as they like) to adjust the privacy settings to a level they are comfortable with.

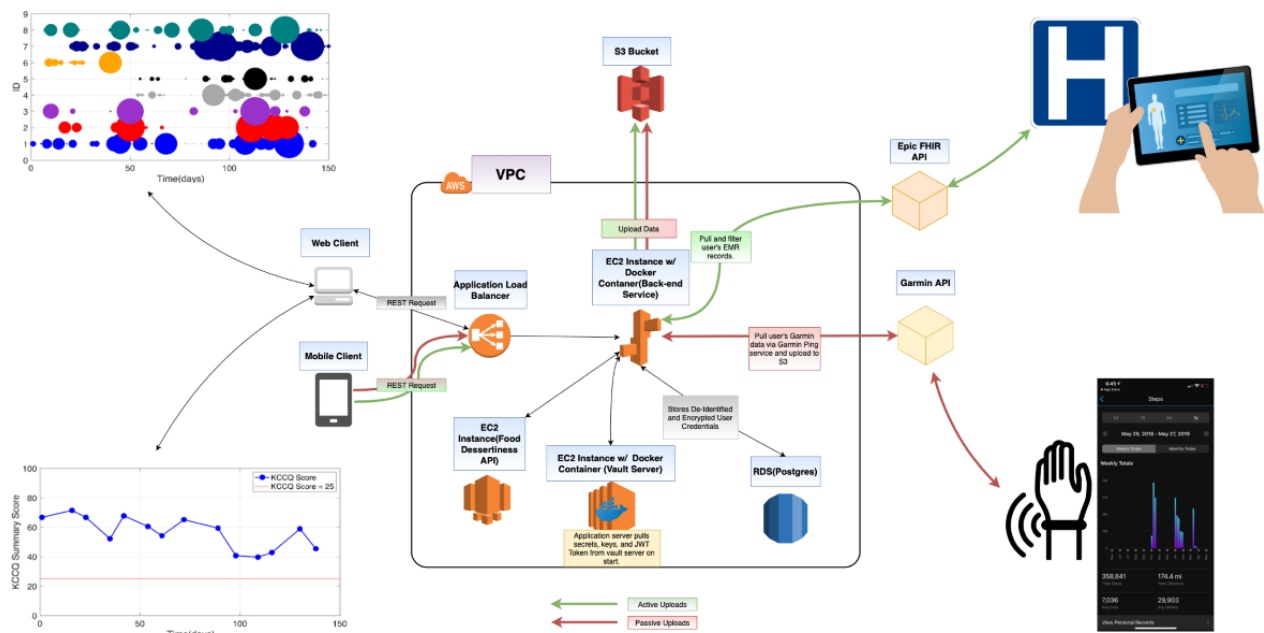
All the above information is synchronized back to the cloud (Amazon Web Services) every 15 minutes and stored in S3

*buckets* in a flat-file data lake organized by study, subject ID, and the week the file was created.

Electronic health record data are extracted from the electronic health record system using Substitutable Medical Applications, Reusable Technologies on Fast Healthcare Interoperability

Resources [35]. The data are then deidentified on our back-end server by dynamically parsing and removing any trace of the subject's identity. Once deidentified, the data are then associated with the user's unique study ID before being uploaded to the S3 buckets. Figure 1 illustrates this framework and the design of the cloud infrastructure.

**Figure 1.** Health Insurance Portability and Accountability Act-compliant cloud-based infrastructure for collecting user input, phone sensor data, wearable technology, and electronic health record data. Upper left: a visualization of social networking behavior. Lower left: daily responses to a standardized questionnaire. Center: the Amazon Web Services cloud infrastructure. Upper right: integration with the electronic health record. Lower right: integration with wearables. API: application programming interface; AWS: Amazon Web Services; EMR: electronic medical record; FHIR: Fast Healthcare Interoperability Resources; JWT: JSON Web Tokens; KCCQ: Kansas City Cardiomyopathy Questionnaire-12; RDS: Relational Database Service; VPC: Virtual Private Cloud.



Each day, a *cron job* on Amazon Web Services identifies all the new data and sends out a comma separated value log file via email to the study coordinator to let them know if any individuals have stopped sending data or types of data are not being received. This could easily be adapted to an interface with alerts or a secondary app with pop-up reminders, but email was the preferred medium for the coordinators.

## Pilot Testing

To stress test the infrastructure, a digital US \$20 Amazon card was offered to encourage the use of the app. No other incentives or approaches to engaging the community were offered during pilot testing. To assess the utility of the app during pilot testing, the research team measured the number of downloads of the app from Google Play Store, the number of users regularly uploading data (ie, at least 7 times a week), and types of data most frequently uploaded to provide a picture of the most engaging aspects of the app.

## Analysis

From the HealthTech Events, the research team collected 13 prototypes, consisting of 297 screens (ie, each frame of a design is counted as one screen). All prototype screens were uploaded by the mentors to a password-protected shared drive. The prototype screens were analyzed using NVivo (version 12; QSR

International), a qualitative analysis software. Using the grounded theory approach, an open-coding method was applied to a subset of data, approximately 20% (5/25) or 5 complete prototypes (5 teams' complete app design) to identify themes. To ensure intercoder reliability, 2 research team members analyzed the same subset of data, ensuring that the emerged themes were consistent. These themes were used to develop a codebook that guided the analysis of the remaining data. Each prototype screen was tagged with the corresponding theme.

## Results

### Overview

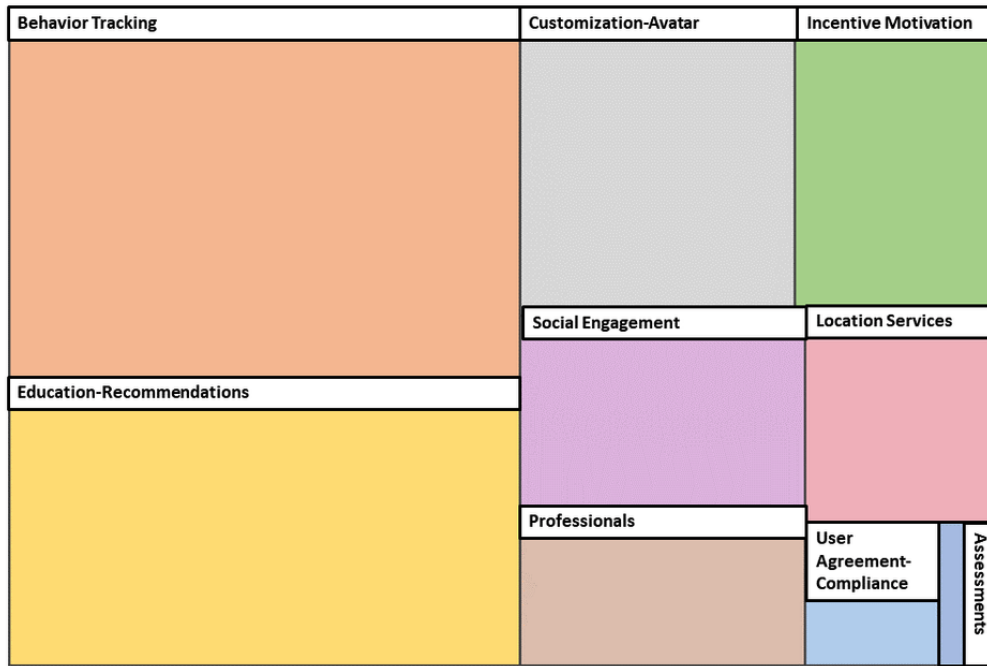
A total of 9 themes were identified from 297 prototype screens as images. Table 1 outlines the emerging themes, corresponding subthemes, descriptions, and frequencies. Figure 2 indicates the frequency; the more significant the box, the more frequent the theme emerged. The findings reveal the factors that the target audience would find most engaging in an app designed to deliver primordial prevention strategies aimed at reducing CVD risk. The elements that emerged can be organized into 4 overarching categories: individual, interpersonal, expert-informed, and technological. These findings are described in the following sections.

**Table 1.** User-centered design session thematic analysis and frequency of themes.

Theme	Frequency (N=297), n	Description
<b>Behavior tracking</b>	74	
Exercise		Record physical activity
Diet		Maintain a food journal
Mental health		Record mood and stress (self-reported)
<b>Education and recommendations</b>	57	
Push messaging		Receiving recommendations to improve deficient areas (ie, tips to improve sleep quality)
Healthy tips		Provision of healthy recipes and/or healthy meal options when eating out
Health considerations		Provide baseline health information (ie, importance of cardiovascular health, BMI, and exercise frequency recommendations)
<b>Customization</b>	33	
Textures		Color scheme, background, and font
Integration		Sync with other apps (ie, Spotify and iTunes)
Avatar		Visual depiction of oneself
<b>Incentive motivation</b>	24	
Competition		Peer-to-peer or group challenges
Leaderboards		Incorporation of a scoreboard and/or ranking system
Rewards		Discounts and point accumulation for reaching goals
<b>Social engagement</b>	22	
Social network integration		Ability to sync social networking sites
<b>Health professionals</b>	17	
Telehealth and telepsychiatry		Ability to interact (ie, video and SMS text messaging) with a health professional
<b>Location services</b>	16	
Diet		Leverage location settings provide health food options
Fitness		Provide nearby physical activity opportunities (ie, exercise classes, park, and track)
<b>User agreements</b>	7	
User security		Consent to data use
<b>Assessments</b>	3	
Mental health		In-depth screening of mental health; survey



**Figure 2.** Theme comparison diagram: box size corresponds with the frequency of prototype themes in the analysis.



**Individual Factors**

**Customization**

Several end users designed their prototypes with features that would allow for a degree of personalization of the app, including selecting themes (color, font, and commonly used features), syncing other apps (iTunes and Spotify), and creating a visual representation (avatar) within the app. The avatar design varied in functionality and utility, ranging from a mere visual depiction to displaying apparent weight and energy changes based on the data collected (ie, food consumed and biometric entries).

**Behavior Tracking**

Most of the prototypes included tracking behaviors associated with CVD risk factors (diet, exercise, sleep, and mental health). In addition to tracking these behaviors, several designs also included goal-setting features. Thus, end users would be able to determine benchmarks, reflect on accomplishments, and identify challenge areas. In many prototypes, behavior-tracking features integrated other apps or leveraged technology to automate data collection and reduce end user burden. For example, to create a food journal entry, the end user can take a picture of their meal instead of entering each item they ate.

**Interpersonal Factors**

**Incentive Motivation**

End users incorporated an array of features that incentivized consistent positive behaviors, including promoting *friendly competition*, leaderboards, and a reward system for accomplishing goals. Several prototypes encouraged the end user to engage their peers by challenging them to attain the set goal. In some designs, the end user could join challenges with other users that they did not know and compete to reach the same goal. Furthermore, end users could also be rewarded for accomplishing their individual goals, such as receiving a coupon for logging health meals for a week.

**Social Engagement**

Many prototypes were built to interface with social networking sites (Snapchat, Instagram, and Twitter). The end user could share their progress on social media and encourage peers to join challenges.

**Expert-Informed Factors**

**Education and Recommendations**

Several prototypes include features that would allow user-specific education and recommendations. The information and recommendations provided are extensions of the self-reported behavior tracking. On the basis of the data entered in the app, end users could receive information to improve or increase activity in certain areas. For example, if the user data shows that the user has poor sleep quality, then using push messaging or prompts after entering the app, the user is provided with information about the relationship between sleep and cardiovascular health and tips to improve sleep quality.

**Health Professionals and Assessments**

A critical feature included in some prototypes was real-time interaction with health professionals. Leveraging telehealth technology, end users can connect with professionals regarding health-related concerns. The communication style with professionals included text messages, video calling, and store-and-forward video messaging. Some design elements were specific to mental health. A few prototypes included a self-reported assessment that screened mental well-being based on mood or responses to external factors (job, stress, and family). On the basis of the end user responses to the evaluation, the user may be advised to talk with a professional. In addition, end users had the option to engage with both mental and physical health professionals at any point.

## Technological Factors

### Location Services

Prototypes leveraged the end user location to provide user-specific diet and fitness recommendations. End users were able to identify the local healthy food options. In addition, location features could encourage users to engage in nearby physical activity opportunities (ie, fitness classes and upcoming races).

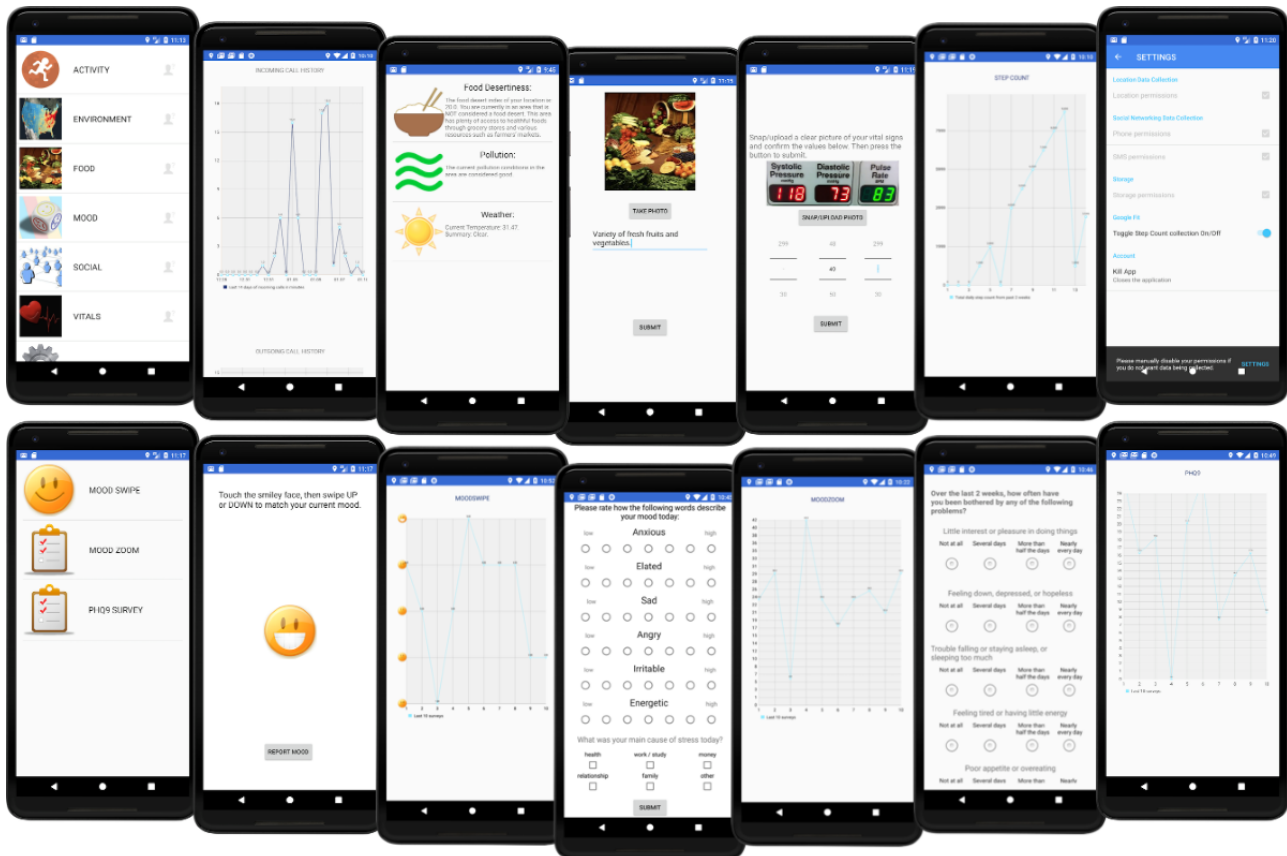
### User Agreements

Prototypes provide end users with easy-to-understand data security agreements. The end users desired the ability to make an informed decision regarding the data shared with the research team and how the research team will use the data.

### Final Design

Figure 3 illustrates the design of the resultant interface. The app covers 6 major categories.

**Figure 3.** Mobile data collection platform prototype design. The 6 major categories of data collected were physical activity, environment, food, mood, social behavior, and physiology (vitals), driven by a main menu (top left screenshot) and represented by 6 different interfaces (second from left to end in the top row).



1. Physical activity: The user can track how much they have moved during the time they have been carrying the phone. Historical graphs provide insight into the regularity of exercise (conscious or otherwise). In the iPhone operating system, this is tracked through the nonscientific notion of *steps* for the lack of another solution. This is only for relative movement information.
2. Environment: Using external APIs, the app collects frequent data (every hour or 100 m moved) on pollution, weather, and food desert indices.
3. Food: Through photographs and diaries, a user can document food consumption
4. Mood: Through standardized, digital self-administered forms, psychological health can be assessed and tracked.
5. Social behavior: The complexity and dynamics of an individual's social network give a perspective on life changes that may affect how their mood changes and help identify positive and negative influences in life.
6. Physiology or vitals: Through photographs of medical devices, vital signs such as blood pressure can be logged at the time of collection. Future work will focus on autotranscribing readings, as demonstrated in [36].

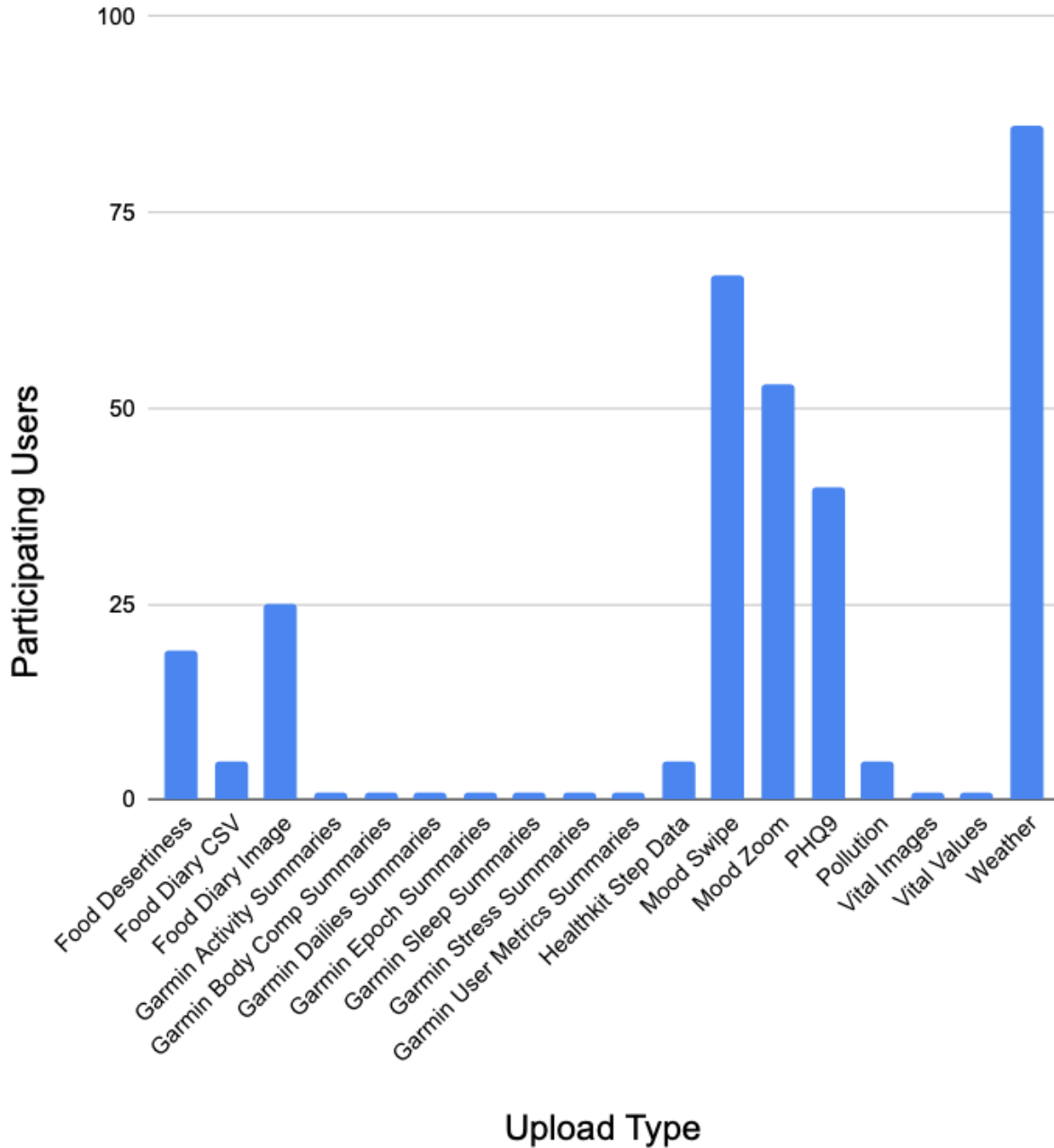
### Pilot Test

Following the design and deployment of the app through the Google Play and Apple app stores, the app was downloaded 181 times during the 24 months, with the bulk being around the HealthTech Events. A total of 116 users regularly uploaded data, with an average of 277 uploads per week. The volume of data uploaded depended on the behavior of the user and whether there was a loss of network connectivity for any extended period (as the missed uploads are synchronized when connectivity is restored). If the user does not move, enter data, or interact with the phone, a lower volume of data is collected. The average payload upload size was 0.024 MB per person per day.

Figure 4 illustrates the relative proportion of upload types throughout the pilot, with passive geolocation-triggered data (weather and food dessert index) being among the most frequently uploaded. However, active self-reported mood

(through 3 separate surveys: mood swipe, mood zoom, and the Patient Health Questionnaire-9) were as frequent, indicating that the app was engaging in tracking mental health.

**Figure 4.** Histogram of the number of users uploading each data type. Most users did not engage with the wearables (which were optional), but both passively collected data and self-reported mental health surveys were often uploaded. PHQ-9: Patient Health Questionnaire-9



## Discussion

### Principal Findings

An extensive app-cloud infrastructure was developed, which provided detailed information on the physical activity, behaviors, and psychosocial and physiological state of urban African American young adults. The research team followed a community-based participatory design approach that provided a simple method for entering or sourcing information that the community considered essential to engaging with the app. As the system design is flexible, the MOYO mobile platform has

broad applicability. Furthermore, because the system is constructed around a cloud platform, the analysis can be automated and scaled.

Integration with wearables has been demonstrated through a proof of concept, but we still warn users against the utility of crowdsourcing quasi-medical data, without standardization. For example, in all our research on pregnant women, blood pressure data capture is standardized to the use of Omron M7, which is validated in preeclampsia. Small changes in the capture protocol, cuff form factor, or device firmware could significantly change the readings. For example, switching to a different version of

the same device halfway through a clinical trial (perhaps because the original device went off-market) could lead to a slight offset across the population after intervention, making the trial seem successful when it was not, or vice versa. Of course, such issues are true for any device, but this problem is particularly exacerbated when using devices that can be updated over the air, such as commercial fitness devices or smartwatches. If the study coordinator or user does not set the device to prevent updates, changes in the device behavior will occur in a somewhat arbitrary manner (depending on when the update is issued and when and if the user decides to accept the update). Even then, devices issued later in a study could carry a later version of the firmware, unknown to the study team.

In an earlier study, where we used the Jawbone UP3 fitness and sleep tracker, we worked with the company to whitelist the study devices to ensure that the company did not update the firmware for the device at any point [21]. We also set the phones to prevent updating Android operating system versions as this can change the resolution of the location and sampling frequency of the accelerometer. We note that the one algorithm over which we have no control is the type of building returned by Google's Map API. However, as retail establishments change over time and maps can be noisy, such information should be treated with caution, and a crowdsourcing approach to relabeling data may be applicable. To some extent, we cannot control any changes in the weather API either, but this is less of a concern because we do not expect the measurement of temperature, humidity, and pollution to change significantly over time. Moreover, the

weather is a relatively coarse concept applied over a wide area, heavily averaged, and interested users can pull historical data from multiple weather APIs to improve accuracy. To mitigate these issues, we suggest relative changes, rather than absolute changes, as features or flags for changes in health and behavior. In terms of engagement, both passive (eg, weather and food desert) data were frequently uploaded and active reports on mental health, whereas wearable-based activity data showed little uptake. This is perhaps not surprising in a young-adult cohort, where perceived barriers and facilitators to mental health help-seeking in young adults occupy more of their time than concerns over physical well-being [37].

## Conclusions

Although we have demonstrated some successes with the use of the app in CVD populations, the potential to shift the needle with young adults who are yet to perceive a health problem is still problematic. As noted above, gamification and use of behavioral economics are perhaps keys to the retention of users and the ability of the information to affect changes in user lifestyles without chronic or acute issues at the start of their journey turning into illness or wellness. However, without strong community participation and ownership of the system, we cannot expect deep engagement. Thus, the findings from this study support a community-based participatory design approach to solve the problems of health inequities. More specifically, African Americans should be meaningfully involved in the design of technologies that are developed to improve CVD outcomes within African American communities.

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## Authors' Contributions

GC and HT Jr conceived the study and were the principal investigators for the funding from the National Science Foundation for this study. GC conceived the original informatics and mobile app infrastructure and designed the modifications to the informatics infrastructure. SF and BN developed the HealthTech Event concept and guidebook. SF and BN led the co-design sessions, trained the mentors, and analyzed the results. MS performed the analysis of the data in the pilot. CE led the project management and managed user recruitment and coordination. TN and CS programmed the mobile app infrastructure. TN led the design and development of the back-end infrastructure. CJ and TA led community-based participatory research engagement. All authors contributed to the text and figures, reviewed, edited, and approved the manuscript.

## Conflicts of Interest

None declared.

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## Abbreviations

- API:** application programming interface  
**CBPR:** community-based participatory research  
**CVD:** cardiovascular disease  
**mHealth:** mobile health  
**UCD:** user-centered design

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Original Paper

# Patients' Expectations and Experiences With a Mental Health–Focused Supportive Text Messaging Program: Mixed Methods Evaluation

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## Abstract

**Background:** Web-based services are an economical and easily scalable means of support that uses existing technology. Text4Support is a supportive, complementary text messaging service that supports people with different mental health conditions after they are discharged from inpatient psychiatric care.

**Objective:** In this study, we aim to assess user satisfaction with the Text4Support service to gain a better understanding of subscribers' experiences.

**Methods:** This was a mixed methods study using secondary data from a pilot observational controlled trial. The trial included 181 patients discharged from acute psychiatric care and distributed into 4 randomized groups. Out of the 4 study groups in the initial study, 2 groups who received supportive text messages (89/181, 49.2% of patients), either alone or alongside a peer support worker, were included. Thematic and descriptive analyses were also performed. Differences in feedback based on sex at birth and primary diagnosis were determined using univariate analysis. The study was registered with ClinicalTrials.gov (trial registration number: NCT03404882).

**Results:** Out of 89 participants, 36 (40%) completed the follow-up survey. The principal findings were that Text4Support was well perceived with a high satisfaction rate either regarding the feedback of the messages or their perceived impact. Meanwhile, there was no statistically significant difference between satisfactory items based on the subscriber's sex at birth or primary diagnosis. The patients' initial expectations were either neutral or positive in relation to the expected nature or the impact of the text messages received on their mental well-being. In addition, the subscribers were satisfied with the frequency of the messages, which were received once daily for 6 consecutive months. The participants recommended more personalized messages or mutual interaction with health care personnel.

**Conclusions:** Text4Support was generally well perceived by patients after hospital discharge, regardless of their sex at birth or mental health diagnosis. Further personalization and interactive platforms were recommended by participants that may need to be considered when designing similar future services.

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**KEYWORDS**

supportive text messages; patients' experience; mental health; mixed methods

## Introduction

### Background

Recently, there has been rapid adoption of computer- and web-based services in health care systems. These services are often highly accessible, remotely delivered, cost-effective, and easy to use [1-3]. These characteristics make computer- and web-based services appealing and attractive to both health care providers and patients.

Wireless and mobile technologies needed to deliver computer- and web-based services have been rapidly expanding. In 2019, there were >8 billion mobile phone subscriptions and >4 billion wireless internet users worldwide [4]. Given this vast reach, the use of these technologies may be beneficial in community mental health where accessibility concerns, service gaps, and high cost of services are often reported [5].

With mobile technologies, text messaging services are increasingly used to serve nontraditional health care service functions across different health concerns. For instance, texting services have been used as medical appointment reminders [6] and to help encourage patients to adhere to medication use [7]. There are approximately 400 mobile phone apps and service programs aimed at helping adults and pregnant women with smoking cessation and improving health beliefs and attitudes for new mothers (eg, Text2Quit, a text messaging program for smoking cessation, and Quit4Baby, a smoking cessation text messaging program for pregnant smokers, both developed and operated by Voxiva Inc) [8-11]. Similarly, Text4Mood and Text4Hope are examples of mobile texting services for mental health. Both programs aimed to help support individuals living with mood disorders and to provide mental health support to the public during the COVID-19 pandemic [2,12].

### Objectives

Text4Support is a service offered by Alberta Health Services, a health authority in the province of Alberta, Canada. This complementary service began in 2018 to support people living with different mental health conditions [13]. Psychiatrists, psychologists, and mental health therapists developed cognitive behavioral therapy (CBT)-based text messaging content. CBT focuses on helping individuals manage their concerns, primarily by targeting negative beliefs and coping behaviors [14].

The purpose of this initiative is to assess user satisfaction and better understand the subscribers' experience with Text4Support. The assessment of user satisfaction can lead to better client retention and clinical outcomes [15]. A recent study reported that a 7.2% reduction in the frequency of reporting *at least good overall satisfaction* was associated with a 1% increase in hospital bed occupancy [15]. Similarly, texting and web-based services are widely accepted by individuals who perceive these services as supportive and acceptable [1,16]. Overall, examining patients' expectations and experiences can help allocate resources, and positive expectations are highly linked to the patient's clinical outcome [17,18].

A recent evaluation of Text4Support indicates that the program is effective and accepted by individuals seeking access to outpatient mental health services in the Edmonton Zone. A large

proportion of these subscribers reported always or often reading of the messages (25/26, 96%), and after receiving the service for 6 months, the majority agreed that the text messages (TxMs) were to the point (18/24, 75%), supportive (22/24, 92%), and positive (22/24, 92%) [19]. In a similar study, the authors reported higher satisfaction with the texting service among female participants, who reported an improvement in coping with different stresses related to the COVID-19 pandemic along with an improvement in their quality of life, compared with their male counterparts [3]. In addition, the literature reported high satisfaction related to different mental health conditions, such as psychotic disorder and depression [1,3,19]. However, the results based on sex at birth or diagnosis were not significant for any of the assessed items. There is also a dearth of research focusing on satisfaction and acceptability among patients based on their diagnosis and in a comparative fashion. This study examines such differences and aims to provide an additional layer of evidence to the field.

This study focuses on the experience of inpatients who are enrolled in Text4Support after their discharge from the mental health units in Edmonton, Alberta. Subscribers are patients with different mental health disorders who received daily TxMs for 6 months.

## Methods

### Research Goals

Research goals included the following: (1) to explore and evaluate the experiences of patients who had been recently discharged from acute care mental health units regarding the supportive TxM service (Text4Support), from which they received daily messages for a 6-month period, and (2) to explore any differences in satisfaction based on sex at birth or the primary diagnosis of subscribers.

### Study Design

This was a mixed methods study (qualitative and quantitative) with data gathered using patients' key informant interviews and a web-based survey. Quantitative and qualitative methods were guided by the Checklist for Reporting of Survey Studies [20] and the consolidated criteria for reporting qualitative research [21], respectively.

### Setting and Study Participants

Data were collected from the subscribers who joined the Text4Support program as part of a controlled observational clinical trial [13]; subscribers received daily supportive TxMs for 6 weeks on their registered mobile phone numbers. The detailed recruitment process is described elsewhere [22] and is briefly highlighted here.

The study was conducted at 5 acute psychiatric care units in Edmonton, Alberta, Canada. Patients were invited to participate in the study from June 2019 to February 2020 before their hospital discharge. The selection criteria for the program were as follows: patients who were hospitalized and imminent to be discharged; patients aged 18-65 years; patients who had a mental health condition other than substance use disorder (eg, mood or psychotic disorder); patients who were able to provide written



consent; and patients who had a mobile phone capable of receiving TxMs.

The research team applied a random allocation thereafter to assign the patients to four study arms: (1) peer support worker (PSW) only, (2) TxM only, (3) PSW plus TxM condition, and (4) treatment as usual.

For the purpose of this study, we focused on the 2 study arms who received TxM services (TxM only and PSW plus TxM). The patients received daily TxMs for 6 months, and we examined the midpoint experience after 6 weeks of receiving the TxM service.

### Text4Support Background and Data Collection

Text4Support is a texting mental health service conceived and designed by a group of psychiatrists, psychologists, and mental health therapists based on the concepts of CBT [23]:

- A bank of messages was generated and included eight different streams of messages tailored for the following mental health conditions: depression, anxiety, psychotic disorders, bipolar disorder, general well-being, anxiety, substance use, personality disorder, and adjustment disorder. About 80% (144/180) of the messages shared a similar content, and 20% (36/180) of the messages were mental health condition-specific.
- The consenting participants provided the research team with their mobile phone numbers. This number was added to a texting delivery platform so that clients received daily messages that catered to their primary mental health concern.
- Patients received automated messages with content aligned with their current areas of diagnosis or concern every day at noon (MST) for 6 months.
- A midpoint web-based satisfaction survey was sent to patients 6 weeks after enrollment in the service.

### Examples of the Messages

Following are examples of general supportive messages:

*Think of your recovery as an opportunity to find new solutions in your life.*

*Remember that the past is gone and what you do is what really matters for depression.*

Following are examples of messages sent for depression:

*Monitor your mood from on scale from 1-10 with 1 being lowest and 10 highest. Make a note of activities that improve your mood.*

*When you notice a change in your mood, ask yourself what went through your mind. Did you notice a thought or an image?*

Following are examples of messages sent for anxiety:

*When you notice an increase in anxiety, pay attention to what triggered it - an interaction, a situation, a memory, a thought, etc.*

*Make a list of what you're avoiding. Rate how anxious each thing makes you. Do what makes you least anxious and work your way up.*

### Quantitative Data

The (midpoint) satisfaction survey included an adopted version of the Text4Mood user satisfaction survey [2]. The survey took 5-10 minutes to complete, and receiving supportive TxMs was not contingent on survey completion.

The survey questions were formulated based on the objectives of the study and available evidence from peer-reviewed literature [2]. The survey consisted of predominately Likert scale responses that evaluated sociodemographic and clinical characteristics, subscribers' responses to and perceptions of the supportive TxMs, and the impact of the program on subscribers' mental well-being. Data were collected between August 2019 and February 2020. The instrument was not validated but was adopted from surveys used in previous text messaging programs [2,3,19]. Participants entered their mobile phone numbers as their unique study ID number, which prevented multiple participation in the study.

### Qualitative Data

Of the 15 randomly selected participants who belonged to the text messaging group and contacted via TxMs, 7 (47%) accepted to participate in a key informant interview via telephone (Table 1). The interviews lasted between 30 and 45 minutes and were conducted by EE with experience in qualitative research. The interviews were recorded and subsequently transcribed verbatim. The interview questions (Multimedia Appendix 1) explored expectations, experiences, anticipated receptivity, and the impact of the daily supportive TxMs received for 6 months from the perspective of the patients who were recently discharged from acute care mental health units in hospitals in Edmonton, Alberta, Canada. Data were collected between August 2020 and October 2020.

**Table 1.** Demographic and clinical characteristics of the respondents to the qualitative assessment.

Participant	Age (years)	Sex	Mental health condition or diagnoses
P1	37	Female	Depression and anxiety disorder
P2	57	Female	Depression and anxiety disorder
P3	62	Female	Bipolar disorder
P4	42	Female	Depression and anxiety disorder
P5	57	Male	Bipolar disorder
P6	47	Female	Bipolar disorder
P7	52	Male	Depression and anxiety disorder

## Data Analysis

### Quantitative Data

Data were analyzed using SPSS Statistics for Windows (version 26; IBM Corporation) [24]. The demographic characteristics were summarized as raw numbers and percentages. Likert scale satisfaction responses to various aspects of the Text4Support service were summarized as frequency counts of response categories and percentages.

We were interested in studying the feedback and satisfaction of the different participant groups. Thus, we examined each of the 25 questions in the satisfaction survey against participants' sex at birth and admitting diagnosis using chi-square analysis and Fisher exact test with a 2-tailed probability of significance,  $P \leq .05$ . There was no imputation for missing data, and the results were based on the completed survey responses.

### Qualitative Data

Participants' answers to the interview questions were transcribed and analyzed thematically using NVivo 12 (QSR International). Both inductive and deductive approaches were used in the analysis. First, structural coding was used to generate the initial codes in line with specific research questions. Thereafter, pattern coding, which allows the identification of explanatory or inferential codes, was applied to the initial codes to identify patterns or emerging themes and subthemes across the data set. Each individual theme and subtheme were further examined for *fit* against the collated extracts for each theme, subtheme, and the overall data set. The final sets of themes and subthemes

were reported alongside verbatim quotes. Owing to the nature of the patients' ill health, repeat interviews, feedback on transcripts, and analysis by participants were not sought to minimize the risk of psychological distress.

### Ethics Approval

The study was approved by the Health Ethics Research Board of the University of Alberta (reference number: Pro00078427) and received operational approval from Alberta Health Services, the regional health authority. Written informed consent was obtained from all the patients. The information sheet contains the details of the researchers and the study objectives. The study was registered with ClinicalTrials.gov (trial registration number: NCT03404882). In relation to the design change to a controlled observational study the amendments to the study protocol [13] are now reflected in a revised registered trial protocol for NCT0340488.

## Results

### Quantitative Data

Of the 89 patients allocated to the texting service, we received complete surveys from 36 (40%) participants.

Table 2 displays subscribers' demographic characteristics, indicating that most respondents (27/36, 75%) were women, aged between 50 and 65 years (10/36, 28%), White (32/36, 89%), reported completion of postsecondary education (27/36, 77%), were unemployed (15/36, 42%), and were divorced, separated, or widowed (14/36, 39%). Most respondents (22/36, 61%) had depression or anxiety.

**Table 2.** Demographic and clinical characteristics of study participants.

Characteristics	Values, n (%)
<b>Sex at birth (n=36)</b>	
Male	9 (25)
Female	27 (75)
<b>Age groups (years; n=36)</b>	
18-30	4 (11)
31-40	6 (17)
41-50	9 (25)
51-65	7 (19)
>65	10 (28)
<b>Ethnicity (n=36)</b>	
Indigenous	1 (3)
White	32 (89)
Asian	3 (8)
<b>Education level (n=35)</b>	
Less than high school	3 (9)
High school degree or equivalent	5 (14)
Above high school education	27 (77)
<b>Employment status (n=36)</b>	
Employed	13 (36)
Unemployed	15 (42)
Other	8 (22)
<b>Relationship (n=36)</b>	
Married, common law, or in a relationship	9 (25)
Single	13 (36)
Divorced, separated, or widowed	14 (39)
<b>Admitting diagnosis (n=36)</b>	
Depression or anxiety	22 (61)
Bipolar disorder	12 (33)
Psychotic disorder	2 (6)

**Table 3** illustrates the subscribers' opinions about the Text4Support messages after receiving 6 weeks of daily TxMs. The data indicate that most of the respondents always or mostly found the TxMs positive (34/36, 95%), affirmative (34/35, 97%), and clear (34/35, 97%). Similarly, 88% (30/34) of the respondents indicated that the messages were always or often relevant.

Most participants reported that they felt supported when receiving the TxMs (30/36, 83%), always read the messages (31/36, 86%), and always understood them (28/32, 88%). Generally, most participants were satisfied with the TxMs

(28/34, 82%) and indicated their preference to receive the TxMs once per day (21/34, 62%).

**Table 4** data show that slightly more than 3 in 4 respondents indicated that they either read and reflected on the TxMs or took positive or beneficial actions after reading the messages (26/34, 76%). No subscribers indicated that they read the messages and took a negative or harmful action. In addition, **Table 4** shows the subscribers' level of agreement regarding the benefits of Text4Support and the perceived impact of the messages after receiving daily messages for 6 weeks. The results indicate that 4 in 5 respondents (28/35, 80%) reported that the TxMs helped them feel connected to a support system.

**Table 3.** Participants' feedback about Text4Support after 6 weeks of intervention.

Feedback	Values, n (%)
<b>When you received the daily messages, how do they make you feel? (n=36)</b>	
Supported	30 (83)
Indifferent	4 (11)
Annoyed	2 (6)
<b>How often did you read the messages? (n=36)</b>	
Always	31 (86)
Mostly	4 (11)
Rarely	1 (3)
<b>How often did you understand the messages? (n=32)</b>	
Always	28 (87)
Mostly	4 (13)
Rarely	0 (0)
<b>Did you find the Text4Support messages to be positive? (n=36)</b>	
Always	19 (53)
Mostly	15 (42)
Sometimes	2 (5)
<b>Did you find the Text4Support messages to be supportive? (n=35)</b>	
Always	22 (63)
Mostly	12 (34)
Sometimes	1 (3)
<b>Did you find the Text4Support messages to be clear? (n=35)</b>	
Always	23 (66)
Mostly	11 (31)
Sometimes	1 (3)
<b>Did you find the Text4Support messages to be relevant? (n=34)</b>	
Always	12 (35)
Mostly	18 (53)
Sometimes	4 (13)
<b>How satisfied were you with the frequency of the text messages? (n=34)</b>	
Satisfied	28 (82)
Neither satisfied nor dissatisfied	5 (15)
Dissatisfied	1 (3)
<b>Ideally, how often would you prefer to receive supportive text messages? (n=34)</b>	
Once daily	21 (62)
Twice daily	9 (26)
Once every other day	1 (3)
Once weekly	3 (9)



**Table 4.** Perceived impact of receiving daily messages for 6 weeks.

Perceived impact of daily messages from Text4Support	Values, n (%)
<b>When you received the texts, what happened next? (n=34)</b>	
Read text and took a positive or beneficial action	8 (23)
Read text and reflected on the messages	18 (53)
Read the text and took no action	7 (21)
Read text and took a negative or harmful action	0 (0)
Did not read the text	1 (3)
<b>The daily messages from Text4Support helps me to cope with stress (n=35)</b>	
Agree	22 (63)
Neutral	10 (28)
Disagree	3 (9)
<b>The daily messages from Text4Support helps me to cope with loneliness (n=35)</b>	
Agree	23 (66)
Neutral	6 (17)
Disagree	6 (17)
<b>The daily messages from Text4Support helps me to manage suicidal thoughts (n=34)</b>	
Agree	12 (35)
Neutral	16 (47)
Disagree	6 (18)
<b>The daily messages from Text4Support helps me to monitor my mood (n=36)</b>	
Agree	21 (58)
Neutral	10 (28)
Disagree	5 (14)
<b>The daily messages from Text4Support helps me to remember my goals (n=35)</b>	
Agree	25 (71)
Neutral	6 (17)
Disagree	4 (11)
<b>The daily messages from Text4Support helps me feel connected to a support system (n=35)</b>	
Agree	28 (80)
Neutral	5 (14)
Disagree	2 (6)
<b>The daily messages from Text4Support helps me feel hopeful I can manage issues in my life (n=34)</b>	
Agree	22 (65)
Neutral	9 (26)
Disagree	3 (9)
<b>The daily messages from Text4Support helps me know where to get help for depression or anxiety (n=34)</b>	
Agree	16 (47)
Neutral	12 (35)
Disagree	6 (18)
<b>The daily messages from Text4Support helps me feel that I could be the one in charge of managing depression or anxiety (n=35)</b>	
Agree	18 (51)
Neutral	13 (37)
Disagree	4 (11)

Perceived impact of daily messages from Text4Support	Values, n (%)
<b>The daily messages from Text4Support helps me feel like I know how to stay on track when life or everyday stressors come up (n=35)</b>	
Agree	23 (66)
Neutral	7 (20)
Disagree	5 (14)
<b>The daily messages from Text4Support helps me feel like I am making a change (n=35)</b>	
Agree	25 (71)
Neutral	6 (17)
Disagree	4 (11)
<b>The daily messages from Text4Support help me feel like I can bounce back if I make a mistake (n=35)</b>	
Agree	20 (57)
Neutral	10 (28)
Disagree	5 (14)
<b>The daily messages from Text4Support help me make better choices (n=35)</b>	
Agree	23 (65)
Neutral	7 (20)
Disagree	5 (14)
<b>The daily messages from Text4Support help me improve my overall mental well-being (n=35)</b>	
Agree	24 (69)
Neutral	5 (14)
Disagree	6 (17)
<b>The daily messages from Text4Support help me enhance my quality of life (n=35)</b>	
Agree	22 (63)
Neutral	9 (26)
Disagree	4 (11)

About two-thirds of respondents agreed that the daily TxMs helped them cope with stress (22/35, 63%) and loneliness (23/35, 66%); remember their goals (25/35, 71%); feel hopeful that they could manage issues in their life (22/34, 65%); feel like they know how to stay on track when life or everyday stressors come up (23/35, 66%); feel like they are making a change (25/35, 71%) and are making better choices (23/35, 66%); improve their overall mental well-being (24/35, 69%); and enhance their quality of life (22/35, 63%).

Approximately half of the respondents agreed with the questions related to mood, such as the questions regarding daily texts helping respondents to monitor mood (21/36, 58%); know where to get help for depression or anxiety (16/34, 47%); and feel that they could be in charge of managing depression or anxiety (18/35, 51%).

A total of 57% (20/35) of respondents reported that the daily Text4Support messages helped them feel like they could bounce back upon making a mistake, and only 35% (12/34) of

respondents reported that the messages helped them to manage suicidal thoughts.

The results of the chi-square and Fisher exact tests did not show significant difference in reporting on any of the questions related to satisfaction with the Text4Support service based on the respondents' sex at birth or admitting diagnosis.

## Qualitative Data

### Overview

This aspect of the study was guided by the phenomenological methodological orientation. Thus, we explored how the study candidates make sense of experience with the Text4Support service and transform this experience into a worldview [25]. The study candidates were asked about their own experiences regarding the TxMs they received daily for 6 months. The outcome results were grouped into 2 main themes and 3 further subthemes (Figure 1).

**Figure 1.** Summative illustration of themes and subthemes.

### Patients' initial expectations

Neutral expectations

Interactive service

Positive impact



### Patients' experiences

Timing and frequency of the text messages

Message personalization

Usefulness of text messages

#### **Patients' Initial Expectations of the Program**

Before subscription to the Text4Support program, the expectations of the program differed among the study participants. Although some respondents expressed neutrality, not knowing what to expect or whether the program would have any impact on their mental health, others had a positive expectation of their experiences and the impact on their mental health:

*I didn't really know what kind of [supportive] messages they were going to send. [P1]*

*When I heard about [the Text4Support program], I thought, oh, that'll be good. [P4]*

One respondent commented that they had expected some form of interactive (2-way flow) component in the messaging program:

*Maybe it's something good because somebody is going to check in with you every day or whatever. [P4]*

#### **Patients' Experiences With the Program**

##### **Overview**

Patients reported varying experiences with the Text4Support program. Although the program was perceived positively, some respondents were unsure of the impact of the program on their mental health. The reported experiences are categorized into three subthemes as follows: timing and frequency of messages, message personalization, and usefulness of the messages.

##### **Timing and Frequency of the TxMs**

Generally, participants expressed satisfaction with the timing of the supportive TxMs, which were received daily at noon. For some employed respondents, this timing aligned with their *lunch break* and was perceived as a good opportunity to read and reflect upon the messages:

*Well, because [the messages] were [sent] at noon. That was good because you're usually on lunch break or starting your lunch break, so you don't get interrupted at work. [P6]*

The frequency of messages was satisfactory for the patients. The regular and consistent nature of the messages seemed to

have improved the perception and impact of the program on the mental health of the patients:

*I think that daily message was fine. I think any more would be overwhelming. [P1]*

*In the beginning [the supportive messages] seemed kind of boilerplate, like it wasn't really something that I could specifically use in my life, [but] as [the program] went on and I got these almost daily messages of techniques and kind of messages of support, I found it very comforting. [P5]*

##### **Message Personalization**

Patients expressed their experiences and concerns regarding the personalization of supportive TxMs. Although some patients reported that some of the messages were personally applicable to them, some patients expressed their desire for a more tailored or even interactive program such that it would speak specifically to the patients' mental health condition or to their particular needs. An interactive program, from the patients' perspective, would involve or simulate *real* persons communicating back and forth with them:

*Some of them [text messages] were very detailed and yes, they applied to me. [P2]*

*They were very generic and very short and very like non-personal. Um, so that part I thought was useless...if you could have a real person doing it, I know they don't have all day to sit and text you back and forth, but if you had the option to respond, like say they texted, something that was meaningful to your experience or your situation, and then you could interact. [P4]*

##### **Usefulness of TxMs**

Patients were very positive about the usefulness and impact of the TxMs on their mental health, and 1 patient commented that using text messaging as a medium was advantageous because they could refer and reflect back on the past TxMs stored on their mobile phones:

*If I was having like a day where my anxiety was worse, sometimes the message would be—give me a chance to sit and have time to reflect and be present*

*in that. Um, it also just gave me a chance to think outside of my perception of what I'm experiencing and that too. [P1]*

*Some of [the messages] lifted your spirits or give you direction. They were positive. [P6]*

Not all patients thought that the messages were helpful. Some commented that the program did not meet their initial expectations. This resulted from the generalized format of some messages. Some believed that more tailored and personalized messages would have been more effective:

*I think it varies amongst people and their diagnosis [for which] the messages were being sent. Some were maybe applicable to me, some..., maybe not. So, and this also depends on the perception of the person receiving it. [P1]*

*I was expecting something different other than, well, I got all the text messages, motivational text messages, but I don't know. I don't know if it helped me or not. [P6]*

## Discussion

### Principal Findings

This study sought to understand the experiences of recently discharged acute care patients with mental health concerns and selected to be Text4Support subscribers. The two key goals were as follows: (1) to examine the general experience of Text4Support subscribers and (2) to explore the satisfaction differences based on sex at birth and admitting diagnoses.

The principal findings of the study were that Text4Support was well-perceived; there was a high satisfaction with the messages and the perceived impact of the messages. However, sex at birth and primary diagnosis did not significantly affect satisfaction. Most of the respondents identified as women, had a high education level, were unemployed, were separated or divorced, and were of White ethnicity. These demographic characteristics are common among research respondents who willingly provide feedback to web-based services, including texting messages [2,3,19].

Similar to previous literature, Text4Support had high satisfaction [2,19]. Most subscribers were satisfied and agreed that messages were positive, affirmative, clear, and relevant. In addition, subscribers felt that the messages helped them cope with stress, feel connected to a support system, remember goals, feel hopeful managing life issues, stay on track when life or everyday stressors came up, feel like changes were being made, and make better choices. Subscribers also reported improved mental well-being and enhanced quality of life. In the same context, a systematic review of clinical outcomes from mobile phone and web-based text messaging interventions reported that texting services are praised and well-perceived in the mental health field, adding that texting services have successfully expanded to provide support to diverse psychiatric disorders and during times of crisis [19,26].

This study differs from previous Text4Support papers [19]. The study population included psychiatric patients who were recently

discharged from the hospital, whereas previous studies examined individuals who were accessing outpatient services and had a lower severity of mental health concerns.

The period between hospital discharge and the first meeting with a health care provider is perceived as critical and detrimental, and the lack of routine postdischarge follow-up care can lead to early readmission and frequent emergency visits [27-29]. Providing help after discharge through supplementary services, such as supportive TxMs, may help to keep these patients connected with the health care system, especially when the patients are satisfied with the service, and further prevent undesired outcomes. In general, the satisfaction results were consistent with the literature, whereby most texting services reported high satisfaction, a better sense of life control, improved physical health, and increased productivity [30,31], and seemingly regardless of the setting or the type of patient.

Our findings indicate that approximately half of the respondents agreed that daily texts helped them monitor their mood, determine where to get help for depression or anxiety, and feel that they could be in charge of managing their depression or anxiety. This is a lower proportion than that reported by Agyapong et al [2] from subscribers of the Text4Hope program. A lower number of people (compared with Text4Hope subscribers) agreed that texts helped in (1) monitoring mood, (2) determining where to get help, and (3) feeling in charge of managing depression or anxiety. This may be explained by the different type of service provided; although Text4Support was supposed to cater to specific types of mental health concerns (thus their population is more complex and has a mental health concern), Text4Hope was a supportive mental health service provided at a time of crisis (COVID-19 pandemic), and the subscribers were members of the general population. In addition, the COVID-19 pandemic hit at the time of our data collection. This may have imposed excessive psychological burdens, such as stress, anxiety, depression, sleep disorder, and posttraumatic stress disorder symptoms, particularly among those who have underlying mental health conditions [32-34].

One-third of clients self-reported that Text4Support helped them manage suicidal thoughts. In France, a randomized controlled trial using suicide intervention assisted by messages, a supportive text messaging service, was designed to provide communication and support for people contemplating suicide [35]. Initial study results revealed that the intervention was promising as it could maintain communication with patients following discharge from the emergency department, encourage them to contact health care services during crises, and ultimately prevent repeated suicide attempts. This may reflect a critical role of texting services such as Text4Support in providing positive guidance to subscribers during such times of vulnerability. Further research may identify the types of patients who could most benefit from such services during times of crisis.

Regarding the results of the secondary outcome, the relationship of satisfaction with sex at birth or with the primary diagnosis of the participants was not significant. According to the literature, satisfaction based on respondents' sex at birth or gender usually produces mixed results, although women are



more inclined to report to such surveys with positive satisfaction, other research has indicated that men also report high rates of satisfaction [32]. In the same context, patients with different mental health conditions, such as psychotic disorder, depression, anxiety, and comorbid alcohol use, often report high satisfaction with mobile mental health services that make them feel in charge of managing their own mental health symptoms [1,19,31]. These findings may need to be replicated on a larger sample size and at successive time-points to better understand and capture differences based on sex at birth and admitting diagnosis and to track any possible changes that evolve over time.

### Patients' Expectations Versus Experience

Our results suggest that the initial patients' expectations were either neutral or positive in relation to the expected nature or the impact of the incoming TxMs on their overall mental health. In addition, the subscribers were satisfied with the frequency of the messages that were provided once daily for 6 consecutive months. Subscribers also recommended and hoped for more personalized messages or mutual interactions with health care personnel. Future services should consider including ways in which clients can personalize their TxMs. The medium of TxMs was perceived as helpful because patients could revisit messages anytime, as they were stored on their mobile phones.

The literature indicates that the majority of patients often expect clinical improvement after a health care intervention, regardless of the service they receive, whereas very few may expect no change or even declining health [18]. It was also reported that patients usually build their expectations in relation to the cost and design or customization of mental health apps, and to a lesser extent put emphasis on the transparency of these apps [36]. Text4Support was a free service for the end users; this may have made it more appealing to complement existing health care services with Text4Support, as combined services are usually preferred by patients in the mental health field [18,19].

Subscribers were satisfied with the frequency of receiving one TxM per day; similar results were obtained from the Text4Mood service [2]. According to one of our subscribers, receiving more frequent messages may be *overwhelming*; however, around 26% (9/34) of participants reported that they preferred the messages to be received twice daily. This discrepancy may highlight the need for more individualized services that can address the patient's preferences in the services received. In addition, our participants also expressed their satisfaction with receiving the messages at noon, as it aligned with their lunch breaks and provide them with some time to read and reflect on the messages.

Some study participants mentioned that having the TxMs saved on their mobile phones helped enhance and secure the sense of being able to return to the messages anytime. In addition, many liked that they could forward the messages to a friend who may benefit from the service. This finding is in line with those of a similar texting service that found that over 60% of subscribers reported that they returned to the messages at least sometimes [3].

Study subscribers emphasized the importance of individualizing and tailoring TxMs. Furthermore, clients recommended the

service to be more interactive, which may be more engaging and supportive. It is usually declared that synchronous programs, where a therapist is involved, can achieve better clinical outcomes and satisfaction among the subscribers [37]. However, these services incur extra costs to the health care system (eg, hiring a clinician or a therapist). Furthermore, therapists may not be available or accessible to support such services; thus, cost-benefit analysis is usually approached under such circumstances. Other options were also available, such as the use of trained volunteers or conversational artificial intelligence systems. A recent study applied a 2-way interactive texting service for patients with chronic medical conditions and their families [38]. Using a design thinking approach, the authors developed a hybrid texting app that allowed the computer to convey bulk messages to the patients, and the health care workers could address them and reply with tailored answers either immediately or within 2 days, according to the urgency.

Generally, asynchronous web-based and text-based services have been accepted by an increasing number of individuals who usually report high satisfaction, ease of use, and better control over life activities (85%), whereas >90% of individuals report increased life productivity after receiving messages from these services [31,39]. In addition, telephone services are frequently associated with a lower attrition rate, compared with face-to-face services, which is likely because of the higher accessibility and lack of geographical barriers [40]. This is also important for those who are hesitant to seek medical attention and may be encouraged to join web-based services [40]. These telephone services could help keep these patients in contact with the health care system.

This study has a number of limitations. First, the small sample size may skew the results and may warrant a larger study that evaluates the service among a larger cohort. In addition, the small sample size means that the study was underpowered, which might affect our ability to detect any differences in satisfaction based on biological sex and primary diagnosis. Second, the messages were partially tailored to the primary diagnosis of the patients; this ratio may need to be increased in future services to fully meet the patients' requests for TxMs that are personalized to their condition. Third, the results were obtained from 2 different patient groups—those who received TxM alone and those who received TxM in adjunction with PSW; therefore, although it is not highly expected, the PSW may have affected the satisfaction level with the TxM as an outcome of the study. Fourth, we did not compare the quantitative responses with the qualitative responses among the respondents. Finally, although the questionnaire used in the study was designed based on the relevant literature, it was not a validated instrument.

Overall, satisfaction with texting mental health services is well-accepted because texting is convenient, inexpensive, and remotely delivered [3]. According to a systematic review of 27 studies that used mobile phone apps and text messaging, the authors reported that the usability and feasibility along with satisfaction with mobile health services are highly rated by their users [41]. In accordance with this finding, we conclude that Text4Support was well-perceived by the patients who had received the service for 6 months after their discharge from the

acute care units. The patients recommended some modifications to the service, including further personalization and interactive services, which may be considered in the design of similar future services.

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## Authors' Contributions

VIOA conceived and designed the study, including Text4Support. RS and EE performed data analysis. RS and WV participated in data collection. All authors participated in the study design, reviewing and editing the initial draft of the manuscript, and approval of the final draft of the manuscript before submission.

## Conflicts of Interest

None declared.

## Multimedia Appendix 1

Key informant telephone interview questions for patients about Text4Support experience.

[[DOCX File, 15 KB - formative\\_v6i1e33438\\_app1.docx](#)]

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## Abbreviations

**CBT:** cognitive behavioral therapy  
**PSW:** peer support worker  
**TxM:** text message

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Original Paper

# Using Facebook Advertisements for Women's Health Research: Methodology and Outcomes of an Observational Study

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## Abstract

**Background:** Recruitment of diverse populations for health research studies remains a challenge. The COVID-19 pandemic has exacerbated these challenges by limiting in-person recruitment efforts and placing additional demands on potential participants. Social media, through the use of Facebook advertisements, has the potential to address recruitment challenges. However, existing reports are inconsistent with regard to the success of this strategy. Additionally, limited information is available about processes that can be used to increase the diversity of study participants.

**Objective:** A Qualtrics survey was fielded to ascertain women's knowledge of and health care experiences related to breast density. This paper describes the process of using Facebook advertisements for recruitment and the effectiveness of various advertisement strategies.

**Methods:** Facebook advertisements were placed in 2 rounds between June and July 2020. During round 1, multiple combinations of headlines and interest terms were tested to determine the most cost-effective advertisement. The best performing advertisement was used in round 2 in combination with various strategies to enhance the diversity of the survey sample. Advertisement performance, cost, and survey respondent data were collected and examined.

**Results:** In round 1, a total of 45 advertisements with 5 different headlines were placed, and the average cost per link click for each headline ranged from US \$0.12 to US \$0.79. Of the 164 women recruited in round 1, in total 91.62% were eligible to complete the survey. Advertisements used during recruitment in round 2 resulted in an average cost per link click of US \$0.11. During the second round, 478 women attempted the survey, and 87.44% were eligible to participate. The majority of survey respondents were White (80.41%), over the age of 55 years (63.94%), and highly educated (63.71%).

**Conclusions:** Facebook advertisements can be used to recruit respondents for health research quickly, but this strategy may yield participants who are less racially diverse, more educated, and older than the general population. Researchers should consider recruiting participants through other methods in addition to creating Facebook advertisements targeting underrepresented populations.

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**KEYWORDS**

social media; surveys; questionnaires; advertising; patient selection; methodology; ethnic groups; health research; healthcare; health care; women's health

## Introduction

To improve health outcomes, researchers must engage in effective recruitment efforts to solicit large data pools of diverse populations for study participation [1]. However, an array of challenges has been noted in the literature, which may hinder these attempts. Specific facets of a study that may impact recruitment include study methodology, recruiter traits, insufficient respondent interest, and recruitment funding [2]. When attempting to attract vulnerable groups (ie, ethnic or racial minorities, those of low socioeconomic status, and residents of rural areas), recruitment has proven even more difficult owing to barriers such as respondent time constraints, reduced levels of health literacy, medical mistrust, and structural factors [3-6].

Consequently, during the COVID-19 pandemic, barriers and challenges of recruitment have expanded [7]. Namely, research activities have been halted or been modified from in-person studies to limit viral transmission, thus reducing participants' interest in or capacity to continue their research engagement [7]. Moreover, financial recessions lead to heightened job loss and subsequent economic deprivation [8]. Therefore, we can assume that in uncertain times, individuals are inclined to focus on tasks that strengthen their day-to-day livelihood rather than health research participation.

Accordingly, the utilization of social media sites for health research data collection may lessen these obstacles. Generally, sites such as Facebook include daily users from various racial and ethnic backgrounds, levels of education and annual income, and geographic locations [9]. This approach also offers increased respondent convenience and volume completion with minimal staffing contribution [10]. In addition, the data collection modality allows participants to remain anonymous and maintain privacy throughout the process, which reduces their potential anxiety of direct research team interaction [11].

While reports of health research recruitment via social media have grown in recent years, the results of these efforts have been inconsistent [9,12]. Furthermore, social media has been used most often to recruit young adult populations for studies of substance abuse or sexual behavior. Less is known about how paid advertisements can be used to recruit participants for studies of specific health conditions such as breast health [9,12,13]. A study by Kapp et al [14] attempted to reach women aged 35-49 years from across the United States to complete a survey about breast cancer screening and was unable to recruit a single participant despite spending US \$300 to field 3 advertisements over a 3-week period [14]. It seems reasonable that the effectiveness of using social media for research recruitment may be influenced by the characteristics of the study

as well as the advertisement options used. As such, our study objectives were to describe the processes and evaluate the outcomes resulting from using Facebook advertisements to recruit a diverse sample of respondents to participate in a breast health study.

## Methods

### Eligibility

Participants were recruited to complete a Qualtrics survey about women's knowledge of and communication with their mammography provider about breast density. Women, aged 40 years and older, who had not been diagnosed with cancer were eligible to participate. The survey tools consisted of 30 questions, and participants were not compensated. This study was approved by the University and Medical Center IRB at East Carolina University. Recruitment took place from June to July 2020.

### Advertisement Design

Advertisements were purchased with US dollars and posted on Facebook and Instagram (Figure 1). The first round of advertisements ran from June 24 to July 1, 2020, and consisted of 45 individual advertisements. Each advertisement was assigned an identification number based on the combination of headings A-E and interest term groupings 1-9 used in this study (Table 1).

The headlines included phrases describing the eligibility criteria or survey topic. Interest terms allow researchers to find their target audience on the basis of the interests selected on the individual's profile and other Facebook pages. Interest terms used during round 1 included topics such as health, cancer, and family. Round 1 included 5 different sets of advertisements; each set of advertisements used a different headline and interchanged the same 9 combinations of interest terms (Table 1).

The second round of advertisements ran from July 9 to July 16, 2020, and consisted of 10 individual advertisements. All round 2 advertisements used the same headline and interest terms found to be most impactful from among those in the first round of advertisements. In round 2, we focused on increasing the recruitment of ethnic and racial minorities to enhance the diversity of our sample. New interest terms related to ethnicity and behavioral targets were included in round 2. Behavioral targeting is based on a person's activity on Facebook, including their purchase habits, travel activities, and internet browser usage. The behaviors selected for this advertisement set included multicultural affinities including African American and Asian American (Table 2).

**Figure 1.** Sample advertisement.

This is a voluntary survey for women residing in the US. In order to participate, you must have internet access and never been diagnosed with cancer.



**Breast Density Survey**

ECU  
HEALTH EDUCATION AND PROMOTION

ECU.AZ1.QUALTRICS.COM

**Breast Density Survey**

Learn More

4 1 Share

Like Comment Share

**Table 1.** Headlines, interest terms, and advertisement IDs used in round 1.

Interest terms	Advertisement ID				
	Breast Density Survey	Voluntary For Women +40	Breast Density Awareness	Breast Density Knowledge	Women's Health Research Survey
None	A1	B1	C1	D1	E1
Health	A2	B2	C2	D2	E2
Family	A3	B3	C3	D3	E3
Fitness and wellness	A4	B4	C4	D4	E4
Cancer awareness	A5	B5	C5	D5	E5
Women's health	A6	B6	C6	D6	E6
Fitness and wellness, women's health	A7	B7	C7	D7	E7
Health and beauty	A8	B8	C8	D8	E8
Fitness and wellness, family, health, cancer awareness, women's health, and health and beauty	A9	B9	C9	D9	E9



**Table 2.** Interest terms, behavior terms, and advertisement IDs used in round 2.

Interest terms	Behavior terms	Advertisement ID
N/A <sup>a</sup>	N/A	AA1
N/A	Multicultural affinity: African American and Asian American	AA2
African American culture, African American history, Latino culture, Native American culture, Native American culture in the United States, and Asian American culture	N/A	AA3
African American culture, African American history, Latino culture, Native American culture, Native American culture in the United States, and Asian American culture	Multicultural affinity: African American and Asian American	AA4
Family, African American culture, African American history, Latino culture, Native American culture, Native American culture in the United States, and Asian American culture	N/A	AA5
Family, African American culture, African American history, Latino culture, Native American culture, Native American culture in the United States, and Asian American culture	Multicultural affinity: African American and Asian American	AA6
Cancer awareness, African American culture, African American history, Latino culture, Native American culture, Native American culture in the United States, and Asian American culture	N/A	AA7
Cancer awareness, African American culture, African American history, Latino culture, Native American culture, Native American culture in the United States, and Asian American culture	Multicultural affinity: African American and Asian American	AA8
Fitness & wellness, African American culture, African American history, Latino culture, Native American culture, Native American culture in the United States, Asian American culture	N/A	AA9

<sup>a</sup>N/A: not applicable.

## Evaluation Metrics

Facebook advertising metrics, such as unique link clicks and cost per link click, were reviewed after each round. Unique link clicks measure how many people clicked on a link using a sampled portion of the data. Cost per link click measures the amount spent per link click [15]. These variables were analyzed to determine which advertisements were the most effective in terms of survey participants and cost per advertisement. All cost data is presented using US currency.

To optimize the budget for round 1 and our goal of generating cost-effective advertisements for round 2, we selected the lowest cost bid strategy. Many advertisements are often competing for the same individuals as they are members of multiple audiences [16]. Facebook uses auctions to determine which advertisement to show to a given user [16]. All advertisements that share target audiences must bid in an auction to be shown to a specific user. Facebook's bid strategy allows advertisements to have the highest reach based on the goals and the budget set for the advertisements [17]. The lowest cost is a bid strategy that allows advertisement placement to be maximized by using the advertising budget to obtain maximum results or placements [18].

The second round of advertisements used cost cap as the bid strategy. Cost cap allows Facebook to determine how high or how low to bid to maximize the results of the advertisement without exceeding the stipulated cost cap [19]. The cost cap was \$1 for round 1 and \$4 for round 2. The daily budget limit for our first round of ads was \$1 per day and \$4 per day for round 2. This meant that Facebook could not spend more than that daily budget limit for each advertisement on a single day. Reach is the number of unique accounts that viewed an advertisement [20]. Overall and age group-stratified reach statistics were reviewed for each advertisement. Placement reach was also analyzed for advertisements posted on both Facebook and Instagram.

## Results

### Advertisement Performance

Despite advertisements being posted on Instagram, virtually all of the participants across both rounds were recruited through Facebook, with 97.4% of link clicks coming from Facebook. Costs statistics for both rounds are displayed in Figure 2.

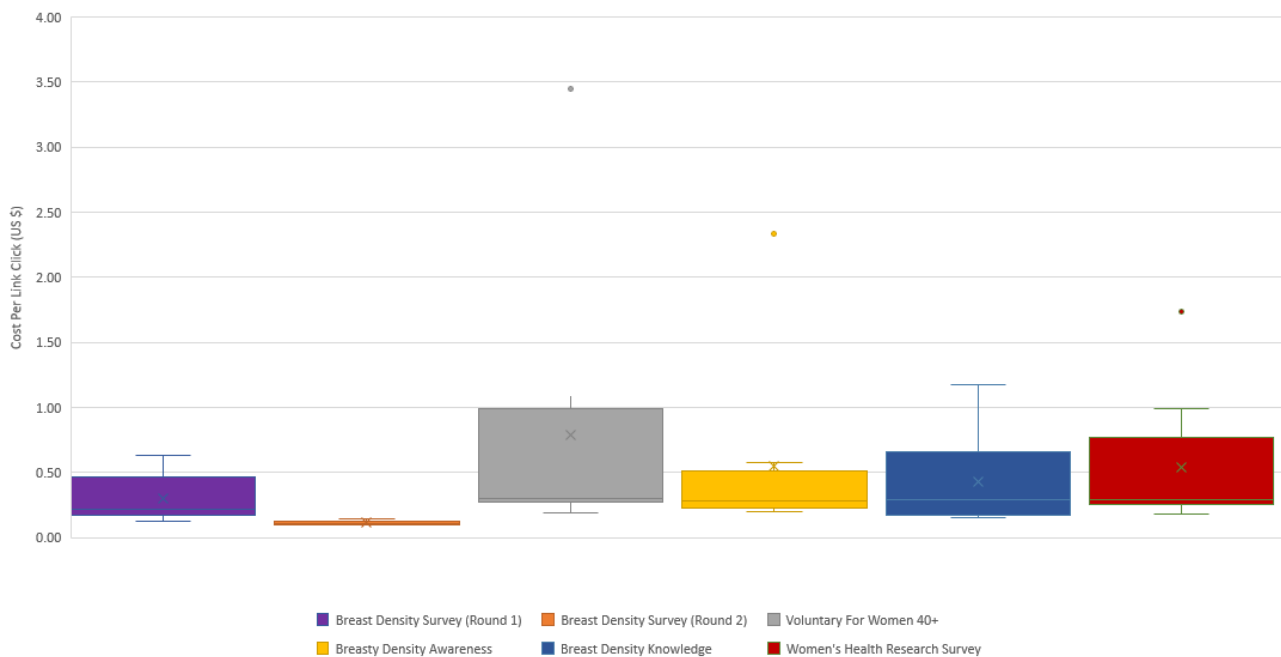
For round 1, the headline *Breast Density Survey* had the highest number of link clicks (n=148), and the headline *Voluntary For*

Women 40+ had the fewest link clicks (n=74). The best-performing advertisement in this round was A7, which had the *Breast Density Survey* headline. Advertisement A7 generated 28 unique link clicks at \$0.12 per link click. *Breast Density Survey* was the best-performing headline in round 1, with an average cost per link click of \$0.30. The worst-performing headline for round 1 was *Voluntary for Women 40+*. This headline had the lowest average unique link click (8) and the most expensive average cost per link click (US \$0.79). Additionally, advertisement B7, which combined this headline

and all of the interest terms, resulted in 2 unique link clicks at \$3.45 per link.

The best-performing headline from round 1, *Breast Density Survey*, was used for all round 2 advertisements. The total average unique link clicks in round 2 was 108, and the average cost per link click was \$0.11. Advertisements AA7 and AA9, which did not contain behavioral terms, generated the highest number of link clicks in round 2 (n=124). However, with one exception, the advertisements which contained behavioral terms AA4, AA6, and AA8 were the most cost-effective at \$0.10 per unique link click.

**Figure 2.** Facebook Recruitment Cost Statistics.



## Respondent Demographics

In round 1, a total of 179 people clicked on the Qualtrics survey link, of whom 164 (91.62%) were eligible to complete the survey (Table 3).

The majority of women recruited were in the age range of 55–64 years or 65 years and older, with each group accounting for 34.33% of respondents. In total, 78% of respondents were White and almost two-thirds (57.43%) had a college or graduate degree. In round 2, a total of 478 people clicked on the survey link, and 418 (87.45%) participants were eligible to complete the survey. The largest group of women recruited were in the 55–64-year age range, representing 36.72% of the participants, and were White, accounting for 81.34% of participants. Over

two-thirds (66.21%) of the women recruited during this round had a college education or more.

Across both rounds, we reached 50,017 unique accounts, 1693 link clicks were generated, 657 people accessed the survey, and 582 women were eligible to complete the entire survey. This resulted in a study conversion rate of 3.38%. The conversion rate (defined as the number of link clicks divided by the number of individuals reached, multiplied by 100) is another measurement of advertisement effectiveness. The survey's participation rate (the number of participants starting the survey divided by reach) was 1.31%, and the eligibility rate was 88.58%. Over half of the eligible respondents were over the age of 55 years (63.94%), and the majority identified as White (80.41%) and had a college degree or higher (63.71%).

**Table 3.** Survey access and eligibility statistics.

Headlines	Survey link clicks by women aged 40-44 years, n (%)	Survey link clicks by women aged 45-54 years, n (%)	Survey link clicks by women aged 55-64 years, n (%)	Survey link clicks by women aged 65 years and older, n (%)	Total link clicks, n (%)	Qualtrics survey accessed, n	Total eligible individuals, n (%)
<b>Round 1</b>						179	164 (91.62)
Breast Density Survey	9 (8.27)	27 (18.35)	55 (34.11)	57 (39.27)	148 (100)		
Voluntary For Women 40+	5 (4.90)	13 (16.50)	28 (41.19)	28 (37.41)	74 (100)		
Breast Density Awareness	4 (4.24)	22 (22.86)	34 (29.33)	50 (43.57)	110 (100)		
Breast Density Knowledge	5 (2.99)	19 (13.64)	38 (32.11)	62 (51.26)	124 (100)		
Women's Health Research Survey	10 (7.21)	19 (18.68)	29 (27.71)	49 (46.40)	107 (100)		
<b>Round 2</b>						478	418 (87.45)
Breast Density Survey	91 (7.96)	273 (24.34)	437 (38.85)	329 (28.86)	1130 (100)		

## Discussion

### Summary of Results

Given the variety of existing social media platforms, we sought to understand how Facebook advertisements could be leveraged to recruit respondents for a survey on breast health. We found Facebook advertisements to be an efficient and effective recruitment tool. Two rounds of Facebook advertisements were fielded over 2 weeks to determine what combinations of advertisements would be the most cost-effective and yield a diverse survey sample. By the final round, we were able to produce advertisements that averaged \$0.11 per link click, a conversation rate of 3.38%, and had a study eligibility rate of 88.58%. We found that advertisements using study-specific headlines (ie, *Breast Density Survey*) and health-related interest terms were most successful.

### Comparison With Other Studies Involving Social Media Recruitment

Our advertisements performed better than those in the majority of studies included in Whitaker et al's [9] systematic review that evaluated the performance of Facebook advertisements used to recruit participants for health research. Our final cost per link click value was \$0.11, compared to an average of \$0.51 per link click across included studies [9]. Additionally, our advertisements ran for a shorter period of time and reached fewer devices but resulted in higher eligibility rates and lower recruitment costs per eligible participant than the averages reported by Whitaker et al [9] and other recent studies [13]. Additionally, the studies included in Whitaker et al's [9] review focused health issues such as drug use, sexual health, and pregnancy in young adult populations. Ours is one of the few studies evaluating the use of Facebook advertisements to recruit middle-aged and older adults for health research [9].

Kapp et al [14] is one of the few accounts describing the use of Facebook advertisements to recruit middle-aged women to assess breast cancer screening beliefs. This study did not recruit any participants through Facebook despite fielding advertisements for a similar number of weeks. However, there are notable differences between both studies. Our study was

conducted in 2020, while Kapp et al [14] recruited during 2012, during which time social media usage has grown. In total, 53% of adults reported using any type of social media platform in 2012 compared to 72% in 2020 [21]. In the same time frame, Facebook usage has increased the most for middle-aged and older adults in the United States, leading to a larger eligible population [22,23]. Kapp et al [14] did not provide information about advertisement characteristics such as the use of interest terms, behavioral targets, or bid strategies. These options were likely not available at the time of the study and are missing from many recent descriptions of social media recruitment [9,12].

Another important consideration is the timing of the data collection. We placed our advertisements during the summer of 2020, a time when a larger percentage of the public stayed home as a result of the COVID-19 pandemic, which may have led to more favorable outcomes. Ali et al [24] used Facebook advertisements to survey adults in the United States about COVID-19 beliefs and behaviors. Ali et al [24] fielded their survey between March 20 and March 30, 2020, at a time when most of the population were subject to stay-at-home orders. Due to both a more expansive target population of all adults and the timing of the advertisements, Ali et al [24] generated a wider reach than our study (ie, 236,017 vs 50,017). However, our outcomes of cost per link click (\$0.09 vs \$0.11), conversation (4.1% vs 3.88%), and eligibility rates (99.4% vs 88.58%) were comparable. These data suggest that the increase in internet activity continued through the summer months despite many locations loosening COVID-19-related restrictions and warmer weather, allowing people to spend more time outdoors. According to the Pew Research Center, Facebook usage in early 2021 remains at 2020 levels [25]. If these trends persist, Facebook advertisements may be an increasingly important and cost-effective way to recruit research participants, but this option is not without its challenges.

Despite the higher percentage of Black and Latinx populations reporting Facebook usage, our first round of survey responses was predominately White (78.05%) [21]. Given that it was not possible to limit advertisement audiences by race, we added interest terms mentioning cultural interests of communities of color and similar behavioral targets to the round 2

advertisements. The individual percentages of all racial or ethnic groups (ie, White women and women of color) rose in round 2, while the percentage of women listing their race as “Other” declined. While culturally specific interest or behavioral terms are assumed to capture mostly women of color, there are likely White women with these interests on their profiles, thus diluting the potential gains in recruitment of women of color. Ali et al [24] described similar challenges and solutions with respect to recruiting a diverse sample but was not able to report the effectiveness of their strategies as they only posted the revised advertisements for 1 day.

While gains in racial diversity in round 2 respondents were limited, the use of culturally specific terms improved the age distribution of respondents with a larger percentage of women under the age of 65 years being recruited. This is likely owing to the fact that populations of color tend to be younger than White populations; hence, efforts to increase racial diversity also generated a younger sample. Facebook has relatively older users than other social media platforms, those in the age range of 30-49 years report using Facebook the most (77%), followed by those aged 50-64 years (73%), compared to only 50% of those aged 65 years and older [25]. The improved age distribution brings the sample more in line with the demographics of Facebook users, but it is unclear how other types of diversity such as sexual orientation or ability status can be addressed during recruitment.

### Limitations

Study findings should be viewed in the context of the following limitations. First, the COVID-19 pandemic has influenced the

number and types of potential survey respondents available. Given that individuals with higher education levels and incomes are more likely to work from home; those same individuals had more opportunities to be on the internet and on social media. As a result, participants recruited during that time were more likely to be of higher socioeconomic status. Additionally, our ability to target specific populations relies on the accuracy of Facebook data. Recent reports indicated that users who accessed the platform more frequently or those with older profiles had more categories listed on their advertisement preference pages and reported these categories with increased accuracy [26]. This might lead to the recruitment of heavier users or earlier adopters of social media. These groups might have different attitudes and beliefs related to the health issue being assessed.

### Conclusions

Our study offers complete information about the development and success of different advertisements and cost strategies, which can help researchers target specific populations for recruitment [9]. A detailed description of a process for developing the most cost-effective advertisement targeting middle-aged adults was described. Considering increased social media usage, these approaches can support health research and accelerate recruitment goals. However, challenges related to achieving a diverse study population were detected. While current approaches do not address all diversity-related concerns, this study provides data that help guide new strategies to create a well-balanced sample.

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### Conflicts of Interest

None declared.

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Review

# Internet Search Results for Older Adult Physical Activity Guidelines: Scoping Review

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## Abstract

**Background:** Older adults seek health-related information through casual internet searches. Yet, researchers focus on peer-reviewed journals and conference presentations as primary dissemination strategies. Representatives of mass media are alerted (passive diffusion) of new studies or recommendations, but the veracity of the information shared is not often analyzed, and when it is, the analysis is often not comprehensive. However, most older adults do not have access to peer-reviewed journal articles or paid subscription services for more reputable media outlets.

**Objective:** We aimed to determine what information was readily available (ie, open access) to older adults who may casually search the internet for physical activity recommendations.

**Methods:** We performed a 6-part scoping review to determine the research question and available evidence, and extract data within open-access top hits using popular online search engines. Results were categorized by a dissemination model that has categories of sources, channels, audience, and messages.

**Results:** After the iterative search process, 92 unique articles were included and coded. Only 5 (5%) cited physical activity guidelines, and most were coded as promoting healthy aging (82/92, 89%) and positive framing (84/92, 91%). Most articles were posed as educational, but the authors' credentials were rarely reported (ie, 22% of the time). Muscle strengthening and balance components of the physical activity guidelines for older adults were rarely reported (72/92, 78% and 80/92, 87%, respectively) or inaccurately reported (3/92, 3% and 3/92, 3%, respectively).

**Conclusions:** Inconsistent messages lead to mistrust of science and public health representatives. This work highlights the lack of evidence within existing open-access resources. Further efforts are needed to ensure evidence-based public health messages are in the sources and channels older adults are using to inform their knowledge and behaviors.

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**KEYWORDS**

dissemination; information seeking; health communication; elderly

## Introduction

The strategic spread of evidence-based information is recognized as a necessity, replacing the passive diffusion of information [1-6]. This active knowledge exchange may reduce unnecessary

duplication, increase the reach to those most in need of intervention, and improve knowledge and health equity [7,8]. In a time of fake news, social media influencers, and mistrust of scientific evidence, what is disseminated to specific audiences and how is it disseminated have become vital lines of scientific inquiry [9,10]. Thus, dissemination research investigates how,

when, by whom, and under what circumstances research evidence is spread among agencies, organizations, and frontline workers who provide public health and clinical services [1,11,12].

A key challenge of dissemination is the discrepancy between how researchers disseminate findings (academic journals and academic conferences) and how end users (community members) seek information. For example, even if an individual seeks evidence-based information, a peer-reviewed journal article may not be open access. While many institutions have access agreements with journals, the public is not generally granted access. Furthermore, even if access is more “open,” people are not typically seeking health-related information through peer-reviewed journal articles.

For example, older adults, a priority population for health promotion efforts, seek information about health through both living and nonliving sources [13]. They report greater trust in living sources (eg, clinicians or friends) due to the ability to actively discuss their health. However, when living sources are unavailable, many older adults report relying on general internet searches and have expressed concerns about their ability to access the veracity of information [14]. Many investigations have explored “getting the word out” [4] and “getting the message across” [15], as well as the information seeking practices of end users [13,14]. However, less attention has been paid to what is actually available after these casual internet searches and the degree to which the information found is evidence-based.

One health behavior older adults seek information on is physical activity. Physical activity compliance decreases the risk for chronic conditions (including obesity, hyperglycemia, hypercholesterolemia, and hypertension) [16]. There are specific multifaceted guidelines for older adults (those aged  $\geq 65$  years) within the Physical Activity Guidelines for Americans (PAGA) [17]. Balance, flexibility, motor coordination, strength training, and cardiovascular components [18] typically deteriorate as we age [19,20]. Therefore, the PAGA for older adults include 150 minutes of moderate intensity aerobic activity, 2 days of muscle strengthening, and balance activities [17]. Yet, 79% of older adults are not meeting the guidelines for aerobic activity, strength, and balance [21-23]. This demonstrates a research-to-practice gap and a need for improved dissemination efforts.

The objective of this work was to understand the existing PAGA messages that older adults receive and how those messages may be tailored to better reach older adults and, ultimately, inform physical activity behaviors. This paper shares the iterative scoping review process for identifying where and what information older adults may be receiving related to the PAGA.

## Methods

### Overview

A modified version of the staged approach of a scoping review was employed. It involved the following: (1) identifying the research question, (2) consultation, (3) identifying relevant studies, (4) study selection, (5) charting the data, and (6)

collating, summarizing, and reporting the results [24]. In a traditional scoping review, consultation is the final step in the analysis. Rather than asking older adults and older adult PAGA researchers at the end of the search process, we used their feedback to inform the search process. The review protocol is available upon request. The PRISMA-ScR (Preferred Reporting Items for Systematic Reviews and Meta-Analyses extension for Scoping Reviews) checklist is provided in [Multimedia Appendix 1](#).

### Step 1: Identifying the Research Question

The first observation was that while most Americans do not meet physical activity guidelines, few Americans meet strength training recommendations when compared with aerobic activity guidelines. One hypothesis was that strength training recommendations are less frequently reported in mass media. However, before understanding what has been reported in mass media, honing in on the appropriate outlets was necessary. Older adults search for information through “simple surfing” on the internet [25], but the web browser, search engine, and search terms have not been reported in the literature. Therefore, the final research question is as follows: If older adults engage in simple surfing, what information would they receive about the PAGA?

### Step 2: Consultation

We distributed a Qualtrics survey through the Virginia Tech Older Adult Research Registry (N= 163). There were 17 bounce-back emails and 32 (22%) survey respondents. The participants were 66 to 85 years of age (mean 73 years, SD 5.01 years). When asked how they would search the internet for information on exercise, the responses included questions about proper form, improved balance and strengthening, safe exercises for the older adult age range, exercises to target specific parts of the body, and exercises to prevent or improve physical conditions. Most (21/32, 66%) of the participants reported using Google Chrome as their web browser, but some also used Internet Explorer (8/32, 25%), Firefox (4/32, 12.5%), Safari (4/32, 12.5%), or Microsoft Edge (3/32, 9%). Google Search was used by 100% of the participants, with only a few also using Bing (3/32, 9%) and Yahoo (3/32, 9%).

### Step 3: Identifying Relevant Materials

First, we selected our search terms based on previous physical activity reviews [26-29] and terms older adults prefer when searching for information specific to their age group [30]. Our final search terms were as follows: Physical Activity OR exercise OR movement OR physical activity guidelines OR activities OR fitness and (Older Adults OR seniors OR senior citizen OR elderly OR retiree OR 65 OR geriatric\*).

Second, we selected our web browser. The research team tested the search terms on 3 different computers, at different IP addresses, and found that the searches within each search engine did not differ based on the browser (Google Chrome, Firefox, and Safari). Therefore, only the web browser Mozilla Firefox was used for the final search protocol.

Third, we selected the most relevant search engines based on the respondents from the Older Adult Research Registry and



the extant data (Google Search, Bing, Yahoo, and Duck Duck Go). In general, 71% of internet searches are conducted through Google Search, and 68% of searchers click on results within the first 5 listings of the first page. This rate drops to only 4% of searchers viewing pages 6 to 10 [31]. Thus, to be overly conservative, the first 10 articles per search engine were extracted. The search included anything from January 1, 2008, to January 31, 2019. All articles had to be open access (ie, no payment or subscription for viewing).

#### Step 4: Material Selection

Articles were eligible for review if the content included recommendations on physical activity or exercise for older adults and was open access (free to view). The initial search resulted in 583 articles. Duplicates were removed (n=153). As many of the articles were not scientific (ie, peer reviewed or structured with an abstract), the typical abstract review process of a systematic review was replaced with a title review and then (1) a visual assessment of the landing page, which eliminated many articles (eg, advertisements, dumbbell purchase, and dead links) and (2) a review of the text (for key terms such as physical activity or older adults). If an article did not meet the eligibility criteria (eg, not about older adults or exercise), it was excluded (n=43). Full-text review was conducted on 110 articles, with 92 meeting the final eligibility criteria. Each article was independently coded. Half of the articles (n=45) were coded by 2 investigators to establish interrater reliability. Once interrater reliability was over 85%, an additional 10% of the articles were

coded to ensure strong interrater reliability. The remaining articles were coded by 1 author (AM).

## Results

### Step 5: Charting the Data

The data extraction form was built around the categories of “getting the word out” [4,32] as follows: (1) *source* can be operationalized as who is sharing the message (ie, credential); (2) *message* is the “what” (content); (3) *audience* is to whom the message is intended (eg, characteristics and values); and (4) *channel* is where the information is provided (eg, the location of the content). In addition, items were crafted in alignment with the Agency for Healthcare Research and Quality guidance for “Communication and Dissemination Strategies To Facilitate the Use of Health-Related Evidence” [33]. For example, 1 variable was the purpose, and independent coders established whether it was educational, entertainment, commercial, or other. Variables also included antiaging and healthy aging, with the former attempting to prevent the effects of aging, and the latter embracing one’s age and the effects. Framing was divided into positive or negative categories. Positive focused on the benefits of exercise training, while negative highlighted the unfavorable effects of not partaking in exercise. Audience, another variable, included tailoring for age (older adult specific or not), sex (male or female), culture (ie, social behavior or customs), and attitudes, norms, or beliefs. The complete list of items is available upon request, and a summary of the data is presented in Table 1. The quality of evidence is summarized in Table 2.

**Table 1.** Summary of dissemination source, channel, message, and audience.

Variable	Value (N=92), n (%)
<b>Channel</b>	
<b>Type</b>	
Internet article	71 (77)
Blog	6 (7)
Commercial	1 (1)
Journal	14 (15)
<b>Resources</b>	
Community	4 (4)
Commercial	10 (11)
Government	1 (1)
Peer review	1 (1)
Not reported	76 (83)
<b>Number of cite visitors/reader (reach)</b>	
Not reported	90 (98)
<b>Source</b>	
<b>Author credentials</b>	
Not reported	72 (78)
PhD or academic	3 (3)
Medical doctor (MD, DO)	4 (4)
Physical therapist	1 (1)
Personal trainer	5 (5)
Freelancer	3 (3)
Aging/health expert	1 (1)
Other	3 (3)
<b>Quotes</b>	
Clinician	5 (5)
Researcher	6 (7)
Instructor	6 (7)
Older adult	1 (1)
No quote	74 (81)
<b>Message</b>	
<b>Purpose</b>	
Commercial	4 (4)
Education	83 (90)
Entertainment	1 (1)
N/A <sup>a</sup>	1 (1)
Other	3 (3)
Cite PAGA <sup>b</sup> 2008, Yes	5 (5)
Cite PAGA 2018, Yes	5 (5)
<b>Include aerobic requirements</b>	
Yes	8 (9)

Variable	Value (N=92), n (%)
Yes, but inaccurately	5 (5)
No	72 (78)
Other <sup>c</sup>	7 (8)
<b>Include strength requirements</b>	
Yes	11 (12)
Yes, but inaccurately	3 (3)
No	72 (78)
Other <sup>c</sup>	6 (7)
<b>Include balance requirements</b>	
Yes	7 (8)
Yes, but inaccurately	3 (3)
No	80 (87)
Other <sup>c</sup>	2 (2)
<b>Aging</b>	
Antiaging	5 (5)
Healthy aging	82 (89)
N/A	5 (5)
<b>Framing</b>	
Negative	6 (7)
Positive	84 (91)
Undiscernible	2 (2)
<b>Audience</b>	
<b>Tailoring, n(%)</b>	
Age	47 (51)
Sex	2 (2)
Culture	2 (2)
Attitudes, norms, and beliefs	83 (90)
Narrative shared (eg, testimonial, experience, and hypothetical or actual story)	5 (5)

<sup>a</sup>N/A: not applicable.

<sup>b</sup>PAGA: Physical Activity Guidelines for Americans.

<sup>c</sup>Other indicates recommendations that are scientific but not the Physical Activity Guidelines for Americans (eg, American College of Sports Medicine).

**Table 2.** Quality of evidence.

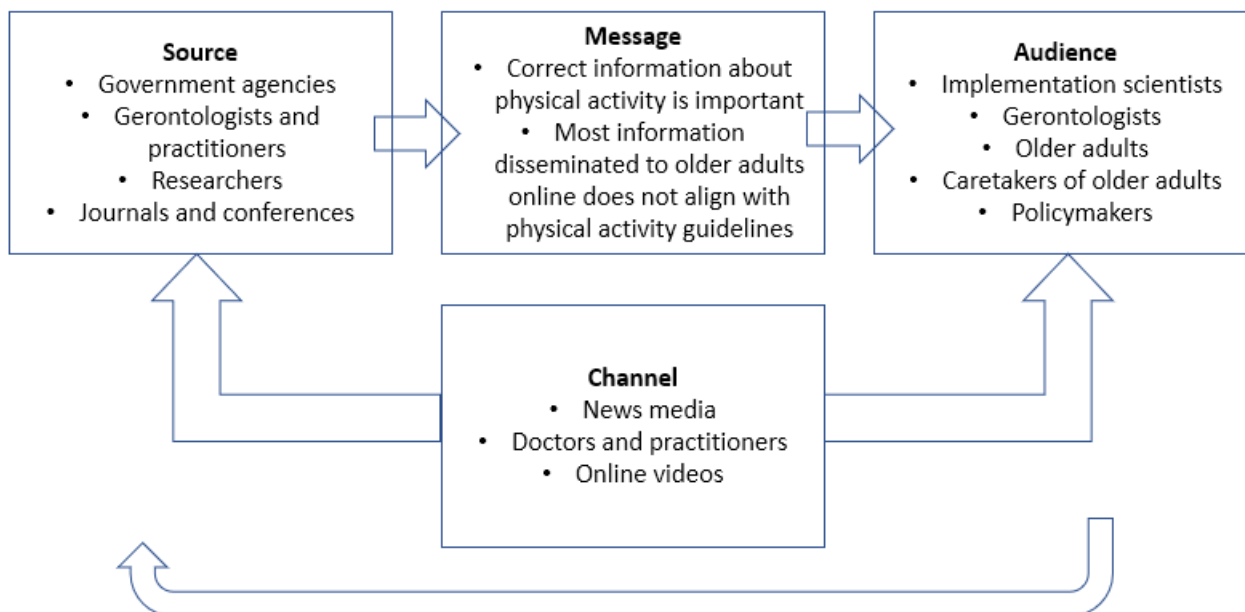
Variable	Value (N=92), n (%)
<b>Strength of evidence</b>	
High	25 (27)
Medium	24 (26)
Low	43 (47)
<b>Risk of bias</b>	
High	37 (40)
Medium	29 (32)
Low	26 (28)
<b>Consistency</b>	
High	28 (30)
Medium	40 (44)
Low	24 (26)
<b>Precision</b>	
High	22 (24)
Medium	31 (34)
Low	39 (42)
<b>Directness</b>	
High	24 (26)
Medium	40 (44)
Low	28 (30)
<b>Net benefit</b>	
High	22 (24)
Medium	32 (35)
Low	38 (41)
<b>Applicability</b>	
High	11 (12)
Medium	57 (62)
Low	24 (26)

## Step 6: Collating, Summarizing, and Reporting the Results

In total, 92 unique articles were included. Example titles were “Exercise for Older Adults,” “Over 65? Cardio Exercise or Weight Training?” and “The Basics of Training Older Adults.” Thirty-three articles did not include their publication date, but for those that did, they ranged from 1999 to 2020, with the highest proportion being from the year after the PAGA 2018 (2019; 11%). Articles took 10.97 (SD 5.2) minutes to read. The full summary of article features across the dissemination categories of source, channel, audience, and message can be

found in [Table 1](#). Only 5 (5%) of the articles reported PAGA editions (2008 or 2018). A majority of the articles were coded as promoting healthy aging (82/92, 89%) and positive framing (84/92, 91%). Most articles were posed as educational, but the authors’ credentials were rarely reported. The specific components of the PAGA for older adults for aerobic activity, muscle strengthening, and balance were usually not reported (72/92, 78%; 72/92, 78%; and 80/92, 87%, respectively) or inaccurately reported (5/92, 5%; 3/92, 3%; and 3/92, 3%, respectively). [Figure 1](#) provides a summary of the source, message, audience, and channel to increase PAGA dissemination to older adults.



**Figure 1.** Dissemination source, channel, message, and audience for the Physical Activity Guidelines for Americans.

## Discussion

This work aimed to understand messages older adults may receive when seeking information related to being physically active. Using a modified scoping review methodology, these internet search results do not represent traditional articles; however, they represent open-access information end users are often receiving to inform their decision-making. Rather than reporting by article, we report as an aggregate the general messages sent to older adults regarding physical activity recommendations. The significant contribution of this work is that, in alignment with a recent review of initial mass media coverage of the PAGA [34], the information available to the public was incomplete and often inaccurate. Notably, while search engines, terms, and top hits have some variability, this work was conducted years after the release of the second edition of the PAGA, so the articles consisted of evergreen content of ongoing relevance [35].

The data were extracted based on the source, message, audience, and channel of dissemination [4]. Most notably, this work found that many common searches resulted in articles that were not evidence-based or evidence-informed [36]. This bold statement is based on the fact that approximately 80% of the articles did not cite any edition of the PAGA or author credentials. This is concerning for 2 primary reasons. First, it is unsurprising that most older adults (90%) are not meeting the PAGA since awareness is essential to any transformation of human behavior [37]. The study presented here unearthed that multicomponent exercise recommendations were rarely disseminated through popular search engines and terms. Second, the sources of these data do not quote experts in the field or share their own credentials. It is important to note that we are not claiming that the authors of the articles do not have the credentials necessarily, just that the credentials were not shared with the general audience. The link between popular sources and channels and the evidence-base is necessary, or the general public may

continue to be misinformed about health-enhancing physical activity (eg, type, intensity, and duration).

This issue is not isolated to the PAGA and the United States. Physical inactivity is a growing global problem [38]. The World Health Organization's Global Strategy on Diet, Physical Activity, and Health provided guidance to member states in establishing national recommendations and plans [39], resulting in the adoption of guidelines across the globe [40-42]. However, it is unknown if the resultant guidelines have been successfully disseminated and implemented. For example, older adults in Ghana reported that they were unaware of the guidelines and how to meet them [43]. More work is needed to determine appropriate communication channels (eg, websites, publications, and mass media) and messages for disseminating the guidelines to both public health practitioners and members of the public [44].

Another challenge in disseminating evidence-based public health information is competing for search engine rankings with those who write blog posts or articles for marketing rather than educational purposes. While many of the articles identified in this review were classified as educational rather than commercial (ie, they did not include links or product advertisements), the sources were for-profit companies rather than nonprofits or educational institutions. Thus, the education is provided for the purpose of drawing in website traffic to increase sales. This distinction is important as those who write for commercial websites may be better trained in search engine optimization (SEO) than those who write for purely educational websites [45].

SEO refers to the methods and techniques used to improve search rankings and increase website traffic [46,47]. One strategy involves selecting specific highly searched terms or phrases and incorporating them throughout an article with the goal of making the article more search engine friendly [45]. For example, "benefits of exercise" has a higher search volume than "benefits of physical activity" [48]. To improve search rankings,

“benefits of exercise” would be used in the title and anchor text (words that are hyperlinked), and multiple times throughout the body of the article.

As search engine users typically only view the first page results [49], articles written without using SEO strategies may appear beyond the scope of what most audiences read and may never be disseminated to the public. To combat this, public health practitioners and researchers can improve dissemination efforts by learning to use SEO [45,49,50]. However, it is recognized that replacing important terms (eg, changing “physical activity” to “exercise”) compromises the scientific integrity of the writing. The best option may be to strive for a balance of using highly searched keywords and phrases when appropriate while also maintaining scientific accuracy.

In addition to the channel and source, the type of message is relevant for behavior change. For example, whether the message is framed positively or negatively influences information retention and behavior change [15,51]. Furthermore, positive messages are more influential for older adults compared to younger adults [15]. Our initial search included articles from *The New York Times* that used negative framing (eg, “25 Again? How Exercise May Fight Aging”). As *The New York Times* requires a fee for access (after 1-3 free article views), the articles were excluded. Using the open-access review criteria, there was a surprising shift toward a goal and theme of healthy aging. After concluding the review, articles with a healthy aging message (82/92, 89%) far surpassed antiaging articles (5/92, 5.4%). We saw the same trend with negative (6.5%) versus positive framing (91.3%) of the articles. Negative framing often focused on the poor outcomes from a lack of exercise and the possible downward spiral in old age. Positive framing concentrated on the benefits and additions that physical activity can provide to older adults. With regard to tailoring, the a priori tailoring categories consisted of age, sex, and culture, as well

as norms, attitudes, and beliefs. There was no specific variable for tailoring for individuals with lower health literacy, which is a limitation of this work.

One further limitation of this review is the inability to be replicated due to the unique nature of the searches. If this review is conducted again, it would likely produce different top hits on the search engines. This review also identified a low response rate (22%) from the Older Adult Research Registry during our consultation process. It is likely that we received interest from the most digitally affluent older adults. The responses could have also been from older adults who were particularly interested in the topic of physical activity research or those who were more knowledgeable about internet searches. This, coupled with the lack of tailoring for older adults with low literacy, may reduce the applicability of the findings and further contribute to disparities of older adults meeting the PAGA [52,53]. This review focused on the dissemination of information about physical activity to older adults through the internet, but there is room for more work to be done in other forms of communication (eg, books, newspapers, and television). One particular challenge of this work was translating typical peer-review journal article critiques and methodologies to grey literature. For example, the risk of bias assessment was particularly challenging. The research team developed a coding guide to clarify operationalization of each of these constructs within this context. Therefore, these results should be interpreted with caution. This is particularly notable for the articles that were not intended to be evidence-based. Finally, while this work focused on the dissemination of PAGA, further work may be warranted to determine the degree to which the American College of Sports Medicine’s Exercise is Medicine initiative is included in more colloquial articles. That said, this study identified that low-quality information is being shared with the public and is being potentially trusted as accurate.

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We would like to acknowledge Steve Poelzing for prompting our interest in how strength training recommendations are communicated, which led to this deeper dive into dissemination strategies and messages.

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## Conflicts of Interest

None declared.

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## Multimedia Appendix 1

Preferred Reporting Items for Systematic Reviews and Meta-Analyses extension for Scoping Reviews (PRISMA-ScR) Checklist. [\[PDF File \(Adobe PDF File\), 107 KB - formative\\_v6i1e29153\\_app1.pdf\]](#)

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## Abbreviations

**PAGA:** Physical Activity Guidelines for Americans

**SEO:** search engine optimization

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Original Paper

# Toward Designs of Workplace Stress Management Mobile Apps for Frontline Health Workers During the COVID-19 Pandemic and Beyond: Mixed Methods Qualitative Study

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**Related Article:**

This is a corrected version. See correction statement: <https://formative.jmir.org/2022/1/e36769>

## Abstract

**Background:** In recent years, mobile apps have been developed to prevent burnout, promote anxiety management, and provide health education to workers in various workplace settings. However, there remains a paucity of such apps for frontline health workers (FHWs), even though FHWs are the most susceptible to stress due to the nature of their jobs.

**Objective:** The goal of this study was to provide suggestions for designing stress management apps to address workplace stressors of FHWs based on the understanding of their needs from FHWs' own perspectives and theories of stress.

**Methods:** A mixed methods qualitative study was conducted. Using a variety of search strings, we first collected 41 relevant web-based news articles published between December 2019 and May 2020 through the Google search engine. We then conducted a cross-sectional survey with 20 FHWs. Two researchers independently conducted qualitative analysis of all the collected data using a deductive followed by an inductive approach.

**Results:** Prevailing uncertainty and fear of contracting the infection was causing stress among FHWs. Moral injury associated with seeing patients die from lack of care and lack of experience in handling various circumstances were other sources of stress. FHWs mentioned 4 coping strategies. Quick coping strategies such as walking away from stressful situations, entertainment, and exercise were the most common ways to mitigate the impact of stress at work. Peer support and counseling services were other popular methods. Building resilience and driving oneself forward using internal motivation were also meaningful ways of overcoming stressful situations. Time constraints and limited management support prevented FHWs from engaging in stress management activities.

**Conclusions:** Our study identified stressors, coping strategies, and challenges with applying coping strategies that can guide the design of stress management apps for FHWs. Given that the pandemic is ongoing and health care crises continue, FHWs remain a vulnerable population in need of attention.

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**KEYWORDS**

mental health; stress; mHealth; frontline health worker; design requirements; pandemic; COVID-19; design; intervention; burnout; perspective; need; user design

## Introduction

Work stress is recognized as the response workers have when they are presented with work responsibilities that do not match their knowledge and abilities and that challenge their ability to cope [1]. Workers may appreciate some demands and pressures to stay alert, motivated, able to work, and learn, depending on their abilities and available resources. However, when these pressures and demands become exorbitant and persist for a long time, they manifest as stress, which can be damaging to worker's health and workplace performance. During the COVID-19 pandemic, frontline health workers (FHWs) were tasked with delivering essential health services in circumstances that surpassed their knowledge and abilities, challenging their ability to cope. Several studies reported high rates of stress-related health issues such as clinically significant depression (23.2%), anxiety (22.8%), and insomnia (38.9%) among the FHWs in primary care and hospital settings [2,3]. Even though similar rates of mental health issues have been reported during and following previous viral outbreaks and pandemics (eg, (Ebola, severe acute respiratory syndrome, and Middle East respiratory syndrome) [4,5], proactive solutions for managing stress do not seem to exist for FHWs. The fear of stigma, time restrictions, and expectation of maintaining phlegm are the main reasons why the mental health of FHWs is often ignored [6,7]. Moreover, it is generally assumed that FHWs are well equipped to handle their mental health challenges by the virtue of their professional training. This understanding needs to change because without adequate support to manage work-related stress, FHWs are at risk of developing a wide range of health problems [2], and the society is at risk of losing a workforce responsible for delivering essential health services in times of crisis.

Stress management interventions come in several varieties. The interventions that directly target sources of stress to improve workers' well-being are called primary interventions. They are concerned with modifying the content and context of the workplace, such as redesigning job descriptions, providing career development opportunities, providing flexible work schedules, encouraging goal-setting, and implementing team-building and diversity [8]. The secondary interventions aim to decrease the intensity or duration of stress response after its occurrence to minimize the damage. These interventions aim to increase workers' resilience by teaching them specific strategies in physical (eg, meditation and relaxation exercises), emotional (eg, externalization of negative emotions), and cognitive (eg, cognitive-behavioral techniques) domains [8]. The tertiary interventions are about treatment and rehabilitation of individuals to facilitate return to work after the damage. They

typically include options such as counseling support and medical interventions [9].

Technology can help deliver such interventions at the organizational or individual level [10]. The organization-level technological interventions are aimed at making organizational practices changes that either target all workers or a specific group of workers. The individual-level technological interventions are aimed at helping workers develop coping skills to manage and control their own stress responses in situations and circumstances they perceive as being stressful. Mobile apps are suitable for delivering both types of stress management interventions as they are easily customizable and can remove barriers to help-seeking and reach FHWs "where they are." Research indicates that mobile apps can reinforce healthy habits and scaffold recovery processes via streamlined designs [11]. They can provide easy access to self-help reference materials while preserving privacy needs and time constraint issues of individuals [12]. Wearable devices, on the other hand, can also passively monitor behaviors to assess user's needs and, in response, curate context-aware, personalized, adaptive, and anticipatory interventions [13]. In other words, mobile apps provide the flexibility to deliver just-in-time and suitable interventions in users' context. Such interventions can help reduce barriers to decision-making and action taking for positive behavior changes [14-16].

During the COVID-19 pandemic, there was an increased interest in developing mobile apps to preserve the mental well-being of FHWs (Table 1). HeroesHealth [17], Be + against COVID [18], Wellness Hub [19], and Clinicoverly [20] are among the apps that were developed during the pandemic to address the stress management needs of different types of health care workers. With these apps, FHWs can assess their own mental health by answering survey questions and reviewing status reports. Another important component included in these apps is professional support, especially information about free and low-cost mental health services. Although many incorporate evidence-based stress management content, the focus of existing project has been development and implementation from a technological perspective [21]. The involvement of the target users—that is, FHWs in the conceptualization and development of these tools—was either limited or missing. The evidence of the effectiveness of mobile apps for addressing stress and other mental health symptoms of FHWs who are involved in the current health crisis is also not available [18]. Moreover, existing stress management interventions do not use any theoretical understanding of stress to explain the mechanism of the intervention [22].

**Table 1.** Feature summary of COVID-19 mental health-related mobile apps.

App name	Features
Heroes Health [17]	<ul style="list-style-type: none"> <li>• Mental health tracking over time via periodic assessments.</li> <li>• Links to instant support and mental health resources.</li> <li>• Summaries of health workers' data for organizational use.</li> <li>• Communication between health workers and organizations.</li> </ul>
Be + against COVID [18]	<ul style="list-style-type: none"> <li>• Rapid resources for combating COVID-19.</li> <li>• Assessments to self-evaluate the ability to adjust to the crisis.</li> </ul>
Wellness Hub [19]	<ul style="list-style-type: none"> <li>• Standardized mental health surveys.</li> <li>• Score-based feedback consisting of resilience-building exercises, resource links, etc.</li> <li>• Private digital journal for self-reflection.</li> <li>• Relaxation videos and other resources.</li> </ul>
Clinicoverly [20]	<ul style="list-style-type: none"> <li>• Written and audiovisual content for addressing various mental health issues.</li> <li>• Daily prompts (notifications) with brief questionnaires to monitor mental health status.</li> <li>• Short messages offering tailored information and resources based on the participants' responses.</li> </ul>

To allay these gaps, we referenced stress, appraisal, and coping theories within the person-environment transactional framework [23,24] to investigate stressors and coping strategies among FHWs. The framework suggests that when an individual reacts to an event on the basis of the notion that it will be harmful to his/her personal well-being, the event becomes a psychological stressor. It also accounts for an individual's coping skills and overall coping mechanisms that can provide directions for designing interventions. Using this theoretical framework as the basis, we explored stressors during pandemic and stress management strategies from FHWs' perspectives. Based on our findings, we discuss implications for designing stress management mobile apps. We make two contributions: first, our human-centered approach elucidates the wants and needs of the target users, which has theoretical implications for conceptualizing the understanding of stress; second, our design requirements and suggestions may be useful to other researchers who are designing stress management mobile apps for FHWs.

## Methods

### Methods Overview

The goal of this study was to provide suggestions for designing mobile apps to address workplace stressors of FHWs on the basis of the Transactional Framework of Stress. Compared to the other approaches to understanding the mechanisms of stress, this framework provides practitioners with all the necessary constructs to work with stress victims by tapping into their existing and personal coping skills and strategies. It has also been previously used to understand implications for clinical practice in working with individuals experiencing acute stress following a disaster in community [25]. The framework recommends taking the person-centered approach; that is, it encourages the involvement of target users in all stages of intervention design, so their needs can be identified, and perspectives integrated [26]. To elicit user needs for the design of the stress management app, we used multiple methods to engage with the target users; that is, FHWs.

### Document Analysis

When we started this study in July 2020, the COVID-19 pandemic was at its peak in the United States, and it was challenging for us to reach the target users. We initiated contact with a few FHWs but found them overstretched with extra responsibilities owing to the pandemic and not interested in participating in the study. Consequently, we resorted to gathering interviews of FHWs, which had been published in reputable web-based news portals such as CNBC and CNN.

Using a combination of words such as "frontline health worker," "stress," "mental health," and "covid-19," we searched for relevant articles on various web-based news sites between December 2019 and October 2020 using the Google search engine. Over 200 articles were found, of which, we selected 41 that discussed challenges and experiences of health workers during the pandemic. More specifically, 3 researchers independently reviewed these articles to identify content relevant for this research. We selected the following content: (1) quotes from interviews with FHWs (ie, FHWs' views and comments) and (2) quotes discussing workplace stressors and related concerns.

### FHW Survey

By October 2020, we had completed the analysis of the gathered interviews. By that time, the pandemic was also under relative control in several US states. To triangulate our findings from the analysis, we prepared a survey in Qualtrics software, informed by the transactional framework of stress. We obtained approval to conduct the survey from the ethical review board of our home institution. Participants were recruited via convenience sampling; the survey was open (publicly available), and emailed to several mailing lists consisting of various FHWs such as nurses and physician assistants. Participation in the survey was voluntary, and no initial contact about the survey with the target audience had been made. No compensation was provided. The main inclusion criteria included being >18 years old and working at a large health care facility. The exclusion criterion was working in small clinics or health centers. The survey remained open from October 4-24, 2020.



The purpose of the survey was to further our understanding of FHWs' needs and challenges regarding stress during the pandemic by understanding their stressors and coping strategies. The first part of the survey was the informed consent process, where participants were briefed about the study purpose and informed about the investigator. In addition, participants were informed that the survey completion time was 30-45 minutes, and that the data will be stored for 1 year after the closing of the survey. The second part of the survey collected demographic

information (eg, age, gender, years of experience, educational background, and job title) and asked the remaining questions listed in Table 2. No identifying information was collected. The survey questions were not randomized, and all main survey questions were on the same page (for a total of 3 survey screens, including one each for informed consent and demographic data). The IP information collected by the Qualtrics was used as a proxy to ensure each survey response was from a different individual.

**Table 2.** Survey questions (questions are categorized in accordance with the subsections describing associated findings).

Question #	Question text
<b>Specific aim 1: to identify the sources of stress or stressors during pandemic and normal situations</b>	
1.1	What kinds of stressors do you face at work?
1.2	What kinds of stressors did you face at work during the pandemic?
<b>Specific aim 2: to examine the stress management strategies of the frontline health workers</b>	
2.1	How do you manage stress at work?
2.2	What types of support does your workplace provide to help you manage stress?
<b>Specific aim 3: to understand challenges of stress management</b>	
3.1	What challenges do you face while managing stress at work during the pandemic?

A total of 25 survey responses were collected. Since the number of individuals who were part of the mailing list is unknown, the response rate cannot be determined. Five response entries were dropped because the questions were inadequately answered (eg, one word or irrelevant response) or left blank (eg, by typing "N/A"). In other words, the completion rate was 80%. The selected responses were 20 (female, n=18) FHWs from 12 US states and the District of Columbia. In total, 18 participants were employed, 1 was a student/intern, and 1 was on high-risk leave at the time of the survey. The ages ranged from 24 to 56 years, while years of experience ranged from 1 to 28 years. According to their occupation, 12 participants were registered nurses (RN) or nurse practitioners (NP), 2 were physician assistants (PA), 4 were certified nurse assistants (CNA), and 2 were respiratory therapists (RT).

### Data Analysis

Two researchers used qualitative content analysis [27] to elicit user needs and design requirements from the interview transcripts and survey responses. The researchers first independently used initial coding and memoing to code keywords that represented stressors and coping strategies of FHWs by reading and re-reading the qualitative data independently. The researchers then met face-to-face to compare their codes and resolve conflicts through discussions. The final codes were first consolidated under categories and then categories were combined into themes presented below.

## Results

### Stressors

We identified four key challenges and concerns that FHWs believed were elevating stress levels during the peak of the COVID-19 pandemic. The most frequently occurring stressor has been described first, followed by the second most frequently

occurring code, and so on. The fourth stressor is not exclusively related to the pandemic, but it uncovers an important source of stress among FHWs during normal situations.

### Coping With Uncertainty

FHWs reported that coping with the uncertainty surrounding the pandemic was extremely stressful. Earlier during the pandemic, hospitals had not had time to revise their guidelines. FHWs did not know how to tackle the infection and how to manage patients. The absence of essential knowledge in response to patients' needs was usual among the FHWs. One FHW remarked the following [28]:

*Everyone had to struggle with the gap between what we believed were the proper procedures and what was possible during the crisis.*

Many participants had to join specialties outside their areas of expertise to address the issue of shortage of FHWs and to serve the patients [29]. Adjusting to the new work environment was difficult for those who had been displaced from their normal work environments. Those who were working in their usual environments found it stressful to manage patient's demands. One FHW reported the following to the Seattle Times [30]:

*If patients have certain symptoms and questions ... we don't have all the knowledge to answer the questions.*

FHWs complained that as the pandemic progressed, they had to cope with frequent changes in rules and regulations. Adjusting to and staying abreast of all the updates in the heat of the pandemic was challenging for many FHWs.

*Adjusting to changing rules and recommendations when you do not know what they are can become a huge stressor. (CNA1 at a surgery center).*

FMWs must work in extremely uncertain and life-threatening circumstances. This stressor can be challenging to address in cases of novel pandemics when there are too many unknowns, and the knowledge is evolving. However, this theme shows that there is a paucity of efficient methods for disseminating necessary and evolving information to FHWs.

### ***Fear of Contracting Infection***

Generally speaking, to avoid the contagion, health workers utilize different types of personal protective equipment (PPE) including face masks, face shields, gloves, goggles, gowns, head covers, and shoe covers. Owing to the global shortage of PPE, many FHWs were working with low-grade and inadequate PPE; for example, PPE that leave necks and most of the face exposed. A nurse explained the following to the New York Times [31]:

*We've been put on the front line not only without enough protection, but also sometimes with the stress of a very different work environment.*

This resulted in many FHWs fearing contracting the infection while serving COVID-19-positive patients at the hospitals and health facilities [32].

*The direct exposure to Covid+ patients exposes us to the risk of infection on a daily basis. [CNA1]*

Related to this, the FHWs were afraid of contracting the infection and then spreading it to family members including children and older adults at home. Many health care workers were taking extreme measures such as not going home and staying in tents and makeshift homes to protect their loved ones. The inability to go home and be with their families was an added stressor for the health care workers. Those who managed to go home were taking extra precautions such as stripping down and putting the hospital clothes in the laundry to ensure they were not exposing their loved ones to the risk of infection. It was challenging to stop feeling the guilt of possibly risking family members' lives. An emergency department nurse spoke anonymously during an interview and reported the following [33]:

*I live with my pregnant wife, son, and two dogs. My wife is also a nurse. We try to strip down as soon as possible when coming in the door; clothes straight to the laundry.*

FHWs may need appropriate tools to monitor their health and provide greater insight into risk factors for reduced physical and mental health. Moreover, FHWs need to understand how to transact their feelings related to changed family dynamics during the pandemic.

### ***Moral Injury***

Several interviews described that as uninsured patients were dying, FHWs were asking who would pay for the uncovered health care expenses. Often, this implied that FHWs were making decisions about who should and should not get the ventilator. Whenever patients died in these situations, and many died without their loved ones by their sides, FHWs experienced guilt, compassion fatigue, and moral injury as they were unable to provide standard care and treatment to the patient.

There are many circumstances that can pose great psychological burden on FHWs and without a proper understanding of how to manage themselves, FHWs are likely to burn out owing to psychological burden.

### ***Lack of Experience***

The FHWs who were in the early stages of their career pointed out that the lack of experience was already a stressor for them. The pandemic created a work environment where finding answers to questions became even more challenging, causing stress levels of exacerbate.

*Working in the ER can be stressful especially early on in my career. Each new experience can be stressful and scary because I don't have a previous encounter with it. Sometimes it is hard to manage stress in some situations because I lack experience, so I feel like that makes the situation worse. [Emergency Department RN3]*

FHWs who are in the early stages of their career may need additional support during public health emergencies to cope with their lack of experience along with specific emergency-related challenges.

### ***Stress Management Strategies***

We found four main stress management strategies that were used by participants: self-care, teamwork, counseling services, and internal motivation. We describe these strategies below in accordance with the frequency (highest to lowest) with which these strategies were reported.

#### ***Quick Coping***

Based on their preferences and time allowances, participants used various quick coping strategies to manage stress. "Taking breaks" (n=12) and "walking away" (n=12) from stressful situations were the most frequently used strategies.

*I try to find moments to step away. Take deep breath and try to remember I can only do one patient at a time. [Emergency Room RN4]*

While, for many participants, simply stepping away from a stressful situation was enough to refocus and destress, others engaged in health-promoting activities such as yoga, meditation, listening to music, and watching funny videos on YouTube. Six participants also reported using mobile apps such as Calm and Headspace to distract themselves from stressful events [34].

*Maintaining daily routines such as regular exercise, clean sleep schedule and periodic meditation sessions.*

Other participants mentioned strategies such as "calling a loved one," "stress eating," and "attending social events" to manage stress levels at work, suggesting that there are many coping methods that are simple and readily available to FHWs.

#### ***Teamwork***

There was a consensus among the surveyed FHWs that sharing their frustrations and experiences with peers was important for them as it kept them grounded and made it easier for them to deal with the challenges of the pandemic. Everyone believed

in supporting one other and creating a safe space to help each other get through the tough times.

*Laughing and venting out with co-workers is my way to manage stress at work.* [RN5]

Moreover, participants relied on teamwork and support of their colleagues at work whenever they wanted to find answers to their work-related questions or manage stressful situations at work.

*When I am at work, I connect with team members, ask for help when I feel overloaded. I try to help others the same way.* [RN6]

*I have coworkers that are open to listen and help in any situation.* [Emergency Room RN2]

When peers share their challenges and frustrations about common issues with each other, they acquire the strength to overcome stress. Gaining support and attention of their peers is important for FHWs. They might need more effective ways to share problems and connect with each other.

### Counseling Support

Many FHWs reported that they were joining weekly virtual healing circles to learn effective strategies to cope with different stressors. One article highlighted a hotline service that was specifically created to support FHWs with distress and mental fatigue. A counselor on a hotline stated that the most common calls from FHWs were related to stress, exhaustion, and worries about families, particularly having to stay away from family members for safety. This theme implies that FHWs actively strive to find resources to handle their problems before, during, and after the stressful situations.

### Building Resilience

FHWs mentioned that they focus on building resilience when they feel challenged or overwhelmed at work. In fact, having internal motivation and drive was an expectation of their work environment, which every FHW considered seriously.

*When things get tough, you power through.* [Rapid Response RN7]

FHWs actively engaged in educating themselves about the unique pressures, fears, and demands about the COVID-19 pandemic and even attended training sessions to cope, persevere, and survive challenges of each day. One FHW reported the following [34]:

*Find peace in preparation and educating oneself about how to deal with stressors. Have a mantra – something that strengthens and brings calm at the same time.*

FHWs might place particular stress on developing their internal motivations to solve their problems. They appreciate having access to training, which can help them develop their internal motivation.

### Challenges of Managing Stress

Two main challenges were mentioned by the FHWs and have been described in accordance with their frequency (highest to lowest) of occurrence in the collected data.

### Time Constraints

During the peak of the pandemic, FHWs had to contend with the high patient load and short staffing issues. As a result, FHWs found themselves working without breaks and without clear end in sight. Many FHWs reported that they had been unable to find time to focus on their own physical and mental health.

*Not having enough time to mentally care for oneself while providing 110% care for a patient (or 2 in the ICU) during a 12-14hr shift.* [Intensive Care Unit RN1]

Many FHWs reported that their routine had been disrupted and they could not engage in routine daily activities at regular times such as meal breaks, sleep, and physical exercises.

*The biggest challenge has been balancing immediate patient needs with immediate personal needs, including basic things like taking time to eat, drink and use the bathroom.* [Emergency Room RN2]

Several FHWs also wanted to engage in productive activities such as attending lectures or seminars on positive thinking, effective time management, etc; however, owing to the heavy workload and back-to-back shifts, they were unable to do so.

*Too much work and high activity patients do not leave enough time to go to lectures or events.* [NP1]

This theme reminds us of the importance of designing interventions that fit effectively into the work life of FHWs. FHWs may understand what their needs are, but time is a scarce commodity. Without time-efficient methods, seeking and utilizing necessary resources to address their needs is bound to remain a challenge for FHWs.

### Management's Limited Capacity

Participants pointed out that during crises, management is also subject to stress and health system inadequacies, which impacts their ability to make appropriate adjustments and changes. In some cases, this resulted in lack of enough resources and support that were desired by FHWs to cope with stress due to the pandemic.

*Management is unwilling to provide ways to alleviate stress.* [PA1]

*I was told at one point to provide my own masks. I intake patients and start their IVs and somehow my employer felt they shouldn't be accountable for providing me with a surgical mask daily.* [CNA2]

On the other hand, some FHWs pointed out that although the employers provided many mental health benefits, these resources were not well-advertised. Hence, many FHWs who required mental health support felt that they needed more commitment from their employers in terms of addressing their mental health needs.

This theme suggests that FHWs want their authorities to provide guidance during the times of stress; however, they might be hesitant to ask for help and resources directly from their management. Moreover, management might not know what kind of resources are needed by their employees.



## Discussion

### Principal Findings

We identified 4 major stressors, 4 stress management strategies, and 2 stress management challenges among FHWs that are specifically related to pandemics as well as general situations. Uncertainty and an unstable work environment owing to frequent changes in work protocols owing to the pandemic and a fear of contracting the infection caused considerable stress among FHWs. Moral injury associated with seeing patients die from lack of care and inexperience with handling other circumstances that occur in health care settings were other sources of stress. FHWs used simple coping strategies such as walking away from stressful situations, entertaining oneself, and exercising to mitigate the impact of stress at work. Peer support and counseling services were other popular methods to learn about strategies to minimize the burden of stress. Building resilience and driving oneself forward using internal motivation were also meaningful ways of overcoming stressful situations. However, time constraints, management's limited initiative taking, and lack of resources prevented FHWs from engaging in activities that could lessen the impact of stress.

### Practical Implications

Our findings show that FHWs experience professional, personal, and social types of stressors in their workplaces during the pandemic. While they can manage certain types of stressors, it is difficult for them to manage other types. Specifically, it is challenging for them to cope with uncertainty, which was the most frequently recounted stressor, and was the subtext in all the other stressors. That is, FHW felt uncertain about their personal health situation, uncertain about their role in providing full care to underprivileged infected patients, and uncertain about handling novel and challenging scenarios that the pandemic created in their work environments. Understanding how other health care professionals manage uncertainty and the resulting stress in their work practices can provide directions for designing interventions for FHWs. For example, research shows that genetic counselors (GCs) routinely encounter uncertainty in their practice, which forces them to engage in a variety of strategies to manage it. Specifically, GCs resort to seeking information, identifying social support, and normalizing uncertainty to cope with uncertainty [35]. Basher's Theory of Uncertainty Management [36] explains that individuals can have negative, positive, or neutral responses to uncertainty and they manage their uncertainty by adopting the aforementioned strategies; that is, knowledge, social support, and normalization. FHWs can be supported with similar strategies to help them manage uncertainty and consequently stress during the pandemic. Below we discuss how mobile apps can be used to support such strategies.

FHWs in our study could not overcome their uncertainty by seeking information because of it was evolving and changing in the heat of the pandemic. The existing COVID-19 apps [17-20] reviewed in the beginning of this paper incorporate a wide array of knowledge resources for health workers but there is no research about the effectiveness of these resources. For example, how accessible are they for handling specific situations

and scenarios? The health workers in our study indicated that lack of time prevented them from taking advantage of the resources around them. Therefore, while mobile apps can reach the health workers with appropriate resources "where they are," strategies are needed to ensure these resources are actionable and effectively utilized.

Mobile apps can increase opportunities for FHWs to seek social support by interacting with their peers to fulfill their emotional and professional needs in times of crisis. Earlier research shows that FHWs appreciate access to an in-app peer support community [37]. Cheng et al [38] had proposed a peer-to-peer psychological support and crisis management infrastructure based on popular social media apps such as WeChat. We extend this proposal by suggesting that FHWs should be able to seek support and answers to their queries from experts within and beyond their institutional boundaries. Care must be taken to ensure that these peer support tools are designed to prevent negative social pressure and other potential risks of digital interactions [37]. Moreover, peer support requires peer time, posing burden on other peers. A possibility is automating peer support by using, for example, artificially intelligent tools such a conversational agent. Institutions can also investigate developing institution-specific conversational agents to help FHWs with personalized searches.

Building resilience and adopting quick coping strategies may be seen as FHWs' effort to normalize uncertainty and deal with psychological issues such as guilt and moral injury. However, our findings also indicate that FHWs reach out to counseling services for support suggesting that certain psychological needs of FHWs are not readily met. Mobile apps can be used to deliver psychological interventions and have shown effectiveness in the past. Ly et al [39] showed that Acceptance Commitment Therapy delivered via smartphones can reduce perceived stress, increase general health, and promote psychological flexibility in business managers [40]. However, none of the COVID-19 apps reported earlier in this paper used any such theoretically driven stress management strategy. Further research should focus on understanding other psychological needs of the FHWs and developing appropriate interventions to address those needs.

### Theoretical Implications

Our results corroborate the existing theoretical frameworks on stress mechanisms and management. The transactional framework conceptualizes stress as an internal representation of a problematic transaction between the person and their work environment [41]. On the one hand, intervention for stressors can reside in the workplace; on the other, interventions or coping are at the individual level. Given that our findings recommend an individual level strategy, our study supports the constructs of transactional theory to mitigate frontline challenges.

Beyond corroborating the existing theoretical frameworks on stress mechanisms and management, this study advances research and theories on stress management in 2 ways. First, the extant research focuses on stress management from a general perspective, we have identified stressors, and coping strategies, specifically in FHWs. Second, we have applied the Theory of Uncertainty Management to suggest strategies to reduce stress in FHWs. In this sense, we have expanded the definition of



stress from being a problematic transaction between an individual and their work environment to also include the cognitive state that develops due to ambiguity and unpredictability. This understanding has practical implications as previously discussed.

### Limitations and Future Work

The work presented here has several limitations that can be addressed in future studies. First, this study does not consider organizational perspective and challenges they face in implementing effective stress management strategies for their workers during the pandemic. Previous work has shown that there are often misalignments between the mental health needs of the employees and what employers' can financially or legally provide [42]. Therefore, a future study can explore health organization's concerns to further refine the presented design suggestions. Second, an important consideration in future research is how geographic location may affect the stressors, strategies, or user needs amid the pandemic. Research has shown that there are differences in health workers' qualifications in urban versus rural areas [43]. These differentials directly impact the level of knowledge and willingness to work during crisis situations [44]. Hence, there might be different challenges and strategies that have been overlooked in this study. Third, there is a possibility that the selection of the article content was influenced by our biases (none of the researchers was a healthcare professional). Therefore, future research in this area should confirm the findings with health care experts or other key informants. However, the logistics of such an endeavor might be challenging to implement in practice. Finally, a quantitative measure-based study may provide generalizable

insights that cannot be achieved via qualitative studies. This would require conducting a large-scale survey with FHWs from varied settings.

### Conclusions

FHWs encounter stressful situations in their workplace and need effective strategies to cope with these stressors. The goal of this study was to provide suggestions for designing mobile apps to address workplace stressors of FHWs based on the understanding of their needs from FHWs' own perspectives and the Transactional Framework of Stress. We identified four major stressors including coping with uncertainty, fear of infection, moral injury, and lack of experience in managing various challenges. The uncovered coping strategies comprised quick coping, peer support, counseling services and building resilience. Time constraints and management's limited capabilities are some challenges that FHWs encounter while managing stress. The findings corroborate the existing theoretical frameworks on stress mechanisms and advance the understanding of stress management from the FHWs' perspective. We extend the definition of stress to include uncertainty and discuss how principles of uncertainty management can provide directions for designing stress management apps for FHWs. Specifically, mHealth apps can be designed to help FHWs seek peer support and information. They can also be used to deliver specific psychological interventions for FHWs. Given that the pandemic is ongoing and crisis at work will continue, FHWs remain a vulnerable population in need of attention. Hence, our efforts have implications for advancing the ongoing efforts aimed at improving FHWs' mental well-being worldwide.

### Conflicts of Interest

None declared.

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## Abbreviations

- CNA:** certified nurse assistant  
**FHW:** frontline health worker  
**GC:** genetic counselor  
**NP:** nurse practitioner  
**PA:** physician assistant  
**PPE:** personal protective equipment  
**RN:** registered nurse  
**RT:** respiratory therapist

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Original Paper

# Evaluating the Quality of Asynchronous Versus Synchronous Virtual Care in Patients With Erectile Dysfunction: Retrospective Cohort Study

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## Abstract

**Background:** Asynchronous health care encounters are becoming an increasingly mainstream form of telehealth. While synchronous phone or video visits have become more widely accepted, US policymakers and other key health care stakeholders have been hesitant to fully embrace asynchronous diagnosis and treatment. This is particularly true in the context of direct-to-consumer (DTC) platforms, where encounters are patient-initiated and there is no preestablished relationship with a provider. This hesitation is compounded by limited research comparing outcomes between asynchronous and synchronous care, especially in the DTC context.

**Objective:** The purpose of this study was to explore whether asynchronous care leads to different patient outcomes in the form of medication-related adverse events when compared to synchronous virtual care.

**Methods:** Using 10,000 randomly sampled patient records from a prominent US-based DTC platform, we analyzed the rates of patient-reported side effects from commonly prescribed erectile dysfunction medications and compared these rates across modalities of treatment.

**Results:** Asynchronous care resulted in lower but nonsignificant differences in the rates of the reported drug-related side effects compared to synchronous treatment.

**Conclusions:** In some circumstances, such as treatment for erectile dysfunction, asynchronous care can offer the same level of safety in prescribing when compared to synchronous care. More research is needed to evaluate the safety of asynchronous care across a wider set of conditions and measures.

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**KEYWORDS**

telehealth; medical informatics; side effect; virtual health; platform; medication; sync; outcome; adverse event; drug; electronic health record; treatment; erectile dysfunction

## Introduction

Asynchronous technology is becoming an increasingly common component of health care delivery following the explosion of telehealth in the wake of the COVID-19 pandemic [1]. This

technology serves as both a complement to synchronous (ie, real time) encounters and, increasingly, as a replacement for other modes of diagnostic and treatment-related interactions between patients and providers.

Asynchronous care relies on “store-and-forward” technology where patients provide necessary health information that is transmitted to providers, who then make a diagnosis and design a treatment plan on secure web-based platforms (sometimes called electronic or e-visits). The growing popularity of asynchronous care reflects the advantages it confers by removing the need for provider and patient co-availability, in which case treatment can be accessed and delivered at everyone’s convenience [2]. Research shows patients will take advantage of timing flexibility to engage in care during evenings and weekends [3] and that both patient and provider satisfaction with asynchronous care are high [4,5]. Evidence also suggests that asynchronous care could help mitigate access barriers associated with the “digital divide,” allowing patients to access services even in areas where high-speed internet required to support video calls is not widely available [6,7].

Though the pandemic led to regulatory revisions permitting reimbursement for asynchronous care [8], policymakers and practitioners have maintained reservations, particularly in direct-to-consumer (DTC) scenarios where care is commonly delivered asynchronously but patients and providers do not have a preexisting relationship [2,9]. This hesitation is justified given the limited evidence on whether telemedicine can lead to inappropriate prescribing and increased risk of failing to identify factors that might contribute to increased side effects [10]. There is also scant evidence on the health and quality outcome implications for e-visits compared to in-person or other forms of virtual care [11]. For example, one recent randomized controlled trial comparing asynchronous and synchronous telepsychiatry showed similar patient outcomes across modalities [12]. However, another study comparing these modalities found that asynchronous care might create conditions that could negatively impact patient safety: providers adopted different prescribing behaviors depending on the modality of treatment for otherwise similar patients [13]. A recent literature review identified only 19 studies that quantitatively evaluated e-visits and concluded that while they appeared to result in similar health outcomes as compared to in-person care, evidence on quality outcomes is mixed, and there were no included studies comparing them to telephone or video visits [8].

The popularity of DTC companies that rely on asynchronous care is increasing, and the sentiment that they are “here to stay” has led researchers to explicitly highlight the need for published data rates on adverse events on these platforms [10,14]. The purpose of this study was thus to explore whether asynchronous care leads to different patient outcomes in the form of medication-related adverse events when compared to synchronous virtual care using a sample of 10,000 men undergoing treatment for erectile dysfunction (ED), a commonly treated condition on DTC platforms.

## Methods

### Study Design

We build on our previously published research regarding the rates of side effects experienced by DTC patients being treated for ED on a platform that offers synchronous and asynchronous telehealth services for a variety of health conditions [15]. This

study was approved by the Biomedical Research Alliance of New York Institutional Review Board.

### Study Sample

In the original study, we analyzed all electronic health records for 10,000 randomly selected ED patients being treated on a single DTC platform starting sometime in 2018. Each patient was prescribed either sildenafil or tadalafil, two generic PDE-5 (phosphodiesterase type 5) inhibitor medications, which serve as first-line treatments for erectile dysfunction [16].

### Study Variables

To compare the differences across treatment modalities, we take advantage of the variations in state laws that dictate whether a patient can be treated asynchronously or that they must engage with the provider via phone or video call. Patients who elect to be treated asynchronously might be systematically different from patients who opt to be treated synchronously, introducing bias (eg, patients who prefer asynchronous treatment might be younger and less likely to have age-related conditions that make them more susceptible to adverse events). However, laws regulating the application of asynchronous treatment vary by state; therefore, a portion of the patients in the sample were required to engage in synchronous information exchange with their provider in order to receive treatment. For the purpose of this study, we assumed population homogeneity and did not consider residence in a different state as a factor that might affect either the rate of side effects or the rate at which those side effects are reported. This mitigates any confounding that might have been introduced by patients self-selecting a given visit modality.

State residency was determined using the patient’s mailing address that was provided for medication shipments. We then defined asynchronously treated patients as those who reside in a state where asynchronous treatment is permitted per state law. Patients residing in these states completed an asynchronous online visit that was reviewed by a provider who then engaged with a patient via chat to discuss the diagnosis and treatment plan and dispensed a prescription. By contrast, we defined synchronously treated patients as those who reside in states where either a phone or video consultation is required by state law in order for a prescription to be dispensed. Patients in these states also completed an online visit, but then scheduled and completed a phone or video call with a provider before a prescription was dispensed. We note that patients who reside in states where asynchronous treatment is permitted can elect to have a phone or video consult before treatment commences; however, instances of pretreatment modality switching are highly uncommon on the platform and did not occur in this sample. A small number of asynchronously treated patients had phone or video conversations with providers after the treatment began, but we did not disqualify them from the asynchronous group because the synchronous interaction did not occur before a prescription was dispensed.

We defined an adverse event as an instance when a patient reported a medication side effect to their provider after beginning treatment on the DTC platform. To determine the rates of reported side effects in the original study, a research

team of medical doctors and scientists reviewed a comprehensive set of patient records that included interactions starting from initial treatment sometime in 2018 through September 2019 and flagged any instance in which a patient contacted their provider to report a side effect [15]. To accomplish this, the team compiled a comprehensive list of side effects based on published literature [17-19] and created a set of colloquial search terms. For example, in addition to “flushing,” we included words like “hot” and “red.” The records were searched against the terms by calculating the Levenshtein distance using the ‘stringdist’ package by R (R Foundation for Statistical Computing) to allow us to capture key terms that were spelled incorrectly or phrased slightly differently than the list verbiage [20]. The records were sorted in order of calculated distance and manually reviewed for categorization until matches were exhausted. The identified side effects were then broken down by medication and type [15]. For quality control purposes, a subset of patient records reported to contain no side effects was manually reviewed to ensure that the search procedure did not systematically overlook any adverse events.

Because there is some evidence indicating that the risk of medication-related adverse events increases with age [21], patient age was extracted from their electronic health records and included as a control variable.

**Table 1.** Rates of reported side effects by modality.

Side effects	Synchronous (n=2150)	Asynchronous (n=7850)
Any side effect, n (%)	24 (1.12)	113 (1.44)
Headache, n (%)	10 (0.47)	56 (0.71)
Dizziness, n (%)	0 (0)	3 (0.04)
Flushing, n (%)	2 (0.09)	31 (0.39)
Congestion, n (%)	12 (0.56)	17 (0.22)
Dyspepsia, n (%)	7 (0.33)	10 (0.13)
Back pain, n (%)	0 (0)	6 (0.08)
Blurry vision, n (%)	2 (0.09)	8 (0.10)
Other, n (%)	2 (0.09)	7 (0.09)

We employed 2 different generalized linear models to determine whether the difference in side effect rates for asynchronously or synchronously treated patients, however small, was statistically significant. The first model was a standard logit model with the dichotomous indicator for whether a patient reported experiencing a side effect as the outcome. We found that asynchronous patients were around 20% less likely to report experiencing a side effect (odds ratio 0.77;  $P=.26$ ), but this difference was not significant.

## Analysis

Each record was also assigned a categorical indicator for whether a patient had a synchronous (either a phone or video call) interaction with a provider before being prescribed medication or that diagnosis and treatment selection occurred asynchronously. We then compared the rates of any side effect reported by patients treated either asynchronously or synchronously. The data were modeled using generalized linear models, and analysis was carried out using R, version 4.03.

## Results

The average age of patients whose records were included in the sample was 44.8 years (SD 12.1). The majority (78% [n=7850]) were treated asynchronously. Overall, patient-reported side effects were rare; less than 2% (n=137) of patients reported experiencing any side effect. In concordance with definitions used by McMurray et al [22] and Montorsi et al [19], we determined that no serious adverse events, such as myocardial infarction, vision or hearing loss, or cerebrovascular accident, were reported. Across modalities, 1.12% (n=113) of synchronously treated patients reported experiencing a side effect compared to 1.44% (n=24) of asynchronously treated patients (Table 1). There were no notable differences across type and distribution of mild side effects.

Because fewer than 2% (n=137) of the patients reported experiencing a side effect, standard logistic regression might bias results toward zero by underestimating the probability of a side effect occurring even with the large sample size [23]. As a sensitivity check, we used a penalized likelihood estimator (the Firth method) [24]. The results in the penalized regression were similar, with asynchronous patients also around 15% less likely to report experiencing a side effect (odds ratio 0.84;  $P=.28$ ), but this difference was not significant.

**Table 2.** Generalized linear model results.

	Standard logit				Binomial response			
	OR <sup>a</sup>	SE	Z	Pr(> z )	OR	SE	Z	Pr(> z )
Intercept	0.02***	0.09	-44.60	.000	0.01	0.11	-38.75	<.001
Asynchronous	0.77	0.23	-1.14	.26	0.84	0.16	-1.077	.28

<sup>a</sup>OR: odds ratio\*\*\**P*<.001

## Discussion

The recent widespread adoption of telehealth as an acceptable treatment modality and the potential expansion of asynchronous care have prompted deeper exploration of the downstream effects. Research that focuses on telehealth treatment outcomes and the reported side effects can facilitate defining standards, improving quality of care, and identifying opportunities for expanding treatment access to more patients and for more conditions.

Our exploration of the rates of reported side effects among people receiving synchronous versus asynchronous care offers a chance to explore any unexpected downstream effects these modalities might have on patient safety and treatment outcomes. Significantly higher rates of side effects for asynchronous treatment might suggest that removing a real time interaction between patient and provider precludes the necessary information gathering in order to make a clinically appropriate assessment of whether a patient should receive medication. Alternatively, significantly lower rates of side effects from asynchronous treatment might indicate that removing the real time patient-provider interaction precludes the necessary rapport building that would encourage patients to contact their provider in case of an adverse event. Overall, we found that though the odds of reporting a side effect were lower for asynchronous patients, they did not significantly differ from the odds among synchronous patients. These results suggest that in this context (DTC treatment for ED), asynchronous care via patient-initiated encounter does not unduly prevent patients from reporting an adverse event, nor does it result in any other notable differences in adverse events when compared to patients who received treatment after a phone or video call. Our findings corroborate those of the handful of other studies in different areas of medicine in which comparisons of patient outcomes across telehealth modalities yielded no disproportionate rates of adverse events [12,25].

Copious research is required to continue to evaluate the safety of asynchronous care across different conditions and circumstances; however, current evidence suggests that lawmakers and practitioners should continue to consider facilitating its adoption with a prudent approach to implementation that takes into account specific circumstances where asynchronous care is safe and appropriate. These

considerations could also factor in circumstances under which certain sites of patients are experiencing access barriers (such as broadband availability) that prevent them from using video technology due to bandwidth limitations [26], or stigma-related barriers that prevent patients from seeking care that requires a face-to-face interaction.

Acknowledging asynchronous care's departure from the traditional practice of medicine while simultaneously embracing its benefits could entail the design and execution of programs that offer training for providers on best practices for care that relies on store-and-forward technology [27,28]. Asynchronous-specific quality metrics could be refined and tracked to ensure that care is of consistently high quality [7]. Both training and metrics could include mitigating and tracking unsafe prescribing practices, respectively.

There are several limitations to this study. First, the results are specific to a single DTC platform and might not be generalizable across all DTC platforms and patients. For example, structured online intake forms and requested patient data vary by DTC platform, thus introducing variation in the evidence-based nature, breadth, and quality of information presented to providers for clinical evaluation. Second, the record lookback window in the sample ended in 2019; COVID-19 has likely introduced changes in the DTC patient population. For example, patients who had not previously considered seeking treatment via telehealth might have been prompted by the sudden and unexpected inability to get in-person care. Lastly, the results also might not be generalizable beyond the condition and medications studied. More research needs to be conducted to determine whether the rates of side effects differ across modalities for other conditions that are commonly treated on DTC platforms, especially as these platforms continue to expand their treatment offerings to provide a more comprehensive suite of services.

Limitations notwithstanding, this study represents an important step toward a more nuanced approach to evaluating the quality of care delivered via telehealth. As telehealth demonstrated its value during the global pandemic and is becoming an increasingly normalized form of care, research needs to evolve beyond comparisons to in-person care toward identifying the most ideal formats, processes, and approaches for collecting relevant clinical information and safely treating and communicating with patients within the suite of virtual options.

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## Conflicts of Interest

LB, MB, KS, and AW are employed by and have stock options at Ro, the Direct-to-consumer (DTC) telehealth company that provided data for this study.

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## Abbreviations

**DTC:** direct-to-consumer

**ED:** erectile dysfunction

**PDE-5:** phosphodiesterase type 5

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Original Paper

# A Smartphone App to Increase Immunizations in the Pediatric Solid Organ Transplant Population: Development and Initial Usability Study

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## Abstract

**Background:** Vaccine-preventable infections result in significant morbidity, mortality, and costs in pediatric transplant recipients. However, at the time of transplant, less than 20% of children are up-to-date for age-appropriate immunizations that could prevent these diseases. Smartphone apps have the potential to increase immunization rates through their ability to provide vaccine education, send vaccine reminders, and facilitate communication between parents and a multidisciplinary medical group.

**Objective:** The aim of this study was to describe the development of a smartphone app, Immunize Pediatric Transplant, to promote pretransplant immunization and to report on app functionality and usability when applied to the target population.

**Methods:** We used a mixed methods study design guided by the Mobile Health Agile Development and Evaluation Lifecycle. We first completed a formative research including semistructured interviews with transplant stakeholders (12 primary care physicians, 40 parents or guardians of transplant recipients, 11 transplant nurse coordinators, and 19 transplant subspecialists) to explore the acceptability of an immunization app to be used in the pretransplant period. Based on these findings, CANImmunize Inc developed the Immunize Pediatric Transplant app. We next held 2 focus group discussions with 5-6 transplant stakeholders/group (n=11; 5 parents of transplant recipients, 2 primary care physicians, 2 transplant nurse coordinators, and 2 transplant subspecialists) to receive feedback on the app. After the app modifications were made, alpha testing was conducted on the functional prototype. We then implemented beta testing with 12 stakeholders (6 parents of transplant recipients, 2 primary care doctors, 2 transplant nurse coordinators, and 2 transplant subspecialists) to refine the app through an iterative process. Finally, the stakeholders completed the user version of the Mobile Application Rating Scale (uMARS) to assess the functionality and quality of the app.

**Results:** A new Android- and Apple-compatible app, Immunize Pediatric Transplant, was developed to improve immunization delivery in the pretransplant period. The app contains information about vaccine use in the pretransplant period, houses a complete immunization record for each child, includes a communication tool for parents and care providers, and sends automated reminders to parents and care providers when immunizations are due. During usability testing, the stakeholders were able to enter a mock vaccine record containing 16 vaccines in an average of 8.1 minutes (SD 1.8) with 87% accuracy. The stakeholders rated engagement, functionality, aesthetics, and information quality of the app as 4.2/5, 4.5/5, 4.6/5, and 4.8/5, respectively. All participants reported that they would recommend this app to families and care teams with a child awaiting solid organ transplant.

**Conclusions:** Through a systematic, user-centered, agile, iterative approach, the Immunize PediatricTransplant app was developed to improve immunization delivery in the pretransplant period. The app tested well with end users. Further testing and agile development among patients awaiting transplant are needed to understand real-world acceptability and effectiveness in improving immunization rates in children awaiting transplant.

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## KEYWORDS

vaccinations; transplantation; mobile app; agile development; immunization; mHealth; mobile health; children; transplant recipients; pediatric transplant recipients; pediatrics

## Introduction

Due to lifelong immunosuppression, solid organ transplant recipients are at increased risk of life-threatening infections [1-3]. Vaccine-preventable infections (VPIs) occur in up to 15% of pediatric solid organ transplant recipients in the first 5 years posttransplant, a rate of up to 87 times higher than in the general pediatric population [4,5]. These VPIs result in lengthy hospitalizations, morbidity, and mortality. In addition, VPIs can increase the cost of transplantation by US \$120,000 [4,5]. To prevent these infections, it is crucial for transplant candidates to receive all age-appropriate vaccines in the pretransplant period. However, less than 20% of pediatric liver transplant recipients are up to date on age-appropriate immunizations at the time of transplant [6]. In a recent qualitative study with 82 transplant stakeholders (including transplant hepatologists, nephrologists, cardiologists, infectious diseases physicians, transplant nurse coordinators, primary care physicians, and the parents of transplant recipients), the following barriers to pretransplant immunization were identified: (1) gaps in knowledge about the timing and safety of pretransplant vaccines; (2) lack of communication, coordination, and follow-up between team members regarding immunizations; (3) difficulty remembering when vaccines were due; and (4) lack of a centralized immunization record that could be easily accessible by all team members [7].

While human resources are an important component in the overall strategy to address immunization rates, provider-driven interventions (ie, phone call reminders and individually created calendar reminders) are expensive and difficult to sustain. Health information technology tools, including health care mobile apps for use on a personal smartphone or desktop computer, have been demonstrated to be a sustainable strategy for facilitating

patient provider communication, disseminating high-quality evidence-based information to end users on a global scale, increasing adherence to medical regimens and tracking when medical interventions are due, and improving outcomes in chronic illnesses [8-12]. mHealth (mobile health) apps have been successfully created and implemented to facilitate immunization delivery [13-20]. However, mHealth apps have never been utilized to improve immunization rates in high-risk populations (such as children awaiting transplant) who require a tailored vaccine schedule (such as the accelerated vaccine schedule) and comanagement by multiple providers (including the primary care physician and transplant team) who in turn may operate on different electronic medical records (EMRs). The goal of this study was to describe the development of a smartphone app, Immune PediatricTransplant, to promote pretransplant immunization and to report on app functionality and usability when piloted in the target population.

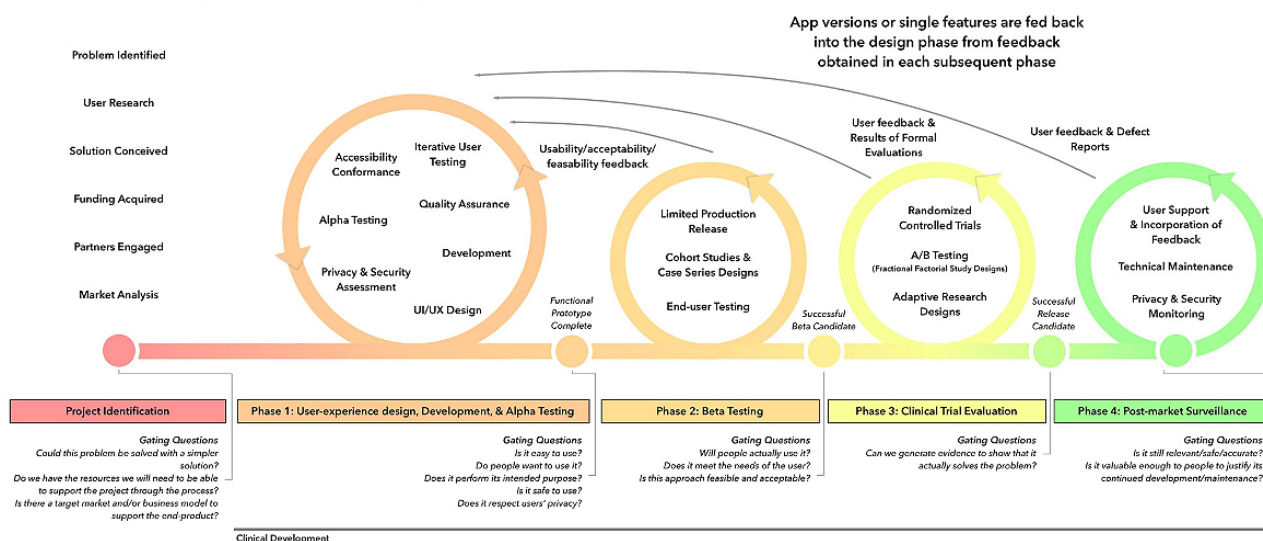
## Methods

### mHealth Agile Development and Evaluation Lifecycle

The mHealth Agile Development and Evaluation Lifecycle guided this study. This lifecycle focuses on safety and efficacy while also allowing for rapid and iterative development and evaluation that is required to create high-quality, effective, thoroughly tested, evidence-based digital tools. The mHealth Agile Development and Evaluation Lifecycle is divided into 5 stages: phase 0—project identification; phase 1—user experience, design, development, and alpha testing; phase 2—beta testing; phase 3—clinical trial evaluation; and phase 4—postmarket surveillance [21] (Figure 1). This study focused on the first 3 phases of this cycle—project identification; user experience design, development, and alpha testing; and beta testing.



**Figure 1.** mHealth Agile Development and Evaluation Lifecycle (adapted from Wilson et al [21]). UI: user interface; UX: user experience.

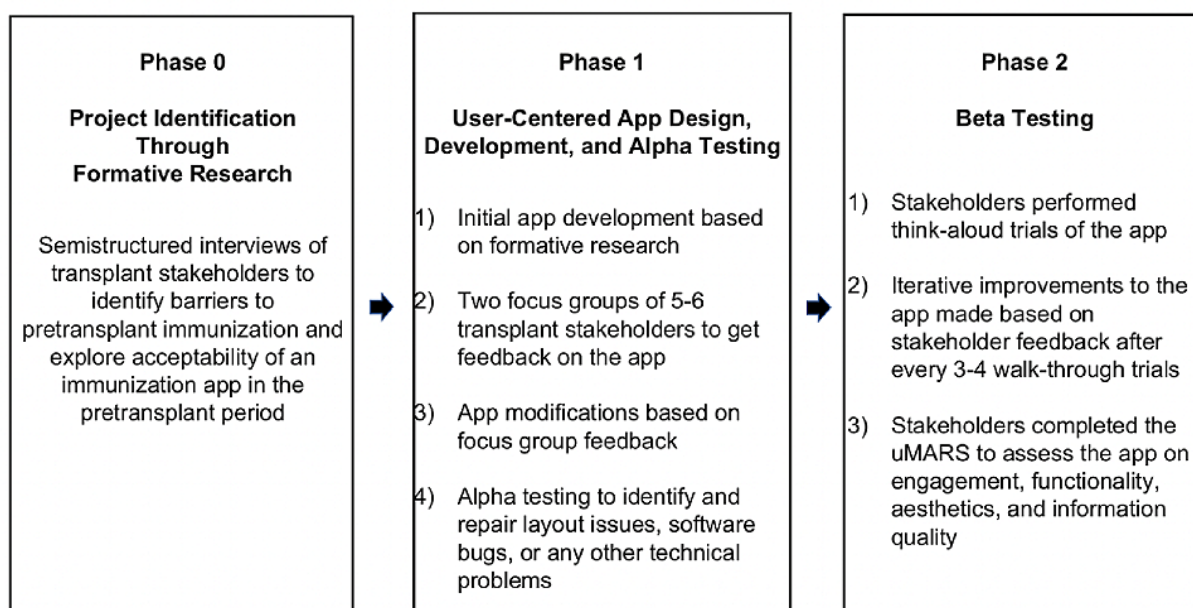


**Approach and Recruitment**

We used a sequential user-centered design process approach focusing on the first 3 phases of the mHealth Agile Development and Evaluation Lifecycle (Figure 2). All English-speaking transplant hepatologists, cardiologists, nephrologists, infectious diseases physicians, primary care physicians, and parents of children who received liver, heart, and kidney transplants between January 1, 2011, and August 30, 2019, at the Children’s Hospital Colorado (CHCO), Ann & Robert H. Lurie Children’s Hospital of Chicago (Lurie) and Children’s Hospital of Philadelphia (CHOP) were invited to participate. Health care

providers were invited to participate via an email invitation. The parents of transplant recipients were approached in clinic or were sent a written invitation. The participants received a reimbursement for participating in the study (US \$10 per interview, US \$150 per focus group, and US \$150 per think-aloud walk-through app trial testing). Institutional review board approval was obtained from the University of Colorado (all research took place through the University of Colorado; CHOP and Lurie only assisted with recruitment), and verbal informed consent was obtained by the interviewer before starting the interview, focus group or think-aloud walk-through app trial [7].

**Figure 2.** Development process of the Immunize PediatricTransplant app. uMARS: user version of the Mobile Application Rating Scale.



**Phase 0: Project Identification Through Formative Research to Understand the Barriers to Pretransplant**

**Immunization and Assess Acceptability of a Pretransplant Immunization App**

To develop an evidence and theory-based app, we identified barriers to pretransplant immunization based on relevant

literature, prior research by our group, and the domains from the Theoretic Domains Framework [4-6,22-26]. We conducted semistructured interviews with 82 transplant stakeholders (including the parents of transplant recipients, transplant nurse coordinators, transplant infectious diseases physicians, primary care physicians, and transplant nephrologists, cardiologists, and hepatologists) to identify barriers to pretransplant immunization and to explore whether an immunization app would be useful in addressing these barriers. We used a team-based inductive approach to analyze the results [7]. Our focus of this manuscript is to present new findings regarding use and acceptability of an immunization app.

### **Phase 1: User-Centered App Design, Development, and Alpha Testing**

Based on the formative research, we worked with CANImmunize Inc to develop a new app for Apple and Android smartphones. The content of the app targets immunization barriers identified in Step 1. Specifically, the app (1) incorporates information about pretransplant vaccine safety and timing; (2) houses an easily accessible cloud-based immunization record for each child; (3) includes a chat or communication feature for providers and parents to communicate about immunizations; and (4) provides reminders for parents and providers when vaccines are due based on the accelerated Centers for Disease Control and Prevention vaccine schedule for transplant candidates.

We held 2 focus group discussions with 5 transplant stakeholder participants in the first group and 6 transplant stakeholder participants in the second group (N=11; 5 parents of transplant recipients, 2 primary care physicians, 2 transplant nurse coordinators, and 2 hepatologists) to obtain feedback on the initial version of the app. We implemented a focus group protocol and semistructured discussion guide consistent with the recommended focus group methodology [27]. We showed the participants screenshots from the app and asked for their thoughts. Both focus groups were led by a moderator, which was held in English and lasted 60 minutes. With the permission of the participants, the focus groups were videotaped, and notes were taken. Based on the findings from the focus groups, we made modifications to the app. Upon completion of the initial

functional prototype, CANImmunize Inc completed alpha testing to identify and repair any layout issues, software bugs, or other technical problems.

### **Phase 2: Beta Testing**

We invited 12 transplant stakeholders (6 parents of transplant recipients, 2 primary care physicians, 2 transplant nurse coordinators, and 2 hepatologists) to perform a lab usability testing of the app. Once they consented, the participants downloaded and trialed the app during a think-aloud walk-through over Zoom. Think-aloud walk-throughs are a standard approach for software development and app testing [28-30]. We asked each of the 12 stakeholders to set up an account, create a new child record, input a 16-vaccine immunization record provided by the research team, connect with the research physician, and utilize various app features (eg, including enabling touch/face ID, setting up notifications to be received via text message, and reading through the informational features of the app). This database captured all information inputted into the app and saved the time stamp at which each change was made to the user's data. This was used to assess how long the participant spent entering the complete vaccine record, the accuracy with which they entered the vaccine record, and the stakeholder's success in connecting with the research physician. After each participant completed the testing, we asked them to independently complete the user version of the Mobile Application Rating System (uMARS), a validated tool for end users to assess the quality of mHealth apps. The uMARS is a 26-item measure that includes subscales to assess engagement, functionality, aesthetics, and information quality of the app [31]. After every 3-4 usability tests, we incorporated feedback into a new version of the app.

## **Results**

### **Approach and Recruitment**

We interviewed 82 stakeholders including parents or guardians of heart, liver, and kidney transplant recipients, primary care physicians who took care of transplant recipients, transplant infectious diseases physicians, transplant nurse coordinators, and transplant hepatologists, nephrologists, and cardiologists (Table 1).

**Table 1.** Participant demographic characteristics (N=82).

Characteristics	Values
Transplant subspecialist, n (%)	16 (20)
Transplant ID <sup>a</sup> physician, n (%)	3 (4)
Transplant nurse coordinator, n (%)	11 (13)
Primary care provider, n (%)	12 (15)
Parent or guardian, n (%)	40 (49)
<b>Transplant center, n (%)</b>	
Children's Hospital Colorado	35 (43)
Children's Hospital of Philadelphia	27 (33)
Ann and Robert H. Lurie Children's Hospital	20 (24)
<b>Gender, n (%)</b>	
Female	68 (83)
Male	14 (17)
<b>Years in practice,<sup>b</sup> n (%)</b>	
0-5	10 (24)
6-10	6 (14)
11-20	10 (24)
Over 20 years	16 (38)
<b>Interview venue, n (%)</b>	
Hospital (office or conference meeting room)	18 (22)
Telephone	64 (78)

<sup>a</sup>ID: infectious diseases.

<sup>b</sup>excluding parents (n=42).

### Phase 0: Project Identification Through Formative Research to Understand the Barriers to Pretransplant Immunization and Assess Acceptability of a Pretransplant Immunization App

Despite being from diverse geographic regions and having experience with different types of organ transplant (heart, liver, and kidney), when asked about feasibility and potential benefit, 80/82 (98%) participants believed that a mobile health app would be useful to help address and overcome these immunization barriers in the pretransplant period. Parent

participants commented that an immunization app could provide educational material on “how vaccines work and what diseases they prevent.” All participants reported that a health information technology tool could improve communication by “getting everyone on the same page, especially when different providers used different EMRs.” Provider participants emphasized that having easy access to a centralized immunization record would “be great, especially for out of state patients whose information is not in the state immunization information system.” Finally, parent and provider participants stated that automated vaccine reminders “would be a huge help in reminding them to get needed vaccines” (Table 2).

**Table 2.** Selective illustrative quotations about how a transplant-specific immunization app might help address immunization barriers in the pretransplant period

Theme	Illustrative Quotation
Increase factual knowledge	<ul style="list-style-type: none"> <li>I don't know a lot of the scientific words of what the doctor says—if the app could explain the vaccine, it would be amazing. [parent]</li> <li>It would be great to have information about what the vaccine is, what it protects against, how often it needs to be given, and why its extra important for a soon-to-be immunocompromised child. [parent]</li> <li>I'd like a place to verify vaccine information; I don't want to mess it up. [primary care provider]</li> <li>If there was a tool where I could enter the child's age, the vaccines they had received, and if needed anticipated transplant date and it would give me their individualized accelerated schedule that would be terrifically efficient. [infectious diseases physician]</li> <li>Because most people haven't seen vaccine-preventable infections like measles or mumps, the diseases aren't as scary as they should be. Providing a brief blurb about what the disease can look like would make families more inclined to follow through on a vaccine. [transplant nurse coordinator]</li> <li>Having education material about each vaccine would be great—a family could click on it and get a recall of why that vaccine's important. [hepatologist]</li> </ul>
Enhance communication and coordination	<ul style="list-style-type: none"> <li>Being able to get everyone on the same page to get questions answered would be great. [parent]</li> <li>An app sounds wonderful—if there could be communication between me, my primary care provider, and the transplant team. Everyone could be on the same track. [parent]</li> <li>It's exhausting trying to get a hold of someone when you have a question, and you can't go forward until you reach them. The tool would improve communication a hundredfold. [parent]</li> <li>Efficient communication to everybody sounds pretty great. [primary care provider]</li> <li>Families live on their phone, that is the way to communicate with them. [hepatologist]</li> </ul>
Centralize vaccine records	<ul style="list-style-type: none"> <li>I have my child's vaccines on a card, but if I lose that card or forget to write a new vaccine on the card, I don't know where that information would be. [parent]</li> <li>When you're dealing with the stress of a super sick kid you can't remember every detail like when vaccines were given. It would be great just to open up the app. [parent]</li> <li>A health tool could be a repository for immunizations, particularly for those children from out of state or those children with gaps in their records. [primary care provider]</li> <li>Being able to see in real time the vaccine record would be great. [transplant nurse coordinator]</li> <li>Centralization of records would be great because right now they're in multiple places. [hepatologist]</li> </ul>
Help track when vaccines are due	<ul style="list-style-type: none"> <li>Reminders would be so big—if all of us transplant families could get reminders, we would be able to get immunizations done on time. [parent]</li> <li>If the app could alert not just me but also the doctor's office that my child had a shot due that would be really helpful. [parent]</li> <li>A reminder on your phone seems simple but it's a huge deal for a transplant patient and their family. [parent]</li> <li>Anything that makes it easier for people to remember when a vaccine is due would help us improve immunization rates. [hepatologist]</li> </ul>

### Phase 1: User-Centered App Design, Development, and Alpha Testing

A total of 11 stakeholders attended 2 focus groups. There were 5 parents of transplant recipients (1 parent of a heart transplant recipient, 2 parents of liver transplant recipients, and 2 parents of kidney transplant recipients), 2 transplant nurse coordinators, 2 primary care physicians, and 2 transplant subspecialists. Of the 11 stakeholders, 9 (82%) were female.

Overall, the participants were enthusiastic about the idea of using an app to help facilitate immunization delivery in the pretransplant period. The participants gave specific suggestions on the app features they would find helpful, including the ability to use the app on both their phone and desktop computer and the ability to use finger-touch capability or facial recognition to login.

*This app would definitely have made things easier when my child was going through transplant.* [parent]

*I think this app is a great idea for caring for kids with complex medical needs.* [primary care physician]

When asked their preference on information delivery about the timing and safety of vaccines in the pretransplant period, the participants uniformly liked the idea of informational text rather than an informational video or interactive learning session.

*I don't think I would ever have time to watch a video with my kids running around.* [parent]

*Short text bullets of information make it easy to skim through information while you're waiting for a visit to start.* [parent]

*I would like information about which specific vaccines my child can and can't receive before and after transplant.* [parent]

*I like text that I can easily reference when I have questions.* [hepatologist]

When talking about how to enter the child's prior immunization records into the app to create a centralized vaccine record, the



participants gave valuable input. They all recommended a scroll down feature to select the month or year in which each vaccine was given as opposed to a free text entry stating that “a scroll down feature would minimize entry errors.” A few participants suggested “visual recognition” whereby the app could take a picture of the child’s previous vaccine record and then input that information directly into the app’s record. All participants were concerned about the amount of time it would take to enter a complete vaccine record into the app. However, they stated that they would be willing to make the initial time commitment if thereafter they could always be able to email or print a copy of the vaccine record from the app.

*I would definitely be willing to spend 30 minutes or even an hour entering my child’s vaccine records if that meant I could have all the records in one place moving forward. [parent]*

*If I could print out the vaccine record from the app it would be great and worth the initial time needed to enter the vaccines. [parent]*

When discussing the communication tool or chat feature, the parents and providers were excited about the possibility of being able to facilitate communication between the family, the primary care doctor, and the transplant team. Multiple people mentioned that when the primary care provider and the transplant team use different EMRs, it makes communication very difficult. A few providers expressed concern about having an additional patient communication tool that they would need to check and respond to.

*As a parent, it would be huge for the primary care physician and the transplant team to talk directly so I don’t have to be the go-between. [parent]*

*My primary care physician and transplant doctor used two different platforms when my daughter went through transplant, and it was very frustrating. This app would have been ideal. [parent]*

*As a primary care physician, we often feel out of the loop when a child is awaiting transplant; this would have helped to close that loop. [primary care physician]*

*I worry a little about now having to check the EMR communication portal and the app. [hepatologist]*

## Phase 2: Beta Testing

A total of 12 stakeholders tested the Immunize PediatricTransplant app (10 on an Apple phone and 2 on an

Android phone). There were 6 parents of transplant recipients (2 heart transplant recipients, 2 liver transplant recipients, and 2 kidney transplant recipients), 2 transplant nurse coordinators, 2 primary care physicians who had cared for transplant patients, and 2 transplant subspecialists. Of the 12 participants, 10 (83%) were female. User testing identified 6 issues related to usability and functionality. Four usability issues were identified including changing the appearance of the home page to make icons more prominent, changing the specific icon for the chat or communication function, changing the appearance of vaccine information sheets to be more readable, and allowing users to bulk enter vaccines given on the same date or enter multiple dates for the same vaccine. In terms of functionality, the participants suggested 2 features: (1) the inclusion of a PDF tutorial on how to use the app; and (2) the placement of priority stars next to the most administered vaccines in the vaccine entry section in order to help the parents easily identify likely vaccines for each age. Through iterative app changes after every 3-4 user walk-through trials, we modified the app to address all of these issues (Figure 3).

Time stamps from the database identified that, on average, it took 8.1 minutes (SD 1.8 minutes) for the 12 users to enter a 16-vaccine immunization record. The participants entered the vaccine record with 87% (14/16) accuracy (range 69%-100%). All participants were able to connect successfully with the research physician.

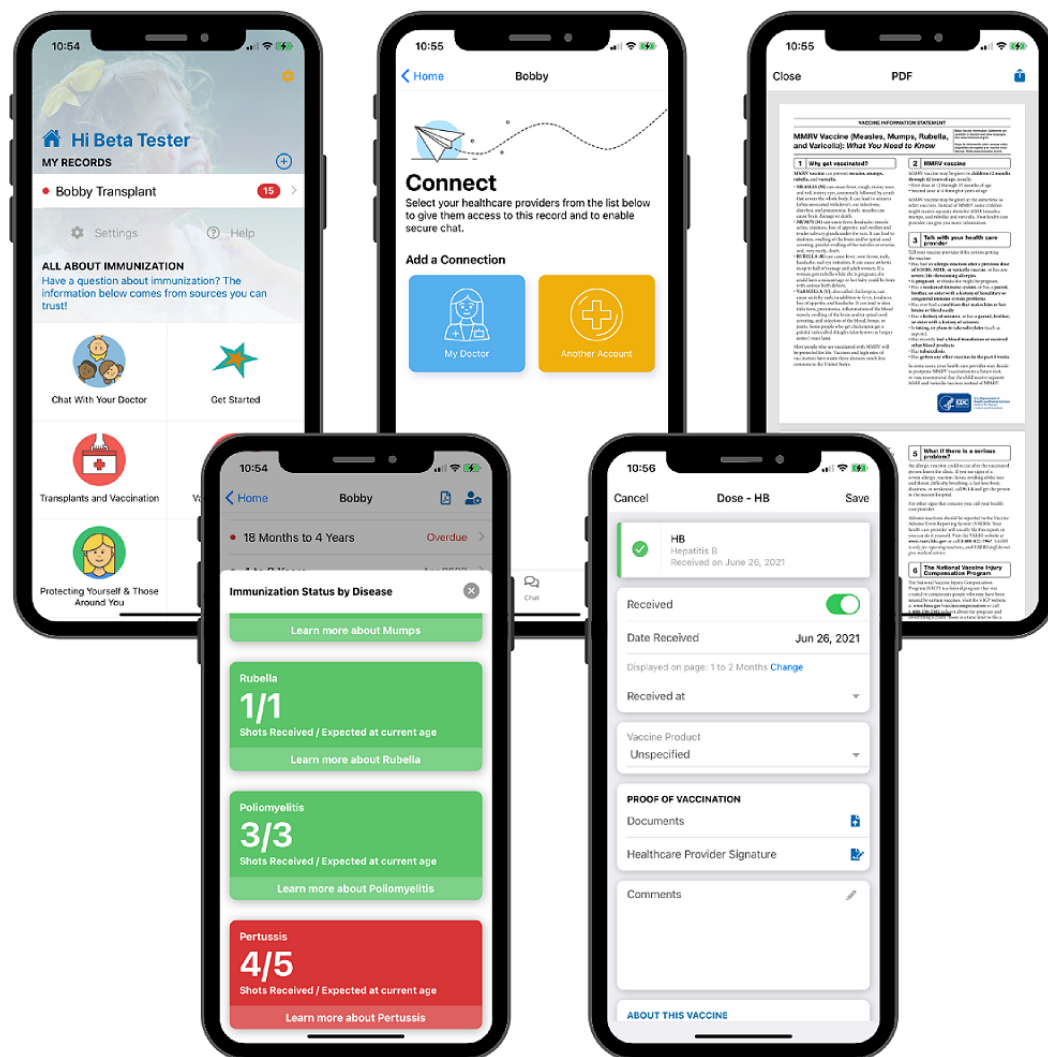
Overall, the participants were enthusiastic about the app. All participants stated that the app had the potential to increase knowledge about vaccines and VPIs and improve immunization delivery in the pretransplant period.

*Overall, the app is excellent. It’s a very easy to use app...you don’t have to be tech-savvy to use this app. [parent]*

*I think this app would be great not just for transplant patients but all children I care for who require care by multiple subspecialists. [primary care provider]*

All 12 participants completed the uMARS after they finished usability testing of the app. The average scores for engagement, functionality, aesthetics, and information were 4.2/5, 4.5/5, 4.6/5 and 4.8/5 respectively. Moreover, 100% of the participants reported that they would likely or definitely recommend this app to everyone.

Figure 3. Screenshots from the Immunize PediatricTransplant app.



## Discussion

### Principal Findings

In this paper, we described the initial design and user-centered iterative development Immunize PediatricTransplant, a mobile health app designed to increase immunization rates in the pediatric transplant population. Immunize PediatricTransplant addresses and attempts to overcome the barriers to pretransplant immunization by providing educational information about vaccines and VPIs, creating a cloud-based central vaccine record that is easily accessible to families and all members of the health care team regardless of which EMR they use, having a chat feature to enable communication between the family and multiple health care providers, and sending automated reminders (based on the accelerated vaccine schedule used for transplant candidates) to remind families and providers when vaccines are due.

While there are other immunization apps on the market that are able to store a vaccine record and provide general information about vaccines (ie, Docket Immunization Records app [Docket Health Inc], Passport Health, Apple Health app [Apple Inc]),

Immunize PediatricTransplant is unique for multiple reasons. First, to our knowledge Immunize PediatricTransplant is the first app that incorporates a communication tool so that multiple providers can communicate directly with the family and other providers about vaccines. Second, Immunize PediatricTransplant is the first app to include an automated vaccine reminder tool that sends out vaccine reminders using a unique vaccine schedule (the accelerated pretransplant schedule). Studies have shown that recall reminders are effective in improving immunization rates regardless of patient age, setting, or vaccination type [32,33]. Additionally, a meta-analysis of 13 randomized controlled studies showed that digital push technologies are more likely to impact vaccine uptake than nondigital interventions [34]. Third, Immunize PediatricTransplant is unique in providing tailored vaccine information for children with a specific health condition (transplant) who require a unique vaccine schedule (the accelerated schedule). The transplant community is a highly motivated and engaged user group that is ideal for pilot testing an mHealth intervention. Fourth, Immunize PediatricTransplant creates a patient-centered cloud-based personal health record across health care networks. Personal health records, which put

consumers in control of their health information, are a key feature in health information exchange [10]. If successful in future pragmatic trials, the app could be modified and used not just for transplant candidates and recipients, but also for children with other diseases who have low vaccine rates despite being at high risk for infectious complications (eg, inflammatory bowel disease, rheumatoid arthritis, and lupus) [35-43]. Overall, the participants were extremely positive in their review of the app with 100% of stakeholders recommending the app for transplant families and providers. However, they did express that input of a child's vaccine record could be improved in future iterations of the app. Currently, the app relies on either the parent or member of the health care team manually entering the name and date of all prior vaccines that the child has received. This leaves potential for error. In this pilot study, 87% of vaccines were entered correctly. Although 7/12 participants (58%) entered the information regarding vaccines with 100% accuracy, there was one participant who had difficulty and only entered 69% of the information correctly. The participants suggested that in the future it would be ideal if one could take a photograph of their child's prior vaccine record with their phone's camera, upload the photograph into the Immunize PediatricTransplant app, and then have the app automatically recognize vaccine names and dates. Optimal character recognition with natural language processing has recently been shown to have the potential to accurately identify clinically relevant information contained within the EMR [44-47].

Alternatively, a participant suggested that future iterations of the app could download vaccine information directly from the EMR or state immunization information systems, a feature that has been highlighted as an important future direction in mHealth [10]. However, there is no uniform EMR utilized across health systems in the United States. As of 2017, there were over 600 health information technology developers supplying certified health information technology [48]. In addition, many primary care providers and transplant teams who comanage transplant patients are on different EMRs. Likewise, if a child received vaccines at multiple locations (eg, at the primary care physician's office, at a community pharmacy, and at their transplant physician's office), vaccine information may exist in pieces across different EMRs. Unfortunately, state immunization information systems are only accessible by certain in-state providers (not all specialists have access), and transplant patients are often cared for by out-of-state transplant centers. The Immunize PediatricTransplant app allows for all providers, regardless of EMR, to access the complete vaccine record, receive vaccine reminders, and communicate easily with all members of the child's transplant team.

Certain participants voiced concern that the app could add to the workload of the providers; that it would be another tool that the providers would be responsible for checking and responding to. In future trials of the app among children awaiting liver, heart, and kidney transplant, survey questions will be designed to further understand whether the app helps facilitate communication between various providers and families or adds additional work burden to the providers.

## Strengths

The development of the Immunize PediatricTransplant app was strengthened by the use of various qualitative research techniques (semistructured interviews, focus group discussions, and lab usability think-aloud testing) to ensure that we had a thorough understanding of the pretransplant immunization process including all potential barriers faced by transplant candidates and their providers. A user-centered design at all stages of the development ensured that the app would meet the needs and preferences of all various transplant stakeholders (parents, primary care providers, transplant nurses, and transplant physicians). Finally, the uMARS survey data and data entered into the app's database complemented the qualitative data to ensure that the app was feasible and acceptable to all transplant stakeholder groups.

## Limitations

Several limitations are potentially present in this pilot study of the Immunize PediatricTransplant app. First, the app was designed and trialed by English speaking transplant stakeholders from 3 large pediatric transplant centers (CHOP, Lurie, and CHCO). As a result, acceptability, feasibility, and usability findings may not be generalizable to all transplant providers and families. Second, participation in the study was voluntary; therefore, it is possible that there was participant bias whereby providers and parents with enthusiasm for mHealth might have been more likely to participate. These individuals may also have above-average technical skills. Third, some app features (such as the chat or communication feature, vaccine reminder notifications, and the outbreak map) were unable to be fully tested during the beta testing since they require a live app environment. In a future study, we plan to trial this app, including the aforementioned features, in real time among parents and providers with a child currently awaiting heart, liver, and kidney transplant. Finally, the app is dependent on the manual entry of immunizations by the family or provider. If vaccine entry is incomplete or incorrectly entered, then individualized vaccine recommendations may be inaccurate. In a future study trialing the app among families awaiting transplant, we plan to assess the degree of accuracy in parental or provider vaccine entry.

## Conclusions and Future Directions

Despite the high risk for infection posttransplant, the majority of pediatric transplant recipients are underimmunized at the time of transplant. A novel app, Immunize PediatricTransplant, has now been developed, which may overcome the barriers to pretransplant immunization including providing knowledge about vaccines, a communication portal, an easily accessible vaccine record, and an automated vaccine reminder system. This developmental study suggests that the app is functional and acceptable to transplant stakeholders. Future randomized clinical trials among all pediatric solid organ transplant candidates across the United States (agile development phase 3) are needed to trial the app in real time to see if it can improve vaccine rates at the time of transplantation. Additionally, future clinical trials will allow us to evaluate whether the app is useful in educating families about novel vaccines (such as COVID-19) in the pediatric population.

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## Conflicts of Interest

KW and CB are cofounders of CANImmunize Inc. CB is also the chief technology officer of CANImmunize Inc. KW is a paid member of the independent data safety board for the Medicago vaccine trial. MMC is a senior developer at CANImmunize Inc.

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## Abbreviations

- CHCO:** Children's Hospital Colorado  
**CHOP:** Children's Hospital of Philadelphia  
**EMR:** electronic medical record  
**mHealth:** mobile health  
**uMARS:** user version of the Mobile Application Rating Scale  
**VPIs:** vaccine-preventable infections

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Original Paper

# A Counseling Mobile App to Reduce the Psychosocial Impact of Human Papillomavirus Testing: Formative Research Using a User-Centered Design Approach in a Low-Middle-Income Setting in Argentina

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## Abstract

**Background:** Human papillomavirus (HPV) testing detects sexually transmitted infections with oncogenic types of HPV. For many HPV-positive women, this result has negative connotations. It produces anxiety, fear of cancer or death, and disease denial. Face-to-face counseling could present many difficulties in its implementation, but a counseling mobile app could be practical and may help HPV-positive women reduce the psychosocial impact of the result, improve their knowledge of HPV and cervical cancer, and increase adherence to follow-up.

**Objective:** This study aims to understand HPV-tested women's perceptions about an app as a tool to receive information and support to reduce the emotional impact of HPV-positive results. We investigated their preferences regarding app design, content, and framing.

**Methods:** We conducted formative research based on a user-centered design approach. We carried out 29 individual online interviews with HPV-positive women aged 30 years and over and 4 focus groups (FGs) with women through a virtual platform (n=19). We shared a draft of the app's potential screens with a provisional label of the possible content, options menus, draft illustrations, and wording. This allowed us to give women understandable triggers to debate the concepts involved on each screen. The draft content and labels were developed drawing from the health belief model (HBM) and integrative behavioral model (IBM) variables and findings of mobile health literature. We used an FG guide to generate data for the information architecture (ie, how to organize contents into features). We carried out thematic analysis using constructs from the HBM and IBM to identify content preferences and turn them into app features. We used the RQDA package of R software for data processing.

**Results:** We found that participants required more information regarding the procedures they had received, what HPV-positive means, what the causes of HPV are, and its consequences on their sexuality. The women mentioned fear of the disease and stated they had concerns and misconceptions, such as believing that an HPV-positive result is a synonym for cancer. They accepted the app as a tool to obtain information and to reduce fears related to HPV-positive results. They would use a mobile app under doctor or health authority recommendation. The women did not agree with the draft organization of screens and contents. They believed the app should first offer information about HPV and then provide customized content according to the users' needs. The app should provide information via videos with experts and testimonies of other HPV-positive women, and they suggested a medical

appointment reminder feature. The app should also offer information through illustrations, or infographics, but not pictures or solely text.

**Conclusions:** Providing information that meets women's needs and counseling could be a method to reduce fears. A mobile app seems to be an acceptable and suitable tool to help HPV-positive women.

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## KEYWORDS

mHealth; mobile application; counseling; HPV test; cervical cancer; health belief model; integrated behavioral model; patient education; Argentina

## Introduction

### Background

Worldwide, more than 600,000 new cases and 240,000 deaths occur annually due to cervical cancer (CC), which disproportionately affects socioeconomically vulnerable women [1]. High CC mortality is related to problems across the cancer control continuum, including low screening coverage and loss to follow-up, diagnosis, and treatment [2,3]. In recent decades, human papillomavirus (HPV) testing has been developed as an alternative screening method. HPV testing has become the standard of care and a main strategy to accelerate the elimination of CC [4]. HPV testing detects sexually transmitted infections (STIs) with oncogenic types of HPV. Triage tests are used to identify HPV-positive women who will require diagnosis and treatment. In Argentina, the prevalence of high-risk HPV among screened women is around 13% [5]. HPV-positive women with negative triage will require rescreening in 12/18 months. Thus, infection with an oncogenic type of HPV can be detected, but positivity does not necessarily mean that the infection will cause cancer or that the woman will require treatment.

These particular characteristics of HPV results may have a negative impact on the psychosocial health of tested women [6,7]. As with other STIs, HPV is often accompanied by a host of negative beliefs and may cause fear, stigma, shame, and anxiety [8,9]. HPV-positive women are usually the target of negative stereotyping and may be questioned about their sexual behavior, situations that only increase their psychological burden [10]. HPV-positive results can also produce anxiety, fear of cancer or death, and disease denial [11-13]. Thus, HPV-positive results disrupt women's lives [14], characterized by uncertainty and ambiguity, and cause emotional impact and changes in their everyday life [15-19].

Relating an abnormal screening test with cancer and inevitable death can result in women being hesitant to continue follow-up procedures [17,19,20]. Women with high distress after abnormal screening tests are more likely to exhibit avoidant rather than adaptive coping strategies [10,21,22], making it more likely for nonadherence to occur [23]. Moreover, stigma related to the screening test result with an STI can also lead to the abandonment of follow-up and treatment [18]. Thus, HPV's psychosocial impact might not only diminish women's quality of life but also reduce their ability to complete diagnosis and treatment, which are essential steps in preventing CC. There is a critical need for interventions to reduce the psychosocial

impact of HPV positivity and increase women's capacity to adhere to follow-up.

Women's negative perceptions and concerns related to a positive HPV result decrease when their information needs are met and reassuring information is provided [24,25]. In addition, counseling has been extensively used for a wide range of health problems [26-28] and has been shown to increase HIV-testing rates [29,30], improve adherence to treatments [31], increase the quality of life of patients with cancer, and facilitate informed health decisions [26]. The World Health Organization recommends counseling as a strategy for interpersonal communication between the health care provider and the woman, as it allows women to become more informed and knowledgeable about HPV and CC prevention; offers a space to discuss sensitive topics, such as sexuality, disease, and death; and may encourage them to adopt preventive practices [32].

However, providing person-to-person counseling to all HPV-positive women presents implementation obstacles that may affect its quality. The main limitations are that it involves 1 or even several consultations, where each is time-consuming and should be provided by well-trained providers in consultation rooms that guarantee privacy [33-35]. Studies have pointed out that women often receive limited support and tools to cope with the psychosocial impact of HPV positivity, especially in settings with limited health resources [17,20,36]. In addition, although prevention programs from all countries in Latin America and globally produce information materials, in general this information is often provided without considering the barriers to comprehending complex information related to HPV [37-39].

In Argentina, women have reported problems in comprehending information during result delivery [20,40]. A study showed that provider communication is mainly focused on informing women of follow-up steps, leaving little to no room to address women's concerns, such as the sexual transmission of the virus and its link with cancer [20]. Results from a study carried out among 200 HPV-positive women showed that almost half of them considered that the information provided by health providers was confusing and lacked clarity [40].

Therefore, women undergoing HPV testing need innovative solutions to provide them with information, counseling, and support that do not depend on extensive use of human resources and time and that may increase their autonomy in accessing patient-centered information. Mobile health (mHealth) interventions can enhance the relationship between patients and health services and have been shown to increase adherence in primary care and gynecology care settings [41-43]. In particular,



the use of mobile apps to communicate with patients showed the improvement of health outcomes for a wide range of health conditions, including mental health [44-46]. In cancer care, apps provide accessible information and education at minimal costs throughout the cancer care continuum [47]. Apps have various advantages over other traditional approaches, including that they can be referenced even after the consultation and that they require less staff [12,48]. They are accepted by most patients, and they positively contribute to strengthening patients' engagement and empowerment [44,49-51].

Studies in low- and middle-income countries suggest that mHealth interventions dependent on mobile phone ownership are feasible and may reach the majority of patients in key subgroups, such as those who have low education and limited access to the health system [48,52]. In Argentina, more than 84.2% of women have access to the internet through a smartphone [53]. Reduced access to sexual health counseling has been reported for minority groups [54]; therefore, the implementation of an app-based tool to provide women with information and support might constitute a key intervention for diminishing inequalities in CC prevention.

## Objectives

In this paper, we report results from formative research carried out to understand HPV-tested women's perceptions about an app as a tool to receive information and support to reduce the emotional impact of HPV-positive results. In addition, we investigated their preferences regarding app design, content, and framing. The analysis was part of a study with the main objective of designing a user-centered counseling app aimed at reducing the psychosocial impact of HPV testing and increasing adherence to follow-up.

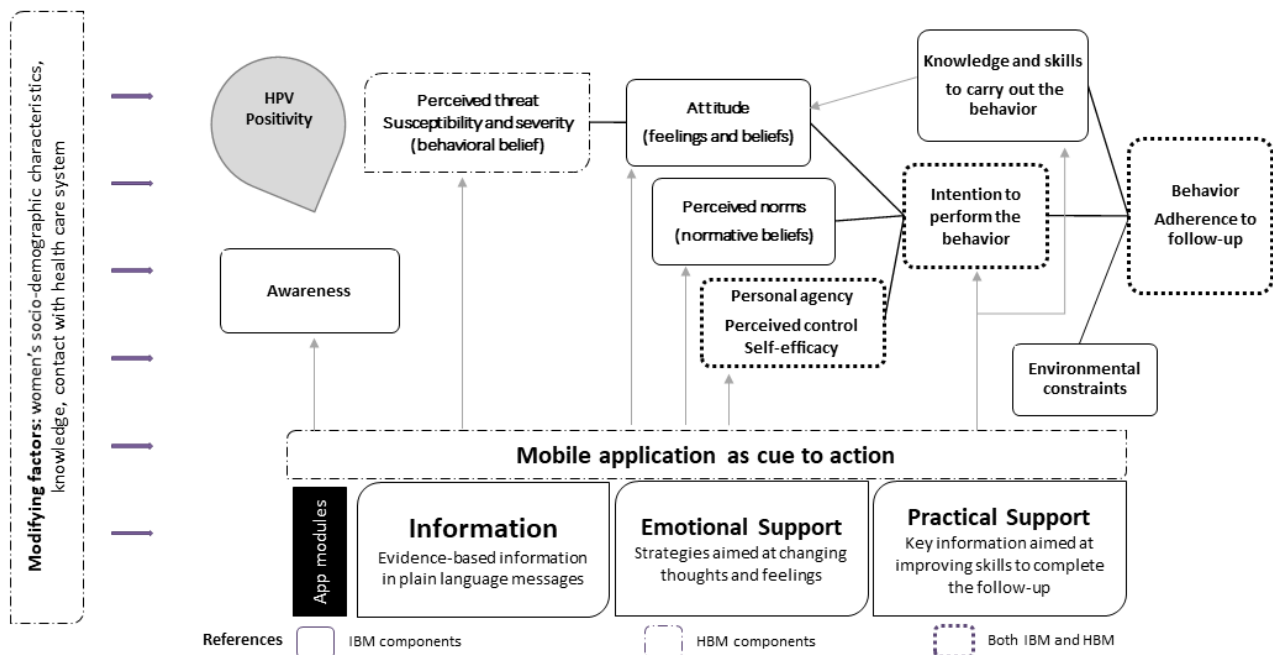
## Methods

### Theoretical Foundation

We relied on constructs from the health belief model (HBM) [55] and the integrated behavioral model (IBM) [56]. Both have been successfully used to explain interventions linked to CC prevention and mHealth intervention [57-61]. Following these models, we posited that the intention to adhere to follow-up after a positive HPV test result is determined by changing attitudes (eg, change of fatalistic thoughts about CC prevention and reduced fear), perceived norms (eg, increased value of cancer prevention care), and self-efficacy (eg, reduced perceptions about barriers to CC prevention and increased motivation to perform follow-up procedures) [55,56]. After delivery of HPV test results, the app will provide HPV-positive women with information and emotional and practical support tools that will influence attitudes, perceived norms, and personal agency, thereby favoring functional coping strategies. It will also improve awareness and knowledge of HPV and the importance of continuing diagnosis and treatment, as well as the significance of having the skills to do so (eg, details on how, when, and where). The app can promote cues to action, which will have an effect on individual behavior by reducing the psychosocial impact and triggering an intention to continue health care [55].

An initial version of the app's information architecture (IA) based on the theoretical framework consisted of 3 modules (Figure 1): (a) an Information module to provide women with evidence-based information in plain language messages; (b) an Emotional Support module to provide HPV-positive women with support in a way that will allow them to change negative thoughts [7,62] that lead to distress, diminished motivation, and less active self-care; and (c) a Practical Support module to provide women with tools to facilitate the continuation of the line of care, including reminders for diagnostics and treatment consultations.

**Figure 1.** Theoretical foundations of the app's IA (based on Skinner et al [55] and Montañó et al [56]). HBM: health belief model; HPV: human papillomavirus; IA: information architecture; IBM: integrative behavioral model.



The app's design process was based on a user-centered design (UCD) approach [63]. The UCD includes the end users' participation as co-designers and considers their specific cultural, social, and economic background to understand their preferences of information organization, features, and navigation flow (sequences of screens and IA) [64,65].

### Design of App Mock-ups

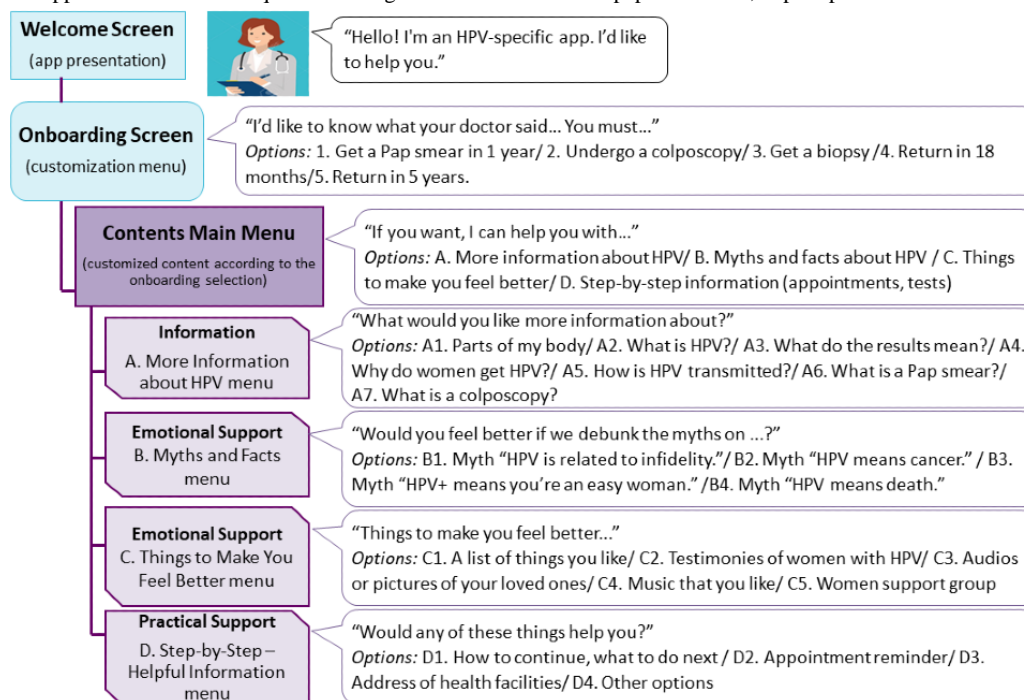
The content and labels of the app draft screens (ie, mock-ups) were designed in relation to the HBM and IBM frameworks. We also incorporated findings of a review we carried out to identify mHealth studies reporting on the development or evaluation of mHealth app components [20,59,66].

The draft mock-ups (Figure 2) consisted of 7 screens, including labels of the potential content, menus of options, and draft illustrations, as follows:

1. Welcome screen: presents the app and its purpose.
2. Onboarding screen: inquires about the medical indication received after the HPV-positive result. It offers the following as possible answers: "You must get a Papanicolaou (Pap) smear in 1 year," "You must undergo

a colposcopy," "You must get a biopsy," "You must return in 18 months," and "You must return in 5 years." The list of responses to this question was based on the guidelines for the prevention of CC established by the health authorities in Argentina [5].

3. Main Menu screen: presents a list of 4 options (Information, Myths and Facts, Things to Make You Feel Better, and Step-by-Step - Helpful Information). The content included on these screens was created from evidence provided by previous studies on women's knowledge and perceptions of HPV, as well as their information needs [6-8,67,68].
4. Information screen: presents a list of topics that the app provides information about.
5. Myths and Facts screen: presents a list of misconceptions about HPV and CC. The app provides information that refutes each myth.
6. Things to Make You Feel Better screen: provides a list of coping strategy-oriented activities.
7. Step-By-Step - Helpful Information screen: We proposed a menu with options to access useful information about the studies and to schedule reminders.

**Figure 2.** Options for app screens and their sequence and organization. HPV: human papillomavirus; Pap: Papanicolaou.

## Setting

The study took place in Ituzaingó, a district located 10 km (6.2 miles) west of the city of Buenos Aires, Argentina. Ituzaingó is part of the Metropolitan Area of Buenos Aires where one-third of the country's population lives. In 2015, HPV testing was established as a primary screening for women aged 30 years or over who were treated by the public health system. The public health system provides health care access to the population not covered by the social security sector (workers in the informal economy and their families). For the uninsured, health services are free of cost.

## Participants

Eligible women were literate, aged 30 years or over, resided in Ituzaingó, and mobile phone users. We carried out a purposive sampling procedure among women HPV-tested in the past 12 months in the public health care sector. We recruited participants by phone calls during which a recruiter explained the study aims and asked for informed consent. If the woman accepted, she consented to participate in the interview and a focus group (FG). We used the Zoom platform because it allowed women to participate without sharing personal data or logging in. We used age as a stratification criterion because it was considered a crucial variable to understand differences in cellphone use [69]. However, we did not find differences among analyzed groups. The FGs conducted were:

- FG1: 6 women aged 30-49 years
- FG2: 4 women aged  $\geq 50$  years
- FG3: 3 women aged 30-49 years
- FG4: 6 women aged  $\geq 50$  years.

## Data Collection

The original research protocol with face-to-face FGs was designed before the onset of the COVID-19 pandemic. Due to social distancing measures, we switched to an online strategy.

Online tools for data collection are suitable for sensitive topics and allowed us to solve logistical issues [70]. However, according to the literature [70,71], FGs using videoconference software require shorter durations and fewer participants per group. In addition, promoting interactions between participants is more challenging than in face-to-face FGs, due to audio delays or interruptions produced by weak internet connections. Therefore, from the original FG guideline, we selected some dimensions to be collected in an individual interview where women were asked about personal experiences and sensitive topics. We carried out individual online semistructured interviews about (1) the participant's profile; (2) use of cellphone, apps, and the internet; (3) personal experiences in the gynecological consultation; (4) information needs regarding HPV/CC; (5) risk perception and attitudes of HPV and CC; (6) perceived norms and self-efficacy to adhere to follow-up procedures; and (7) perceptions regarding an app as a tool to receive HPV testing-related information and support. The interviews also helped instruct women in the use of a virtual platform during the FGs, if necessary.

Second, we carried out 4 online FGs using the same virtual platform. Discussion in the FGs began with general questions on women's knowledge, beliefs, and attitudes regarding HPV results and CC prevention. This information was used as a trigger to introduce questions about women's preferences regarding the app and contextualize their answers. We then shared the draft app's mock-ups (Figure 2). This allowed us to give the women understandable triggers to debate the concepts presented on each screen. We asked the women about each screen's content and their preferences for app features. This paper presents the results we obtained from these FGs.

Two trained female researchers collected the information from the FGs in Spanish. One of these women has a background in social sciences and acted as a moderator (author VSA), while the other woman, who has a background in app design and

user-experience research (author DS), acted mainly as an observer but added further questions when needed; neither of them lived in Ituzaingó, nor did they have any relation with the health care institutions or their authorities. This was also stated during the FGs. At the end of each FG and if needed, we provided women with accurate information regarding HPV/CC prevention and answered their questions to reduce confusion related to discussed topics.

We carried out the fieldwork during the COVID-19 pandemic (November and December 2020). In that period, social distancing and semilockdown measures were in force for nonessential activities, including most services for nonurgent health issues. Despite this unprecedented context, we recruited 29 women during the individual interviews, of whom 19 (66%) participated in the 4 FGs. We also carried out a pilot FG to test the guide in a virtual environment. Each FG lasted 1 hour 55 minutes on average. Both were digitally recorded to transcribe verbatim.

### Analytic Approach

FG audios were transcribed to carry out thematic analysis of the debates [72], based on an iterative and flexible process following 6 steps:

1. To ensure coding reliability, 2 researchers (authors VSA and LS) become independently familiar with the data through transcriptions and the video recording.
2. We classified data using an initial codebook based on the theoretical constructs (eg, knowledge, beliefs, and attitudes), and in accordance with our research objectives, we identified the reactions to the app and to each draft mock-up screen (opinions).
3. We analyzed each category to generate new themes (eg, “a salient aspect of the data in a patterned way, regardless of whether that theme captures the majority experience of the participants” [72]).
4. Both researchers met to review themes to identify consistencies and resolve the inconsistencies with the other members of the team.
5. We grouped the emergent themes according to their conceptual similarities to define and name the subthemes.
6. We sought examples that adequately graphed each theme. Women’s preferences, reactions and opinions regarding the app draft screens were coded into emergent categories (subthemes) that identified their preferences with regard to content, tool, feature, and design aspect.

For data processing, we used the RQDA package from R software (R Core Team) [73,74] to organize, code, and summarize patterns. RQDA is a tool that assists the analysis of textual data, and it includes a number of standard computer-aided qualitative data analysis features, such as character-level coding, creation of documents or codes memos, and organization of codes into code categories.

To ensure coding reliability, a third author (SA) verified coding against a sample of transcripts and critically reviewed the data and themes to improve the trustworthiness of the study [75]. A detailed description of all procedures used to guarantee the trustworthiness of data collection and analysis is included in [Multimedia Appendix 1](#).

Method details and FG results are presented following the Consolidated Criteria for Reporting Qualitative Research (COREQ).

The study’s protocol was approved by the Diagnóstico por Imagen Morón (DIM) private clinic’s ethics committee. Before the study began, women provided orally informed consent, which was audio-recorded for documentation. The anonymity of participants was guaranteed at each step of the study.

## Results

### Characteristics of the Women

A total of 19 women participated in 4 FGs. Most of them had secondary-level education or less (12/19, 63%) and were employed (11/19, 58%). Most of them lived with a partner and had children, and near three quarters of them had public health insurance ([Table 1](#)).



**Table 1.** Characteristics of the focus group participants (N=19).

Variables	n (%)
<b>Age (years); mean 47.4 years, range 31-66 years</b>	
30-39	5 (19)
40-49	4 (21)
50+	10 (60)
<b>Educational level</b>	
Secondary (incomplete and complete)	12 (63)
Tertiary incomplete	5 (26)
Tertiary complete	2 (11)
<b>Economic activity status</b>	
Economically active (labor force)	14 (74)
Economically inactive (out of labor force)	5 (26)
<b>Family status</b>	
In a relationship with children	9 (47)
Single with children	8 (42)
Single without children	2 (11)
<b>HPV<sup>a</sup>/Pap<sup>b</sup> results</b>	
Positive/Normal	13 (68)
Positive/Abnormal	4 (21)
Negative	2 (11)
<b>Health insurance</b>	
Public	14 (74)
Private/social security	5 (26)

<sup>a</sup>HPV: human papillomavirus.

<sup>b</sup>Pap: Papanicolaou.

## Knowledge, Beliefs, and Attitudes Regarding HPV and CC

Most of the participants were unclear on certain aspects related to HPV and CC. HPV transmission was the topic that generated the most questions and caused the most confusion. Although most of the women knew about the sexual transmission of HPV, some mentioned other possible routes of transmission, such as poor hygiene or sharing clothes. The women also asked questions, such as who is at risk of HPV, what type of organism HPV is, what its symptomatology is, what the prognosis is in the case of HPV-positive results, and follow-up or treatment required. They also expressed interest in vaccines and recommended screening tests according to age. The lack of information led 1 of the women to conclude, "We don't know anything" [FG3].

*It would be great to have information because sometimes they say, "No, I won't do this to you because of such and such protocol," and you're just left thinking, "But how come they did it to my friend?"* [FG3, 30-49 years old]

Likewise, in the FGs, results identified recurrent beliefs in the different groups, such as that the virus affects more young

women or women of childbearing age, that it is transmitted in the context of heterosexual relations, and the idea of dormancy of the virus associated with cancer being something that is awakened.

The concerns that the participants mentioned were related to infidelity, partner conflict in the face of an HPV-positive result, possible discomfort during sexual intercourse due to HPV, or the consequences on fertility. In at least 2 of the groups, the women had initially mistaken the positive HPV test result for a cancer diagnosis.

In all groups, receiving the HPV-positive result triggered negative emotions, such as distress, anger, anxiety, shame, and fear. Those who had a medical consultation where they received information reported that it was a satisfying experience and reduced their concerns. However, those who did not get an opportunity to speak with a doctor shared a lot of concern, which was only increased by the difficulties in obtaining an immediate appointment during the COVID-19 pandemic.

*[After receiving the HPV+ result] . . . I spent entire nights crying, days with swollen eyes because I didn't know what I had. And I couldn't rely on a professional, there was nobody open for an*

*appointment, it was terrible because it was just when the pandemic started. They didn't take appointments anywhere and only cared about COVID cases, but people also have other issues. [FG2, 50 years and over]*

### App Acceptability

Participants in the different FGs expressed their willingness to use an app to access information about HPV and CC, especially to clarify doubts and have access to quality information until they could consult a health professional. In all the groups, the participants indicated that the health authorities, such as the Ministry of Health or the Health Secretariat of the municipality, would be reliable sources that would give legitimacy to the content of the app. The presence of institutional logos would provide an endorsement and, therefore, trust. Most of the participants indicated that they would trust the app if a physician or health professional recommended its use.

*Woman 1: The idea [of the app] is great. Yes, I would download it, but if someone recommends it to me...*

*Moderator: Who has to recommend it?*

*Woman 1: The doctors.*

*Woman 2: Well, if the doctor recommends it, even better.*

*Woman 3: Yes, if it's the doctor, even better.*

*Woman 2: Yes, I agree with the ladies. Professionals that come from the Ministry of Health and are approved for everything. [FG1, 30-49 years old]*

### Preferences on App Content, Features, and Design

#### Communication Style

All groups mentioned that the app should address the user's doubts, offer advice, and provide information in a way that is easy to understand: "It should be like a psychologist; it should listen but also give you advice, guide you" (FG1) and "It should explain things clearly" (FG2).

*[How should the app be?]*

*Woman 1: . . . It should know how to emotionally support us and how to respond to our questions. It should know how to give the user peace of mind and the information they need.*

*Woman 2: It has to seem human . . . [FG4, 50 years and over]*

#### The Welcome Screen

This screen included the sentence "Hi, I'm an HPV-specific app. I'd like to help you" as an introduction to the app. Several women criticized that it says, "I'm an app," and suggested that it should have a person's name, otherwise they would discard its use. Some positively valued the illustration that was included the draft, a health professional taking notes, which was interpreted as a receptive gesture: "Like they're listening to what you tell them" (FG1).

*Woman 1: I would put, instead of "I'm an app," I would give it a name to generate a more personal bond more human, you know?*

*Woman 2: Yes, because the greeting "I'm an app" sounds like a robot, and you delete [an app] . . . so they have a human identity, that looks like, simulates being human. [FG3, 30-49 years old]*

#### The Onboarding Screen

Faced with the options presented on the screen (Figure 2), several women expressed confusion:

*Woman 1: I don't understand . . . so you open the app, and it says it's going to help you, and now it jumps to "What did the doctor say?"*

*Woman 2: . . . So, you open the application knowing that you have HPV?*

*Woman 1: . . . I think there could be another [screen] before asking, "Did you get an HPV test?" [FG2, 50 years and over]*

Some women were unaware of the different tests listed: "What would be the difference between a Pap smear and colposcopy?" (FG3). Regarding their results, several women had been told that "everything was fine, that I should come back in a year" (FG1), even though they registered an HPV-positive result. This fact influenced the women's reaction as to which option they should choose, causing doubts as to whether the doctor's indication was the right one for their case.

*Woman 1: I was told that I have to get a PAP [smear] and colpo[scopy] every year, as well as a mammogram, which doesn't appear here [as an option on the screen].*

*Woman 2: [Reacting with doubts regarding the screen] . . . Sometimes you think you have to undergo such and such study, and you don't actually have to undergo it, and you never know if that's right or not. [FG3, 30-49 years old]*

#### The Main Menu Screen

The women's reaction to the Main Menu screen (Figure 2) was positive, with a high level of acceptability of the options: "I would like to read everything; if I open [the app], in just a day I'd explore the whole application, from top to bottom" (FG3).

*Woman 1: It's great.*

*Woman 2: I think it's good.*

*Woman 3: I think it's very good.*

*Woman 4: I would separate "If you like, I can help you with . . ." and you have all the information, "Would you like more information?" and then, absolutely, refer you with an appointment . . . make an appointment to have the study done, no matter what, and to consult a specialist, always. [FG4, 50 years and over]*

#### The Information Screen

When evaluating the Information screen (Figure 2), the women agreed that all the contents displayed were particularly important and interesting to them. Moreover, these contents led to proposals from the women on topics that this module of the app should address.

*[The app should provide information about] "call or contact us if you have any symptoms," or give guidelines on at what age you should do it . . . "If you are over 30 years old, you have to get a specialized test. "In other words, more controls, to have all that at your fingertips. "Babies must be vaccinated from this age to that age" . . . That would help us a lot. [FG2, 50 years and over]*

### **The Myths and Facts Screen**

This screen generated both positive and negative reactions. Among the positive comments, the women recognized that debunking inaccurate beliefs reduces concern: "It's important to debunk myths because they generate a lot of stress" (FG4). Among those who rejected the Myths and Facts screen, it was observed that the contents were interpreted as statements about their behaviors, not as a myth to be refuted. In some cases, the contents generated discomfort: "It's like they blame us" (FG1).

*[After reading the screen] . . . You don't have to be unfaithful or suffer from . . . it isn't cancer . . . nor is it because the person is an easy woman . . . nor did they die; in other words, they live with HPV and nothing else . . . I mean, I tested positive, but I wasn't unfaithful or anything like that; I got it and I don't know where. It could have been in a gynecological study that I had done . . . [FG2, 50 years and over]*

### **The Things to Make You Feel Better Screen**

This screen proposed a list of activities so that the user could find emotional support. Among the options on the screen, women were asked to indicate which options they preferred (Figure 2). Of the proposed alternatives, the favored ones were "Listening to other women's stories" and finding "Women support groups that help each other." Some participants stated that they wanted to hear testimonies from other women to know "how she coped with the HPV result" and "how it went" (FG3). They also suggested that the app provide statistics about women with HPV "who got cured because they did everything" (FG3).

The other proposed activities, such as "List of activities you like," "Listen to messages or see pictures of loved ones," and "Have music you like," were discarded because, on the one hand, "People already have [music or photos] on their cell phone" (FG1), while, on the other hand, they generated doubts about the personal information shared with the app.

*Woman 1: [The "Things to Make You Feel Better" screen] . . . I don't get it. In the app, are you going to hear or see stories of other women who went through the same thing? That's good. But . . . "Listen to messages from your loved ones" what would there be there? Audios in there, or is that something you would have to add? Have music that you like to listen to? I kind of don't relate it to the issue . . .*

*Woman 2: I already know what makes me feel better; why remind me of it?*

*Woman 3: Would we put pictures on the app? I wouldn't let it, for example . . . [when] it asks for*

*permissions to access [meaning not giving permission to access photos or files]. [FG4, 50 years and over]*

### **The Step by Step - Helpful Information Screen**

The women of all the FGs named the Reminders function as the most relevant: "I think it's great that it notifies you that you have to have a check-up" (FG4). Likewise, many participants proposed including a directory with care centers specialized in CC prevention. They also proposed a function that would allow scheduling appointments or "to be able to make an appointment directly there [in the app], you can enter your address, and they will give you an appointment at the nearest clinic" (FG1).

Several women showed interest in receiving notifications of the availability of results: "so that you can go and know that it's ready" (FG2). Others proposed including a function that would allow them to store or record previously performed studies: ". . . maybe the doctor asks me and I don't remember (. . .) I have to go and rummage through all the papers to see when [the last study] was" (FG2).

*. . . [in the app] you list the tests you should get done, you have the doctors' appointments, and you go . . . you have an agenda where you have all the tests you should get, so, well, you check off: "I've already had this done, ah, I need . . ." I don't know, "next time I go to the doctor's office, I'll ask them if this test is suitable or not," but you already have an agenda to follow and comply with. [FG3, 30-49 years old]*

### **Screen Flow**

One criticized aspect of the draft shown to the women was the sequence in which the screens were displayed.

*Woman 1: I would like that before choosing an option on "What did the doctor say?," it would say, "Do you know what HPV is?" first. Then if they don't know, send the user to an option where you give her all the information. If she already knows what it is, then follow with the "What did the doctor say?" options.*

*Woman 2: I want to find out what [HPV] is all about first, then I want to see "What method should I follow?" Or, if I already know what I should do, "What is [that test] for?"*

*Woman 1: Also . . . if you're already in treatment, "What step are you in?," the "step by step" of the process, the appointments and the studies would be missing. If you're already in treatment, "How are you?" Give other options there: "How are you feeling?," "Are you going to a center?," "Are you talking to anyone?" That would also be another bonus point, after the step by step. [FG2, 50 years and over]*

### **Format Preferences**

Regarding the different contents proposed in the app, the women proposed videos with explanations provided by professionals and testimonial videos with women relating their cases and evolution. They pointed out the need for a feature that would also allow sharing the information in the app with other women.

As for formats, women positively valued infographics and illustrations and, to a lesser extent, texts. Two groups stressed the importance of providing content using different formats to ensure accessibility: texts with audio for people with visual impairment or videos with text for those with hearing impairment.

Regarding the use of images, opinions were divided. On the one hand, there were some who argued that health contents through realistic images "are shocking" (FG1) and "are very off-putting" (FG4). On the other hand, women who were in favor of using real images pointed out that "if they're real, they help to raise awareness" (FG2).

*Woman 1: I would like there to be a video with a specialist who can clearly explain what this disease is and what steps you have to follow or what has to be done . . . so that a registered specialist can guide you. Not just anyone talking . . . and that they go straight to the point . . . In the general framework, they can guide you and tell you what you can do.*

*Woman 2: . . . but women's opinions too, there are some videos . . . of real cases, it would be good too, real cases . . . [FG3, 30-49 years old]*

**Table 2** summarizes the themes and subthemes obtained during analysis. Additionally, in [Multimedia Appendix 1](#), we present verbatim examples for each theme and subtheme.



**Table 2.** Knowledge, attitudes, and beliefs, acceptability, and screen evaluation: the app's content and features (themes and subthemes).

Themes	Subthemes	Subtheme definition
<b>Knowledge</b>		
	Lack of information	The questions and concerns the women expressed during FGs <sup>a</sup> that showed a lack of general knowledge of HPV <sup>b</sup> and CC <sup>c</sup> prevention
	Partial or incorrect information about HPV transmission	The questions and statements the women expressed during FGs that showed incomplete or incorrect information about HPV transmission
	Information needs: nature of HPV	The questions and concerns the women expressed during FGs regarding the nature of HPV ("What kind of disease is it?")
	Information needs: symptomatology	The questions and concerns the women expressed during FGs regarding possible HPV symptoms
	Information needs: prognosis	The questions and concerns the women expressed during FGs regarding the forecasting of the probable course of HPV and the chances of recovery
	Information needs: who is at risk for HPV?	The questions and concerns the women expressed during FGs regarding who is at risk for HPV (what kind of person or age/gender/sexual behavior profile)
	Information needs: follow-up medical procedures	The questions and concerns the women expressed during FGs regarding the follow-up medical procedures required after an HPV-positive result
<b>HPV beliefs</b>		
	Only affects young people	Narratives showing women's perceptions on HPV as a disease that only affects young people
	Is only transmitted via heterosexual intercourse	Narratives showing women's perceptions on HPV as a disease that is only transmitted in heterosexual intercourse
	HPV and cancer as dormant diseases	Narratives showing women's perceptions on the asymptomatic nature of HPV linked with the idea of cancer as a dormant disease
<b>Attitudes</b>		
	An HPV-positive result causes conflicts with partner over infidelity.	Emotional reactions related to the HPV-positive results (such as anger) that may cause conflict with partners due to suspicions of infidelity
	An HPV-positive result causes fear of consequences in sexual intercourse.	Narratives around fear of having consequences in sexual intercourse due to HPV-positive results (such as feel pain or discomfort)
	An HPV-positive result causes concerns on infertility.	Narratives around concerns that HPV causes infertility
	An HPV-positive result causes distress.	Narratives around concerns due to distress caused by an HPV-positive result
<b>App acceptability</b>	Trust	Reactions to the app in terms of acceptability and the criteria to be considered trustworthy
<b>Welcome screen</b>	App preferences identity: age/gender	Preferences around the app's character identity in terms of age and gender
<b>Onboarding screen</b>	Reactions: confusion	Women's comments, concerns, and questions that showed the confusion produced by the Onboarding screen
<b>Contents Menu screen</b>	Reactions: positively evaluated content	Reaction expressed in terms of approving the displayed content
<b>Information screen</b>	Reactions: positively evaluated content	Reaction expressed in terms of approving the displayed content
<b>Myths and Facts screen (Emotional Support module)</b>		
	Accepts the Myths and Facts screen	Reaction expressed in terms of approving the displayed content
	Rejects the Myths and Facts screen	Reaction expressed in terms of rejecting the displayed content (includes other reactions such as confusion or misunderstanding of the displayed content)

Themes	Subthemes	Subtheme definition
<b>Things to Make You Feel Better screen (Emotional Support module)</b>		
	Preferred activity: listening to other women	The main activities the women preferred from a list of displayed options
	Preferred activity: sharing with other women	The main activities the women preferred from a list of displayed options
	Dismissed activities	The activities dismissed as app features
<b>Step by Step - Helpful Information screen (Practical Support module)</b>		
	Reminder to make an appointment	App features proposed/accepted as practical support
	Results availability reminder	App features proposed/accepted as practical support
	Reminder of having an appointment	App features proposed/accepted as practical support
	Directory	App features proposed/accepted as practical support
<b>General app design</b>		
	Communication style	Preferences on the app's contents communication style (how it should be)
	Contents organization: screen flow	Preferences and suggestions on the app's screens sequence (order in which screens must be displayed in the app according to its content)
	Formats preferences: videos	Preferences on the app's content formats
	Formats preferences: multiple formats for accessibility	Preferences on the app's content formats
	Formats preferences: images/photographs	Preferences on the app's content formats

<sup>a</sup>FG: focus group.

<sup>b</sup>HPV: human papillomavirus.

<sup>c</sup>CC: cervical cancer.

## Discussion

### Principal Results

Our results showed that women positively valued the app as a tool to obtain information and counseling about HPV and CC. Similar findings were reported by studies that analyzed women's preference for apps aimed at providing support to women diagnosed with cancer [43,76-80]. Two studies analyzed the acceptability of an app oriented toward educating people on HPV and CC prevention. A research team from Norway designed an app called FightHPV [81]. The app is a digital game-based learning tool for mobile devices that aims to communicate concepts that help people understand HPV-related diseases, such as CC, and their prevention. Authors reported positive reactions from potential users toward the educational game (they enjoyed the game, and the game was challenging). Additionally, a study carried out in the United States reported the development of an interactive virtual patient educator for Hispanic women about CC and HPV. During the design process and in the pilot study, participants reported high levels of satisfaction with the interaction with the system [82].

Our app was conceived to provide support to HPV-tested women after the delivery of the test results. Our study showed that women would accept and trust its contents as long as a physician recommended it. Greenhalgh et al [83] analyzed dimensions that influence the diffusion and adoption of health innovative interventions. They conducted a systematic review, and many of their conclusions were used to develop the Consolidated

Framework Intervention Research (CFIR). Following Greenhalgh et al's [83] conclusions, the CFIR states that a key element to achieving the acceptability and adoption of health innovations is leader endorsement during its implementation. According to this finding, experts' opinions have a particular influence on the beliefs and actions of those who have to adopt the health innovation. In our case, health professionals can be perceived as experts who may exert influence through their authority and status, instilling credibility to the contents provided by the app (legitimacy).

Evidence has shown that it is important to offer users personalized contents [84]. Initially, we chose an onboarding screen to provide customized content according to the clinical screening, diagnosis, and treatment protocol recommended by the National Ministry of Health and the National Cancer Institute [5]. However, our study concluded that women find the onboarding options based on these recommendations confusing, as they cannot relate them to the explanation provided by the health professional. Adherence of health professionals to national screening-diagnosis-treatment recommendations is rather low [3], so women are often given instructions on follow-up that do not align with national guidelines. This is the case, for example, of the woman who was told to repeat a Pap smear and colposcopy annually, an option not endorsed by the national guidelines. In addition, evidence shows that women lack general knowledge on HPV and CC prevention and have problems understanding what their health professionals tell them [39]. Therefore, our study showed the importance of an

initial screen that provides a menu to access information regarding HPV, and the purpose of screening tests before providing customized content.

Following our theoretical framework, the app initial draft included 3 separate modules: Information, Emotional Support, and Practical Support. However, the FG participants rejected this scheme and suggested reorganizing the screens and a new hierarchical organization of modules. They agreed that more knowledge helps them face fears and that the emotional support tools (eg, Things to Make You Feel Better) should complement the provided information, not be the central content of the app. This result enhances the importance of user perceptions of the app content and its organization as a key element in the design process in order to ensure high final user engagement [78].

Our study showed that women highly value having a medical appointment reminder feature (Practical Support module). Similarly, the study Application of Communication and Information Technologies to Self-Collection (ATICA study, for its initials in Spanish), conducted in Jujuy, Argentina, found that HPV-positive women highly accept receiving reminders through the Short Messaging Service (SMS) to increase their adherence to a Pap-based triage [85]. This is an important result for the app design as reminders (eg, through SMS) have been found to improve medication adherence and other treatment compliance [48].

Regarding the app style and tone, women asked for an empathic communication style even when clearly acknowledging that they were interacting with a device (mobile phone). Similar findings were found in a previous study that analyzed women's preferences regarding SMS content design [86] to receive information about triage after an HPV-positive result. In that study, also carried out in Argentina, women requested the SMS content to emulate the overall friendly style of community health workers. Other authors found that empathy is positively valued among women when receiving information about being HPV-positive and follow-up [39]. Additionally, our results found that women positively value the application as it can provide information through multiformat content. They agreed that subtitled videos, illustrations, or infographics with audio help them understand the content while ensuring accessibility.

However, we did not find agreement on preference related to real pictures or only text content.

Our findings have some implications for the design of mHealth interventions targeted toward HPV-tested women. Health care providers may consider using electronic health (eHealth) technologies, such as smartphone apps, to provide patients with psychosocial support after HPV-positive result delivery. Furthermore, policy makers may consider funding and supporting evidence-based interventions delivered through eHealth platforms. This is particularly important in the midst of the COVID-19 pandemic, as using mHealth strategies has been signaled as a key intervention that may help women in a context where we must minimize face-to-face encounters.

### Limitations

This study had some limitations. Due to the COVID-19 pandemic, we conducted online FGs, and we reduced the number of participants for each group. The small sample and the specific study setting may have limited the generalizability of our findings. However, it is considered sufficient for qualitative research, and clear themes emerged from the data. However, the pandemic created an optimal setting as it hinders physical interaction, thereby strengthening the argument for an mHealth approach. In addition, we achieved theoretical saturation to the main findings, such as content presence and screen organization. The study results were limited to the women's points of view and did not include health providers' opinions regarding the app; however, we plan to interview physicians from the Ituzaingó health system as part of the app process design.

### Conclusion

This formative research has shown that women accept an app that provides information and counseling as part of the health provider-woman encounter. A lack of knowledge or misinformation about HPV and CC was the core of their opinions and demands regarding the app design. Our findings highlight the need to involve end users in the early stages of the conceptualization and design process of mHealth innovations. The key elements of the app design must be carefully chosen in an endeavor to guarantee both comprehension of the contents and usefulness to the end user.

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### Conflicts of Interest

None declared.

## Multimedia Appendix 1

Thematic analysis: results and procedures.

[\[PDF File \(Adobe PDF File\), 287 KB - formative\\_v6i1e32610\\_app1.pdf \]](#)**References**

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## Abbreviations

**CC:** cervical cancer  
**CFIR:** Consolidated Framework Intervention Research  
**eHealth:** electronic health  
**FG:** focus group  
**HBM:** health belief model  
**HPV:** human papillomavirus  
**IA:** information architecture  
**IBM:** integrative behavioral model  
**mHealth:** mobile health  
**Pap:** Papanicolaou  
**SMS:** Short Messaging Service  
**STI:** sexually transmitted infection  
**UCD:** user-centered design

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Original Paper

# Assessment of Social Support and Quitting Smoking in an Online Community Forum: Study Involving Content Analysis

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## Abstract

**Background:** A key factor in successfully reducing and quitting smoking, as well as preventing smoking relapse is access to and engagement with social support. Recent technological advances have made it possible for smokers to access social support via online community forums. While community forums associated with smoking cessation interventions are now common practice, there is a gap in understanding how and when the different types of social support identified by Cutrona and Suhr (1992) (emotional, esteem, informational, tangible, and network) are exchanged on such forums. Community forums that entail “superusers” (a key marker of a successful forum), like QuitNow, are ripe for exploring and leveraging promising social support exchanges on these platforms.

**Objective:** The purpose of this study was to characterize the posts made on the QuitNow community forum at different stages in the quit journey, and determine when and how the social support constructs are present within the posts.

**Methods:** A total of 506 posts (including original and response posts) were collected. Using conventional content analysis, the original posts were coded inductively to generate categories and subcategories, and the responses were coded deductively according to the 5 types of social support. Data were analyzed using Microsoft Excel software.

**Results:** Overall, individuals were most heavily engaged on the forum during the first month of quitting, which then tapered off in the subsequent months. In relation to the original posts, the majority of them fit into the categories of sharing quit successes, quit struggles, updates, quit strategies, and desires to quit. Asking for advice and describing smoke-free benefits were the least represented categories. In relation to the responses, encouragement (emotional), compliment (esteem), and suggestion/advice (informational) consistently remained the most prominent types of support throughout all quit stages. Companionship (network) maintained a steady downward trajectory over time.

**Conclusions:** The findings of this study highlight the complexity of how and when different types of social support are exchanged on the QuitNow community forum. These findings provide directions for how social support can be more strategically employed and leveraged in these online contexts to support smoking cessation.

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**KEYWORDS**

qualitative research; smoking cessation; social media; social support; smoking; tobacco use; tobacco; online forum

## Introduction

### Background

Tobacco use continues to be the number one cause of preventable disease and death around the world, including North America [1,2]. Approximately 12% of Canadians (3.7 million) and 14% of Americans (40 million) smoke cigarettes [3,4]. More than 50% of these smokers in both countries report a desire to quit [5,6], and 54% of Americans and 42% of Canadians who smoke stated that they tried to quit in the last year [3]. Although most of the smoking population has stated a desire to quit or has attempted to quit, a little over 6% of Americans who smoke were able to successfully quit in 2018 [5]. There is a similar proportion in Canada, where only 6% of former smokers quit within the last year [6].

There are many cessation services and interventions now available to support and enhance the cessation efforts of individuals. A recommended strategy in North American best practice guidelines for smoking cessation interventions and services is the inclusion and recommendation of social support [7,8]. Social support is defined as interpersonal communication that is characterized by the exchange of informational and emotional resources among and across networks [9]. In addition to receiving support from clinicians and tobacco specialists, engagement with social support communities/networks has been consistently found to be a key factor in successfully reducing and quitting smoking, as well as preventing relapse [10-14]. Because of the benefits that social support offers, smokers participating in behavioral interventions for smoking cessation are commonly advised to seek social support [15-19]. Recent technological advances have made it possible for social support to be available online through community forums associated with cessation services and interventions, enabling significant reach to a variety of populations [20]. While community forums associated with smoking cessation interventions are now common, there is a gap in understanding the nature of social support exchanges on such forums.

Social support has been broken down into the following 5 different types according to Cutrona and Suhr [9]: emotional, esteem, informational, tangible, and network support (Multimedia Appendix 1). This social support framework is useful for understanding what types of social support are most useful in different behavioral contexts [21]. However, little is known about what types of social support are needed and when, especially when it comes to a behavior like smoking, which is often not a linear process. Understanding what types of social support are provided at different time points throughout the quitting trajectory would provide both service providers and end-users with specific directions for maximizing social support associated with an intervention. Community forums for smoking cessation are ripe platforms for investigating the different types of social support exchanges at different points in time.

A key marker of successful community forums on health-related topics is the engagement of superusers [22,23]. Superusers are voluntary users who remain disproportionately engaged and essentially serve to keep the forum “alive” through their active engagement over a long-term timeframe [22]. Superusers play

a critical role in generating and exchanging content, support, and advice, and prompting discussions [22]. QuitNow is an example of a community forum for smoking cessation that includes superusers. However, little is known about the nature of the social support provided on these forums in general, and especially on forums that entail superusers. Unpacking how social support is activated on a successful forum will assist in leveraging its success, as well as enhancing other aspects of cessation services and interventions. The purpose of this study, therefore, was to characterize the posts made on the QuitNow community forum at different stages in the quit journey, and determine when and how the social support constructs are present within the posts.

### QuitNow

QuitNow is British Columbia’s free online smoking cessation service delivered by the British Columbia Lung Association on behalf of the Government of British Columbia. It is a customized program for British Columbia residents who are looking to quit or reduce tobacco use, including smoking. On the website, there are resources for different stages of quitting (eg, thinking about quitting, preparing to quit, and staying quit). There are also resources for health professionals, families, and friends to support smokers who want to quit. Individuals are encouraged to create an account with QuitNow, which gives them access to free quit coaching, live chat with a quit coach, and a community forum. A quit coach is an individual trained and paid to provide cessation support to individuals trying to quit smoking. The community forum is the primary social support feature of QuitNow and is moderated by quit coaches. The content is publicly available, but engagement with the forum requires registration. Given that the posts examined for this study are publicly available, in consultation with the Behavioral Research Ethics Board and the University of British Columbia’s Okanagan campus, it was agreed that ethical approval was not required.

## Methods

### Data Collection

For this study, a total of 506 QuitNow community forum posts spanning the month of December 2019 were collected and entered into Excel for conventional content analysis. These posts were collected in reverse chronological order so that the most recent activity on the QuitNow community forum page was represented. Sampling was driven by saturation of codes, where posts were collected until no new categories or subcategories were identified [24].

### Data Analysis

Using conventional content analysis [25], we developed both inductive and deductive categories to identify what types of social support smokers need at different stages in their quit journey. First, we inductively assigned codes to categorize the original posts, noting the user’s stage in quitting. The frequency of posts per category was investigated. Next, 5 quit stages were identified and classified as follows: (1) before quitting, (2) 1st month, (3) 2nd month, (4) 3+ months, and (5) relapse. The variability of user engagement over time and per quit stage was

examined. Next, we applied the social support framework developed by Cutrona and Suhr [9] to deductively code the responses to see what types of social support were given in response to the original posts. We also inductively coded responses that did not fit within the definitions of the social support constructs. Two authors (LS and AA) engaged in 3 collaborative coding sessions via UBC Zoom to code 75 posts. Through these collaborative coding sessions, the authors developed a coding legend and assigned codes directly onto the Excel document. As the authors applied the coding legend to the posts, any discrepancies in coding were brought up in real time. The coding legend was revised, and the parameters for what is included in a code were revisited for enhanced clarity. The 2nd coder (AA) then independently coded the remaining posts, consulting with the 1st author regularly as needed. Finally, 2 different authors (SK and RS) developed analytic tables and charts to offer a visual display of what types of supports were provided and when in the quit smoking trajectory as discussed by users on the QuitNow forum.

## Results

### Users

In total, 89 unique users are represented in this sample of posts, with 413 posts made by QuitNow users and 93 made by a Quit coach.

### Posts

Of the 506 posts, 76 were original posts and 430 were responses or subresponses to these posts. The average number of responses

per original post was 6, with a range of 4 to 8 responses. Each post contained an average of 46.27 words.

### Original Posts

The data within the 76 original posts were coded (n=145); these codes were subsequently classified into the following 7 categories: (1) quit desires, (2) quit struggles, (3) updates, (4) successes, (5) quit strategies, (6) advice requests, and (7) smoke-free benefits (Table 1).

The frequency of posts per category was examined. The greatest numbers of original posts were in the categories *successes* and *quit struggles*, followed by *updates*, *quit strategies*, and *desires to quit*. *Advice requests* and *smoke-free benefits* had the lowest numbers of posts.

Next, variability in user engagement over time was investigated. The 1st month entailed the most engagement, followed by the 2nd month (Table 2). During the before quitting stage, users primarily posted about their quit desires. During the 1st month of quitting, all categories other than *quit desires* and *smoke-free benefits* were almost equally represented. During the 2nd month, *successes* and *quit strategies* were the most commonly posted categories. In 3+ months of their quit journeys, users most frequently shared *successes*. Finally, during the relapse stage, sharing struggles was most common. Figure 1 displays a visual representation of the variability in category representation throughout the quit journey.

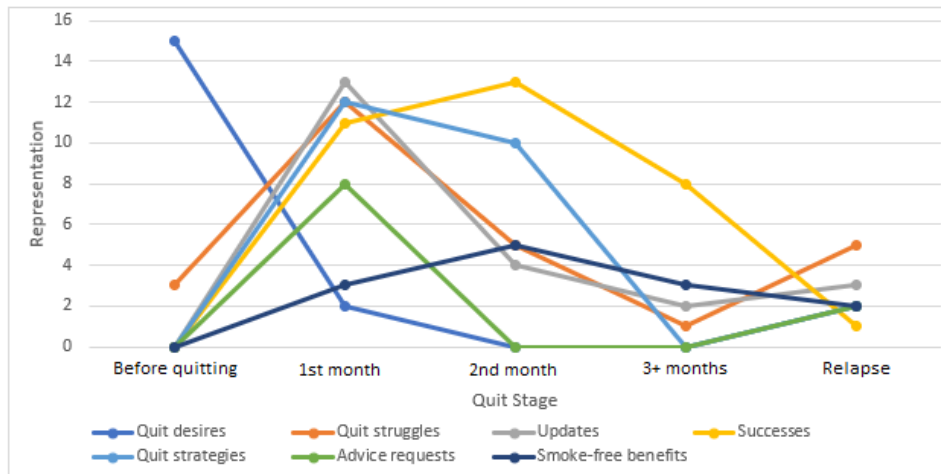
**Table 1.** Categories of original posts.

Category	Description	Exemplary quote	Total value (N=145), n
Quit desires	Sharing their desires, plans, or intentions to quit.	<i>Been battling for a while with quitting and starting quitting and starting. But ready to just call it quits. I hate smoking and no longer want it in my life or in my thoughts. It's time!</i>	19
Quit struggles	Sharing past, current, or anticipated struggles that make quitting more difficult.	<i>I have tried numerous times to quit. I was vaping to help cut down, but with all the problems people are having from vaping, I stopped using my vape. But I smoke more now.</i>	26
Updates	Sharing an update on their quitting status.	<i>Hello. This is day 8 and still doing well, I am using the patch and its working as well.</i>	22
Successes	Sharing their experienced successes.	<i>I've made it 3 weeks! Longest smoke-free run since starting when I was 19. I've tried seriously quitting since January of this year, &amp; kept hitting a wall at 3-days, even made 2 weeks in April, but got confident and had "one puff" at my birthday party, and you know how that turned out. Although I don't always post, I do look to this community daily for inspiration. Thanks to all who share their experiences, I can relate to so many of you. :)</i>	33
Quit strategies	Sharing tips and strategies that worked for them, and strategies they will use.	<i>As an aside, if you don't exercise regularly, I highly recommend you try doing that now. It does wonders to blow off steam and reduce withdrawal anxiety for me. Maybe it will for you, too.</i>	24
Advice requests	Asking for advice to navigate circumstances they are experiencing.	<i>I bought smokes yesterday because I got stressed and anxious. I think I will get the patch. What ways are you all using to quit?</i>	10
Smoke-free benefits	Sharing benefits of being smoke free.	<i>My favorite thing about being quit is not being a slave to this addiction anymore. I am mindful [of] all the times I would have been thinking "this is when I'd go for a smoke" or "do I have enough cigarettes till tomorrow?" or "Where can I smoke?" or "when will I have a chance to smoke?" .... and the list goes on. What a giant, toxic waste of time smoking is!</i>	11

**Table 2.** Representation of categories at each quit stage.

Stage and category	Representation (N=145 posts)
<b>Before quitting (18 posts), n (%)</b>	
Quit desires	15 (83.3)
Quit struggles	3 (16.6)
<b>1st month (61 posts), n (%)</b>	
Quit desires	2 (3.3)
Quit struggles	12 (19.6)
Updates	13 (17.5)
Successes	11 (18.0)
Quit strategies	12 (19.6)
Advice requests	8 (13.1)
Smoke-free benefits	3 (4.9)
<b>2nd month (37 posts), n (%)</b>	
Quit struggles	5 (13.5)
Updates	4 (10.8)
Successes	13 (35.1)
Quit strategies	10 (27.0)
Smoke-free benefits	5 (13.5)
<b>3+ months (14 posts), n (%)</b>	
Quit struggles	1 (7.1)
Updates	2 (14.3)
Successes	8 (57.1)
Smoke-free benefits	3 (21.4)
<b>Relapse (15 posts), n (%)</b>	
Quit benefits	2 (13.3)
Quit struggles	5 (33.3)
Updates	3 (20.0)
Successes	1 (6.7)
Quit strategies	2 (13.3)
Advice requests	2 (13.3)



**Figure 1.** Trajectory of post category representation throughout the quit journey.

## Response Posts

In relation to the 430 responses or subresponses to the original posts, 1100 codes were assigned and broken down into the following 5 social support categories: (1) emotional support, (2) esteem support, (3) informational support, (4) tangible support, and (5) network support, as well as an “other” category, the latter of which was inductively derived (Table 3). With the exception of tangible support, the remaining 4 social support constructs were present within the responses. Emotional, esteem, and informational support were the most prominent social support categories present. Network support was the least present. Most posts contained multiple social support constructs, which are exemplified in the following quote:

*...I really admire you for remaining so positive and so proud of you for not giving up (**compliment under esteem support**). I know you'll beat the nicodemon and send him back to where the sun don't shine (**encouragement under emotional support**). Just look at him in the eye and tell him “You're not in control anymore, I am” (**suggestion under information support**). 30 days is awesome and quitting is one of the best gifts you can ever give yourself (**compliment under esteem support**).*

Out of the possible 26 social support subcategories, 14 were present within the responses. Encouragement under emotional support and compliments under esteem support were the most strongly represented at 20.9% (n=230) and 20.4% (n=224) of

the 1100 codes, respectively. Suggestion/advice under informational support was the next most common at 15.6% (n=172). The least represented subcategories fell under emotional, esteem, and informational support (sympathy, relief from guilt, and teaching, respectively) at 0.9% (n=10) each.

Parallel to how the number of original posts was the highest during the 1st month, the numbers of user responses and subresponses were also at their highest during this time (Table 4). Additionally, responses were also very high during the before quitting stage as well as during the 2nd month. Overall, encouragement, compliment, and suggestion/advice consistently remained the most prominent types of support throughout all the stages. Companionship maintained a steady downward trajectory, with the most companionship posts during the before quitting stage and the least during the 3+ months stage.

During the before quitting stage, encouragement, compliment, and suggestion/advice were the most prominent types of support offered to users. During the 1st month, these were also the most prominent but in the reverse order whereby suggestion/advice was the most prominent, followed by compliment and then encouragement. During the 2nd and 3rd months, again, these were the most prominent types of support but with compliment being the most prominent, followed by encouragement and then suggestion/advice. During the relapse stage, encouragement and suggestion/advice were the most prominent, and were equally followed by compliment and companionship. The above trends can be visualized in Figure 2.

**Table 3.** Social support responses to original posts.

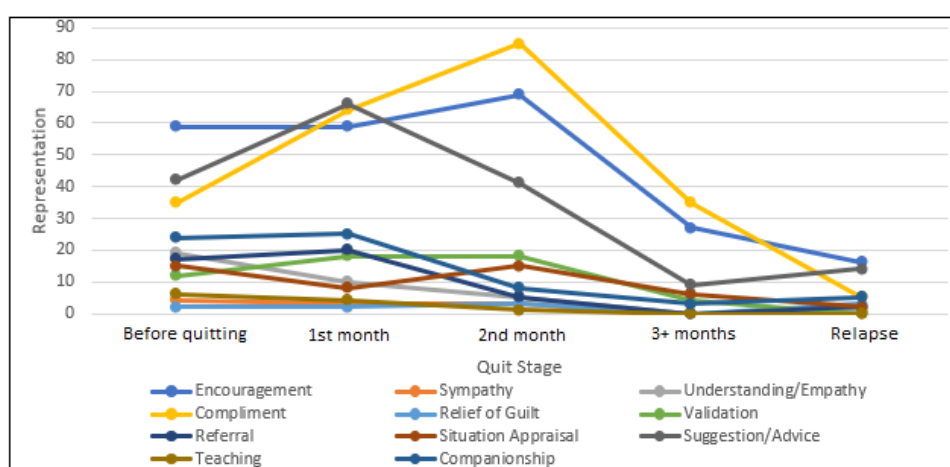
Code and subcode	Exemplary quote	Value (N=1100), n (%)
<b>Emotional (n=275)</b>		
Encouragement	<i>So glad you're trying again. I hope this is the one for you! Good luck, and keep strong, you can do this!</i>	230 (20.9)
Sympathy	<i>I'm sorry to hear that you were allergic to the patch...Did you have a chance to discuss with your doctor or pharmacist?</i>	10 (0.9)
Understanding/empathy	<i>I know what you are going through. I was a two pack a day smoker and it was killing me as well, it has been ten days since my last smoke and I was smoking for 30 years.</i>	35 (3.2)
<b>Esteem (n=286)</b>		
Compliment	<i>With your commitment to quit and all these great strategies, you seem well prepared and equipped to fight the cravings and conquer this nicotine addiction!</i>	224 (20.4)
Relief of guilt	<i>You can only do what you can, try again, and one of these times it will stick for good. Don't be too hard on yourself.</i>	10 (0.9)
Validation	<i>Quitting is difficult and most people try several times before they are successful.</i>	52 (4.7)
<b>Informational (n=283)</b>		
Referral	<i>BC Quit Now helpline is always available to help you plan and provided you with tips and tricks to make your quit successful. If you need extra support, give us a call, we would be happy to help you 1-877-455-2233.</i>	44 (4.0)
Situation appraisal	<i>Quitting is a selfish thing that you do for yourself but the benefits carry over to all the other people in your life!</i>	56 (5.1)
Suggestion/advice	<i>I'm using the patch and lozenge and went down a step on the patch last week. Slow and steady, right? Remember - this is a marathon, not a sprint.</i>	172 (15.6)
Teaching	<i>Many studies have shown that physical activities such as aerobic exercise help reduce the urges to smoke and decrease the withdrawal symptoms and cravings for cigarettes.</i>	11 (1.0)
<b>Network (n=85)</b>		
Companionship	<i>There's lots of support here on the forum; take time to read the others and their quit journey. You can also call a quit coach to help you make a plan. Good luck!</i>	85 (7.7)
<b>Other (n=191)</b>		
Appreciation	<i>Awe thanks for your support...I am hanging in there and I know with time it will get easier!</i>	82 (7.5)
Happy holidays	<i>Hope you have a very Merry Christmas and Happy New Year. Hugs.</i>	89 (8.1)

**Table 4.** Social support responses represented in each quit stage.

Stage and category	Representation (N=1100 posts)
<b>Before quitting (235 posts), n (%)</b>	
Encouragement	59 (25.1)
Sympathy	4 (1.7)
Understanding/empathy	19 (8.1)
Compliment	35 (14.9)
Relief of guilt	2 (0.9)
Validation	12 (5.1)
Referral	17 (7.2)
Situation appraisal	15 (6.4)
Suggestion/advice	42 (17.9)
Teaching	6 (2.6)
Companionship	24 (10.2)
<b>1st month (279 posts), n (%)</b>	
Encouragement	59 (21.1)
Sympathy	3 (1.1)
Understanding/empathy	10 (3.6)
Compliment	64 (22.9)
Relief of guilt	2 (0.7)
Validation	18 (6.5)
Referral	20 (7.2)
Situation appraisal	8 (2.9)
Suggestion/advice	66 (23.7)
Teaching	4 (1.4)
Companionship	25 (9.0)
<b>2nd month (253 posts), n (%)</b>	
Encouragement	69 (27.3)
Sympathy	3 (1.2)
Understanding/empathy	5 (2.0)
Compliment	85 (33.6)
Relief of guilt	3 (1.2)
Validation	18 (7.1)
Referral	5 (2.0)
Situation appraisal	15 (5.9)
Suggestion/advice	41 (16.2)
Teaching	1 (0.4)
Companionship	8 (3.2)
<b>3+ months (84 posts), n (%)</b>	
Encouragement	27 (32.1)
Compliment	35 (41.7)
Validation	4 (4.8)
Situation appraisal	6 (7.1)
Suggestion/advice	9 (10.7)

Stage and category	Representation (N=1100 posts)
Companionship	3 (3.6)
<b>Relapse (48 posts), n (%)</b>	
Encouragement	16 (33.3)
Understanding/empathy	1 (2.1)
Compliment	5 (10.4)
Relief of guilt	3 (6.3)
Referral	2 (4.2)
Situation appraisal	2 (4.2)
Suggestion/advice	14 (29.2)
Companionship	5 (10.4)

**Figure 2.** Trend of social support response representation throughout each quit stage.



## Discussion

### Principal Findings

This study highlights the complexity of how and when different types of social support are exchanged among individuals quitting smoking on the QuitNow online community forum. Application of Catrona and Suhr’s [9] social support framework to such a successful online community forum enabled the ability to identify specific ways in which individuals support each other at different stages in the quit process. This extends what was previously known about the role of social support on online forums for quitting smoking. Previous work has examined the overall purpose of social support exchange online [26], the different types of social support provided [27], and the impact of different types of social support on communication patterns for smoking cessation [28]. In this study, by unpacking how specific types of social support are most fruitful during different stages of quitting, the findings provide directions for how social support can be more strategically employed in these online contexts to support smoking cessation.

### User Engagement

The highest and most varied engagement on the forum occurred throughout the 1st month of quitting. This coincides with the biological processes that occur during cessation. Many users

face withdrawal symptoms in the short term following an attempt to quit [6]. These symptoms of withdrawal will last 2 to 4 weeks, with symptoms typically emerging within the initial couple of days following quitting, and peak in the 1st week [6]. To manage withdrawal, individuals often rely on the support of others, such as through community forums for smoking cessation. Our finding that people asked for advice mostly in the 1st month or during relapse may be an example of users seeking more strategies and support when their withdrawal symptoms are the highest. Given that engagement on the forum parallels these biological processes, this carries implications for how social support may be optimized to assist individuals in getting through withdrawal symptoms (eg, strategically offering advice, distraction tips, what to expect, etc) during that 1st month.

We also found that user engagement steadily decreases after 2 to 3 months. Again, this likely reflects the nicotine dependence trajectory, wherein receptors in the brain fully adapt to nonsmoking after 3 months due to organic reversals in brain matter; nicotine-related deficits in brain dopamine are often a consequence of chronic smoking that revert to baseline 3 months after quitting [29]. Additionally, individuals may feel confident in their quit status by this time, so the need for support consequentially drops.



## Original Posts

Forum users increasingly shared their cessation journey successes and strategies with others during the 1st and 2nd months of quitting. This may suggest that, by this time, individuals feel confident enough to share their successes and feel that they have enough personal credibility to offer advice. Previous literature has found that individuals are often reluctant to share their successes too early due to a fear of failure and a lack of confidence in their ability, which is consistent with these findings [30]. In keeping with these findings, individuals on the forum appear to be less likely to share their success unless they are confident in their ability to sustain their behavior change. These findings are significant in that sharing successes may serve as an effective measure of quit success and self-efficacy when evaluating the impact of smoking cessation forums.

In response to individuals sharing successes, others primarily provide esteem support, possibly further boosting their self-efficacy, a key ingredient to behavior change overall [31] and to maintaining a successful quit status and preventing relapse [32]. While the findings of this study are helpful from a cessation success perspective, there may be smaller successes worth sharing (eg, overcoming the 1st couple of days), wherein individuals can receive that esteem support earlier, potentially retaining individuals in their quit trajectory due to a boost in their self-efficacy. While more research is needed, calls to invite individuals to share their “smaller” successes may prove beneficial.

## Social Support Responses

Overall, the types of social support that were most consistently present included emotional and esteem support. This is in keeping with previous research, whereby nurturant support (including emotional and esteem support) was found to be most common in responses to original posts [33]. Tangible support was not present in this analysis, possibly due to the limitations of the forum. One way to provide tangible support is through active participation in an activity, like quitting with a quit buddy. This was not enabled via the forum, but may be a worthwhile area for exploration.

It is important to note that companionship demonstrated to have a steady downward trajectory over time; it was most prevalent before quitting but less so over time, with the exception of relapse. This is significant as it exemplifies the importance of letting people know that they are in this together at the beginning and particularly before the quitting process, and once again speaks to the importance of a tailored individualistic intervention process. Simply, individuals need to feel like they are not alone as they embark on the journey to quit using nicotine.

## Recommendations and Future Research

The results of this study encompass several recommendations that could benefit QuitNow, as well as smoking cessation community forums at large. One recommendation is to provide community forum users, as well as family and friends, with a tip sheet based on the findings (eg, emphasizing understanding and companionship at the before quitting stage; emphasizing encouragement and compliments during active quitting; and helping them reappraise the situation/offer relief from guilt

during relapse). In addition, community forums may benefit from having discussion tags, whereby users can decide what types of content they are most interested in viewing. For example, a user who is thinking about quitting might want to know what the 1st month is like and may filter forum content through a “1st month” tag. Finally, the results have implications for the implementation of online programs in which community forums are embedded. For example, now that we know companionship is key at the beginning of the quit journey, the affiliated website would benefit from emphasizing the presence of social supports (including the forum), which may subsequently retain individuals in the program. As soon as a new user joins a forum, a quit coach could send a text or email message about being there for them and referring them to the community forum (offering companionship early on).

Future research is needed to assess how changes made to the QuitNow forum as a result of this study’s findings impact engagement and cessation outcomes among users. For example, do more strategic prompts to use the forum and to post about smaller successes result in more month-to-month engagement (eg, more original posts and responses)? Moreover, it would be interesting to determine how different groups are engaging on the forum (eg, are certain populations staying in a particular quit stage longer?). This would carry implications for more tailored support for different groups. It would also be worthwhile assessing whether posting about big successes (eg, 2 months smoke-free) can be an effective measure and possible predictor of abstinence. This could potentially lend to an innovative and nonintrusive way of determining the success of a forum in supporting cessation.

## Limitations and Strengths

This study has several limitations. First, the frequency, duration, and number of cigarettes smoked among the various forum users could not be collected. These factors may play a role in shaping individual behaviors during a cessation attempt and/or journey. Second, we did not analyze intersections of identity (eg, gender, race/ethnicity, orientation, education level, or socioeconomic status) and their impact on how support was exchanged on the forum. In this regard, we were not able to collect data on nuances regarding what type of support is most beneficial to whom at different points in the quit trajectory. Third, it may be possible that some forum users did not update their quit status on the forum. Finally, the data collected for this study represent a specific point in time (leading up to Christmas and the new year), which may influence the type of communication and motivation of the users, and possibly atypical engagement on the forum. While this may be a limitation, it is also a strength in that these posts reflect the most recent and up-to-date posts at the time of the analysis. Another strength of the study is that data available in real-time were collected to gather insights into user engagement. Finally, this study encompassed the use of inductive qualitative methods to identify key themes and a theoretical framework to understand social support exchanges on the forum. This lends to a strong evidence base from which to move forward with recommendations.

## Conclusions

The findings of this study highlight the complexity of how and when different types of social support are exchanged on the QuitNow community forum. These findings provide directions

for how social support can be more strategically employed and leveraged in these online contexts to support smoking cessation. Both community forum end-users and service providers would benefit from understanding the nuanced support needs of those trying to quit smoking.

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## Conflicts of Interest

None declared.

## Multimedia Appendix 1

Social support framework.

[[DOCX File, 14 KB - formative\\_v6i1e34429\\_app1.docx](#)]

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Original Paper

# Leveraging a Consumer-Based Product to Develop a Cancer-Specific Mobile Meditation App: Prototype Development Study

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## Abstract

**Background:** Mobile meditation apps may offer a long-term, accessible, and effective solution for ongoing symptom management in cancer patients/survivors. However, there are currently no commercial cancer-specific meditation apps that reflect cancer specialist expertise, input from cancer patients/survivors, and features and content specific to cancer patients'/survivors' needs.

**Objective:** The aim of this study was to gain insight (via surveys, daily journals, and focus groups) from cancer patients/survivors, health care providers, and current subscribers of Calm (a consumer-based mobile meditation app) who were patients/survivors to develop a prototype of a mobile meditation app specifically designed for cancer patients/survivors.

**Methods:** Participants were recruited via prior partnerships, word-of-mouth referrals, and recruitment posts on Facebook and Instagram. Cancer patients/survivors and health care providers were instructed to download and use the Calm app for at least 10 minutes a day for 7 days, complete an online daily journal for 7 days, and participate in a virtual focus group (one for cancer patients/survivors and one for providers). Current Calm subscribers who were cancer patients/survivors completed an online survey about different aspects of the Calm app and participated in a third virtual focus group. Data were qualitatively analyzed using a combination of deductive and inductive coding.

**Results:** A total of 27 participants (11 cancer patients/survivors, 10 health care providers, 6 current Calm subscribers) completed the study. Similar themes and subthemes were found across surveys, daily journals, and focus groups, and fell into two major categories, content and functionality, with cancer-specific and noncancer-specific themes identified within each category. The majority of content preferences and suggestions that arose were cancer-specific, such as content related to negative emotions or feelings (eg, anxiety, grief, trauma/posttraumatic stress disorder, fear of recurrence, isolation), positive feelings and finding meaning (eg, gratitude, storytelling, acceptance), scenarios and experiences (eg, waiting, treatment-specific meditations), type and stage of cancer journey, and movement modifications. Some of the noncancer-specific themes under app content included sleep, music, and visualizations. In terms of app functionality, the majority of participants expressed interest in having a section/tab/area of the app that was specifically geared toward cancer patients/survivors. Preferences and suggestions for cancer-specific functionality features included options based on symptoms or journey, being able to communicate with other patients or survivors to share suggestions for specific meditations, and having an emergency toolkit for patients/survivors.

**Conclusions:** Findings from cancer patients/survivors, health care providers, and current Calm subscribers who were patients/survivors to be incorporated into the development of the prototype fell into two major categories: (1) content of the app and (2) functionality of the app. The prototype's form and function will be pilot-tested among 30 cancer patients/survivors in a 4-week study, and the resulting feasibility data will be used to inform the final app design and an efficacy study.

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## KEYWORDS

cancer patients/survivors; meditation; mHealth; app development; qualitative research

## Introduction

The chronic symptom burden among cancer patients/survivors is debilitating and costly. Many survivors have ongoing symptoms that can last for 10 or more years that severely affect their quality of life, ability to return to work, and independence [1]. Long-term, accessible, and effective solutions for ongoing symptom management for the ~15.5 million US cancer patients/survivors are sorely needed as the chronic symptom burden costs the health care system an estimated US \$125 billion annually and impacts the economy through US \$115 billion in lost worker productivity [2,3].

Meditation has been shown to improve symptoms such as pain, sleep disturbance, anxiety, and fatigue in cancer patients and survivors [4-7]. Such programs are often delivered in person, usually at a cancer center. However, these programs are expensive and difficult to sustain. Some patients struggle to attend even short-term programs at specialized clinics due to distance, scheduling, and symptom burden [8]. There is a need to translate beneficial meditation interventions into more accessible and sustainable formats.

Mobile apps can provide effective, accessible meditation instruction to cancer patients/survivors. Mobile apps and online meditation programs have demonstrated short-term benefits for cancer patients/survivors [9,10]. Positive effects have been reported from even 10 minutes of daily meditation practice [11-13], and research suggests that the therapeutic benefits of brief daily sessions can be seen in as little as 4 weeks [9,10]. In one study, 97.0% (318/328) of cancer patients had access to a smartphone and were willing to use app-based meditation [9,10].

Cancer-specific meditation apps are needed to ensure clinical acceptability, effectiveness, and safety for patients/survivors. Research shows that targeting specific patient groups allows for wider reach, higher adherence rates, and greater impacts on health behaviors [14,15]. To improve the targeting, uptake, and long-term impact of eHealth interventions in patient populations, the Center for eHealth Research and Disease Management recommends obtaining patient user and health care provider feedback in the early design phase [16]. Although cancer patients/survivors have reported that meditation apps targeting the general population are useful [9], there are important differences in cancer patients' physical, emotional, and social needs that are not met by a general meditation app. These needs are incorporated into in-person meditation programs in cancer centers, because they are led by cancer experts who can modify the program according to the symptom burden and cancer-specific psychological states and experiences, and

because they include the shared experiences of other cancer patients facing the challenge of meditating [10,17-19]. There is a need for such tailoring into commercial mobile apps. A standalone cancer-specific app that reflects cancer specialist expertise, input from cancer patients/survivors, and provides features and content specific to the unique physical and psychological needs of cancer patients/survivors is urgently needed.

Of the 150 apps marketed for cancer to date, there are no evidence-based, commercially available meditation apps for cancer patients/survivors [17,20]. A systematic review [19] identified only two app-delivered meditation studies, both focusing on breast cancer, and ultimately neither program aimed for commercialization. Most app companies lack the scientific expertise needed to develop such tools or lack access to clinical populations for tailoring the app to their needs. There is a dearth of evidence-based cancer-specific apps because behavioral researchers have worked in isolation, and once evaluated in a clinical trial, no meditation apps have reached commercialization [19]. Although technological solutions hold promise for accessible, low-cost, and scalable approaches to meditation delivery, many studies have shown that long-term engagement with standard commercial apps is very low [21]. Companies make profits for the app purchase and subscriptions but are not incentivized to deliver effective strategies to measurably improve outcomes; this is particularly the case for specialized populations. To address these barriers to developing, testing, and eventually making available an evidence-based meditation app for the millions of cancer patients and survivors, behavioral scientists at Arizona State University, cancer care providers at Mays Cancer Center, and designers at Calm (a meditation app company) have partnered to accelerate the integration of effective techniques for patients'/survivors' long-term symptom-management needs.

Calm is the top-grossing health and fitness app in the United States, with over 100 million downloads and 4 million paying subscribers. Calm is subscription-based, and has over 220 guided meditations to teach users the basics of meditation, how to incorporate meditation into one's life, and programs for intermediate and advanced meditators [9,10]. Calm effectively teaches the skills and practice of meditation, using generic meditations to address various sources of stress (eg, work, relationships) experienced by the general population. Research suggests that Calm can reduce stress and increase mindfulness, and its use is also associated with incremental increases in mental and physical health, stress, and sleep in the general population [22,23]. Calm is also an effective short-term meditation program to reduce the symptom burden among

cancer patients/survivors [10]. Based on the clinical needs of cancer patients/survivors and the lack of standalone commercialized cancer-specific apps, the purpose of this project was to gain insight (via surveys, daily journals, and focus groups) from cancer patients/survivors, health care providers, and current Calm subscribers who were patients/survivors to develop a prototype of a mobile meditation app for cancer patients/survivors. We here describe how our findings from surveys, daily journals, and focus groups will be used to develop content for and produce the cancer-specific meditation app prototype.

## Methods

### Participants

This study was approved by a university-affiliated institutional review board. Potential participants were cancer patients/survivors (diagnosed within the last 3 years), health care providers (physicians, oncology nurses, cancer care coordinators, directors of integrative programs in cancer centers, and not-for-profit partners), and current subscribers to the Calm app who were cancer patients/survivors (diagnosed within the last 3 years).

### Participant Recruitment

Cancer patients/survivors were recruited via word-of-mouth referrals by cancer care physicians who had previously partnered with the investigative team (eg, from the Mays Cancer Center

at UT Health San Antonio, MD Anderson; the Mayo Clinic in Scottsdale, AZ, and Rochester, NY; University of Arizona; Wake Forest; Leukemia and Lymphoma Society; and the American Cancer Society). The investigative team recruited health care providers by compiling a list of providers who had diverse backgrounds in cancer care (nursing, social work, physician), cancer types, and patient demographics, along with their contact information. Cancer patients/survivors who were referred to the team and health care providers from the list were then sent an email that included a brief study description and asked if they were interested in participating in the study. Current Calm subscribers who were patients/survivors were recruited via recruitment posts on the Calm Community Facebook and Instagram pages. The recruitment posts included a brief study description and a link to the online eligibility screening survey.

### Eligibility and Consent

All interested potential participants were directed to complete an online eligibility screening survey (via REDCap). See [Textbox 1](#) for inclusion criteria.

Eligible participants (cancer patients/survivors, health care providers, and current Calm subscribers who were patients/survivors) were sent a link to an online informed consent document (via REDCap) with details about the study. All participants provided consent via an electronic signature prior to participating in the study.

**Textbox 1.** Eligibility criteria for inclusion in the study.

#### Patients/survivors

- Cancer diagnosis within past 3 years
- Own a mobile smartphone (iPhone with iOS 9.0 or later or Android 4.1 or later)
- Willing to download a mobile app
- Able to read and understand English

#### Health care providers

- Physicians, oncology nurses, cancer care coordinators, directors of integrative programs in cancer centers, or not-for-profit partners
- Own a mobile smartphone (iPhone with iOS 9.0 or later or Android 4.1 or later)
- Willing to download a mobile app
- Able to read and understand English

#### Current Calm subscribers

- Cancer diagnosis within past 3 years
- Currently have a subscription to and uses Calm
- Own a mobile smartphone (iPhone with iOS 9.0 or later or Android 4.1 or later)
- Willing to download a mobile app
- Able to read and understand English

### Study Procedures

Cancer patients/survivors and health care providers completed a brief online survey assessing the birth date, cancer patient/survivor or health care provider status, current meditative

practice, and current or prior use of the Calm app. These participants were then sent instructions on how to download the Calm app on their smartphone and instructed to (1) use the Calm app for at least 10 minutes a day for 7 days, (2) explore the content and features of the app, and (3) complete an online

daily journal (via RedCAP) for 7 days. The daily journal included (1) time of day and time spent using Calm; (2) responses to app options and what motivated them to make certain choices; (3) their experiences during the guided meditations; (4) ideas about life experiences of a cancer patient to include in a prototype; (5) responses to prompts related to strategies from social cognitive theory, such as “In what ways might the content or features of the app support a sense of social modeling from other cancer patients or providers?” and “How might goal setting and rewards be incorporated appropriately?”; and (6) if not a cancer patient or survivor, to reflect upon the perspective of those they treat or serve. For the purpose of this analysis, only the qualitative answers (3-6) were included as they were formative responses to the app’s development. The link to the online journal was sent to participants daily during the 7-day period. After using the Calm app for 7 days and completing the daily journal, cancer patients/survivors and health care providers were emailed to schedule a date and time to participate in a virtual focus group.

Current Calm subscribers who were patients/survivors were directed to complete an investigator-developed online survey assessing demographics; what they currently liked and disliked about the Calm app; which Calm series, instructors, and components they found helpful or unhelpful; and their suggestions for cancer-specific adaptations/modifications to the Calm app. At the end of the survey, current Calm subscribers who were patients/survivors were given the opportunity to provide their email address to be entered into a drawing to win one of 10 Magic of Sleep books from Calm and were asked if they wanted to opt-in to participate in a virtual focus group. Those who expressed interest in participating in the focus group were emailed to schedule a date and time.

### Focus Groups

Three total focus groups were conducted: one with cancer patients/survivors, one with health care providers, and a third with current Calm subscribers who were patients/survivors. The focus groups were conducted by a member of the research team, were held virtually using Zoom teleconferencing software, and took approximately 1 hour to complete. Focus groups explored specific domains of design: acceptability, demand, practicality, adaptation, and integration (ie, open-ended experiential and cancer-referenced content explorations). See [Multimedia Appendix 1](#) for the specific focus group questions. Three app developers from Calm participated in the focus groups for practical guidance and to meet target needs in the prototype design (only participating in the groups to develop the app and not for data purposes). Prior to participating, the developer signed a confidentiality agreement. The focus groups were

audio- and video-recorded. The audio recordings from the focus groups were sent to a professional, Health Insurance Portability and Accountability Act-compliant transcription company (Landmark Associates, Inc, Phoenix, AZ) to be transcribed. Transcripts were used for qualitative data analysis.

### Qualitative Analysis

The focus group transcripts were imported into NVivo 12 qualitative analysis software (QSR International) and the survey responses and daily journal text files were imported into MAXQDA qualitative analysis software (VERBI Software) for the purpose of coding and analysis. The research investigators developed a codebook to be used in the qualitative analyses. Using the codebook, one investigator independently coded the surveys, a second investigator independently coded the daily journals, and a third qualitative analyst independently coded the focus group transcripts. All qualitative analyses followed the recommended approaches of Braun and Clarke [24] and Swain [25], and a combination of deductive and inductive coding was used to analyze the data. Top-level categories and themes were identified deductively based on the main information requirements of the study and the categories of issues covered in the surveys, daily journals, and focus group discussions. Emergent themes were identified inductively from the transcripts and text files. The coding and analysis process was iterative, with identified themes and subthemes being continually reviewed and revised until these were felt to most accurately represent the expressed experiences and views of the participants and also to allow for comparability of findings between the focus groups (ie, patients/survivors, health care providers, and current Calm subscribers). Findings are summarized using verbatim quotes to illustrate these themes and subthemes and to ensure that these views and experiences are conveyed in the voices of the participants themselves.

## Results

### Demographic Characteristics

A total of 27 participants (11 cancer patients/survivors, 10 health care providers, and 6 current Calm subscribers who were patients/survivors) completed the surveys or daily journals and participated in the focus groups. Participant characteristics can be found in [Table 1](#). These sample sizes were chosen and deemed appropriate based on previous qualitative research studies utilizing similar methodology [26-29].

The themes and subthemes identified in the surveys, daily journals, and focus groups are summarized in [Table 2](#), and are described more in-depth below.



**Table 1.** Descriptive characteristics of the focus group participants.

Characteristic	Cancer patients/survivors (n=11)	Health care providers (n=10)	Current Calm subscribers (n=6)
Age (years), mean (SD)	47.7 (13.1)	46.7 (6.6)	50.5 (12.2)
<b>Gender, n (%)</b>			
Female	9 (82)	8 (80)	6 (100)
Male	1 (9)	1 (10)	0 (0)
Prefer not to answer	1 (9)	1 (10)	0 (0)
<b>Race, n (%)</b>			
White, European-American, or Caucasian	9 (82)	8 (80)	5 (83)
Black or African American	1 (9)	0 (0)	0 (0)
Asian or Asian American	0 (0)	1 (10)	0 (0)
Arab or non-Arab North African/Middle Eastern	0 (0)	0 (0)	1 (17)
Prefer not to answer	1 (9)	1 (10)	0 (0)
<b>Ethnicity, n (%)</b>			
Hispanic or Latino	1 (9)	0 (0)	0 (0)
Not Hispanic or Latino	9 (82)	9 (90)	6 (100)
Prefer not to answer	1 (9)	1 (10)	0 (0)
<b>Education, n (%)</b>			
Employed	7 (64)	9 (90)	5 (83)
Unemployed/unable to work	1 (9)	0 (0)	1 (17)
Homemaker	1 (9)	0 (0)	0 (0)
Retired	1 (9)	0 (0)	0 (0)
Prefer not to answer	1 (9)	1 (10)	0 (0)
<b>Annual income (US \$), n (%)</b>			
≤50,000	0 (0)	0 (0)	0 (0)
50,000-74,999	1 (9)	0 (0)	1 (17)
74,000-99,999	2 (18)	1 (10)	0 (0)
>100,000	7 (64)	7 (70)	4 (67)
Prefer not to answer	1 (9)	2 (20)	1 (17)
<b>Education, n (%)</b>			
≤Associate/2-year degree	0 (0)	0 (0)	0 (0)
Associate/2-year degree	1 (9)	0 (0)	0 (0)
Bachelor's degree	6 (55)	3 (30)	3 (50)
Graduate school or above	3 (27)	6 (60)	3 (50)
Prefer not to answer	1 (9)	1 (10)	0 (0)
<b>Cancer type, n (%)</b>			
Breast	4 (36)	N/A <sup>a</sup>	4 (67)
Ovarian	2 (18)	N/A	0 (0)
Endometrial	1 (9)	N/A	0 (0)
Colon	1 (9)	N/A	0 (0)
Rectal	1 (9)	N/A	0 (0)
Blood	2 (18)	N/A	1 (17)
Jaw	0 (0)	N/A	1 (17)

Characteristic	Cancer patients/survivors (n=11)	Health care providers (n=10)	Current Calm subscribers (n=6)
<b>Currently undergoing cancer treatment, n (%)</b>			
Yes	7 (64)	N/A	4 (67)
No	4 (36)	N/A	2 (33)
<b>Current mindful practice, n (%)</b>			
Yes	4 (36)	6 (60)	6 (60)
No	7 (64)	4 (40)	0 (0)
Mindful practice (days/week), mean (SD)	5 (2.5)	3.3 (2.9)	5 (5.2)
<b>Current Calm use, n (%)</b>			
Yes	4 (36)	3 (30)	6 (60)
No	7 (64)	7 (70)	0 (0)
Calm use (days/week), mean (SD)	4 (4.2)	1.1 (0.9)	5 (5.2)

<sup>a</sup>N/A: not applicable.

**Table 2.** Overall themes and subthemes identified from participants' preferences and suggestions for app adaptations and modifications for a cancer-specific meditation app.

Themes and subthemes	Surveys	Daily journals		Focus groups		
	Current Calm users	Patients/ survivors	Health care providers	Current Calm users	Patients/ survivors	Health care Providers
<b>App content</b>						
<b>Cancer-specific</b>						
Gratitude		✓	✓	✓	✓	✓
Grief		✓			✓	
Waiting		✓	✓		✓	✓
Type and stage of cancer journey		✓	✓		✓	✓
Movement modifications <sup>a</sup>			✓		✓	
Self-care	✓			✓		
Pain <sup>a</sup>	✓	✓	✓		✓	
Nausea		✓	✓			
Storytelling	✓	✓	✓	✓	✓	✓
Acceptance	✓	✓	✓			
Anxiety	✓	✓	✓	✓	✓	✓
PTSD <sup>b</sup> /trauma	✓					
Fear of recurrence	✓					✓
Isolation	✓	✓			✓	
Perspective	✓	✓				
Treatment-specific meditations <sup>a</sup>	✓			✓		✓
Breathing based meditations	✓	✓				
Positive feelings and finding meaning <sup>a</sup>				✓	✓	✓
Negative emotions or feelings <sup>a</sup>				✓	✓	✓
<b>Noncancer-specific</b>						
Sleep	✓	✓	✓			
Music		✓	✓			
Visualizations		✓	✓			
<b>App functionality</b>						
Community features			✓	✓	✓	✓
Scheduling/tracking	✓	✓				
More options to personalize	✓	✓	✓	✓	✓	✓
Cancer-specific vs noncancer-specific	✓	✓	✓		✓	
<b>App navigation</b>						
Suggest specific options to others	✓	✓		✓	✓	✓
Algorithm that provides options based on symptoms or journey	✓	✓	✓			
Searching for topics	✓	✓				✓
New users/meditators	✓	✓	✓			
Guide to the app	✓	✓	✓			✓
Accessibility for disabilities		✓				
Emergency toolkit		✓				

Themes and subthemes	Surveys	Daily journals		Focus groups		
	Current Calm users	Patients/survivors	Health care providers	Current Calm users	Patients/survivors	Health care Providers
Terminology						✓
Accessible to families/caregivers	✓	✓				✓

<sup>a</sup>In the analyses of the focus group data, these indicated subthemes were categorized as themes. See [Textbox 2](#) for details regarding which subthemes were linked to these overall themes in the focus group analyses.

<sup>b</sup>PTSD: posttraumatic stress disorder.

## Surveys

The overall completion rate for the surveys was 100% (eg, all 6 current Calm subscribers who were patients/survivors submitted an online survey). The completion rate for the questions in the survey ranged from 92% to 100% (12/13 to 13/13 questions completed) for the demographic questions and from 70% to 100% (7/10 to 10/10 questions completed) for the questions assessing Calm preferences and potential adaptations/modifications. Survey responses fell into two major categories: (1) content of the app and (2) functionality of the app. Themes and subthemes identified in the surveys are represented in [Table 2](#), and full illustrative verbatim quotes from the surveys representing each theme and subtheme can be found in [Multimedia Appendix 2](#).

## Journals

Completion rates for the daily journals varied from the providers and patients/survivors with 77.1% (54/70) of the providers' daily journals being completed and 87.0% (67/77) of the patients'/survivors' journals completed. However, in the

provider group, only 53.4% (187/350) of the questions were answered during the 7 days the daily journal was administered compared to 66.9% (206/308) of the questions being answered by the patients/survivors group. Daily journals fell into two major categories, content of the app and functionality of the app, and within each category, themes that were cancer-specific and noncancer-specific emerged. Themes and subthemes identified in the daily journals (completed by patients/survivors and health care providers) are represented in [Table 2](#), and full illustrative verbatim quotes from the daily journals representing each theme and subtheme can be found in [Multimedia Appendix 3](#) (cancer patients/survivors) and [Multimedia Appendix 4](#) (health care providers).

## Focus Groups

Findings from the focus groups fell into two major categories: (1) content of the app and (2) functionality of the app. These themes are categorized under patients/survivors focus group, health care provider focus group, and current Calm subscriber focus group in [Textbox 2](#), and a written description of each theme/subtheme follows.



**Textbox 2.** Focus group themes and subthemes.**Cancer patients/survivors**

## Content themes (subthemes)

- Negative emotions or feelings (anxiety, fear, grief)
- Specific situations or experiences (isolation, waiting)
- Positive feelings and finding meaning (storytelling, gratitude)
- Types and stages of cancer
- Pain or physical discomfort
- Movement modifications

## Functionality themes (subthemes)

- Overall focus and features (cancer-specific or not, community features, personalization)
- App navigation (having options suggested)

**Health care providers**

## Content themes (subthemes)

- Negative emotions or feelings (anxiety, fear)
- Specific situations or experiences (treatment-specific, waiting)
- Positive feelings and finding meaning (storytelling)
- Stages of the journey

## Functionality themes (subthemes)

- Overall focus and features (options and personalization, community features, terminology, accessible to family or caregivers)
- App navigation (guide to the app, emergency toolkit, search facility)

**Current Calm subscribers**

## Content themes (subthemes)

- Negative emotions or feelings (anxiety)
- Specific situations or experiences (treatment-specific, waiting)
- Positive feelings and finding meaning (gratitude, self-care, storytelling)

## Functionality themes (subthemes)

- Overall focus and features (options and personalization, community features)
- App navigation (having options suggested)

**Patient/Survivor Focus Groups****Content of the App****Negative Emotions or Feelings**

Participants identified a range of negative emotions or feelings that they had experienced during their cancer journeys, which they felt that the Calm app might help with. The most commonly cited types of emotions were anxiety and fear.

*There is still that fear and anxiety every time I go back, for—for 3 months, 3 months, 3 months, 3 months, and then it was 6—now it's 6 months. And I'm like, "What if I missed something?" What if I missed something? Every little symptom is, like, oh, my gosh. What now?*

Helping cancer patients deal with feelings of anger and grief about what they feel they have lost in terms of health or body parts that were removed was also seen as an important function of the Calm app. Some participants highlighted the risk of triggering negative reactions in cancer patients, and expressed a preference for generic content rather than content focused specifically on cancer patients.

**Situations or Experiences**

Various experiences associated with the cancer journey were identified; in particular, the app is seen to be helpful for the experiences of isolation and waiting.

Several participants explained the ways in which they had experienced forms of isolation while undergoing cancer treatment, as a result of having to give up work and avoidance of usual social interactions because of their treatment schedule

or symptoms. A sense of isolation was often felt particularly by those with rare forms of cancer who struggled to find others with whom to share their experiences: “Cancer is very isolating. People cut themselves off from others and it’s hard to figure out how to deal with other people.”

The participants also stressed the anxiety often associated with periods of waiting for appointments or test results, and suggested that perhaps the app might include content relevant to typical milestones in the cancer journey and the emotions associated with these.

### Positive Feelings and Finding Meaning

Many of the focus group participants reported that they felt reassured or encouraged by hearing the stories of others, especially cancer survivors. They stressed that it was the sense of connection with the actual storytellers based on shared or relatable experiences that was most appealing, and were less keen on having celebrities narrate their stories.

*When you hear it come from another patient, there is a different level of, you know—um, you know, it...it is authentic. It is...it is insightful. It is beyond what someone that might have a canned speech or a celebrity might even say.*

The focus group participants also discussed the importance to them of content that helped to process their emotions and accept or come to terms with their cancer experience, without imposing pressure to feel a particular way: “If the app could help you process, sort of like therapy, frankly...what you’re dealing with and what you...what you bring out of it without, um, telling you, you have to be happy.”

For some, learning to feel gratitude for what they value in life was an important aspect.

### Types and Stages of Cancer

The focus group discussion highlighted the ways in which the Calm app can be helpful for individuals at different stages of their cancer journey or with different forms of cancer. For example, participants contrasted the anxiety of a new cancer diagnosis with the ongoing stress of long-term or rare forms of cancer. The ongoing effects on individuals even after successful treatment were also highlighted.

### Pain or Physical Discomfort

Two particular aspects of pain or discomfort that the app might potentially help with were discussed: the need for movement modifications due to pain or surgery and the experience of hot flashes.

*I just had surgery, um, 4 weeks ago today, um, and I have to sleep in a new position with, like, compression garments on, and it’s very uncomfortable, um, and it takes me a long time to fall asleep because I’m not getting enough exercise. Um, and so I think that the—that was something that I took from the Calm app that I didn’t really—um, hadn’t really done in other, like, meditation practices.*

*A meditation for hot flashes, but anything that would help everybody who gets that—like you said, we’re all in the same room.*

### Movement Modifications

It was stressed that the app content should take into account any mobility restrictions that users might be subject to.

*I think it needs to be tailored to those people that may not, you know, be—they have—they’re compromised as far as what they can do, uh, to the Calm Body side of—like, without makin’ ‘em feel bad, so to speak, you know.*

### App Functionality

#### Overall Focus and Features

##### Cancer-specific or Not

The participants discussed whether the content of the app should be specifically tailored to cancer patients or be more generic, and a range of views were expressed. Some highlighted the benefits of having cancer-specific content that patients could relate to: “I think that it would be really helpful to be able to tailor it to cancer patients and some of those fears and—and anxieties that are inherent, I think, to—to cancer patients in general.”

Others expressed the view that some experiences of cancer patients are similar to those of individuals with other conditions or life circumstances, and that more general content should therefore be included to appeal to a wider population of users.

*It could be accessible and relevant to a lot of different people, but that theme of—of loss and grieving what you wish you had and finding a place of acceptance with this is what I have and I’m grateful for what I have, um, or I can make my peace with it, or just accepting it for today is enough to get me to the next day, and then to the next week, and moving on.*

It was suggested that achieving an appropriate balance between cancer-specific and more general content would be helpful, especially to meet the needs of cancer patients themselves and to meet different psychological needs at various stages of their journey.

*I think you would want to have it tailored enough that it was relevant to a cancer patient, but also broad enough that it felt relevant on the days when you’re 13 days out of chemo and you’ve still got 6 more days and it’s of just kind of a regular day.*

##### Community Features

Most participants indicated that they would be in favor of a community area on the app where users could interact and post comments. Some explained that they would feel reassured by knowing that others share and understand their own experiences in ways that other people cannot, regardless of the specific type of cancer they have.

*I can’t do all the things I would like to do, you know, as—as a mother and all, but I realize there’s other people there with—with my same problem and my,*

*you know, same issues and my same concerns, but I no longer feel alone, like there's something wrong with me 'cause there's other people that are in the same boat with me. And so I think those stories are really important.*

However, one participant argued that they would not be in favor of a community feature as any cancer-specific content would be likely to trigger negative emotions: “I like the app because it’s not social media, and I want to not be triggered by the cancer content, whether it’s, like, knowingly or unknowingly.”

### **Personalization**

Some indicated that they would like to be able to personalize the app to their own circumstances, or to have the option of monitoring their heart rate before and after meditating.

*If you could just put some of your own notes or tags that are personal to you, um, I thought that might have been a helpful way that if I was looking back a month later, thinking, “Why was I so frustrated that day?” or “Why was I anxious that day?” to be able to give yourself those tags to help give it context.*

*When you do the check-in kind of thing, I thought if you, um, gave the option to the person to record the heart rate.*

### **App Navigation**

Several participants suggested that they would appreciate being able to see suggestions or recommendations for particular meditations, or to have options suggested for them depending on how they felt or what they were dealing with at the time.

Many were in favor of having a search facility for meditations on particular topics, with some indicating that it can be hard to find what they need in the current version of the app: “it’d be helpful if you had a way of finding these topics that were on the cancer patient’s mind, either by filters or topics, subjects.”

It was stressed, however, that descriptions and terminology need to be carefully considered to enable cancer patients to find suitable content but without triggering negative emotions.

*the words are important, and we have to find words in the cancer scenario that wouldn’t trigger the anxiety of people...it can be, you know, anxiety over appearance, over deformities due to cancer, over certain parts of the body...So the words are important, and...we wanna be able to give people the option of not having certain triggers.*

Participants also stressed the importance of ensuring that the app is accessible for use by the many cancer patients who also have disabilities such as sight or hearing disorders.

### **Provider Focus Groups**

#### **Content of the App**

#### **Negative Emotions or Feelings**

The provider focus group participants indicated they felt their patients would mostly find the Calm app beneficial for dealing with feelings of anxiety or fear: “I think people would use it during treatment, either when they’re sitting in an infusion chair,

when they’re waiting for a scan—there needs to be a scanxiety section to this somehow.”

#### **Specific Situations or Experiences**

The participants also identified waiting for and undergoing treatment as situations in which patients might benefit from using the app, along with experiences such as insomnia.

#### **Positive Feelings and Finding Meaning**

Similar to the patients and user participants, many of the providers indicated that cancer patients can find it reassuring or helpful to hear the stories of others who have gone through or survived similar experiences. Similar to the patient participants, the health care providers also expressed the view that the authentic shared experience is more important than having a celebrity narrator.

*I don’t think it matters as—as long as the person is, um, is, you know, kind of breaking that fourth wall and saying, “I’ve had dark days, too,” or, “I’ve been there. I have a similar experience.” Doesn’t matter if it’s a celebrity or the guy next door. I think people will—will connect with that.*

One of the participants indicated that the app might be more helpful for individuals who have completed their treatment and are trying to process and make sense of what they have been through. Another stressed its potential importance in helping to provide hope at earlier stages of the cancer journey.

#### **Stages of the Journey**

It was suggested that the app might usefully act as a type of roadmap to the experiences and stages involved in a cancer diagnosis and journey, helping patients feel less overwhelmed and providing support with the various experiences involved.

*A cancer patient’s journey is really complicated and overwhelming. And so one thing that I thought of is, you know, having a roadmap as you get into cancer is really helpful, and having different sorts of meditations through chemo, surgery, radiation, the waiting room, infusion, et cetera.*

### **App Functionality**

#### **Overall Focus and Features**

The provider participants reported that they liked the variety and different lengths of meditations available on the Calm app, as well as the range of narrators and voice tones, which were felt to meet the different needs and preferences of their patients: “I think different people resonate with different types of meditations in different voices, so I actually think a variety is really nice to have.”

#### **Community Feature**

Most of the provider participants indicated that they would be in favor of a community area on the app where users could interact and post comments, highlighting the perceived benefits to patients of connecting with those going through similar experiences. Like some of those in the users group, however, they also acknowledged the potential risks of this that need to be managed.

*I think you have to be really careful because, like, even in facilitating support groups, right, you have those people who kind of take over and you—or you have to—you have to have kind of very strict guidelines, um, of what they, you know, what they can share...I kinda see it more like a support group, that there's gotta be rules and kind of very strict guidelines of what is said.*

### Terminology

Several of the provider participants discussed the importance of using the right terminology to attract a range of people, and noted that the term “meditation” has negative connotations for some. They suggested using more neutral terms such as symptom management, or terminology relating to specific situations such as sleep or stress reduction.

*One time, a patient was asking me what she could do to, you know, help herself, and I said, “Well, some people believe in meditation,” and she said to me, “Oh, I don't meditate. I pray.” You know? So sometimes, the word “meditation” for a certain patient, um, means something that they don't believe in, and so I feel like sometimes I have to be very careful when I recommend something like that, 'cause pe—people get the wrong idea.*

### Accessible to Family or Caregivers

Some suggested that the app should also be designed for use by the family or carers of cancer patients.

### App Navigation

#### Guide to the App

Many of the provider participants argued that the current app can be overwhelming and confusing for many cancer patients, and suggested that it would be beneficial to have a simple step-by-step guide or roadmap for how to use it.

*Having some sort of roadmap of either a landing page for a first-time user or almost an aerial view of Calm and the different pieces of it, or, like, a 1-minute tour of Calm. You know, something that a person can press on really quickly to just get their bearings.*

One recommended that the guide might take the form of a video of a real person such as a cancer survivor to provide a sense of personal connection.

It was also suggested that the guide might provide options based on how the user indicated they were feeling at the time.

#### Emergency Toolkit

Some participants suggested that it would be helpful for the app to be designed at least in part as a type of “emergency toolkit” that would allow patients to quickly identify resources helpful for dealing with particular needs or situations. This was conceptualized by some as “symptom management.”

*I almost wonder, like, if you logged in, what would you like to address today, like, symptom management versus stress. Like, I'm feeling nauseous, I'm feeling, you know, I have anxiety about, you know, I have to*

*lay on this—on the radiation table for 15 minutes and I need something that's 15 minutes long, or, you know, I need something—I'm waiting for my test results back from the doctor that I can just put in. Like, you almost wonder if you could have a symptom checklist because it's, you almost need, like, an emergency toolkit and then you almost need, like, your day-to-day stuff.*

### Search Facility

One participant expressed the view that patients with specific requirements from the app would appreciate the inclusion of a search facility and that this would help reduce a sense of overwhelm from all the options available.

### Calm Subscribers Focus Group

#### Content of the App

##### Negative Emotions or Feelings

The user focus group participants identified in particular the importance of the Calm app in helping them deal with anxiety during treatment or when waiting for test results.

*Some of my chemo were, like, 6, 7 hours. That's a long time to be in a chemo chair, and I would listen to podcasts and I'd get really bored, especially, like, during COVID 'cause they were all in isolation. Um, so I was doing a lot of Calm stuff 'cause my anxiety would go up and down.*

##### Specific Situations or Experiences

Various experiences associated with the cancer journey that the app is seen to be helpful for were identified, including undergoing treatment or waiting for test results, but also dealing with the experience of being a survivor and the continuing uncertainties that this can involve.

*Once you're done with chemo, then what? And I think that's where...just the fear of, you know, every 3 months you have to have scans and what's that gonna show and trying to be brave through that. So I think, maybe, that should be part of, you know, maybe, a Calm, you know, app for cancer is not just while you're in it but the—the next steps as well 'cause it does—as we all know, it doesn't just end. You know, it's—it's here with us.*

One participant stressed that they prefer the meditations that relate to concrete daily experiences rather than those that were more abstract or general. Suggestions were also made for specific types of content, including healing visualizations and meditations suitable for teenage patients.

##### Positive Feelings and Finding Meaning

Many of the focus group participants indicated that they would like content that helped them process their experiences and develop a sense of positivity or acceptance. Meditations that helped them focus, be mindful, or feel a general sense of gratitude in their lives were regarded as helpful in this respect. Some participants emphasized the importance of self-care and self-compassion in the process of coming to terms with their diagnosis and coping with their treatments, and found the



meditations that supported these types of feelings particularly helpful.

*We're so trained to go, go, go, go, go, take care of other people, it's really hard to retrain myself that right now, my job is to heal and take care of myself and that that's okay, and that it's okay to slow down. It's okay to lay down. It's okay to have bad days, and we're not—that's not a mentality that we're used to hearing and that—that's cultivated in our society. So that's been very helpful for me, the self-compassion one.*

Some participants also mentioned that they would welcome the inclusion of educational snippets or stories of interest to them or relevant to their own experiences, such as content narrated by survivors, other cancer patients, or doctors.

*It could be doctors. It could be nurses talking. It could be cancer survivors. It could be people talking about, like, what—what should be in a chemo bag. You know? I mean, typical little tidbit-type things of, you know, 1- or 2-minute wisdom of how to cope. It could patients telling their stories, uh, u-, up-lifting stories, um, but practical wisdom, that type of thing. I think that would be—I know I would love to hear that.*

## App Functionality

### Overall Focus and Features

#### Options and Personalization

Some participants indicated that they would like to be able to personalize the app to suit their personal preferences, for example by varying the volume or voices of narrators or the background music. One also mentioned that they would like the option of longer guided meditations.

*I would love to have, um, some of the longer guided ones. You know, have the option of doing a 10 or a 20 minute. I've recently found where I can set—I can do independent ones that are longer, and I just found that option, but, um, I would love a little bit of the guided ones to be longer as well.*

#### Community Features

The participants in the user focus group were split in their views about whether the app should include a community feature where users could interact and post comments. Like many of those in the patient group, several explained that they would like to be able to connect with people going through similar experiences.

Although broadly in favor of a community feature, some highlighted that there can be risks involved in interacting with other cancer patients, such as increasing anxiety.

*When you don't hear from them for a while, like, the brain starts to go in directions that you don't want it to go. So there's—there's a little bit of a balance that has to be managed here because of the anxiety that you already have and then anxiety that you're—you may, sort of, take on because you're worried about other folks that are managing their cancer.*

Other participants were firmly opposed to the idea of having a community feature to the app, indicating that they would have no interest in using this feature or that would be off-putting to them: “That would be a very big negative for me, and it would be a drawback. It's not what I want in an app. I don't wanna social group.”

### App Navigation

Some participants suggested that they would appreciate being able to see suggestions or recommendations for particular meditations, and to have these grouped together within themes using an autoplay facility.

*I'd end up, like, endlessly tryin' to scroll through tryin' to find the stuff that I wanted to. If there was some way that they could loop or, um, go from one—like if there was series of, um, like, okay, if you're a cancer patient doing treatment, here's, like, a block of something that might be relevant for you. And maybe they can loop together.*

Some of those in the user group were also in favor of having a search facility for meditations on particular topics, and indicated that it can be hard to find what they need in the current version of the app.

## Discussion

### Principal Findings

The purpose of this project was to gain insight (via surveys, daily journals, and focus groups) from cancer patients/survivors, health care providers, and current Calm subscribers who were patients/survivors to develop a prototype of a mobile meditation app for cancer patients/survivors. Findings from the surveys, daily journals, and focus groups fell into two major categories, content and functionality, and within these, themes that were cancer-specific and noncancer-specific. The major themes and subthemes that emerged within these categories will be integrated into the development and design of the cancer-specific meditation app prototype.

This study included both cancer patients/survivors who currently had paid subscriptions to the Calm app and cancer patients/survivors who did not have any prior experience using the Calm app. Although these differing experiences (ie, prior experience with the Calm app vs no prior experience with the Calm app) were expected to shape the participants' responses to the survey, daily journal, and focus group questions, we found that the majority of the emergent themes and subthemes were consistent across these groups. Our findings suggest that prior use or familiarity with the current Calm app did not make a major difference in cancer patients'/survivors' preferences and suggestions for a cancer-specific meditation app prototype.

All three groups (cancer patients/survivors, health care providers, and current Calm subscribers who were patients/survivors) shared themes that were both cancer-specific and noncancer-specific. Overall, the majority of content preferences and suggestions that arose were cancer-specific, such as content related to negative emotions or feelings (eg, anxiety, grief, trauma/posttraumatic stress disorder [PTSD],



fear of recurrence, isolation), positive feelings and finding meaning (eg, gratitude, storytelling, acceptance), scenarios and experiences (eg, waiting, treatment-specific meditations), type and stage of cancer journey, and movement modifications. Similarly, in terms of app functionality, the majority of participants (including cancer patients/survivors, health care providers, and current Calm subscribers who were patients/survivors) expressed interest in having a section/tab/area of the app that was specifically geared toward cancer patients/survivors. Some preferences and suggestions for cancer-specific functionality features included an algorithm that provides options based on symptoms or journey, being able to suggest specific meditations to others or receive suggestions from other patients/survivors, and having an emergency toolkit for patients/survivors. Some of the noncancer-specific themes fell under the content of the app category, such as sleep content, music, and visualizations. Participants expressed that these content suggestions would not only be helpful to cancer patients/providers but could also be helpful to individuals without cancer.

Interestingly, some participants expressed that they wanted to be able to use the app without being reminded of their cancer and some indicated that they did not want to use this app as a tool to connect with other cancer patients/survivors. Given these findings, the final meditation app prototype will likely include a majority of cancer-specific content and functionality features but may also include more general content and features that are not cancer-specific.

Overall, the themes and subthemes that emerged in this study confirm the app content and functionality features found in previous research with cancer patients/survivors. For example, prior studies have found that cancer patients/survivors also experience more daily stressors than the general population that current apps fail to address, and need specific content on managing grief, PTSD symptoms, trauma, fear of death, pain, positivity, strong emotions, worry, life after cancer, body positivity, and others, in relation to meditation practice [21]. Other prior research found that due to the prevalence and burden of symptoms, cancer patients/survivors need to be aware of improvements in symptoms that accompany meditation and that further reinforce continued meditation practice [20]. A similar finding was reinforced in this study, in which participants suggested that an algorithm that provides options based on symptoms and being able to track symptoms would be functionality features that would be helpful for cancer patients/survivors. Finally, support from other patients/survivors specific to the challenges and benefits of meditation practice is also needed to help patients/survivors adapt their practice to their clinical manifestations, and cancer patients need brief calming meditations for very specific contexts (eg, before doctor visits or during chemotherapy). In these emergency scenarios, meditations that acknowledge the context and heightened stress are needed. Overall, many of our results reinforced or were in line with findings from previous studies assessing mobile app preferences and needs of cancer patients/survivors. In addition, we found similar themes across our three groups: the cancer patients/survivors, health care providers, and current Calm subscribers who were patients/survivors. Thus, these study

findings will allow us to develop a mobile meditation app prototype that is targeted toward and can specifically meet the needs of cancer patients/survivors.

A future direction for this research is to finalize the development of the cancer-specific meditation app prototype, which is currently under development. The investigative team will work in partnership with developers from Calm to integrate the overall findings from this study to rapidly develop a server-side application programming interface (API) and an app for iOS. Themes and feedback from the surveys, daily journals, and focus groups will be used to extend the current Calm design, APIs, and app, so that the content, layout, and features in the app will address specific cancer-related long-term needs.

We will then beta test the feasibility of the cancer-specific meditation app prototype with a sample of cancer patients/survivors (N=30). We will recruit cancer patients/survivors with varying cancer types and stages, race/ethnicity, rural/urban geographic settings, and genders via social media and partnerships with nonprofit organizations. Beta-test participants will be asked to use the prototype for 4 weeks for at least 10 minutes per day, but will be encouraged to use it as much as they would like, mimicking how a new paying member would use the existing Calm app. Participation (meditations completed, time of day, length of time, components used) will be tracked over the 4 weeks. To determine acceptability, demand, and practicality, participants will be asked to complete weekly satisfaction questionnaires in addition to a final overall study satisfaction questionnaire immediately postintervention. In addition to a satisfaction questionnaire, we will ask the participants to volunteer for a semistructured interview to determine, using Bowen's feasibility model [30], acceptability, demand, practicality, adaptation, and integration to optimize potential for uptake, engagement, and continued use at recommended levels (ie, at least 10 minutes a day). Themes and findings from the interviews will be used to translate findings into app-relevant recommendations (ie, further revisions if necessary) for efficacy testing. This approach is similar to methods used in other studies designing and developing mobile apps [31,32].

### Strengths and Limitations

This study has a number of strengths. The biggest strength of this study is the inclusion of three groups: cancer patients/survivors, health care providers, and current Calm subscribers who were patients/survivors. We were able to gain insight from end users at both the individual and clinic levels. We had contributions from those who will use the app and those who will prescribe the app. This is in alignment with the call from health service managers who recommend integrating accessible, complementary treatments into regular medical practice [33]. Another strength of this study was leveraging a popular consumer-based app (ie, Calm) to increase the potential success of the cancer-specific app. Calm has a large reach (~4 million paying users) and is a household name, which is likely to help the cancer-specific meditation app be successful on the market [34]. Additionally, when marketed to cancer care clinics, professionals, and patients/survivors, Calm may have the ability to offer subscriptions at highly reduced rates.

There are some study limitations to note. One study limitation was the lack of double coding during the qualitative analyses, as we did not have a second individual independently code the surveys, daily journals, or focus groups. Instead, one author (NB) coded the surveys, another author (TN) coded the daily journals, and a third author (LJ) coded the focus group transcripts. However, we found similar themes and subthemes across surveys, daily journals, and focus groups. Another limitation of the study was the limited generalizability, given that the majority of the sample was female, non-Hispanic White, and of relatively high socioeconomic status. Therefore, the results may not represent the views of male, racial/ethnic minority, and/or low-income populations. However, we did have broad representation of cancer type. The next step of this formative research is to pilot-test the app prototype among a

sample of 30 cancer patients/survivors, and to address the current limitations in generalizability, we plan to recruit a more diverse population to participate in the pilot study.

### Conclusions

Cancer patients/survivors, health care providers, and current Calm subscribers who were patients/survivors completed surveys, daily journals, and focus groups to provide insight into the development of a cancer-specific mobile meditation app prototype. Findings fell into two major categories, content of the app and functionality of the app, and will be incorporated into the development of the prototype. The prototype's form and function will be pilot-tested among 30 cancer patients/survivors in a 4-week study, and the resulting feasibility data will be used to inform the final app design and an efficacy study.

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### Authors' Contributions

JH, RM, and LL conceptualized the study and guided the study design. NB, TN, and LJ performed the data analyses, and assisted with data analyses, interpretation of results, and drafting the manuscript. All authors critically reviewed and edited the manuscript and approved its submission.

### Conflicts of Interest

JH serves in a consultant role as the Director of Science for Calm. She oversees Calm's Scientific Advisory Board and consults on an as-needed basis to ensure the quality of Calm's science. She has no specific obligations to the company nor does she own stock in the company or receive financial reward from the sale of the product. JH conducts investigator-initiated research with Calm as a partner. LL also serves on Calm's Scientific Advisory Board. She does not financially benefit from the sale of the product nor does she own stock in the company. TN is a research affiliate at Arizona State University, supervised by JH. TN is financially supported by Calm as a contractor to help JH with her research but she is not an employee of Calm and does not have equity in the company.

#### Multimedia Appendix 1

Focus group questions.

[[XLSX File \(Microsoft Excel File\), 11 KB - formative\\_v6i1e32458\\_app1.xlsx](#) ]

#### Multimedia Appendix 2

Themes, subthemes, and illustrative quotes from current Calm subscribers' surveys.

[[XLSX File \(Microsoft Excel File\), 13 KB - formative\\_v6i1e32458\\_app2.xlsx](#) ]

#### Multimedia Appendix 3

Themes, subthemes, and illustrative quotes from cancer patients'/survivors' daily journals.

[[XLSX File \(Microsoft Excel File\), 16 KB - formative\\_v6i1e32458\\_app3.xlsx](#) ]

#### Multimedia Appendix 4

Themes, subthemes, and illustrative quotes from health care providers' daily journals.

[[XLSX File \(Microsoft Excel File\), 13 KB - formative\\_v6i1e32458\\_app4.xlsx](#) ]

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## Abbreviations

**API:** application programming interface

**PTSD:** posttraumatic stress disorder

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Original Paper

# A Self-help Tool to Facilitate Implementation of eHealth Initiatives in Health Care (E-Ready): Formative Evaluation

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## Abstract

**Background:** eHealth interventions have the potential to increase the efficiency and effectiveness of health care. However, research has shown that implementing eHealth in routine health care practice is difficult. Organizational readiness to change has been shown to be central to successful implementation. This paper describes the development and formative evaluation of a generic self-help tool, *E-Ready*, designed to be used by managers, project leaders, or others responsible for implementation in a broad range of health care settings.

**Objective:** The aim of this study is to develop and evaluate a tool that could facilitate eHealth implementation in, for example, health care.

**Methods:** A first version of the tool was generated based on implementation theory (E-Ready 1.0). A formative evaluation was undertaken through expert panels (n=15), cognitive interviews (n=17), and assessment of measurement properties on E-Ready items from 3 different workplaces (n=165) using Rasch analyses. E-Ready 1.0 was also field tested among the target population (n=29). Iterative revisions were conducted during the formative evaluation process, and E-Ready 2.0 was generated.

**Results:** The E-Ready Tool consists of a readiness assessment survey and a hands-on manual. The survey measures perceived readiness for change (willingness and capability) at individual and collective levels: perceived conditions for change at the workplace, perceived individual conditions for change, perceived support and engagement among management, perceived readiness among colleagues, perceived consequences on status quo, and perceived workplace attitudes. The manual contains a brief introduction, instructions on how to use the tool, information on the themes of E-Ready, instructions on how to create an implementation plan, brief advice for success, and tips for further reading on implementation theory. Rasch analyses showed overall acceptable measurement properties in terms of fit validity. The subscale *Individual conditions for change* (3 items) had the lowest person reliability (0.56), whereas *Perceived consequences on status quo* (5 items) had the highest person reliability (0.87).

**Conclusions:** E-Ready 2.0 is a new self-help tool to guide implementation targeting health care provider readiness and engagement ahead of eHealth initiatives in, for example, health care settings. E-Ready can be improved further to capture additional aspects of implementation; improvements can also be made by evaluating the tool in a larger sample.



**KEYWORDS**

implementation science; health care sector; telemedicine; organizational readiness for change

## Introduction

### Background

During the last few decades, eHealth solutions have been increasingly introduced in routine health care. Indeed, technological innovations are gradually changing the landscape of health care delivery, monitoring, efficiency, and decision-making [1,2]. eHealth has been defined by the World Health Organization as “the use of information and communication technologies for health,” and it can include a broad spectrum of different types of methods and interventions such as electronic health records, telehealth, web-based health care, and mobile health. However, research has shown that it is difficult to implement and incorporate eHealth in complex and multi-professional settings such as health care organizations [3,4].

Key barriers to implementing eHealth have been highlighted, such as perceptions of an increased workload and workflow disruptions, misalignment with clinical processes, undefined and changed roles, disruptions to face-to-face communication, and staff turnover [4,5]. However, factors that could facilitate implementation have also been identified, such as perceptions that using innovative eHealth could increase quality of care [4]. A review of reviews concluded that activities such as carefully considering the choice of an eHealth solution, engaging key stakeholders, and offering training and education, as well as allowing for adaptations of eHealth solutions, is central to succeeding with implementation efforts [6]. These recommended activities are in line with prevalent implementation theory and research arguing that factors at multiple levels in an organization together influence and contribute to implementation [7]. Furthermore, the aforementioned meta-analysis highlighted perceived benefits and harms to be especially important in eHealth implementation, for instance, perceived consequences on workflow and productivity, as well as expected costs of implementing eHealth [6].

Thus, implementation of eHealth initiatives in health care occurs at multiple organizational levels, is complex, and requires considerable work to succeed. Within implementation science, different theoretical approaches (theories, models, and frameworks) aim to describe, guide, explain, and evaluate implementation efforts [7]. These approaches can be used by implementers to plan, execute, and evaluate implementation efforts. However, in the hierarchical system of health care, clinicians and health service managers, who may have limited knowledge in implementation science, often find themselves responsible for the implementation of new digital solutions. Although, for example, a well-operationalized, multilevel framework derived from implementation theory and empirical data can guide the implementation process, lack of time, resources, and knowledge may lead to a nonsystematic implementation [8]. In addition, failures in implementation may not only lead to loss of money and time, but can also contribute

to a decreased willingness among staff to adopt eHealth innovations in the future [9,10].

Furthermore, organizational readiness for change has been recognized and shown to be central to successful implementation [11-13]. It has been conceptualized by Weiner [14] as the shared determination and sense of collective capability to change. The concept of *eHealth readiness* has been proposed as important for implementing digital innovations in health care successfully [15]. A review on eHealth readiness highlighted multiple dimensions involved in the concept, such as technological aspects (eg, the extent to which technical requirements can be met), motivational aspects (eg, perceived need for technology among users), and availability of resources (eg, financial resources and competency to use technology) [15]. Tools and frameworks for measuring eHealth readiness within health care contexts also exist and are proposed to be used to facilitate implementation [15-17].

Incorporating eHealth solutions in routine health care may encompass a number of different aspects, for example, intervention conception, eHealth readiness assessment, and business and financial plans, as well as a change management plan and details on how implementation can be performed, monitored, evaluated, and sustained. Tools that assess readiness can facilitate the implementation process by guiding and informing stakeholders in a hands-on manner. In addition to improved compliance, targeted implementation efforts are more effective in terms of both costs and use of professionals' time [18]. However, previous research has highlighted a number of challenges with regard to readiness measures, such as the measures are too theoretical, they do not address implementation issues at employee level, the scope of the measures is too broad, and the measures capture determinants for readiness rather than actual readiness [15,19].

### Objective

The aim of this study is to develop and evaluate a tool that could facilitate eHealth implementation in, for example, health care. Thus, this paper describes the development and formative evaluation of E-Ready, a generic self-help tool targeting some domains of eHealth readiness to support implementation of eHealth initiatives. The tool comprises 2 parts: (1) a survey assessing implementation readiness and (2) a hands-on manual with recommended strategies and activities to facilitate implementation.

## Methods

### Overview

The E-Ready Tool was developed to be used by managers, project leaders, and/or change leaders to facilitate and plan for implementation. E-Ready 1.0 was generated and examined in a formative evaluation process to support its validity.

## Development of E-Ready

E-Ready 1.0 was developed based on theory appraisal. This version comprised a survey assessing implementation readiness and a manual that included general information about implementation and strategies that can be used to promote practice change.

### Theory Appraisal

Theories on organizational change, implementation, and behavior change were reviewed, for instance, organizational readiness to change [14], determinants of implementation [20-23], and individual behavior change [24,25]. Theoretical constructs from these theories were listed and used to design the content and structure. For the assessment survey, items were generated to capture all the theoretical constructs that had been identified. The theoretical constructs were categorized into 5 domains: (1) capacity to change at organizational and individual levels, (2) culture to change, (3) leadership promoting change, (4) motivation to change among staff, and (5) perceived characteristics of the implementation object. These 5 domains provided an initial structure for both the survey and the manual.

### Development of the Readiness Assessment Survey

Survey items were generated for each domain and theoretical construct, that is, providing evidence based on test content [26]. For example, in the domain *implementation object*, one of the theoretical constructs was “perceived need to conduct the change among the staff.” This construct resulted in 2 proposed items: *I understand why we are implementing X at my workplace* and *I can see a need for X at my workplace*.

A total of 38 items were generated initially. Revisions were made in an iterative process and included survey structure, wording of items, wording of response options, and order of items. For example, an effort was made to tailor response options to questions. Furthermore, we revised the structure and divided the survey into main questions and subitems to facilitate the completion of the survey. The response scales were tailored to each item and were formulated to force respondents to choose an answer, that is, the items do not include a middle alternative such as “I have no opinion.” The structure of the survey no longer followed that of 5 theoretical domains; rather, the survey was constructed in a way that facilitated completion. These revisions resulted in 6 sections of questions and additional items, for instance, profession, giving a total of 33 items ([Multimedia Appendix 1](#)).

### Development of the Manual

The manual was also drafted grounded in the aforementioned 5 theoretical domains: capacity, culture, leadership, motivation, and implementation object. For example, text on why and how the factors relating to the 5 domains are important for successful implementation was included in the manual. The manual was developed with a need to know perspective so that it could also be useful for novice implementers.

### Formative Evaluation

Formative evaluation of E-Ready was undertaken in 3 ways: expert panels, cognitive interviews, and statistical tests. In addition, E-Ready was field tested among health care

professionals. Revisions of the assessment survey and the manual were conducted continually during the formative evaluation process.

### Expert Panels and Cognitive Interviews

In all, 3 workshops with experts (n=15) were conducted with the aim of investigating the content validity and structure of the tool. Participants' expertise consisted of knowledge as potential end users of the tool (physicians with clinical experience) as well as knowledge and experience in implementation. All participants had explicit responsibility for integrating eHealth in their organization. The first workshop focused on the survey items. Participants were asked to individually complete the assessment survey and then provide written feedback on how they interpreted the items and how they perceived the structure and content of the questions. The individual feedback was later discussed at the workshop. For example, to ensure that individual items captured specific theoretical constructs, the discussions focused on formulations and on how items were understood. During the second and third workshops, the manual was scrutinized. The physicians were asked to give feedback on the content of the manual, for example, the introduction of theories, information on how to use the guide, the layout, if the guide gave enough information, and if the information was clear and understandable.

Cognitive interviews were conducted with health care professionals from 2 health care settings (university hospital and specialist outpatient clinic), including physicians (n=5), registered nurses (n=4), physiotherapists (n=2), behavior therapists (n=2), and dietitians (n=4). Cognitive interviewing is a psychologically oriented method for empirically studying the ways in which individuals mentally process and respond to survey questionnaires. Cognitive interviews provide validity evidence based on response processes by allowing for potential differences in the interpretation of test items.

Data from cognitive interviewing can form the basis for appropriate modifications before further field testing [27]. Cognitive interviews were conducted by letting the participant read the question and then explaining their interpretation and meaning of the question. This technique was used in an applied sense—for the purpose of pretesting questions and determining how the items could be modified—before field testing to make the items more understandable or otherwise easier to answer. Participants were first asked to complete the survey while thinking of an eHealth initiative that they had experienced. They were then further interviewed regarding how they perceived the tool, its structure, content, and if there were survey items that were unclear or should be rephrased. Comments were noted by the researcher throughout the interview.

Iterative revisions were made in parallel with conducting expert panels and cognitive interviews. Revisions of the survey predominantly included eliminating overlap across the items and wording of the items. For example, comments based on the cognitive interviews showed that the content of 4 of the items covered similar areas, resulting in the omission of items. Revisions of the survey during this phase resulted in 29 items. Furthermore, expert data showed that the manual offered a structured way to organize the implementation process and

provided insights into how to think about readiness and implementation. Revisions of the manual thus mainly covered language editing.

### Statistical Tests

To assess the measurement properties—specifically, evidence based on the internal structure [26] and fit validity [28]—of the E-Ready survey, we conducted a Rasch analysis using Winsteps software (version 4.3.1). In this analysis we included the E-Ready survey data from participants at 3 different workplaces ( $n=165$ ), all of whom had filled in the E-Ready survey ahead of different eHealth implementation initiatives.

Each subscale was individually evaluated in terms of the following attributes: (1) sample to item targeting, (2) item fit to the model, (3) unidimensionality, and (4) person reliability. Each attribute is described briefly as follows:

1. The distributions of the item-threshold measures compared with those of the person measures indicate how well the items fit to the sample. The mean person measure indicates whether the sample is off-center with respect to the items. Ideally, it should be close to 0 [29].
2. Fit statistics evaluates how well the data fit the Rasch model by assessing for both inlier-pattern (INFIT)- and outlier-pattern (OUTFIT)-sensitive fit statistics. Mean-square (MNSQ) fit statistic is recommended to be between 0.5 and 1.5 to provide a productive measure. Z-standardized (ZSTD) fit statistics should be within  $-2$  to  $+2 \sigma$  to support good model fit [30].
3. A principal component analysis of the fit residuals is used to assess unidimensionality. The eigenvalue is not expected to be  $>2$  to support unidimensionality. If the eigenvalue

does not support unidimensionality, high disattenuated Pearson correlation coefficient of the person measures can still prove that the dimensions are statistically the same, thus providing a unidimensional measure [31].

4. The consistency of a measure is evaluated in terms of its reliability, that is, the proportion of variance that is true variance. The reliability of the person measures should be interpreted as 0 (implies all error) or 1 (implies no error) [32].

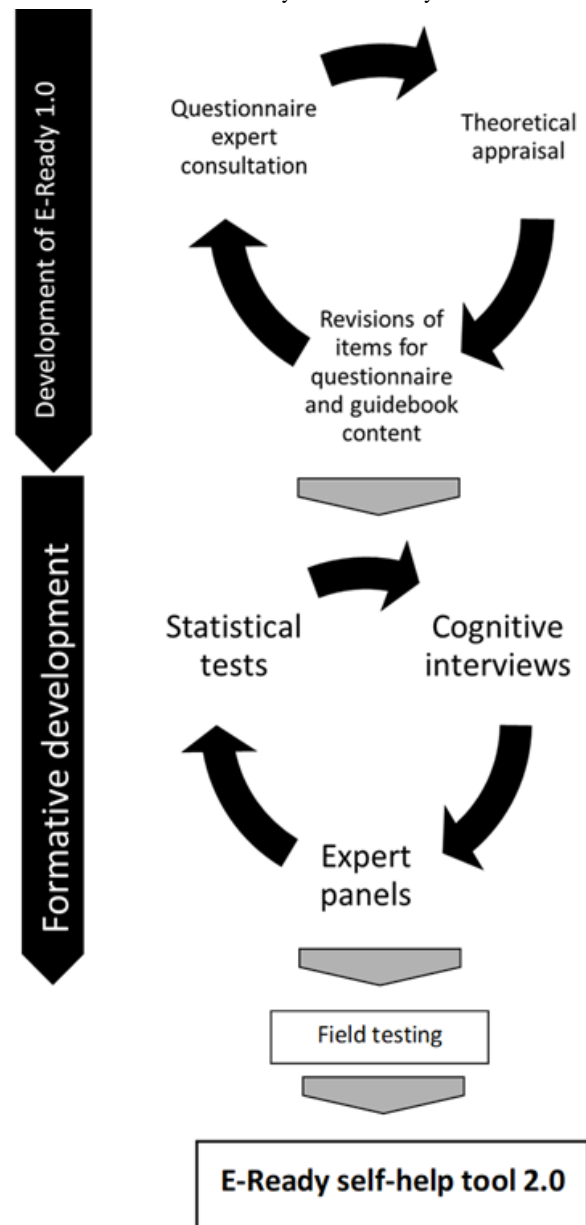
Moreover, we hypothesized that there were positive correlations between person measures from all subscales and no differences in person measures between men and women. These analyses were conducted by means of Pearson correlation coefficients and 1-way analysis of variance in SPSS software (version 26.0; IBM Corp).

### Field Testing

As a last step, E-Ready was field tested among health care professionals. The tool was sent through email to 29 physicians and registered nurses at Karolinska University Hospital in Stockholm, Sweden. Participants were asked to complete the survey from personal experiences of implementation of an eHealth initiative. At the end of the survey, they were asked to leave comments. The feedback was positive, and no additional revisions were made. For example, positive feedback was provided regarding using the survey to engage employees in the change process. Furthermore, items investigating leadership and manager support were perceived to be specifically important.

Figure 1 illustrates all activities and their time points.

**Figure 1.** Process of the development and formative evaluation of E-Ready 1.0 to E-Ready 2.0.



## Results

### Readiness Assessment Survey

The survey ([Multimedia Appendix 1](#)) aims to assess implementation readiness. The 6 sections investigate the following: (1) *Perceived conditions for change at the workplace*, for example, competency and resources for practice change (8 items); (2) *Perceived individual conditions for change*, for example, prior experience of changing practice (3 items); (3) *Perceived support and engagement among management*, for example, how urgency for change is communicated by management (5 items); and (4) *Perceived readiness among colleagues*, for example, how change is collectively valued by colleagues (5 items). There are also items aiming to capture (5) *Perceived consequences on status quo*, for example, worries regarding how practice change can influence current workflows

(5 items) and (6) *Perceived workplace attitudes toward change*, for example, self-reported attitude toward the proposed change (3 items). In addition, 7 single items investigate compatibility with current work routines: commitment to change and perceived need for change, gender, years worked at current workplace, profession, and years worked in profession. In total, there are 36 items in the final assessment survey, E-Ready 2.0. It takes approximately 10 minutes to complete the survey.

Results from the Rasch analyses showed that item-threshold measures were well covered by the person measures and person measures were fairly well covered by the item thresholds. As illustrated in the person-item threshold histograms ([Figure 2A-F](#)), there are gaps among the item thresholds. Furthermore, the subscale *Perceived readiness among colleagues* ([Figure 2D](#)) was negatively skewed (mean  $-1.91$ , SD 2.19), and *Perceived consequences on status quo* ([Figure 2E](#)) was positively skewed (mean 1.05, SD 2.88).



**Figure 2.** Person-item threshold histograms for each subscale. <sup>1</sup>Conditions for change at the workplace; <sup>2</sup>Individual conditions for change; <sup>3</sup>Perceived support and engagement among management; <sup>4</sup>Perceived readiness among colleagues; <sup>5</sup>Perceived consequences on status quo; <sup>6</sup>Workplace attitudes.

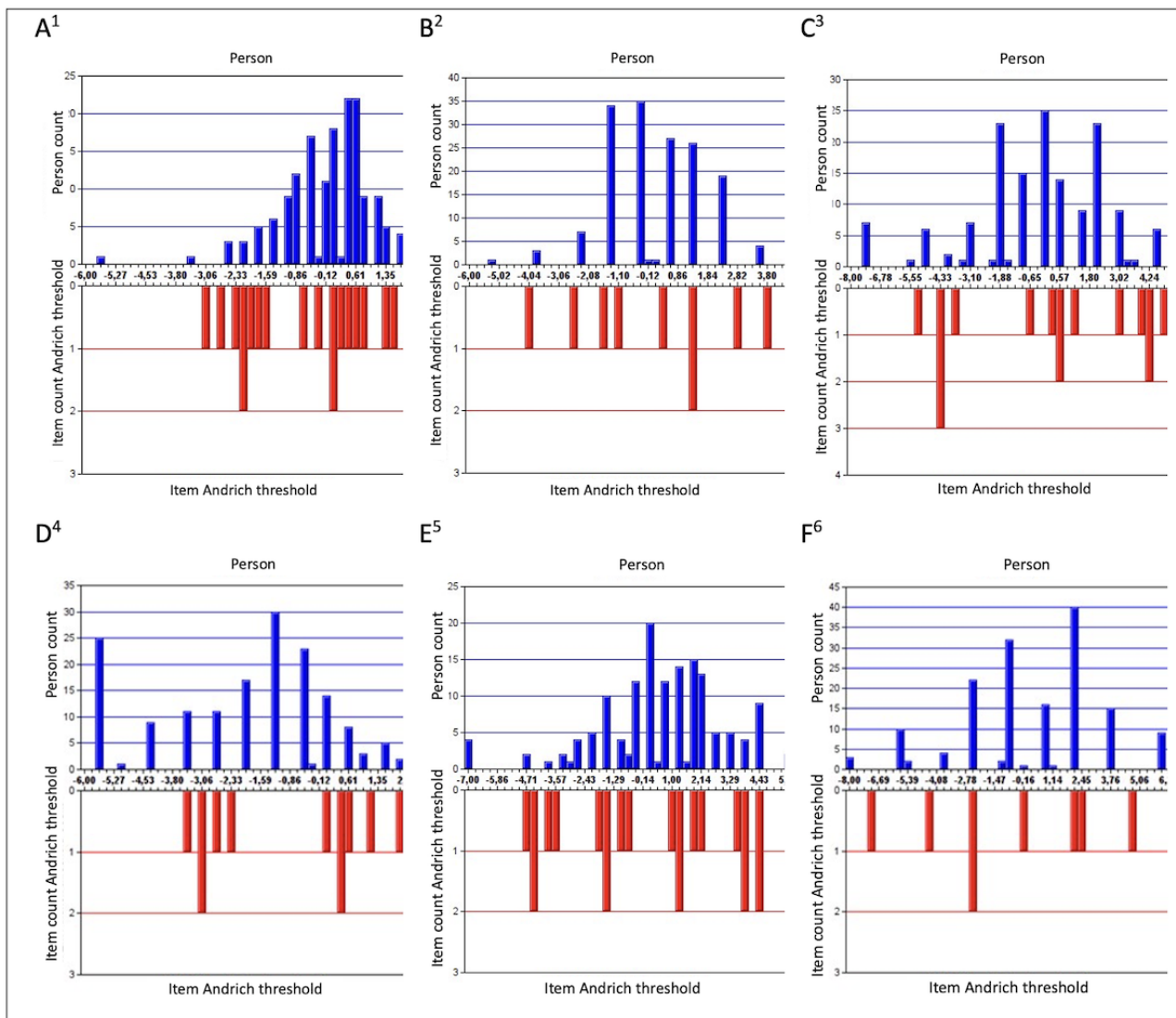


Table 1 provides a summary of the Rasch analysis of the subscales. In short, the subscale Conditions for change at the workplace had all INFIT and OUTFIT MNSQ values within the acceptable range, and the 2 items with INFIT and OUTFIT ZSTD values were slightly outside  $2\sigma$ . By a closer inspection of the principal component analysis loadings, we found that a cluster of 3 items addressed the conditions among the employees, whereas the others addressed organizational conditions. The subscale Individual conditions for change also had all INFIT and OUTFIT MNSQ values within the acceptable range, but 2 items with INFIT and OUTFIT ZSTD values were

slightly outside  $2\sigma$ . The person reliability was lowest for this scale, which, speaking reasonably, is a consequence of having only 3 items. The subscale Perceived support and engagement among management showed some statistical item misfit but supported unidimensionality. By removing the most misfitting item (item E of the E-Ready survey, which addresses management competence and knowledge unlike the others that address management actions), we found that the fit statistics were improved, and the person reliability increased from 0.84 to 0.86.



**Table 1.** Summary of the Rasch analysis of the E-Ready subscales.

	Conditions for change at the workplace, 8 items	Individual conditions for change, 3 items	Perceived support and engagement among management, 5 items	Readiness among colleagues, 5 items	Perceived consequences on status quo, 5 items	Workplace attitudes, 3 items
<b>Item fit statistics</b>						
MNSQ <sup>a</sup> INFIT <sup>b</sup> , mean (SD)	1.00 (0.17)	1.00 (0.26)	0.99 (1.22)	0.99 (0.27)	0.99 (0.42)	0.98 (0.04)
ZSTD <sup>c</sup> INFIT, mean (SD)	-0.10 (1.60)	-0.20 (2.30)	-0.20 (1.40)	-0.20 (2.10)	-0.60 (3.60)	-0.20 (0.40)
MNSQ OUTFIT <sup>d</sup> , mean (SD)	0.99 (0.18)	1.02 (0.29)	1.00 (1.25)	0.98 (0.27)	1.02 (0.46)	1.03 (0.09)
ZSTD OUTFIT, mean (SD)	-0.10 (1.70)	0.00 (2.50)	-0.2 (1.40)	-0.40 (2.10)	-0.40 (3.80)	0.20 (0.50)
MNSQ INFIT (number of items misfitting)	0	0	1	0	1	0
ZSTD INFIT (number of items misfitting)	2	2	2	3	3	0
MNSQ OUTFIT (number of items misfitting)	0	0	1	0	1	0
ZSTD OUTFIT (number of items misfitting)	2	2	2	3	4	0
<b>Unidimensionality</b>						
Eigenvalue unexplained variance in first contrast	2.43	1.78	1.65	2.37	2.22	1.48
Disattenuated correlation cluster, 1-3	0.21	0.13	0.66	0.37	0.61	1.00
<b>Person reliability</b>						
Reliability index	0.69	0.56	0.84	0.72	0.87	0.77
Separation index	1.50	1.13	2.30	1.60	2.55	1.85

<sup>a</sup>MNSQ: mean-square.

<sup>b</sup>INFIT: inlier-pattern-sensitive fit.

<sup>c</sup>ZSTD: Z-standardized.

<sup>d</sup>OUTFIT: outlier-pattern-sensitive fit.

The subscale *Readiness among colleagues* had acceptable INFIT and OUTFIT MNSQ values but INFIT and OUTFIT ZSTD misfit and suffered from unidimensionality. The items comprised both specific tasks (eg, having discussions among colleagues) and overall collaboration, which might explain the weaknesses. The subscale *Perceived consequences on status quo* showed the highest person reliability, but, at the same time, it suffered from several item misfittings. This could possibly be explained by the nature of the response options and statements, that is, the extent to which the implementation of X would affect several working tasks might not be quantified in a common scale for different implementations at different workplaces. Finally, the

subscale *Workplace attitudes* did not have any misfitting items; it supported unidimensionality and had a person reliability close to the desired 0.8.

As shown in [Table 2](#), correlations among the person measures were low to moderate for all subscales except *Perceived consequences on status quo*. This subscale showed some negative correlations, especially toward *Workplace attitudes* ( $r=-0.30$ ). Statistical differences between the person measures of men and women were present for 1 subscale, *Individual conditions for change*, where the men had higher measures than the women.

**Table 2.** Correlations among person measures for the E-Ready subscales.

	Conditions for change at the workplace	Individual conditions for change	Perceived support and engagement among management	Readiness among colleagues	Perceived consequences on status quo	Workplace attitudes
Conditions for change at the workplace	1.00	— <sup>a</sup>	—	—	—	—
Individual conditions for change	0.48	1.00	—	—	—	—
Perceived support and engagement among management	0.50	0.28	1.00	—	—	—
Readiness among colleagues	0.29	0.21	0.53	1.00	—	—
Perceived consequences on status quo	-0.16	-0.02	0.01	-0.02	1.00	—
Workplace attitudes	0.52	0.31	0.41	0.27	-0.30	1.00

<sup>a</sup>Not applicable.

## The Manual

The manual is in the form of a 56-slide PowerPoint (Microsoft Corp) document. The manual predominantly includes recommendations for strategies and activities that facilitate implementation. Recommendations are tailored to low-score areas as identified by the survey. The manual includes the following:

- A brief introduction, including aspects of organizational readiness to change and implementing innovations in practice. This section is written as executive summaries, for example, “Don’t focus solely on technology” and “Involve staff from the beginning.”
- Step-by-step instructions on how to use the E-Ready Tool. For example, what to do, when, and how, as well as suggestions on how to communicate the E-Ready scores to personnel.
- Text that describes the themes of the E-Ready Tool and why they are essential when planning a change process: (1) capacity to change (organizational and individual), (2) culture to change, (3) leadership promoting change, (4) motivation to change, and (5) characteristics of the implementation object.
- Guidance on how to create an implementation plan, including linking your plan to your E-Ready scores and the E-Ready themes.
- A narrative of a case example using the E-Ready Tool, including how readiness assessment can guide and inform an implementation plan.
- “12 Tips for Success,” for example, how to engage staff or measure practice change.
- Recommended reading for those who wish to learn more about implementation theory and a more extensive explanation of the theories underpinning the tool. This part includes scientific references.

## How to Use the E-Ready Tool

Using the E-Ready Tool involves 6 steps where the person responsible for the implementation performs the following actions:

1. Informs relevant personnel in the organization about the plan to use the E-Ready Tool in conjunction with the upcoming eHealth implementation.
2. Reads the manual to gain basic knowledge of readiness and implementation and obtain instructions on how to use E-Ready.
3. Informs the personnel about the upcoming eHealth implementation and the use of the E-Ready Tool in the implementation process. The assessment survey is then sent to the personnel.
4. Receives a summary report of the results in the form of a report that visualizes the results. The results indicate which areas for implementation the personnel have estimated as high or low in terms of readiness.
5. Analyzes the results with the implementation team (if there is one), uses the guide, and discusses which activities can be performed to improve readiness or implementation.
6. Creates an implementation plan with the use of the guide. The guide also includes instructions on how to follow through and measure the implementation process.

## Discussion

### Description of Development and Formative Evaluation of E-Ready

Here, we describe the development and formative evaluation of a novel implementation tool: E-Ready. The tool is a theory-based self-help tool to measure individual and organizational readiness to facilitate eHealth implementation in, for example, health care. The tool consists of a readiness assessment survey and a hands-on manual. The survey measures perceived readiness for change (perceived willingness and capability) in a workplace setting at individual as well as collective levels.

eHealth readiness assessment can be seen as a holistic approach from intervention conception to evaluation and monitoring, as well as sustainability of implementation. The E-Ready Tool considers some key aspects of eHealth readiness, such as perceived conditions for change at group and individual levels, support and engagement level among management, and

perceptions among stakeholders about the change per se. In addition, the manual can be used to guide the generation of implementation and evaluation plans. Thus, the tool primarily considers implementation in the local health care setting using a stakeholder perspective. That is, the tool does not explicitly consider other dimensions of eHealth readiness that have been highlighted in previous research, such as governance or societal readiness [33].

The E-Ready Tool was developed from a need to facilitate systematic implementation of eHealth in health care and the urge to meet health care challenges with regard to new digital solutions. Previous research has highlighted difficulties and delays in integrating new technology with existing workflows, tasks, and organizational processes [3,4,34]. Furthermore, studies suggest that measuring and considering the readiness for change within an organization or workplace can facilitate implementation [12,13]. Readiness assessments can thus help to predict and plan for implementation [15]. However, future studies will need to assess the effect of measuring tools such as E-Ready on implementation outcomes, for example, the reach, adoption, and acceptability of eHealth interventions among health care professionals and patients [35]. For example, more knowledge is needed on how different dimensions of organizational readiness (eg, capacity or willingness among staff) influence implementation outcomes in general and at different levels of an organization over time and at specific time points, as well as how the degrees of readiness differ within an organization and how this variance influences implementation outcomes and potentially can be addressed. In addition, an important aspect to be considered for future research is at what time point readiness assessment is the most valuable. As any measurement only captures readiness for the next step of a change process rather than readiness for the implementation as a whole, multiple measurements of readiness may be needed. E-Ready and similar instruments could be used to investigate these knowledge gaps to further our knowledge on the relationship between organizational readiness for change and implementation.

Previous research has highlighted several challenges with existing readiness-measuring tools, for instance, the importance of tools with regard to targeting and capturing issues at employee level, acknowledging that readiness is change- and situation-specific, and the need for tools to capture readiness (eg, perceptions about capability for change) rather than its determinants (eg, resources for enabling change) [15,19]. We have attempted to address these issues in the development of the E-Ready Tool. Our ambition is to provide a brief, theory-based tool that can be used by stakeholders who are novices at implementation. Specifically, E-Ready 2.0 combines readiness assessment with a hands-on manual on how to plan and promote implementation. Combining these 2 components could offer stakeholders accessible and concrete guidance on implementation. The themes that are assessed in the survey and discussed in the manual, although theory-based, were perceived to be relevant among end users, suggesting that E-Ready addresses appropriate employee-level implementation issues. Furthermore, although the themes of the questions in the survey are generic and can be applied to a broad range of eHealth

initiatives, the eHealth initiative in question is to be specified at the top of the assessment survey, which will tailor the questions and guide responders toward specific eHealth initiatives. We have striven to enable E-Ready to measure and address readiness for change rather than its determinants mainly by reviewing relevant theory [14] and linking theoretical constructs to the survey items and manual content. Finally, the tool is generic and could potentially also be used as a change management component of implementation in fields other than health care, although the testing so far has been conducted in the health sector. Future studies will have to further investigate the validity and reliability of the E-Ready Tool in larger effectiveness studies.

By considering the fairly well-targeted sample to item and by following the general principle of Rasch fit statistics, we found acceptable measurement properties of E-Ready in terms of internal structure and fit validity. However, both the assessment of unidimensionality and provision of a highly reliable measure suffer from including few items in some of the subscales. Thus, there is room to further extend the survey with additional items to improve the measurement properties of the E-Ready subscales. There is indication of construct underrepresentation [28]; thus, items investigating perceptions of privacy issues associated with eHealth interventions, for example, could be added to improve content coverage and content validity. Moreover, despite the practical significance of measures of different aspects with the subscales, the moderate correlations among person measures indicate that a couple of items could be combined to provide a higher-ordered E-Ready measure. This can reduce the measurement uncertainties and further improve the reliability; however, at the same time, a higher-ordered E-Ready measure might not be of the same clinical significance as measures of subscale attributes.

### Methodological Considerations

Among the limitations is the relatively small number of respondents involved in the initial formative evaluation. Considering the qualitative methodology used in the evaluation (ie, expert panels and cognitive interviews), we estimated that the number of participants included would be sufficient to achieve our aim. However, a larger number of participants could have improved generalizability; especially if participants from various health care settings and professions had been included, the rigor would have been enhanced. Thus, continued development work to, for example, better assess the validity and reliability of the survey is needed, as is research on the usability of the manual.

Potential strengths of the study are that end users were included in the formative evaluation, in the expert panels as well as in the cognitive interviews. Involving end users could have increased the usability and acceptability of the tool. However, this needs further investigation in future studies. Using qualitative data from both clinicians and implementers improved and gave support that the content and structure of the tool were relevant and understandable for end users.

Another strength was that we applied the Rasch analysis as part of development. This is not simply a mathematical or statistical approach; rather, it is a specifically metrological approach to

human-based measurement [36]. The Rasch analysis provides separate measures of persons and items scaled on the conjoint interval logit scale [37], which in turn provides objective measures that can be used for arithmetic operations.

The Rasch analysis can be viewed as a statistical model used for validating assessment tools [38]. In this work we have addressed some aspects of validity, that is, the expert group provided *evidence based on test content*, the cognitive interviews provided *evidence based on response processes*, and the Rasch analyses provided *evidence based on internal structure* [26,39]. However, we have not evaluated the 2 remaining validity aspects in the *Standards for Educational and Psychological Testing* [26], namely relations to other variables or consequences of testing. Furthermore, the evidence provided on validity aspects in this study may benefit re-evaluations with added items and

in larger samples. Moreover, it should also be noted that validity evaluations of relations to other variables is not a straightforward process because the constructs purported to be measured with E-Ready do not have a gold standard to be compared with. We therefore encourage further work with a focus on construct modeling [40] and qualitative understanding of implementation readiness theory.

## Conclusions

E-Ready 2.0 is a new self-help tool to guide implementation targeting health care provider readiness and engagement readiness ahead of eHealth initiatives in, for example, health care settings. E-Ready could be improved further to capture additional aspects of implementation; improvements could also be made by evaluating the tool in a larger sample.

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## Authors' Contributions

PD and YTL designed the study, and YTL applied for funding. PD conducted the data collection and analysis of the expert panel workshops, cognitive interviews, and field tests. Statistical tests were conducted by JM and AC. PD and KT generated the E-Ready 1.0 and iterative revisions of the E-Ready Tool. All authors contributed to writing the manuscript.

## Conflicts of Interest

None declared.

## Multimedia Appendix 1

E-Ready 2.0: Readiness assessment survey.

[[DOCX File, 30 KB - formative\\_v61e1e17568\\_app1.docx](#)]

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## Abbreviations

**INFIT:** inlier-pattern-sensitive fit  
**MNSQ:** mean-square  
**OUTFIT:** outlier-pattern-sensitive fit  
**ZSTD:** Z-standardized

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Original Paper

# Efficacy of Digital Health Tools for a Pediatric Patient Registry: Semistructured Interviews and Interface Usability Testing With Parents and Clinicians

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## Abstract

**Background:** Acute respiratory infection (ARI) in childhood is common, but more knowledge on the burden and natural history of ARI in the community is required. A better understanding of ARI risk factors, treatment, and outcomes will help support parents to manage their sick child at home. Digital health tools are becoming more widely adopted in clinical care and research and may assist in understanding and managing common pediatric diseases, including ARI, in hospitals and in the community. We integrated 2 digital tools—a web-based discharge communication system and the REDCap (Research Electronic Data Capture) platform—into the Pragmatic Adaptive Trial for Acute Respiratory Infection in Children to enhance parent and physician engagement around ARI discharge communication and our patient registry.

**Objective:** The objective of this study is to determine the efficacy and usability of digital tools integrated into a pediatric patient registry for ARI.

**Methods:** Semistructured interviews and software interface usability testing were conducted with 11 parents and 8 emergency department physicians working at a tertiary pediatric hospital and research center in Perth, Western Australia, in 2019. Questions focused on experiences of discharge communication and clinical trial engagement. Responses were analyzed using the qualitative Framework Method. Participants were directly observed using digital interfaces as they attempted predetermined tasks that were then classified as *success*, *failure*, *software failure*, or *not observed*. Participants rated the interfaces using the System Usability Scale (SUS).

**Results:** Most parents (9/11, 82%) indicated that they usually received verbal discharge advice, with some (5/11, 45%) recalling receiving preprinted resources from their physician. Most (8/11, 73%) would also like to receive discharge advice electronically. Most of the physicians (7/8, 88%) described their usual practice as verbal discharge instructions, with some (3/8, 38%) reporting time pressures associated with providing discharge instructions. The digital technology option was preferred for engaging in research by most parents (8/11, 73%). For the discharge communication digital tool, parents gave a mean SUS score of 94/100 (SD 4.3; A grade) for the mobile interface and physicians gave a mean usability score of 93/100 (SD 4.7; A grade) for the desktop interface. For the research data management tool (REDCap), parents gave a mean usability score of 78/100 (SD 11.0; C grade) for the mobile interface.

**Conclusions:** Semistructured interviews allowed us to better understand parent and physician experiences of discharge communication and clinical research engagement. Software interface usability testing methods and use of the SUS helped us gauge the efficacy of our digital tools with both parent and physician users. This study demonstrates the feasibility of combining qualitative research methods with software industry interface usability testing methods to help determine the efficacy of digital tools in a pediatric clinical research setting.

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## KEYWORDS

usability testing; REDCap; discharge instructions; acute respiratory infection; digital health technology; mobile technology; semistructured interview; pediatric acute respiratory infection; mobile phone

## Introduction

### Acute Respiratory Infection in Children

Globally, acute respiratory infection (ARI) is a major cause of childhood morbidity and mortality; pneumonia alone is estimated to cause approximately 15% of all global deaths in children aged <5 years [1]. In Australia, children are known to have an average of 13 discrete episodes of ARI before the age of 2 years [2], and 1 in 4 presentations to Western Australian pediatric emergency departments (EDs) is due to ARI [3].

Our understanding of the burden of ARI in Australia is largely derived from hospital inpatient data [3]. Although the severe spectrum of ARI is important, most pediatric patients with ARI are discharged from the ED and recover at home or are treated by family physicians in the community. A better understanding of the burden and natural history of ARI in the community is required to improve our approaches to support parents and carers managing their sick child at home and to assess the efficacy of treatments.

### Digital Health Tools

Digital health is a broad term encompassing “digital information, data, and communication technologies to collect, share, and analyze health information for purposes of improving patient health and health care delivery” [4]. With smartphones now the new *normal computer* [5], there is increasing interest in how digital tools can be used to assist in improving clinical care and clinical research [6-8]. A recent systematic review of discharge communication practices in the pediatric ED examined 23 studies primarily focused on an education intervention involving “delivering information about an illness or instructions for managing care at home.” Of the 23 studies, 10 used technology to deliver this education intervention to parents, with the authors concluding that “technology-enabled *education* type interventions for parents had a positive impact on parent knowledge acquisition and adherence to guidelines, but were not effective in reducing unnecessary return visits to the ED” [9].

Research, particularly communicating study information and consent processes, may also be improved with digital tools [10]. Traditional paper-based informed consent involves a participant reading over long and complex text documents [11]. Evidence suggests that parents may have a poor understanding of the study information provided even when they have no other barriers to understanding (eg, limited English proficiency) [12]. The aim of integrating technology into research processes should

not simply be to transform paper-based resources into digital resources; rather, technology may offer an opportunity to rethink and optimize existing processes. For example, a more participative electronic consent process can feature mobile technology with multimedia components such as video to better align with basic principles of human learning [13].

The ongoing COVID-19 pandemic has led to renewed interest in overcoming the challenges associated with the adoption of digital health tools. Strict data-protection and privacy regulations, a lack of funding, and complexity around interoperability of systems have been long-term challenges [14]. In addition, a lack of user-centered design of digital health tools is common. Unlike other industries such as aviation, in health care “the culture is still to train people to adapt to poorly designed technology, rather than to design technology to fit people’s characteristics” [15]. This was demonstrated in a large US cross-sectional survey where 870 physician users gave an average of an *F* grade (representing 0-60/100 on the System Usability Scale [SUS]) for the usability of their electronic health record system. A strong relationship between electronic health record system usability and the odds of physician burnout was also observed [16].

The Pragmatic Adaptive Trial for Respiratory Infection in Children (PATRIC) was established at a tertiary pediatric hospital to collect prospective data from both parents and health care providers and to assist in the understanding and management of pediatric ARI in the ED and in the community. The first step in PATRIC was the development of a patient registry (PATRIC Registry) that aimed to integrate digital tools into the workflows to enhance engagement with parents and clinicians. Sharing of study information, consent, and follow-up surveys were conducted using REDCap (Research Electronic Data Capture) tools [17,18]. REDCap is a secure, internationally used web-based platform designed to support data capture for research studies.

A second web-based system, Parent Engagement through Technology Solutions (PETS), was used allowing physicians to create personalized discharge instructions for 6 common pediatric ARI diagnoses. These personalized instructions were accessible to parents on a mobile phone or could be printed if an electronic option was not acceptable to the parent.

Before the launch of the PATRIC Registry, we conducted sessions with parents and physicians that comprised semistructured interviews as well as usability testing of our mobile and desktop interfaces.

The aims of this study are to understand parent and clinician experience of discharge communication and engagement in clinical research and to determine the efficacy of 2 different digital tools integrated into a pediatric patient registry for ARI.

## Methods

### Overview

This study was carried out over 2 weeks in September 2019 at Perth Children's Hospital (PCH) and at the Telethon Kids Institute located in Perth, Western Australia. PCH is the sole tertiary pediatric hospital for the state of Western Australia. The PCH ED has approximately 70,000 visits per year. Research on patterns of presentations to 11 Australian and New Zealand pediatric EDs has demonstrated that the most common diagnoses are for infectious (usually viral) respiratory infections [19].

The Telethon Kids Institute is a child health research institute focused on the prevention and management of pediatric childhood diseases and is colocated with PCH.

The human research ethics committee of the Child and Adolescent Health Service approved this study (RGS3078). All participants received a participant information sheet and provided written consent to be part of the study.

### Study Design and Setting

#### Exploratory Study

The study was designed as an exploratory study. Each session with parents and physicians featured (1) a semistructured interview, (2) usability testing of system interfaces with direct observation, and (3) completion of the SUS.

#### Semistructured Interviews

All participants were interviewed with 2 research team members present. A researcher asked predetermined questions, and the other researcher acted as notetaker. RP, BB, and SD took turns as interviewer and notetaker.

#### Usability Testing

Usability testing is the direct observation of participants completing a series of tasks and measuring speed, accuracy, and understanding (as well as other specific, largely qualitative results). Usability testing methods are widely used in the design and development of digital interfaces, especially for websites and software. In formulating the script and materials for usability testing of the interfaces, the team relied on guidance from a user experience design consultant with field usability testing expertise (SH).

#### SUS Scores

On completion of direct observation, all participants rated the interface with the SUS, a widely used Likert-type 10-question survey measuring a user's satisfaction where responses are converted into an overall usability score out of 100 [20]. SUS scores can be converted into equivalent school grades, with scores >90 representing a grade of A and a score of 0 to 60 representing a grade of F for usability [21,22].

### Digital Tools

We integrated 2 digital systems into the PATRIC Registry. The first was a web-based digital discharge communication system allowing physicians to choose from disease-specific templates using a desktop interface to create personalized discharge instructions that can be sent to a parent's mobile phone. The system, first piloted in an adult ED in 2018 [23], is referred to as PETS for discharge communication. Content for 6 common diagnoses of ARI was developed for the PATRIC Registry with senior physician and consumer input. Discharge instructions were written at a level of readability appropriate for the general population, with accompanying pictograms targeted at those with low health literacy (Multimedia Appendix 1).

The second digital system used for the PATRIC Registry was the REDCap platform. PATRIC Registry parent information, including a 2-minute explainer video, electronic consent, and surveys, was developed for mobile phones using the existing functionality of REDCap (Multimedia Appendix 2). Digital copies of the PATRIC Registry information sheet and electronically signed consent form were automatically sent to the email address of the parent using the mobile interface.

### Participants

The ideal sample size for usability testing methods is highly debated. A literature review on this topic advises that a sample size range from 5 to 10 participants is likely to be effective for usability studies focused on problem discovery. Accordingly, we aimed at recruiting 8-10 participants for each group [24]. Participant demographic information was not collected, and all responses and comments were deidentified.

To recruit parent participants, an email invitation was sent to all current nonclinical staff members at the Telethon Kids Institute.

A convenient sample of staff members who were parents of children aged 1-12 years with no detailed knowledge of the technology workflows of the PATRIC Registry were enrolled in the study. A total of 12 parents expressed interest through email in participating in the study, and 11 parents were scheduled over 4 days for a 30-minute session that featured semistructured interviews followed by interface usability testing for both the PETS mobile interface and the REDCap mobile interface. One parent was unavailable during the allocated time slots scheduled for usability testing; therefore, they did not participate in the study.

The inclusion criteria for clinician participants were being a physician currently employed on rotation or as a permanent staff member in the ED at PCH with no prior knowledge of the technology workflows of the PATRIC Registry. A convenient sample was used whereby a senior ED physician and research team member (KB) asked physicians meeting the inclusion criteria whether they would be interested in participating in the study. A total of 8 physicians agreed to participate, and all sessions were carried out on the same day in a nonclinical area of the ED.



## Semistructured Interviews

Semistructured interview questions for parents were focused on experiences after visiting an ED with a child. If the participant had no experience of attending an ED with a child, they were asked to reflect on an experience after a family physician visit with a child. They were also asked about their experiences of information seeking and technology use after an ED visit. Further questions centered around the parent experience of information-seeking and engagement in clinical research studies ([Multimedia Appendix 3](#)).

Interview questions for physicians were based around their experience of discharge practice and different modes of communication at discharge ([Multimedia Appendix 4](#)).

The Framework Method [25] using Microsoft Excel was used to analyze participant responses from the semistructured interviews with parents and physicians. Authors SD, RP, and SJC met to discuss the development of a working analytical framework. Authors SD and RP then independently familiarized themselves with all response notes and coded the responses to identify important issues in the data set. Although areas of interest had been identified for the study, both authors sought to identify any unexpected perspectives within the response data. Both authors then charted the data into the Framework Method matrix and met again with author SJC to further discuss how the data had been charted and to identify the main themes of the data. This was followed by discussions about the main themes, impressions, and ideas based on the data, which led to a written analysis.

## Usability Testing

The usability testing component of the sessions followed the semistructured interview.

All participants were directly observed carrying out a series of predetermined tasks using the interface. The *think aloud* method was also used where participants were actively encouraged to “verbalize their thoughts while performing a computer-supported task” [26].

Each task consisted of any combination of one to three actions: *Start Action*, *Find Method*, and *Select Method*. *Start Action* represented the initiation of a task, such as pressing a button or opening a calendar picker. *Find Method* represented the way a user searched for information, such as using a QR code, browsing, or searching, and *Select Method* related to response actions such as use of a radio button or typing.

Task outcomes were then recorded as *success*, *failure*, *software failure*, or *not observed*. Tasks *not observed* usually described noncompulsory tasks; for example, where a participant was invited to add a comment. Notes on the outcomes of all tasks as well as successes and difficulties with task completion were recorded.

To test the PETS mobile interface, parents were supplied with a mobile phone similar to their personal mobile phone (Android or iOS) to protect privacy. They were then given a fictional scenario to read about a child presenting to the ED with community-acquired pneumonia. Parents were asked to assume that their treating ED physician had sent some discharge

instructions for their child to their mobile phone. They were then asked to access the instructions on the mobile phone using a link embedded in an SMS text message.

For usability testing of the REDCap mobile interface, parents were given the same fictional scenario of a child presenting to the ED with community-acquired pneumonia and asked to assume that they were interested in finding out more about the PATRIC Registry. They were observed using the REDCap mobile interface to learn more about the PATRIC Registry and to electronically provide consent for their child to take part.

For usability testing of the PETS desktop interface, the ED physicians were given a fictional scenario of a child with mild community-acquired pneumonia mocked up on a routine preprinted ED triage sheet. Physicians were then asked to create discharge instructions using the PETS desktop interface on a desktop computer. Following creation of the instructions, the physicians were asked to send the instructions to the parent’s mobile phone.

## Mean Usability SUS Score

After being directly observed using their respective interfaces, all parent and physician participants completed the SUS. In this study, the participants’ individual SUS scores were added and then divided by the number of participants to give a mean usability SUS score for each interface tested.

## Results

### Semistructured Interviews

#### *Experience of Discharge*

Most parents (9/11, 82%) indicated that they receive verbal discharge information for their child when visiting an ED or a family physician. Some parents (5/11, 46%) mentioned having received preprinted discharge information in addition to verbal information about their child’s condition. Of the 11 parents, 3 (27%) described anxiety about the ability to recall all the information given verbally, particularly in regard to what to do if a child’s condition deteriorated after a visit.

When the parents were asked how they would seek further information after an ED or family physician visit with their child, many (8/11, 73%) mentioned using the internet or *Dr Google* (4/11, 36%). Many of the parents (8/11, 73%) stated a preference for receiving discharge information through digital technologies. An unexpected theme was the importance of being able to share information with a partner or other caregiver (3/11, 27%).

In describing their discharge practice, the physicians commonly mentioned giving verbal information (7/8, 88%). All physicians interviewed sometimes used accompanying printed information in the form of a template document or condition-specific health fact sheet either locally sourced or obtained from a reputable tertiary pediatric hospital website. Physicians mentioned a wide variety of challenges with the provision of discharge instructions, such as the amount of time required to provide comprehensive verbal instructions (3/8, 38%) and concerns around some parents’ understanding of written discharge



materials (2/8, 25%). Of the 8 physicians, 1 (13%) highlighted a need for discharge materials in languages other than English.

### Experience of Participation in Clinical Research

In regard to participation in clinical research studies, most of the parents (9/11, 82%) suggested various digital technologies as a preferred way for engaging with research initiatives. Some of the parents (5/11, 46%) specifically mentioned a website as the preferred technology for engagement. Some of the parents expressed frustration associated with participation in clinical research studies, including a lack of complete information (2/11, 18%) and too much information and difficulties contacting study staff (1/11, 9%). Several (4/11, 36%) of the parents wanted

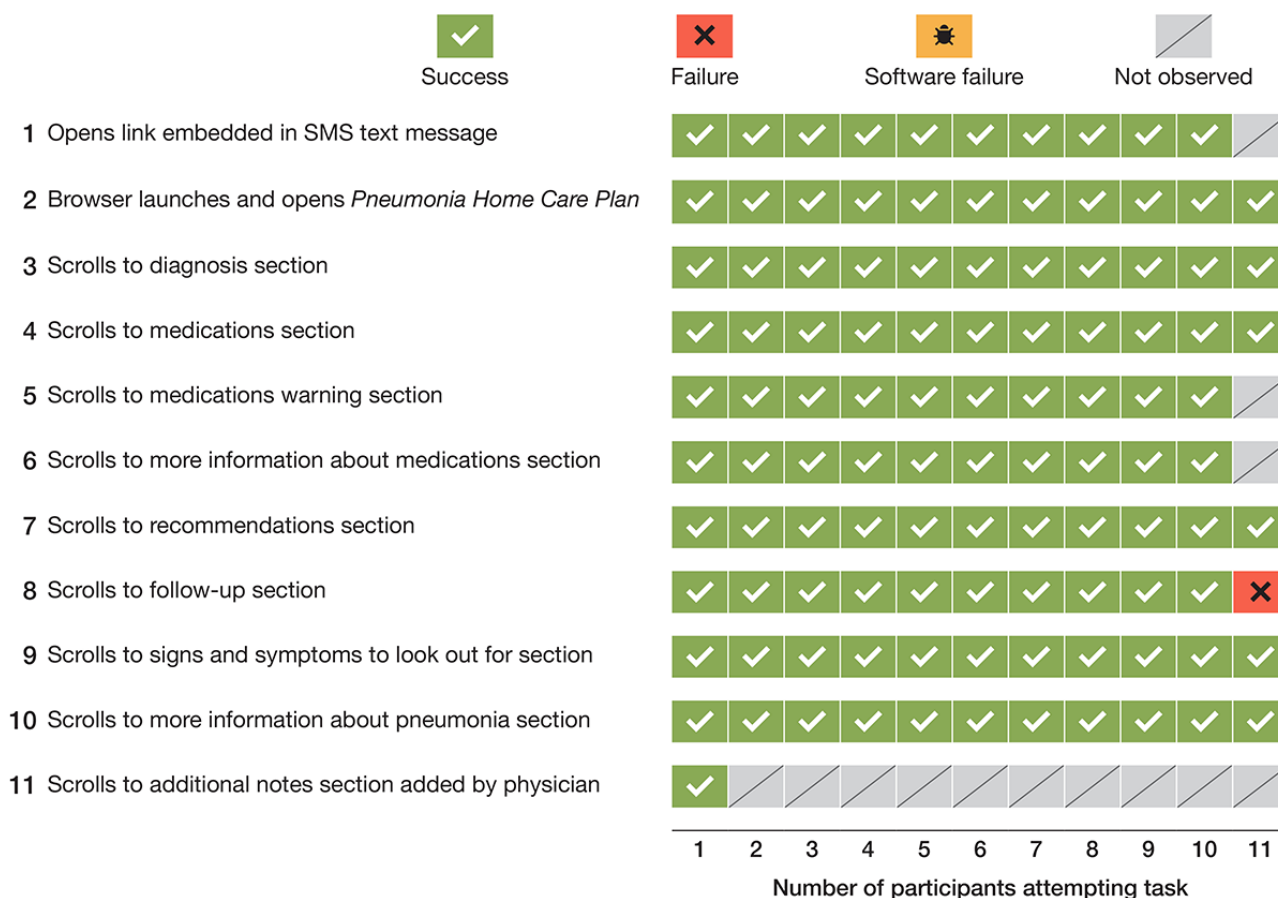
initial personal information from researchers or the physician. Many (7/11, 64%) of the parents mentioned the need for electronic surveys to be short and easy to fill out, and others (4/11, 36%) found it frustrating to be asked to enter free-text responses or comments.

### Usability Testing

#### PETS Mobile Interface for Parents

Each of the 11 parents was directly observed using the PETS mobile interface to complete 11 tasks. Of a total of 121 tasks undertaken by all parents, 107 (88.4%) were a *success*, 1 (0.8%) was a *failure*, no task was ascribed to *software failure*, and 13 (10.7%) were *not observed* (Figure 1).

**Figure 1.** Task outcomes for parents using the PETS mobile interface for discharge instructions (N=11). PETS: Parent Engagement through Technology Solutions.



#### PETS Desktop Interface for Physicians

A total of 8 ED physicians were observed carrying out a series of 22 tasks using the PETS desktop user interface. Of a total of 176 tasks, 155 (88.1%) were a *success*, 9 (5.1%) were a *failure*, 6 (3.4%) were ascribed to *software failure*, and 6 (3.4%) were *not observed* (Figure 2).

Of the 9 failures that were *not due to software*, the most common (3/9, 33%) occurred when physicians selected an add or edit option for the nonpharmacological advice section of the instructions. The drop-down list of options to choose from included several options not relevant for the diagnosis of pneumonia.

Other examples of failures *not due to software* occurred in relation to input into free-text fields. For example, of the 8 physicians, 1 (13%) was unsure of the amount of content typed into a free-text field because of a restriction of the field-viewing window.

In all, 2 *software failures* occurred when 1 of the 2 methods to add a medication to the instructions did not function because a button was inactive, whereas 4 *software failures* were due to the incorrect function of an external link, where a new tab did not appear in the browser window. This required the ED physicians to use the browser's *back* button to preserve their work.

**Figure 2.** Task outcomes for emergency department physicians using the PETS desktop interface for creating discharge instructions (N=8). PETS: Parent Engagement through Technology Solutions.

	Success	Failure	Software failure	Not observed				
1 Selects from radio buttons (male or female)	✓							
2 Selects from radio buttons (child or adult)	✓							
3 Types into open field to input child's weight	✓							
4 Presses <i>Next: Diagnosis</i> button to open list of diagnoses	✓							
5 Clicks on <i>Pneumonia</i> from list to open <i>Pneumonia Home Care Plan</i>	✓							
6 Presses <i>Add Medications item</i> button or clicks link to open medication list	✓							
7 Clicks to select medication required	✓							
8 Clicks to expand details of medication selected	✓							
9 Clicks on a drop-down list and selects course duration of medication	✓							
10 Presses <i>Add Medication</i> to add medication to <i>Pneumonia Home Care Plan</i>	✓							
11 Interviewer asks participant to pause and describe what the parent is being asked to do	✓	✗						
12 Interviewer asks participant if added medication instruction information is clear or unclear for parent or guardian	✓	✗						
13 Types into open field to add notes relating to medication instruction	✓							
14 Adds to or changes or accepts default items providing advice on nonpharmacological recommendations	✓	✗						
15 Adds to or changes or accepts default items providing follow-up advice	✓							
16 Types into open field to add notes relating to follow-up advice	✓	✗						
17 Adds to or changes or accepts default items providing more information on pneumonia	✓			✗				
18 Adds to or changes or accepts default items providing more information	✓							
19 Presses <i>Share with Patient</i> button to open sharing options	✓							
20 Checks box for SMS text message sharing option	✓							
21 Types mobile phone number into open field	✓							
22 Presses <i>Send</i> button to share <i>Pneumonia Home Care Plan</i> with parent or guardian	✓							
	1	2	3	4	5	6	7	8
	Number of participants attempting task							

### REDCap Mobile Interface for Parents

For the REDCap mobile interface, parents were directly observed attempting a series of 23 tasks that involved accessing PATRIC Registry information and completing the electronic consent process. Of a total of 253 tasks, 226 (89.3%) were a

success, 18 (7.1%) were a failure, none were due to software failure, and 9 (3.6%) were not observed (Figure 3).

Several of the failures occurred when parents attempted to enter their mobile phone number in a format that did not conform to the required field format. Other failures occurred when parents had not noticed the link to the PATRIC Registry explainer video and had not entered email address details.

**Figure 3.** Task outcomes for parents using the REDCap (Research Electronic Database Capture) mobile interface for the eConsent process (N=11). PIF: participant information form; DOB: date of birth.



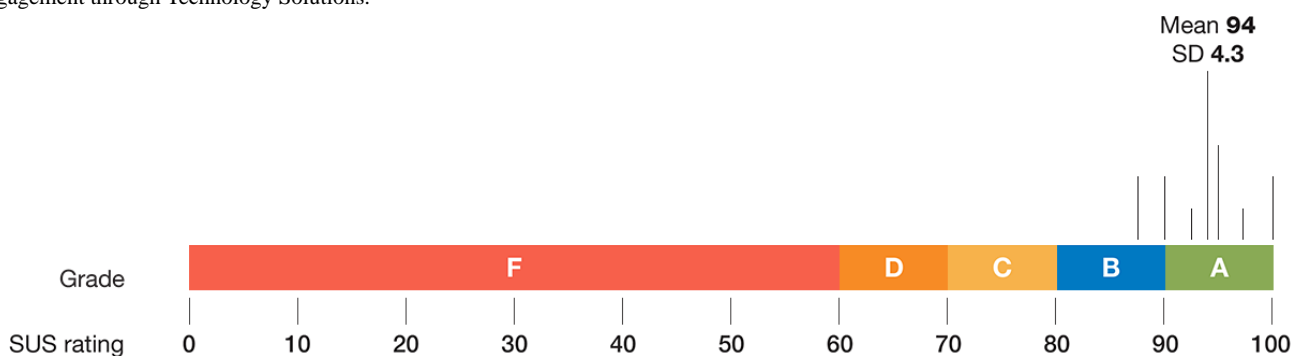
**SUS Mean Scores**

Parents gave the PETS mobile interface for discharge instructions a mean score of 94 out of 100 (SD 4.3) on the SUS, which is equivalent to an A grade (Figure 4).

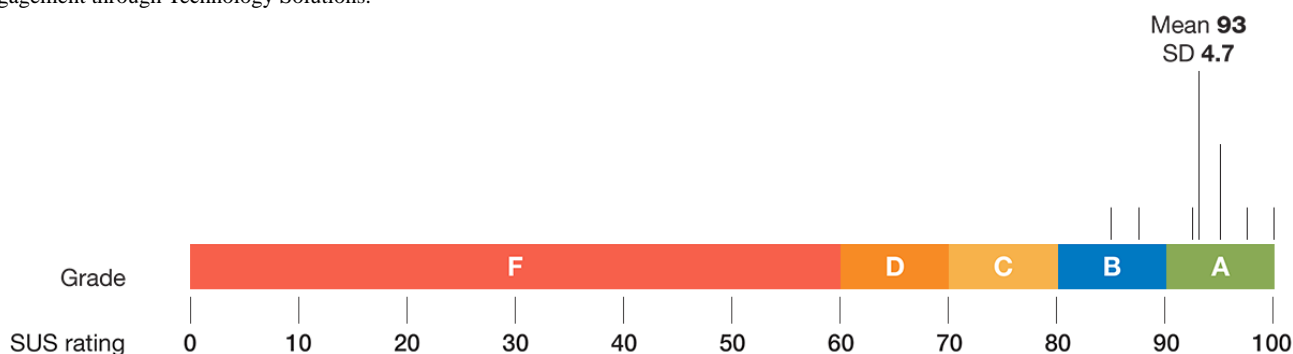
ED physicians gave the PETS desktop interface a mean score of 93 out of 100 (SD 4.7) on the SUS, which is equivalent to an A grade (Figure 5).

Parents gave the REDCap mobile interface a mean score of 78 out of 100 (SD 11.0) on the SUS, which is equivalent to a C grade for usability (Figure 6).

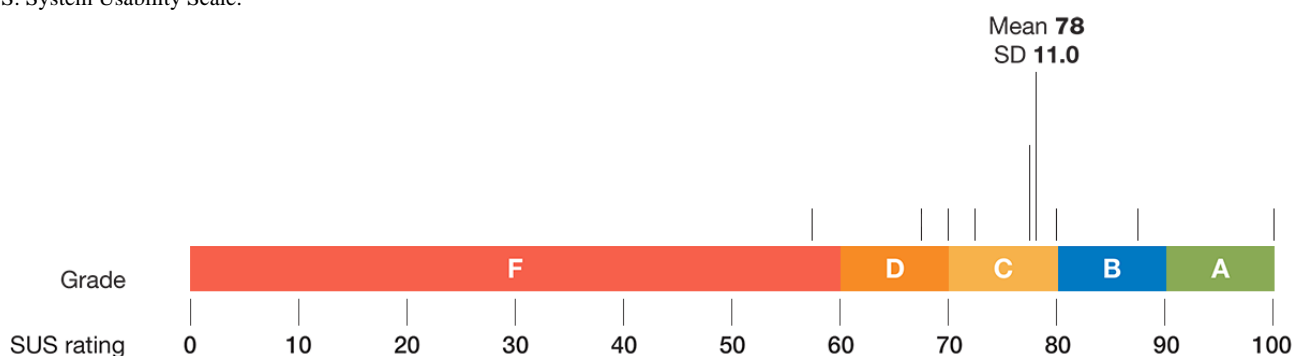
**Figure 4.** Mean SUS score and equivalent grade given to the PETS mobile interface by parents (N=11). SUS: System Usability Scale; PETS: Parent Engagement through Technology Solutions.



**Figure 5.** Mean SUS score and equivalent grade given to the PETS desktop interface by physicians (N=8). SUS: System Usability Scale; PETS: Parent Engagement through Technology Solutions.



**Figure 6.** Mean SUS score and equivalent grade given to the REDCap (Research Electronic Database Capture) mobile interface by parents (N=11). SUS: System Usability Scale.



## Discussion

### Principal Findings

To our knowledge, this is the first study conducted to determine the efficacy of digital tools for discharge communication and clinical research engagement with parents and physicians before the launch of a pediatric patient registry for ARI. Analysis of semistructured interview responses using the Framework Method helped to identify communication challenges around discharge communication and clinical research engagement. Software interface usability testing methods and the use of the SUS helped to identify potential addressable issues for users of our digital tools before the launch of the patient registry.

In prior experience of the discharge process, parents expressed concern regarding their ability to correctly recall and follow all verbal discharge instructions given to them. This highlights a known need for improvement to current discharge communication practice, supported by recent evidence in a systematic review demonstrating that many parents make errors related to knowledge and execution of ED and inpatient discharge instructions [27].

Parents in our study also indicated a need for written advice to help reinforce verbal discharge advice. Current literature suggests that providing written instructions accompanied by verbal advice improves patient recall and comprehension [28-30], although this is not standard in current practice, as demonstrated in our study. Parents in our study highlighted technology as a viable option to reinforce verbal discharge advice, reflecting the widespread uptake of health technology in everyday life over the past 10 years [8,31]. The COVID-19

pandemic has further hastened the adoption of digital health tools. For example, telehealth visits for patients on Medicare in the United States increased from 13,000 weekly visits before the pandemic began to 1.7 million weekly visits in April 2020 [8]. Despite this unprecedented interest and uptake, the question is yet to be answered as to which form of the emerging digital tools is the most effective for improving discharge communication [32,33].

In our study, physicians described challenges associated with the time required to provide comprehensive verbal discharge instructions. Dean et al [34] suggest that although ED physicians are cognizant that effective communication with patients demands establishing rapport and ensuring comprehension, many physicians find themselves prioritizing efficiency in the time-pressured and chaotic environment of the ED. This is reflected in a study where verbal discharge communication in the ED was recorded and medical staff took an average of 76 seconds to impart verbal discharge advice to patients [35]. Digital tools may assist physicians to provide discharge information in a timely manner to patients. More research is required to determine how this might best be achieved.

Physicians raised concerns around the level of parent understanding of written discharge information. There is limited evidence demonstrating how often parents read written materials given to them. In one US study, only a few parents read through their child’s written discharge instructions and Hispanic families and those without health insurance were least likely to read the instructions [36]. Evidence also suggests many printed materials are written at levels of readability that are too high for the general population, making them inaccessible for those with low health literacy and limited English proficiency [37,38].



In exploring experience of engagement with clinical research studies, parents described the importance of having a reliable and central source of information. Similar to feedback on discharge advice, they mentioned electronic options such as a website, Twitter, or email as viable for information seeking. A 2021 US review of digital tool use in clinical research states that in the past 5 years “digital health technologies have exploded” and are now increasingly being integrated into clinical trials operations and that this accompanies the ubiquity of smartphone technology use [8].

The usability component of our sessions, featuring direct observation of participants using the software interfaces, was successful in identifying potential issues with our digital tools before the launch of the PATRIC Registry; for example, 1 of 2 methods allowing a physician to add a medication to the discharge instructions was nonfunctional (the button did not work). Interface usability testing allowed this to be easily identified so that it could be addressed before the launch. Furthermore, the A grades on the SUS for both the mobile and desktop PETS interfaces confirmed that parent and physician users endorsed the use of the PETS system for providing discharge instructions.

The REDCap system mobile interface for eConsent and survey completion was less favorably received by parents, who gave it a C grade. Task failures with inputting mobile number and email address details were deemed critical, given that this information is key to successful clinical trial enrollment and ongoing parent engagement. Best practice for web-based form design suggests that entry help by way of stating the rule imposed on a restricted field for a mobile phone number or an email address can lead to fewer input errors [39]. The failure of several parents to notice the link to the explainer video was also an important insight. Design recommendations suggest that users are more likely to see hyperlinks on an uncluttered layout with larger font sizes and simple terminology [40,41]. Although some issues concerning the usability of the REDCap mobile interface would not be easily solved because of the limitations around changing design features of an existing and widely used technology, we nevertheless found that usability testing was effective in identifying these and other addressable issues before the launch of the PATRIC Registry.

Unlike health care, industries such as aviation have made use of well-established computer science practices based on user-centered design theories that aim to create a positive experience for users of new digital tools [15,42]. The COVID-19 pandemic has led to a significant increase in the use of digital tools for clinical research purposes and for delivering clinical care [8]. This moment offers the health care industry a key opportunity to develop more efficient and usable digital tools for patients and clinicians.

Pediatric ARI places a huge burden on the community both in Australia and worldwide. Initiatives such as the PATRIC Registry rely on the engagement of parents and physicians to help better understand and manage ARI in the community.

This study assisted us to better understand parent and physician experiences around discharge communication and participation in clinical research. The study also serves as an example of how

clinical researchers can adopt an interdisciplinary approach with user experience experts to integrate qualitative research methods and interface usability testing methods in determining the efficacy of digital tools in the pediatric clinical research setting.

### Limitations

We decided to have a notetaker to create a record of participants’ comments and feedback rather than creating a video recording of each session for posttesting transcription. Note-taking may have introduced bias because we relied on the notetaker’s records rather than on a direct transcription of each participant’s comments for our analysis. Similarly, we chose not to adopt screen-recording software to measure the time taken by users to complete tasks, meaning that we were unable to include this metric.

In terms of selection of participants, parent participants came from a convenient sample of staff working at a colocated research institute. Parents who are nonclinical research staff may have higher levels of education and health literacy and be more familiar with clinical research processes than parents selected from the general population. The parent group who volunteered their time for the study may have also had significantly more interest in the use of technology in clinical research than other institute staff members.

Not all parents had experienced a visit to an ED with their child. If this was the case, we asked parents to reflect on experiences visiting their family physician with their child. It is possible that the family physician experiences differed significantly from ED experiences. Similarly, feedback from a parent with lived experience of a child with pneumonia as presented in our case study may have differed from a parent who had not experienced this.

Physician participants also came from a convenient sample. This may have resulted in a group more open to the use of new technology and discharge communication than a randomly selected sample group of physicians from the ED.

Finally, our tools are currently only in English, and our assessment was limited to participants who could read, speak, and write English. Further work in this area is important to understand and cater to the needs of those who access pediatric EDs with limited English proficiency in terms of discharge communication and participation in clinical research.

### Conclusions

This study shows the feasibility of combining qualitative research methods with software industry interface usability testing methods to help determine the efficacy of digital tools in a pediatric clinical research setting.

Analysis of semistructured interview responses using the Framework Method allowed us to better understand parent and physician experiences of discharge communication and clinical research engagement. Technology was identified by parents as a viable means to reinforce discharge advice and for engagement in clinical research. Software interface usability testing methods and the use of the SUS assisted us in gauging the efficacy of our digital tools with parent and physician users before the launch of our pediatric registry.



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## Authors' Contributions

CCB, SH, SD, KB, and RP conceived and designed the study. CCB, MLB, KB, RP, BB, MB, and SD supervised the conduct of the trial and data collection. RP, BB, MB, and KB undertook recruitment of participants, and RP, BB, MB, KB, and SD managed the data, including quality control. SJC provided qualitative methods expertise, and SD, RP and SJC carried out the qualitative analysis using the Framework Method. SH provided software interface usability testing expertise. SD drafted the manuscript, and all authors contributed substantially to its revision. SD takes responsibility for the paper as a whole.

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## Conflicts of Interest

SD used funds from the Myer Foundation to form What the Doctor Said Pty Ltd, a company created for the purpose of developing a web and mobile system for physician and patient communication at emergency department discharge referred to in this study as the Parent Engagement through Technology Solutions system. SD has equity in What the Doctor Said Pty Ltd. The terms of this arrangement have been reviewed and approved by the human research ethics committee of the Child and Adolescent Health Service in accordance with its policy on objectivity in research.

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### Multimedia Appendix 1

Example of pneumonia discharge instructions on the Parent Engagement through Technology Solutions mobile interface for parents.

[[PDF File \(Adobe PDF File\), 544 KB - formative\\_v6i1e29889\\_app1.pdf](#) ]

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### Multimedia Appendix 2

Example of eConsent on the REDCap (Research Electronic Database Capture) mobile interface for parents.

[[PDF File \(Adobe PDF File\), 891 KB - formative\\_v6i1e29889\\_app2.pdf](#) ]

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### Multimedia Appendix 3

Semistructured interview questions for parents relating to discharge and clinical research experience.

[[PDF File \(Adobe PDF File\), 28 KB - formative\\_v6i1e29889\\_app3.pdf](#) ]

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### Multimedia Appendix 4

Semistructured interview questions for physicians relating to discharge.

[[PDF File \(Adobe PDF File\), 22 KB - formative\\_v6i1e29889\\_app4.pdf](#) ]

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## Abbreviations

**ARI:** acute respiratory infection

**ED:** emergency department

**PATRIC:** Pragmatic Adaptive Trial for Respiratory Infection in Children PCH: Perth Children's Hospital

**PETS:** Parent Engagement through Technology Solutions

**REDCap:** Research Electronic Database Capture

**SUS:** System Usability Scale

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Original Paper

# Stakeholder Power Analysis of the Facilitators and Barriers for Telehealth Solution Implementation in China: A Qualitative Study of Individual Users in Beijing and Interviews With Institutional Stakeholders

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## Abstract

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**Background:** Facing COVID 19, the use of telehealth solutions grows exponentially. However, despite the large investments made into telehealth solutions, the implementation process remains slow and sluggish. Moreover, during COVID-19, older people experienced difficulties and had the highest mortality rates, and those lucky enough to survive faced tremendous pressure to use QR code-based health monitoring systems.

**Objective:** This paper aims to determine the barriers and incentives for the implementation of telehealth solutions via a case study about telehealth implementation in China.

**Methods:** We conducted 8 semi-structured interviews following the design of the interactive learning framework (research question defining, participant recruitment, exploratory stage, consultation stage, integration stage, and follow-up interview). One interview with a government official from the National Health Commission and another interview with a government official from the China Center for Disease Control and Prevention was conducted in the exploratory stage. The consultation stage comprised one interview with a business manager from the Huawei Wearable Unit, one interview with a business manager from Alibaba Health Brain Unit, and one interview with a business manager from Xiaomi. Two interviews with doctors from Fudan University-affiliated Huashan Hospital and Fudan University-affiliated Zhongshan hospital were conducted in the integration stage. In addition, 8 focus group studies with 64 participants from rural and urban Beijing were conducted. Finally, another telephone interview with a business manager of the Xiaomi Wearable Unit was conducted in the follow-up stage.

**Results:** Telehealth solutions are designed to assist health care providers in realizing the quadruple aim of better health outcomes, lowering health care costs, improved health care quality, and improved doctor and patient experiences. Governments have high incentives to improve health care efficiency via telehealth solutions. However, they have limited resources to make the necessary infrastructure transformation.

**Conclusions:** To fully realize the potential of telehealth devices, heavy infrastructure investment in the telecommunication network is required beforehand to resolve the interoperability issue occurring during the data collection process for telehealth solutions. The industry also demands a mature business model incorporating collaboration between various stakeholders and industrial partners to invest in infrastructure. Governments have high interest and significant influence on building the necessary infrastructure for telehealth solution implementation in China. Industrial actors have a high interest and a medium level of power for telehealth solution implementation. Users have high interest but a lower level of power for the usage of telehealth solutions, and doctors have low interest and a medium level of power for telehealth solutions implementation.

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**KEYWORDS**

aging; telehealth implementation; stakeholder mapping and power analysis

## *Introduction*

### **Background**

COVID-19 has posed great challenges for unprepared public health care systems with an aging population. The sad truth seems to be countries with an older population with preexisting chronic disease conditions (eg, hypertension, cardiovascular disease, and diabetes) such as Italy, Spain, the Netherlands, the United Kingdom reported higher mortality rates than countries with a younger population, such as China [1,2]. The poor and older people were the proportion of the population hardest hit by the pandemic. Public health care systems lacking hospital beds, intensive care units, and qualified trained medical staff can use remote monitoring solutions to resolve the challenges encountered in combating COVID-19 [3]. Remote monitoring solutions can potentially improve prevention, diagnosis, treatment, and recovery efficiency by promoting data accuracy [4].

The World Economic Forum has listed the 7 biggest breakthroughs in the health care industry with “Artificial intelligence (AI) can detect skin cancer better than a doctor,” and “your phone will know if you are depressed or not” ranked 3rd and 4th on the list [5]. Exciting innovations in the health care industry, including utilizing telemedicine to transfer care to the home setting, using AI to reduce physician workload and divert patients to the right doctor, and the internet of things (IoT) to improve patient monitoring and coaching have signaled the health care industry is on the cusp of an AI revolution. Huge amounts of investment made by the public and private sectors have poured into big data, cloud computing, and utilizing such tools in the health care continuum. AI promises high-value health care and the potential to achieve the impossible health care trinity of access, quality, and cost. This paper aims to determine whether AI has achieved such an aim using empirical evidence from China.

### **Concept Development**

#### *The Use of AI and IoT in Health Care*

COVID-19 had pushed the digitalization of the health care system. As a result, investments in health-related projects have grown rapidly. For example, AI has been deployed to detect disease concentration and spread, provide real-time monitoring, and predict pandemic outbreaks and mortality risk [6]. AI has also been instrumental in COVID-19 diagnosis by performing image recognition for x-ray and magnetic resonance imaging results. For hospital management, AI has become useful in facilitating resource allocation by automizing resource management and supply chain management, assisting staff training with virtual reality (VR) and augmented reality tools, maintaining health care records, and identifying patterns for trend recognition [6].

In pandemic tracking and prediction, AI has been useful for collecting social media data and identifying disease clusters. At the beginning of the pandemic, BlueDot reported the disease

cluster of pneumonia cases in Wuhan by analyzing news reports on December 31st, 2019, well ahead of public health administrations in China and other economies [7]. The Johns Hopkins University Coronavirus Resource Centre collects publicly available information and visualizes the data, making it possible to actively track the spread of the disease [8]. It is now possible to use Google Maps to estimate active COVID-19 cases by country [9].

In contact tracing, US universities such as MIT and Harvard University have been developing and using contact-tracing apps such as Safe Paths [10]. Tech companies such as Google and Apple are also working together to develop contact tracing application programming interfaces (Apple, 2020). In addition, mobile apps were developed quickly by different governments and tech companies to facilitate contact tracing in China (WeChat) and the Netherlands (Coronamelder). For example, apps such as AI4COVID-19 have enabled COVID-19 detection based on 3 seconds of coughing and delivering the diagnosis with 2 minutes [11].

During the early diagnosis of COVID-19, algorithms were rapidly developed and deployed by tech companies in China to identify patients with COVID-19 symptoms. After the Chinese New Year, where large-scale infections were reported, Yitu Technology developed the algorithms to facilitate diagnosis and treatment [12]. The software quickly received clinical approval and was deployed in Hubei and then nationally within health care systems hardest hit by the pandemic. The AI assistant received approval from the health care service staff. Congestion in hospitals was relieved with the deployment of such systems, with patients diverted to infectious disease hospitals. Yitu aims to establish the AI-assisted paradigm in four stages of the pandemic control process. In the prevention stage, chatbots and online consultation can educate users and help users perform self-examinations. In the quarantine stage, the system can help doctors monitor patients and manage their conditions.

Regarding patient management, AI has been deployed at hospitals to automate asset management [13] and prioritize COVID-19 patients in intensive care units for access to ventilators. AI can also predict the possibility of patient recovery and mortality by monitoring patients' daily electronic health records and helping doctors to make decisions regarding the subsequent treatment steps [6].

In pharmaceutical development, AI can accelerate drug and vaccination discovery by reducing the time for drug discovery, virtual screening, and validation [6]. As a result, researchers have quickly obtained genetic information from patients and offered it to the international community [14]. In addition, AI has made it easier to predict the protein structure [15], allowing pharmaceutical companies to rapidly develop the vaccination for COVID-19. For instance, AI has been used to develop the messenger RNA vaccine by Oxford University and Moderna [16].

## ***Stakeholder Analysis for the Implementation of Telehealth Solutions in Developing Economies: The Case of South Africa***

The implementation of telehealth solutions in low-income economies may encounter different challenges compared to high-income economies. Therefore, when analyzing the available literature, it is necessary to address the challenges posed by the health care system in low-income economies. This paragraph considers, as an example, the case of South Africa.

Lack of infrastructure and trained medical care staff [17-19] has been known to be a hurdle to providing health care services in low-income economies. However, telehealth solutions can become a means for providing health interventions [20-23], preventing communicable disease, and improving the health literacy of health care workers and patients.

The author used a meta-study methodology and surveyed 108 papers to analyze the interactions between different stakeholders for implementing telehealth solutions in low-income economies [24]. Overall, 65% of all sample papers are from African countries. Around 26% of the sample papers come from Asia. Most of the initiatives in Africa are funded by public-private partnerships, nongovernmental organizations, or overseas initiatives [25]. The stakeholders are organized into five categories: patients, health care workers, facilitators, knowledge base, and system developers. Each stakeholder's perspective was then investigated for the interaction with other stakeholders and among themselves. For example, the interactions between patients and health care workers, patients and facilitators, patients and system developers, patients and the knowledge base, and patients and other patient groups were investigated.

The meta-study suggests that there is extensive literature on the perspective of health care workers; however, there is a gap for studying the interaction between patients and other patient groups and, most importantly, the limitation for researching the interaction between system developers and users. In rural areas in low-income economies, when patients are trained to care for other patients, the peer exchange can provide support for counseling and information [20]. Moreover, the interaction with system developers is key to discovering problems early, identifying demands and requirements, and presenting solutions for complex problems [26]. The gap identified in the literature suggests there lacks a design context for system developers to identify the needs and demands of health care workers and patients. Therefore, creating an open-source mHealth platform to collect data in a limited resource setting is needed. The collaborative development approach will create an open-source interface that will encourage telehealth solutions to adopt common standards and solve the data interoperability problem, making it more cost-effective [24,27]. South Africa was used as a case study for analyzing the barriers and facilitators for implementing telehealth solutions in resource-restricted settings. The study was based on the implementation of a hearing screening device in South Africa over two years. The study analyzed the implementation process at four levels: the community level (individuals), the health provider level (health care professionals), the district health system level, and the macro health level for oversight.

The study concluded that need-based innovation improves the possibility of implementation. Meanwhile, changing the device language to a local language would improve the device's interoperability. Still, having a feedback channel, improving communication with community health care workers, and having protocols to resolve conflicts have been identified as key barriers to implementation. Lacking long-term national-level political support for the program and dissemination channel is also one of the barriers identified. In addition, there is a need to improve health education on hearing and promoting patient mobility on a patient level. Finally, changing patients' perceived views on the public health system is also important [27].

Compared with the Chinese health care system, where most of the high-quality hospitals are public, and there is heterogeneity in the culture and language amongst the population, the lessons learned from the South Africa health care system include promoting health literacy for patients and health care workers, offering health education regarding the use of telehealth solutions, and building the education and feedback channel of community health workers.

## ***Methods***

### **Overview**

We used the research methodology inspired by the interactive learning and action (ILA) approach to design the data collection process and the analytical framework developed by Cesuroglu [28] to perform data analysis.

The study conducted by Dijkman et al [29] suggests that value proposition, customer relationships, and partnerships are the most important attributes of the business model for IoT systems. The study conducted by Cesuroglu [28] identified a modified Murray and Frenk's framework [30] to assess the performance of the health systems. The barriers and incentives for implementing telehealth solutions at a primary level of health care and the hospital level were identified with this framework. By understanding the demand of each stakeholder on a national and local level, the study can serve as a guide to help telehealth solution providers implement their solutions in China.

### **Study Design and Data Collection**

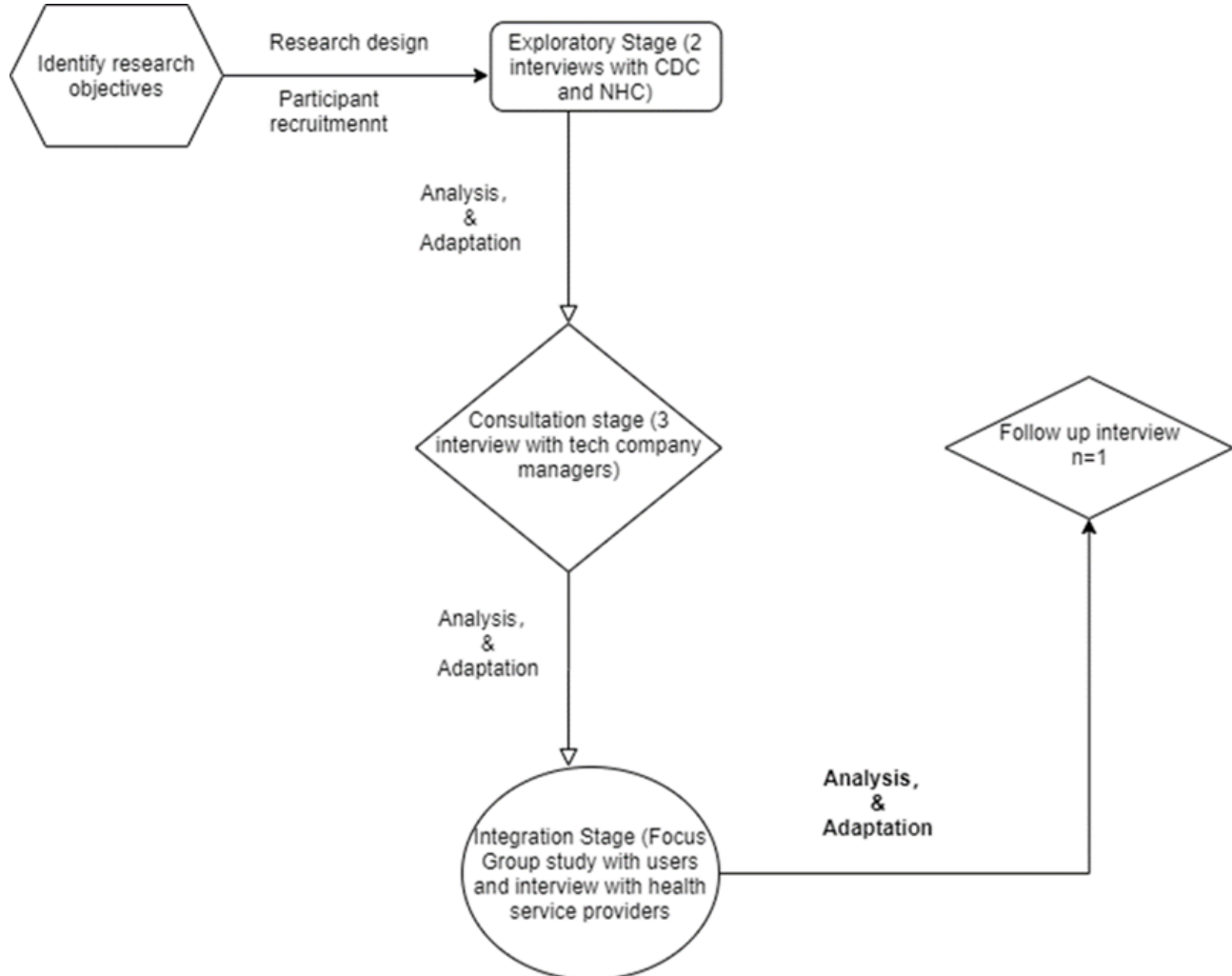
The study uses an ILA approach to reach patients and health care service providers in the decision-making process. The study covers the three phases of the ILA approach: exploration, consultation, and integration stages (Figure 1).

The first step of empirical analysis is to get insights from stakeholders within the health care system in China. The stakeholder mapping and power analysis is an essential tool to identify the structure of the Chinese health care system. By identifying key stakeholders and their positions, it was plausible to conduct early-stage market surveys regarding the needs and demands of the health care system; moreover, it is key to start with stakeholder analysis when researching business model and market penetration strategies for telehealth solutions in China. Nine stakeholder interview requests were sent with 8 confirmations.

In terms of selecting semi-structured interviews with policymakers, interviewees among the key actors within the telehealth sector were selected, including representatives from the government (n=2), tech companies (n=6), health service

providers (n=2), and individual users (n=64). The list of stakeholders interviewed is presented in [Textbox 1](#). The data collected fits into the stakeholder mapping structure mapped in [Figure 2](#).

**Figure 1.** Interactive learning and action process in the research design. CDC: China Center for Disease Control; NHC: National Health Commission.



**Textbox 1.** List of stakeholders interviewed in China.

**Tech companies:**

- Vice President for Wearables (Huawei)
- Director for Investment MIUI (Xiaomi)
- Product Manager for Wearables (Xiaomi)
- Business Manager for Alibaba Cloud ET Medical Brain

**Government officials:**

- Ministry of Human Resources and Social Security (Director for Social Security Pension Fund)
- Interview with the Chronic Disease Management Center Director
- Visited Disease Control Center in Hua Rou, rural Beijing
- Visited Infectious Disease Control Center in Changping

**Doctors/hospitals:**

- Doctor from Cardiovascular Department of Zhongshan Hospital affiliated with Fudan University Medical School
- Doctor from Rehabilitation Department at Hua Shan Hospital affiliated with Fudan University Medical School



Figure 2. Stakeholder overview for the Chinese health care system.



### Exploratory Stage

In the exploration stage of the study, interviews (n=2) were carried out with the vice chief of the Basic Medical Insurance Scheme Fund in China and the Director for Chronic Disease Management Unit for the Chinese Centre for Disease Control and Prevention (CDC), respectively.

At the local government level, a brief interview was conducted while visiting the local CDC in Qiaozhi county at Huairou district, a rural district of Beijing. By monitoring national pandemics such as SARS, COVID-19, and noncommunicable diseases such as hypertension, diabetes, cardiovascular diseases, etc, the CDC is a key policy advising institution for both the central and local governments [31].

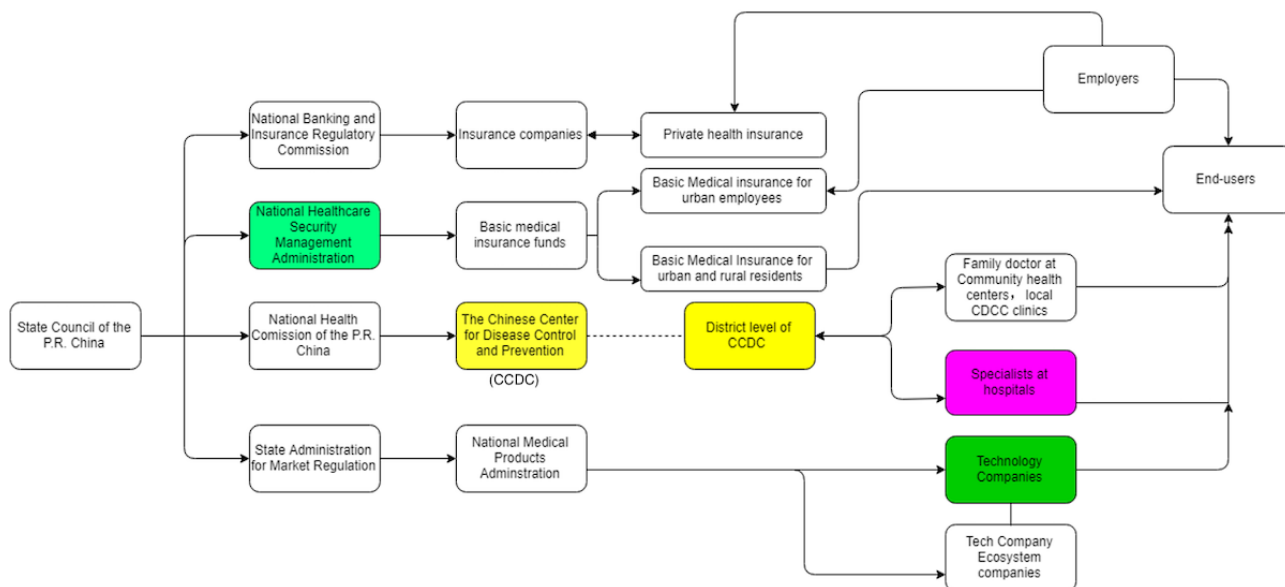
The basic structure and the position of the CDC in the health care system in China are shown in Figure 2 and Figure 3. As indicated by the graph designed by MENG Qingyue [31], the CDC is the National Health Commission (previously named the “National Health and Family Planning Committee” [NFPC]). It conducts the research and monitoring of communicable and noncommunicable diseases in China. The National Health Commission has replaced the NFPC as the leading health-related

policy maker and health insurance administrator. Different provinces and prefectures in China are under the responsibilities of local health commissions. For instance, during COVID-19, the local health commission collected data on new infections, made policy decisions on testing and quarantine, and distributed vaccines to hospitals and community health care centers. By monitoring national pandemics such as SARS, COVID-19, and noncommunicable diseases such as hypertension, diabetes, and cardiovascular diseases, the CDC serves as the key policy advising institution for the central government.

In recent years, a centralized data monitoring system was established where data was reported from local CDC to their supervisors at the local health commission, as showcased in Figure 3. However, this has slowed down the information flow significantly in terms of COVID-19 monitoring and prevented the local CDC in Wuhan from reporting the pandemic directly to the central government. Instead, early COVID-19 cases were reported by hospitals to the local health commission in Wuhan, preventing the implementation of effective measures against the spread of the virus. This suggests a power imbalance between local health care demands and needs and the management of a centralized health data-sharing platform.



**Figure 3.** Simplified structure of the Chinese health care system. CCDC: China Center for Disease Control and Prevention.



**Consultation Stage**

In the consultation stage of the study, interviews with wearable and AI business unit managers from Huawei (n=2), Xiaomi (n=3), and Alibaba (n=1) were carried out. Huawei, Xiaomi, and Alibaba were selected as interview subjects because the three companies are the biggest information and communications technology-related solution providers in China. Alibaba was chosen as the leading software solution provider, whereas Huawei and Xiaomi stand out as hardware solution providers. Two interviews were conducted with two business unit leaders

in Xiaomi—the Xiaomi MIUI business unit and the Xiaomi wearable business unit. Other tech start-ups follow the lead of Alibaba, Huawei, and Xiaomi. Tech companies dominating the market are often challenged by tech start-ups, with tech giants opting to acquire start-ups challenging their market positions. Alibaba and Tencent have effectively become the most aggressive venture capital funds in China.

For instance, Huawei has developed a data-based driven business model for its wearables and has taken the business model overseas to South Africa, as shown in Figure 4.

**Figure 4.** The data-driven business model developed by Huawei. The data collected fits into the mapped stakeholder structure.

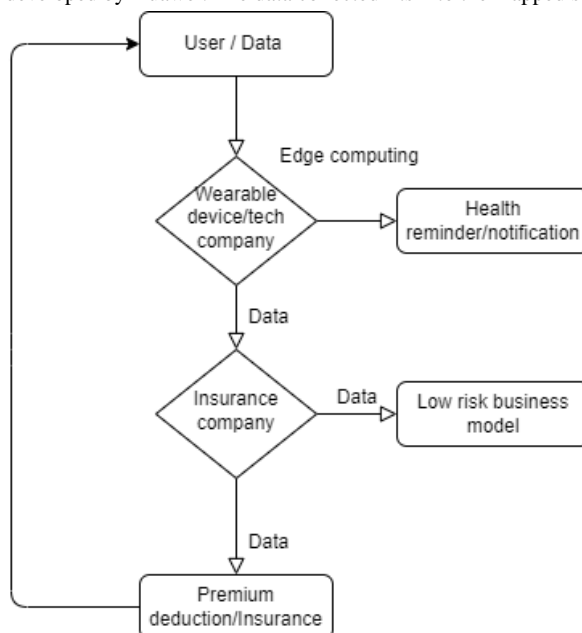


Figure 5 shows a categorized analysis of their roles in the health care system to effectively illustrate the role of each stakeholder interviewed.

In the era of the general data protection regulation (GDPR), the Health Insurance Portability and Accountability Act, and the Personal Information Protection Law of the People's Republic

of China, users have the uttermost say in the success of IoT ecosystems. Therefore, this section focuses on presenting factors affecting users' preference and the use of remote monitoring solutions in four aspects: access to health care, healthy living, elderly care, and chronic disease management.

To explore the attitudes of individual users towards remote monitoring solutions, a focus group study has been conducted in Beijing with support from the research group at the University of China Academy of Science and Beijing Cinsu Consulting Co, Ltd. Beijing Cinsu Consulting recruited the data subjects, and the study was conducted on the premises of Beijing Cinsu Consulting from March 29, 2019, to April 4, 2019.

There were 4 groups discussing access to health care, healthy living, elderly care, and chronic disease management. Each group consisted of 16 members, 8 from urban Beijing and 8 from rural Beijing; the focus group data collection process is shown in Figure 6.

Figure 5. Place of stakeholder (interviewed) in the health care system.

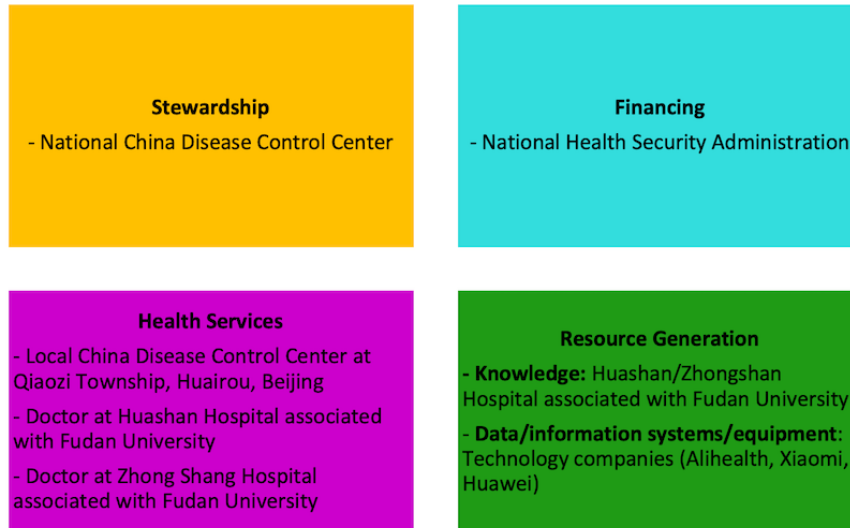
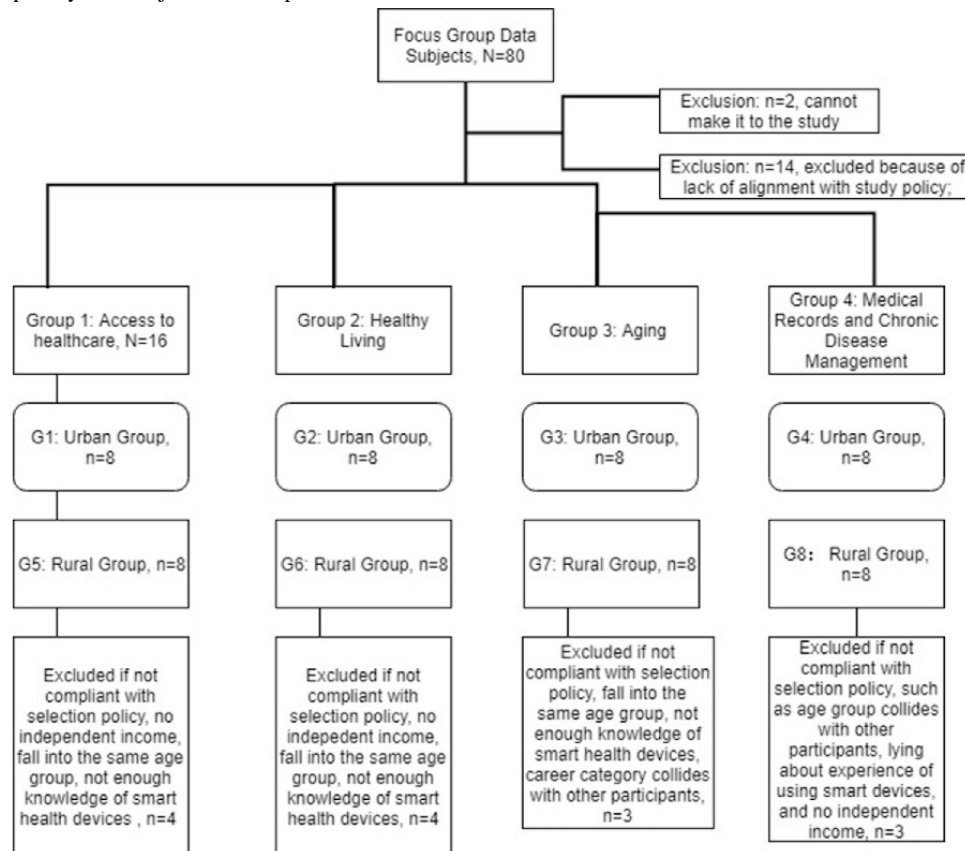


Figure 6. Focus group study data subject selection procedure.



**Ethics Approval**

The stakeholder interviews did not collect any personal or sensitive data; therefore, no ethics issues were incurred. The

questionnaire study and focus group study underwent the ethics procedures at the University of Macerata. Therefore, the Philips Internal Committee Biomedical Experiments does not apply

here. Informed consent forms and background information were provided in both English and Chinese.

Following the GDPR requirements on individual data collection, all participants were informed about the purpose of the study, including the scientific research, study procedure, data formats, and processing procedure. The data subjects of the study were informed that the participation was voluntary, and they could leave the study at any time. The participants were also informed that all data would be processed anonymously. Participants were offered RMB 400 (US \$62.74) to compensate for their time and transportation. The group discussions were recorded in video and voice, with transcripts taken onsite. All data were stored on an online storage space created by KU Leuven (The Box). Vulnerable groups, such as children and older people (more than 60 years old), were not selected. Some participants in discussion group 3 (elderly care) and group 4 had chronic comorbidities such as obesity, hypertension, or diabetes. Their health conditions were collected to identify whether health factors affect their attitudes towards using remote monitoring solution services and products in different user scenarios. The study has obtained ethics approval from the University of Macerata.

### Stakeholder Power Analysis

Stakeholders can influence and have an impact on the implementation of telehealth solutions. The influence of stakeholders refers to the power of stakeholders in pushing for policies and regulations advantageous for the implementation of telehealth solutions, while the impact of stakeholders refers to the power of stakeholders in promoting the use of certain telehealth solutions. There are three levels of power [32], high-level influence/impact, medium level of influence/impact, and low level of influence/impact.

Bally and Cesuroglu [32] defined the three levels of influence as:

1. **Control:** The stakeholder has the power to control the implementation of telehealth solutions or stop the integration process.
2. **Influence:** The stakeholder can influence the integration of telehealth solutions within the health care system. Compared to control level stakeholders, the stakeholder, in this instance, is important but has no decision-making power.
3. **Interest/concern.** The stakeholder is interested in the use of telehealth solutions but has no significant influence over the integration process.

Each stakeholder's interest, influence, and impact are presented to perform the power analysis for stakeholders related to telehealth solutions in China. Meanwhile, further analysis has been done to understand the attitudes of each stakeholder towards funding, developing, and purchasing internet hospitals services, continuous health management in the home setting services, value-based health care payment systems, the interoperability of health care data services.

## Results

In this section, results from the focus group study within urban Beijing are presented. The stakeholder power mapping framework is used to analyze the facilitators and barriers to implementing telehealth solutions in China.

### Focus Group Study Findings

**Table 1** summarizes the findings from the focus group study (group 1: use of telehealth solutions for access to health care services).

Participants indicated their use of telehealth solutions, including smartphones, monitoring devices (cameras and smart audio systems), and wearables. First of all, the telehealth solutions have utility function value, meaning telehealth solutions (devices or services) offer:

1. Convenience by saving time, effort, and money of users.
2. Remote monitoring for users.
3. Environment monitoring functions such as air quality monitoring.

For instance, one participant had installed a smart camera at home to monitor the health condition of her brother, who had experienced a cardiovascular attack. Another participant installed a smart camera at home to monitor the condition of older parents. One participant has a grandmother with hypertension and diabetes; he uses Mi Band to monitor daily steps and sleep quality even though they live together. For those who do not live together, communications happen through WeChat, telephone calls. Some bought smart bands for their parents; however, some older people find it troublesome to use as it needs to be charged all the time.

For smart home devices, some participants resort to smart plugs or switches to control devices at home for safety reasons. For example, some use smart cookers to prepare meals in advance. Some use smart home cameras to monitor their children doing homework. Some use smart floor sweepers for cleaning. When air pollution in Beijing is bad, some use a smart air purifier to monitor air quality and clean the air at home. Some use smart home cameras to talk with pets at home. Some use the camera to monitor people near the door.

There are community projects in rural China where the government offers services checking the health of older people regularly by calling, visiting, conducting medical checkups, and offering lectures for public health purposes.

Most participants do not trust online hospital consultations provided by tech companies such as Alihealth, Ping An Good Doctor, etc. Some participants call the online consultation service with doctors fraudulent, untrustworthy, and profit-originated service. They rely on the services mainly to register at hospitals. For participants residing in rural areas, wait times for seeing doctors at tier-2 and tier-3 hospitals range from half an hour to 2 hours. They also find it difficult to know the specific doctor to reach in the hospital as there is no prior general practitioner consultation. Medical services offered for chronic disease treatment are, in general, expensive and time-consuming.

Long-term relationships between patients and doctors do not exist for almost all participants. Trust between the doctor and patient is low as patients find doctors are unaware of their past problems and unfamiliar with their lifestyles to offer any related advice.

All participants were covered by the basic medical insurance schemes offered by the government, such as Basic Medical Insurance Scheme for Rural Residents, Basic Medical Insurance Scheme for Residents, and Basic Medical Insurance Scheme for Employee. In addition, some participants have private insurance coverage, which offers additional services such as free ultrasound scans and genetic testing, fast-track tier-3 hospital registration, and family doctor consultation services.

Some participants chose to purchase IoT devices because of the embedded hedonistic value. For instance, some participants buy VR goggles to watch movies and play online games. Some buy smart cameras because they are fun to use. Some have smart audio systems for entertainment during dinner time to prevent kids from watching TV.

Factors affecting buying decisions regarding smart devices include function, price, brand, and convenience of use. For the cost of services, participants report price acceptance between RMB 10-3000 per month (US \$1.57-470.56), depending on the service quality offered and whether it is personalized or not. For devices, their price acceptance level ranges from RMB 100 to 30,000 (US \$15.69-4705.59), depending largely on the brand. Participants demonstrate a wide knowledge of local brands such as Xiaomi, Huawei, Alihealth, and Chun Yun Doctor and foreign brands such as Philips, Apple, Sony, Samsung, and Siemens.

Participants who own multiple smart home devices are more likely to use telehealth devices such as sports bands. They also

tend to exercise regularly and maintain a healthy living style. There is no significant difference between rural and urban residents, given many work in urban areas and live in rural areas in Beijing.

Other factors affecting the use of telehealth devices include trust concerning the data collected from smart devices. For instance, users find the data collected from wearables and smart blood pressure monitors inaccurate or find it impossible to share the data with doctors. This corresponds with interviews where doctors mention they do not trust internet hospital services or the data collected from smart medical devices at home.

Regarding sharing data with insurance companies, about 70% (45/64) of users do not want to share data collected from wearables and smart home devices. They believe insurance companies will surely increase premiums once they find out about their health problems. They also do not trust insurance companies to keep their data safe. However, some are willing to share data with insurance companies for the benefits of accessing a family doctor, free insurance package, reduced/eliminated term payments for wearables, and coverage for expensive diseases such as cancer.

Regarding sharing data with tech companies, most participants acknowledge that tech companies collect their data thoroughly and may share it with third parties. They acknowledge they have no control of the data once it has been collected.

Regarding sharing data with governments, some indicate they want to benefit from the services offered with sharing. Others want to know the purpose of the collection. Most participants want to share health-related data anonymously.

**Table 1.** Summary of the focus group responses on the use of telehealth solutions in accessing health care (urban residents).

	Interviewee 4	Interviewee 1	Interviewee 3	Interviewee 7	Interviewee 2
Private insurance	Yes	No	Yes	No	Yes
Career	TR <sup>a</sup>	NTR <sup>b</sup>	NTR	NTR	NTR
Health awareness	Yes	Yes	Yes	Yes	Yes
Knowledge of telehealth solutions	High	Medium	Not mentioned	Medium	High
Marriage status	MWK <sup>c</sup>	Single	MNK <sup>d</sup>	MWK	MNK
Chronic disease status	Yes	No	Yes	Yes	No
Health status	Suboptimal health status	Suboptimal health status	Suboptimal health status	With chronic disease (diabetes, hypertension)	Suboptimal health status
Health knowledge	High	Medium	Low	Medium	Low
Frequency of the use of telehealth devices	High	Not mentioned	High	Medium	High
Experience in using telehealth devices	Yes, hospital registration (WeChat)	Yes (WeChat)	Yes (WeChat, AI guided patient registration, online consultation)	Yes (WeChat, AI guided patient registration, medication reminder)	Yes (WeChat patient registration, Ping An Online Consultation, Medication reminder)
Community health care/family doctor	Yes	Yes	Yes	Yes	No
Trust of family doctor	High	Not mentioned	High	Low, only to get prescriptions	Low
Prefer online service	Yes	Possible	Yes	Yes	Yes
Pay for online family doctor service	No.	Not mentioned	Yes (prefer service packages or pay for outpatient service)	Yes, pay by the number of times used	Yes, depends on the quality of service
Elderly care service door to door	Yes	Not mentioned	Not mentioned	Not mentioned	No
Prefer service offered, transfer to a specialist at tier-3 hospitals	Yes	Yes	Yes	Not mentioned	Yes
Expected family doctor type	Experienced one's retired doctors	Save the time for registration with hospitals.	Serving the whole family, offers services such as making an appointment with doctors; pricing mechanism: yearly base plus multiple times payment	Not mentioned	Already use Ping An Good Doctor: pay 199 RMB <sup>e</sup> for health management package.
Sharing data with the insurance company (trust)	No	Not mentioned	No, I can share with doctors.	No, for privacy reasons, do not wish to disclose medical information with insurance companies; willing to share with family	Yes, the current insurance scheme promotes data sharing with the provider
Age group <sup>f</sup>	3	2	3	5	3
Gender	Female	Male	Female	Male	Female
Household income	High	High	High	High	High
Sharing data with health care providers	Yes (there is no alternative)	Not mentioned	Yes	Not mentioned	Not mentioned
Private insurance coverage	Yes	Not mentioned	Yes	No	Yes

<sup>a</sup>TR: tech-related jobs.

<sup>b</sup>NTR: nontech-related jobs.

<sup>c</sup>MWK: married with kids.



<sup>d</sup>MNK: married, no kids.

<sup>e</sup>A currency exchange rate of ¥1=US \$0.16 is applicable.

<sup>f</sup>Proxy for age groups: (2) aged 20-30 years; (3) aged 30-40 years; (4) aged 40-50 years; (5) aged 50-60 years.

## Stakeholder Power Mapping

Among all the stakeholders, except the demand for individual users, the attitudes of institutional stakeholders are important to evaluate as well. In addition, the digitalization of the health care system creates demand from government and health care service providers for telehealth solutions. Before discussing the implementation of specific telehealth solutions, it is thus beneficial to find out the barriers and facilitators for telehealth solutions in China.

Compared with the European telehealth solution implementation process, Chinese medical data are shared more often between different stakeholders. Both European and Chinese governments have national-level digital health development strategies. Before the pandemic, China was leading in providing online medical consultation and prescription services, yet the trust level remained low. During the pandemic, more AI-related image recognition software was fast deployed in China to facilitate COVID-19 diagnosis and treatment. Large-scale data monitoring via mobile phone apps was deployed to track COVID-19 cases and prevent the disease from spreading.

## Stakeholder Identification

Key stakeholders involved in implementing the internet of health care things are categorized into 5 main groups as illustrated in [Figure 2](#):

1. Stewardship group.
2. Financing group.
3. Health services group.
4. Resource generation group.
5. Individual users and civil society groups [32].

Remote health monitoring solutions directly influence groups 3 and 5. Groups 1, 2, and 4 can influence the integration of the internet of health care things solutions. The stakeholder groups can facilitate the development of telehealth solutions by providing infrastructure (such as 5G network), regulation frameworks, financing, and knowledge to help the health care system function.

Among all the stakeholders, 8 semi-structured interviews were conducted to explore attitudes, user experiences, and the needs of stakeholders for telehealth solutions.

## Stakeholder Positioning

The Chinese health care system is a top-down system consisting of several layers: the central government level, the provincial government level, the prefectural level, the county level, and the village level. Top hospitals such as Peking Union Medical College Hospital and China-Japan Friendship Hospital are supervised and financed directly by the National Health Commission. Provincial and prefectural hospitals are supervised and largely financed by the designated provincial and prefectural health commissions. Village clinics are largely self-funded with a small amount of public financial support.

Urban residents spend more on health care than rural residents. Residents in tier-1 cities such as Beijing and Shanghai spend more than the national average on health care services. Meanwhile, local governments finance public health care costs, including funding for hospitals, suggesting developed regions in China have more health care resources than less developed regions in China. The local government and local health commission often have a larger role in providing an immediate response for pandemics such as COVID-19 than the central government. Given the many layers of hierarchy between local and central governments, it may explain why at the beginning of the pandemic, the disease was not recognized as a major public crisis when the first case was reported to the health commission in Wuhan.

Local health security administrations set prices for health care services at public hospitals and decide the coverage of public health insurance schemes. Different regions also have different health insurance coverage and reimbursement standards.

The National Health Commission assumes stewardship function, making health care policies, supervising health service providers, and collecting public health-related data. The National Healthcare Security Management Administration aims to become a strategic buyer of health care services in China and denotes the coverage of public health care insurance schemes. The Basic Employee Medical Insurance Scheme and the Basic Resident Insurance Scheme currently cover 92% of the population in China. Private insurance schemes complement the public health insurance scheme by offering coverage for medical incidents not included in the public health insurance package. Employers can pay for private and public insurance coverage for employees. The State Administration for Market Regulation supervises medical devices, including smart medical devices. Most services tech companies offer land in the lifestyle domain and are not subject to medical device regulation procedures.

To summarize, institutional stakeholders have five types of incentives to implement telehealth solutions.

Firstly, institutional stakeholders implement telehealth solutions because of financial incentives. For instance, companies may wish to improve their market share, promote brand value, enter a new business sector, or promote sales and look for new profit sources. The government may wish to control health care costs.

Secondly, institutional stakeholders may implement telehealth solutions to improve operational efficiency. Health care efficiency may increase by connecting different data sources. Algorithms used to assist health care service providers in making decisions may also improve health care efficiency. Governments may wish to allocate limited financial resources in health care more efficiently.

Thirdly, tech companies may choose to develop telehealth solutions to win government contracts and support. Companies feel the need to answer government policy initiatives for the

Internet + Health, Healthy China 2030 Initiative. Companies may also want to participate in smart city initiatives to profit from government contracts and cooperate with local governments for policy support.

Finally, stakeholders may choose to implement telehealth solutions because of special incentives such as health care quality concerns. For example, government agencies may wish to create more employment opportunities. In addition, hospitals and companies may wish to obtain more expertise in AI to improve the health care quality for patients.

### Stakeholder Power Analysis

In the interviews, each representative estimated the power of each stakeholder in implementing telehealth solutions. Three levels of influence were used to estimate the power of each stakeholder.

1. **High influence:** The stakeholder has the power to control the adaptation of new technology or facilitate such solutions. It also can stop the integration of telehealth solutions.
2. **Medium level of influence:** The stakeholder plays an important role in the adoption of telehealth solutions but has less control of the process. It can influence the process of adaptation.
3. **Low level of influence:** The stakeholder is interested in the adoption of telehealth solutions but has little and no significant impacts on adaptation development.

The most relevant quotes from stakeholders' interviews are presented in [Textbox 2](#).

[Figure 7](#) describes the stakeholder power analysis, including their influence, interest, and the impact they may have in implementing telehealth solutions, such as personalized electronic health records and value-based payment systems for health care services.

#### Textbox 2. Quotes from stakeholder interviews.

##### Resource Generation (Tech companies):

"Currently, profits (from telehealth solution platforms) come from online drug sales. This is because, in the short term, it is difficult to transfer users from offline to online to seek healthcare help."

"It is not an industry-wide approach to integrate all the healthcare-related data of users into a single platform. There is no industrial agglomeration effect."

"The ownership right of the user's personal data is not clear...data collected from personal medical devices cannot be shared on third-party platforms."

##### Stewardship/Financing (National Health Commission and China Disease Control Center):

"The family doctor system and the smart health solutions are in the early stage of development."

"...the supply side of GP services is small (with 309,000 doctors in China, around 2.2 GPs per 10,000 people at the end of 2018), with little recognition level from the society, and little trust from patients."

"Seeing a doctor is not as easy as uploading the blood pressure data online. Treating patients demand more communication."

##### Health Services (Hospitals/doctors):

"From our perspective, the data from medical devices at home settings is very valuable."

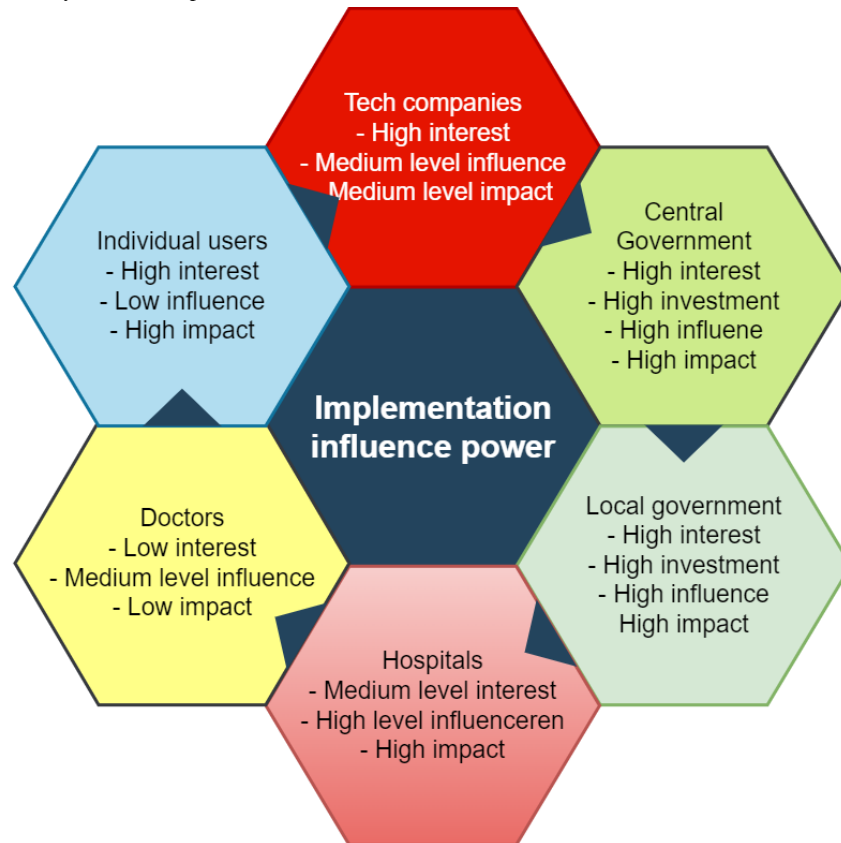
"I would like to consider such data and take it as a reference when I make my diagnosis."

"The premise for use of data obtained from wearables, except for the convenience provided, is data accuracy. The most important aspect for the use of medical devices in diagnosis is accuracy."

"The wearable device is at least a few hundred yuan, and the patient may not spend more than ten yuan in the hospital."

"...the elderly will not use smart medical services. Patients do not trust Internet medical services."

"The hospital has no motivation to unify the medical record standards."

**Figure 7.** Stakeholder power analysis on the implementation of telehealth solutions.

Tech companies have a high interest in the integration of telehealth solutions, but they have a medium level of influence and impact. Tech companies train the algorithms with hospitals and doctors and participate in the technical standard-setting process. However, tech companies cannot decide whether or not telehealth solutions can be integrated. Therefore, tech companies have a medium-level influence in standard-setting and a medium level of impact in telehealth solution integration.

Tech companies are subject to strict regulation from the National Medical Products Administration (NMPA) to develop and commercialize telehealth solutions. NMPA is responsible for approving medical devices, in vitro diagnostic solutions, pharmaceutical products, cosmetics, health food, infant formula, and food for special medical purposes. The NMPA promulgated “Medical Device Adverse Event Monitoring and Re-evaluation Management Measures” in August 2018. In 2019, the NMPA issued the “Key points and explanation of deep learning-assisted decision-making medical device software review standards” [33].

When it comes to using AI for diagnosis and triage, tech companies need to obtain level II or level III certificates. Level III devices cover the following categories: active surgical medical devices; passive surgical devices; neuro and cardiovascular surgical instruments; medical imaging equipment; devices for blood transfusion, dialysis, and cardiopulmonary bypass; active implants; passive implants; infusion, recovery, and protective devices; and ophthalmic instruments.

The standards point out that any AI-assisted diagnostic software needs to submit applications regarding the data source, data collection, data processing, and algorithm design and

performance, as well as undergo clinical trial and adverse studies submitted to NMPA for approval. In 2020, 9 solutions from 8 companies obtained Level III certificates [33]. These algorithms cover cardiology, neurology, endocrinology, orthopedics, and thoracic surgery. COVID-19 has certainly accelerated the approval process.

From the analysis above, the central government in China can set the standards for the use of AI and IoT devices in the medical setting, while local governments can decide the budget for such solutions. Therefore, both central and local governments have a high influence and impact.

Hospitals care more about reducing misdiagnosis and the prevention of medical accidents. Therefore, they have a medium level of interest in the integration of telehealth solutions. The director of hospitals usually decides whether hospitals will spend on telehealth solutions. Therefore, hospital management has both a high influence and impact regarding the integration of telehealth solutions.

Doctors care about reducing workloads, publishing papers, and getting involved in research projects. They cannot decide whether a hospital can purchase or integrate telehealth solutions. However, top doctors can participate in the policy-making process and have a medium level of influence regarding the formation of policy and standards. Doctors have a low level of influence on integrating processes as they do not have the financial resources to decide the use of such solutions within hospitals.

Individual users are highly interested in using such solutions to save the trouble of going to hospitals or waiting in long queues

for treatment. However, they often do not set technical standards or make policies regarding developing telehealth solutions. Yet individual users can decide whether to use telehealth solutions at home; therefore, they have a low level of influence but a high level of impact when it comes to integrating such solutions.

**Table 2** illustrates each stakeholder's position for funding/developing/purchasing specific telehealth solutions such as internet-based hospitals service, personalized/continuous electronic health care records (EHR) service, family doctor service for chronic disease management, etc.

**Table 2.** Stakeholder position on adoption of telehealth solutions.

Key points of view	Tech companies	Doctors	Government organizations	Consumers
General attitudes about smart health solutions	Positive	Positive	Neutral/negative	Neutral
Interact with patients via internet-based hospitals	Positive	Negative	Negative	Negative
Personalized electronic health records	Positive	Neutral	Positive	Neutral
Family doctor service for chronic disease management	Negative	Negative	Positive	Positive
Continuous health monitoring with home devices	Negative	Negative	Positive	Negative
Share health-related data with insurance companies	Negative	Negative	Neutral	Negative
Using public medical insurance to pay for smart health solutions	Positive	Neutral	Negative	Positive
Using private medical insurance to pay for smart health solutions	Negative	Neutral	Negative	Negative
Value-based health care payment schemes	Neutral	Negative	Positive	Positive
Separate approval process for medical use of wearable devices	Positive	Positive/neutral	Negative	Neutral
Interoperability of hospital information system	Positive	Positive/neutral	Negative	Positive

The stakeholders point out the challenges for realizing telehealth solutions in China.

First, strict regulations for medical use lead to difficulties in the commercialization of the health-related functions for wearables. Relevant approval usually takes 5 to 10 years, depending on the country and specific function submitted for approval. Some of the monitoring methods, like the pumping in blood pressure monitoring, disturb users' sleep, and therefore, cannot be used for 24/7 monitoring. However, this is the only acceptable method for medical device regulators. However, new ways of monitoring blood pressure via photoplethysmogram cannot be commercialized due to strict regulations on medical use of biometrics data monitoring.

Second, most doctors do not make decisions based on data collected via wearables or home medical devices for diagnosis or treatment. Currently, wearables and home medical devices are not connected with the hospital EHR system; therefore, doctors only use data collected by patients at home for reference.

Third, there are no national and regional level health care data-sharing platforms.

Fourthly, the social security system does not cover the cost of wearables. There are no standards for evaluating the effectiveness of wearable devices for chronic disease management on a population level. It is also difficult for patients to be reimbursed by the public insurance system.

Fifthly, consumers often find it untrustworthy to share biometrics data with different stakeholders. Users are not willing to share their data, whether it is with doctors, insurance providers, or family and friends. Most people, however, do not know how the data collected on wearables are stored, shared,

and used; data can flow to Facebook, Apple, Google, Baidu, and Amazon without users' knowledge, let alone consent. This leads to a monopoly in tech companies with regard to data storage and processing. These companies already have the most robust computing power and storage units and the best algorithms.

Lastly, there is no clear legal definition of the ownership of personal data. Users may find they have lost the rights to their data-to-data controllers easily. Given the wide industrial approach of uploading and processing data on the cloud, it is almost impossible to track data flow once it leaves the device.

## Discussion

To fully implement IoT solutions within the health care industry, health care service providers need to work with government officials to build up data-sharing platforms, eliminating duplicated procedures and facilitating access to medical records. Medical device regulators shall adopt the technology standards along with technology development.

Local authorities shall be given more authority to test the health care programs based on their priorities and get involved with retired populations that may return to the workforce. Employers may find older people more patient, careful, trained, and trustworthy than imagined. In this way, health care quality variation can be adjusted, and optimal pathways can be promoted. In addition, when it comes to new drugs and new technology approvals, population health assessments based on big data will make it possible for more policymakers to say yes or no to new drugs and treatment methodologies with much more efficiency.

Rising health care costs associated with the aging population have led to concerns that the retired and older people may inflict great stress on the welfare system. Wearable devices may make it possible to monitor the health conditions of older people and allow them to live independently for as long as possible. By interacting with technology and initiating data sharing, the life quality of older people may also improve. There are barriers to data interoperability, technology standards, and privacy and safety concerns involved with the medical use of IoT devices.

Policymakers may need to follow up more closely with technological development to adapt the technology usage standards and improve public awareness about the data storage, usage, and sharing involved in wearable technology and AI for medical use. A clear definition of data ownership would also help determine the ethical and legal methods of personal biometrical data collection in the coming era of the internet of health care things.

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## Conflicts of Interest

None declared.

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## Abbreviations

- AI:** artificial intelligence
- CDC:** Chinese Centre for Disease Control and Prevention
- EHR:** electronic health care records
- GDPR:** general data protection regulation
- ILA:** interactive learning and action
- IoT:** internet of things
- mHealth:** mobile health
- NFPC:** National Health and Family Planning Committee
- NMPA:** National Medical Products Administration
- VR:** virtual reality

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Original Paper

# Patient Utilization of Online Information and its Influence on Orthopedic Surgeon Selection: Cross-sectional Survey of Patient Beliefs and Behaviors

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## Abstract

**Background:** Patient attitudes and behavior are critical to understand owing to the increasing role of patient choice. There is a paucity of investigation into the perceived credibility of online information and whether such information impacts how patients choose their surgeons.

**Objective:** The purpose of this study was to explore the attitudes and behavior of patients regarding online information and orthopedic surgeon selection. Secondary purposes included gaining insight into the relative importance of provider selection factors, and their association with patient age and education level.

**Methods:** This was a cross-sectional study involving five multispecialty orthopedic surgery groups. A total of 329 patients who sought treatment by six different orthopedic surgeons were asked to anonymously answer a questionnaire consisting of 25 questions. Four questions regarded demographic information, 10 questions asked patients to rate the importance of specific criteria regarding the selection of their orthopedic surgeon (on a 4-point Likert scale), and 6 questions were designed to determine patient attitude and behaviors related to online information.

**Results:** Patient-reported referral sources included the emergency room (29/329, 8.8%), friend (42/329, 12.8%), insurance company (47/329, 14.3%), internet search/website (28/329, 8.5%), primary care physician (148/329, 45.0%), and other (34/329, 10.3%). Among the 329 patients, 130 (39.5%) reported that they searched the internet for information before their first visit. There was a trend of increased belief in online information to be accurate and complete in younger age groups ( $P=.02$ ). There was an increased relative frequency in younger groups to perceive physician rating websites to be unbiased ( $P=.003$ ), provide sufficient patient satisfaction information ( $P=.01$ ), and information about physician education and training ( $P=.03$ ). There was a significant trend for patients that found a surgeon's website to be useful ( $P<.001$ ), with the relative frequency increased in younger age groups.

**Conclusions:** This study shows that insurance network, physician referrals, appointment availability, and office location are important to patients, whereas advertising and internet reviews by other patients were considered to be not as helpful in choosing an orthopedic surgeon. Future studies may seek to identify obstacles to patients in integrating online resources for decision-making and strategies to improve health-seeking behaviors.

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**KEYWORDS**

orthopedics; practice management; physician selection; internet reviews; patient decision; practice; patient online review; social media; physician perception; patient choice; health literacy

## Introduction

Health literacy is a complex concept, defined by both the Institute of Medicine and the World Health Organization as incorporating cognitive and social skill sets that are distilled through patient experiences and are necessary to obtain, understand, and apply information to make appropriate health decisions [1,2]. Health organizations have underscored the importance of health literacy as an essential component of patient-centered care [3,4]. Consequently, a rich body of literature established factors that influence health care choices [4-8] and investigated trends in health care consumerism [9-11].

Online tools and information are postulated to disrupt the traditional patient-physician relationship and traditional metrics of health care assessment with the expanded use of social media and physician rating websites (PRWs) [9,12-15]. Physician websites, social media venues, and online review sites are the most common spaces in which patients can discover information about physicians and their practices [16]. Previous studies sought to investigate online patient behavior and classify the information posted online by patients [11,13,17-19]. The rating scales on PRWs were found to be inaccurate and with significant limitations; as such, concerns regarding misalignment of consumer satisfaction and quality were raised because health care incentives are not aligned as in other consumer industries [17,20,21]. Roughly 59% of US respondents indicated that they believed that the information on PRWs is either somewhat or very important [22], despite the documented disparity between conventional quality metrics and crowd-sourced online reviews [20,21,23,24]. Thus, it remains unclear why patients use these platforms and if this information influences their behavior [4].

The impact of misinformed or uninformed patients is consequential [25-30]. Limited health literacy has been associated with low patient satisfaction, worse patient outcomes, and higher costs [31,32]. In orthopedic surgery, there is a unique form of health literacy and a more sophisticated skill set required for making informed decisions [33-35]. Decision-making has been found to not be strictly rational but is rather a complex and heterogeneous process that is distilled through patient preferences, values, and social influences [5,36]. Improved understanding of these influences on patient decision-making may identify actionable opportunities to practice patient-centered care. To our knowledge, there is a paucity of investigations eliciting how patient attitudes and behaviors related to information online influence provider selection factors. Considering that such information may be of low quality and inaccurate [23,37], it is important to explore if online research alters a patient's decision-making for provider selection.

Accordingly, the aim of this study was to define the internet sources that patients are using to research their orthopedic surgeons and to quantify the importance placed on those findings. In addition, we investigated the demographic variables that may influence the reliance on internet websites, and further aimed to define the importance of other variables involved in choosing an orthopedic surgeon. The purpose of this study was to explore the attitudes and behavior of patients regarding online information and its influence on establishing care with an

orthopedic surgeon. Secondary purposes included a description of the relative importance of provider selection factors, and their association with patient age and education level.

## Methods

We performed a cross-sectional survey of patients at orthopedic offices in Las Vegas, Nevada. The study group included six orthopedic surgeon practices screening patients in their clinics. Subspecialties included were foot and ankle, hand, spine, and sports medicine. The surveys were completed by patients that were seen at the clinics over the course of 3 months. This study was approved by OptiWest institutional review board. Strengthening the Reporting of Observation studies in Epidemiology (STROBE) and Statistical Analyses and Methods in the Published Literature (SAMPL) reporting guidelines were followed during the study design and manuscript preparation to ensure methodologic quality and transparent reporting [38,39].

Consent from each patient was obtained before participation. The survey was confidential and anonymous, with no identifiers linked to individual responses. All participants completed the survey.

The survey consisted of seven questions, which aimed to gauge patient opinion and define patient behavior (see [Multimedia Appendix 1](#)). The survey asked patients to report their demographics, attitudes, and behaviors. Three questions documented patient demographics: patient age, education level, and frequency of internet use. One question prompted patients to rate specific orthopedic surgeon selection criteria [6-8,36] on a 4-point Likert scale ranging from 1 defined as "not important" to 4 defined as "very important." Two questions polled patient opinion regarding internet patient reviews and if patient satisfaction equates to a successful treatment outcome. One question assessed the patient's use of websites prior to their clinic visit. The participants completed their surveys in person and responses were kept anonymous. Notably, the survey is not a validated questionnaire of a measure of a specific outcome but rather represents a survey of questions. This article reports the results of the descriptive analysis of the responses for an exploratory investigation into patient beliefs, behaviors, and trends.

Respondents were grouped into the following age ranges: 18-25, 26-35, 36-45, 46-55, 56-65, and 76-85 years. Respondents were stratified based on their highest level of education: elementary/middle school, high school, some college, bachelor's degree, master's degree, and doctoral degree. A trained medical assistant or research assistant explained each question to the participants while administering the survey.

Basic descriptive statistics were analyzed using MedCalc Software. Ordinal Likert-scale data are reported using median for central tendency and frequencies, and Kendall  $\tau$  was used to analyze associations. Associations are reported as the correlation coefficient with a precision estimate (95% CI) [40]. The Cochran-Armitage test was used for analysis of categorical variables [41,42], which is considered to be more powerful than the  $\chi^2$  test to assess trends in proportions and frequencies. The statistical significance level was set at  $P < .05$ .

## Results

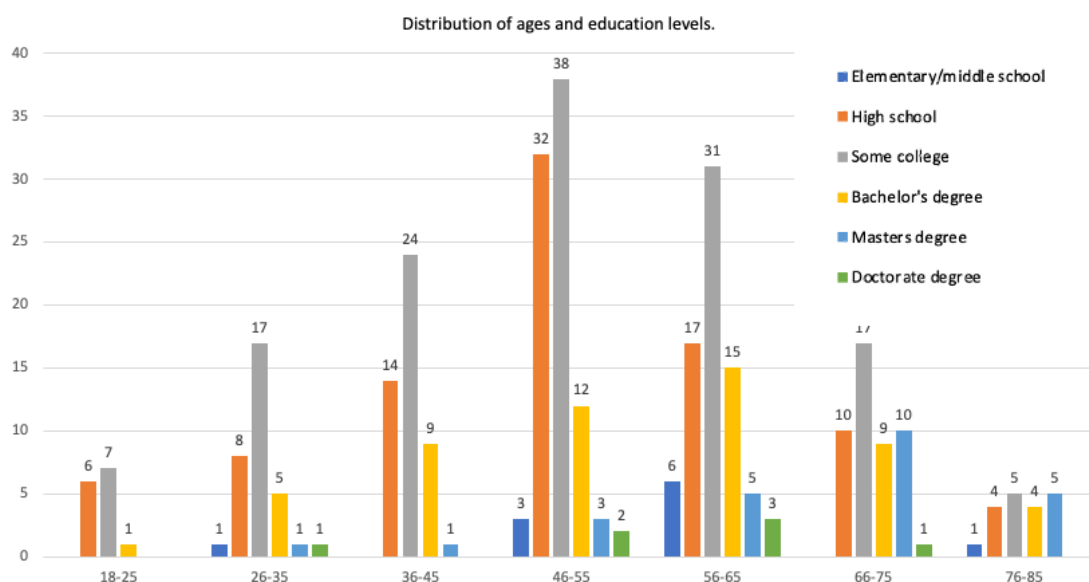
Between July 2017 and August 2017, all 329 patients that were administered the survey completed the survey. Table 1 delineates the distribution of patients that completed the survey according to the subspecialty of the orthopedic surgeon they were

consulting. The majority of patients reported daily baseline internet use (227/329, 69.0%), followed by 2-3 times per week (23/329, 7.0%) and 4-5 times per week (20/329, 6.1%). The histogram of the number of patients that responded according to age group and stratified by the highest education level is shown in Figure 1.

**Table 1.** Survey participants stratified by orthopedic subspecialty (N=324; subspecialties were not documented by 5 patients).

Subspecialty	Patients, n (%)
Spine	150 (46.3)
Sport	119 (36.7)
Hand	33 (10.2)
Foot and ankle	22 (6.8)

**Figure 1.** Respondent age and highest education stratification of all participants (N=329).



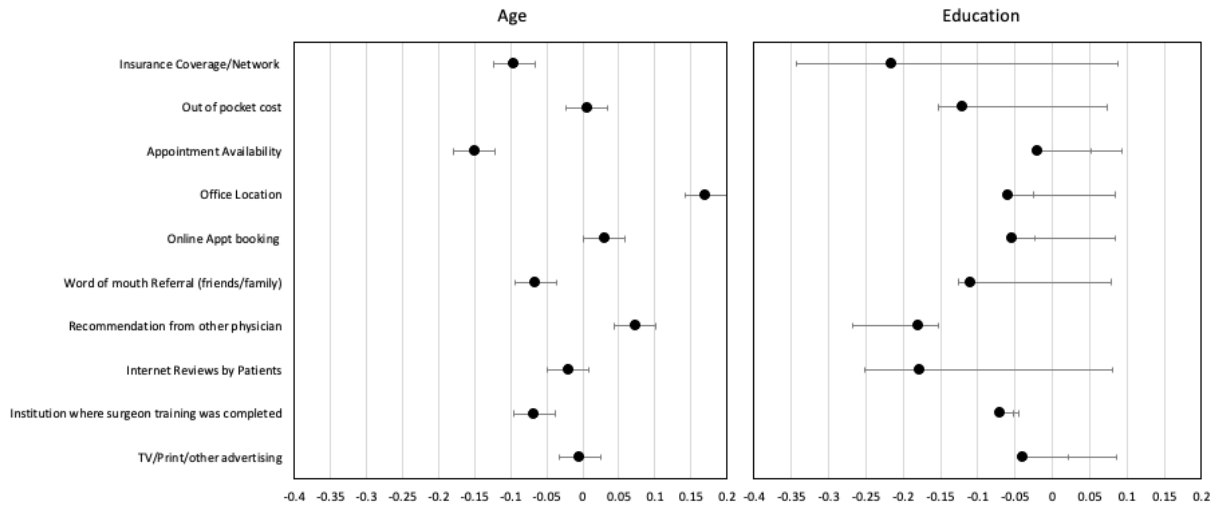
The patient-reported referral source was the emergency room (29/329, 8.8%), friend (42/329, 12.8%), insurance company (47/329, 14.3%), internet search/website (28/329, 8.5%), primary care physician (PCP; 148/329, 45.0%), and other (34/329, 10.3%). Among the 329 patients, 130 (39.5%) reported that they had searched the internet for information about the surgeon before their first visit. The majority of these patients had visited the surgeon’s website (63/130, 48.5%), followed by the website of the office or surgical group (35/130, 26.9%). Other websites visited included webmd.com (34/130, 26.2%), yelp.com (26/130, 20.0%), healthgrades (21/130, 16.2%), ratemd.com (20/130, 15.4%), and the Nevada medical board website (7/130, 5.4%).

The ranking of important factors in selecting the orthopedic surgeon is displayed in Figure 2 as well as the association of these factors with age and level of education. Patient age was

significantly associated with office location ( $P=.05$ ), physician recommendation ( $P<.001$ ), internet reviews ( $P<.001$ ), and advertising sources ( $P=.01$ ). Patient education level was significantly associated with out-of-pocket costs ( $P=.05$ ), availability ( $P<.001$ ), office location ( $P<.001$ ), online appointment booking ( $P=.004$ ), surgeon training ( $P=.002$ ), and advertisement sources ( $P<.001$ ). Patients reported insurance coverage (260/329, 79.0%), out-of-pocket costs (217/329, 66.0%), availability (184/329, 55.9%), and recommendation by another physician as “very important” (score of 4). Surgeon advertising was rated 1 (not important) by 204 (62.0%) of the 329 patients. The frequency at which internet reviews were deemed to be important ranged between 21% and 29% in each category. The institution where the surgeon trained was only deemed to be very important for 82 (24.9%) and as moderately important for 99 (30.1%) of the 329 respondents.



**Figure 2.** Relative importance of orthopedic surgeon selection factors, and their associations with patient age and education level.



The attitudes of patients toward online information are summarized in Table 2. The highest frequency of patients indicated that they found the surgeon’s website to be useful. Among the factors included in the questionnaire, the lowest

number of patients indicated that online information is accurate and complete. There were no significant associations found between patient education groups in regard to their online information or PRW beliefs.

**Table 2.** Attitude toward online information (“is it important?”) (N=329).

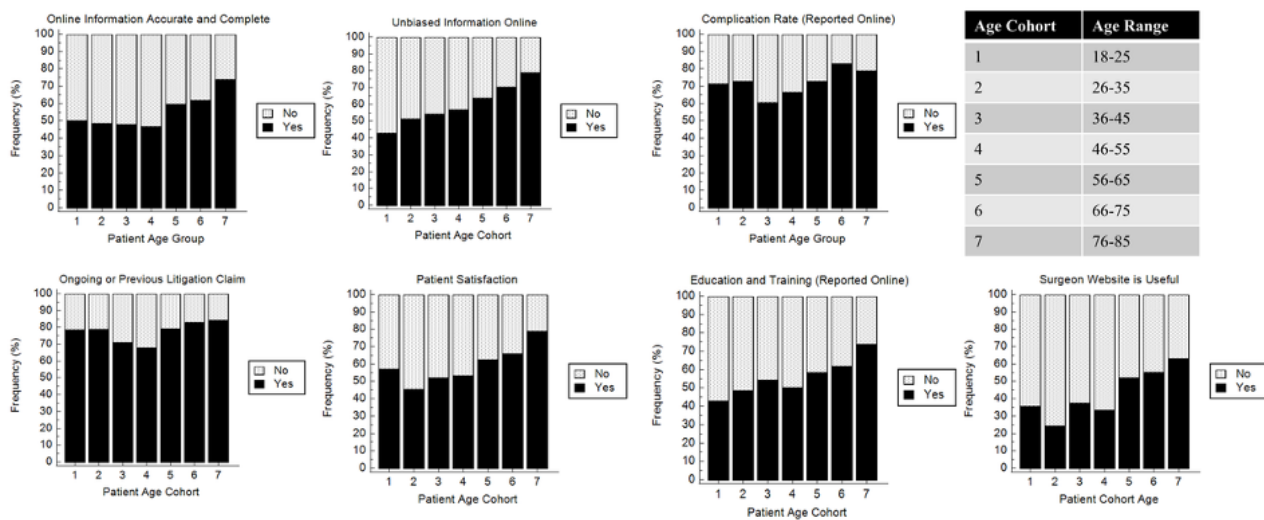
Question	Yes, n (%)	Age P value	Education P value
Online information is accurate and complete	40 (12.2)	.02	.99
PRW <sup>a</sup> is unbiased	131 (39.8)	.003	.32
PRW has complicated rate information	95 (28.9)	.09	.21
Ongoing or previous litigation claims	80 (24.3)	.24	.52
PRW shows patient satisfaction	138 (41.9)	.01	.95
PRW indicates education and training	147 (44.7)	.03	.58
Surgeon website useful	189 (57.4)	<.001	.18

<sup>a</sup>PRW: physician rating website.

Significant trends were found in beliefs regarding online information and PRWs between age groups (Figure 3). There was a trend of increased belief in online information to be accurate and complete in the younger age groups ( $P=.02$ ). There was an increased relative frequency in younger groups to perceive PRWs to be unbiased ( $P=.003$ ), provide sufficient

patient satisfaction information ( $P=.01$ ), and information about physician education and training ( $P=.03$ ). There was also a significant trend for patients that found the surgeon’s website to be useful ( $P<.001$ ), with the relative frequency increased in younger age groups.

**Figure 3.** Trends in relative frequency of patient perceptions. Each subgraph, further categorized by age, shows if a specific factor influences the patient’s selection of orthopedic surgeons.



## Discussion

### Principal Findings

Only 28 of the 329 patients (8.5%) that completed the survey selected their orthopedic surgeon using internet search/websites. Notably, 205 (62.3%) patients were referred to their orthopedic surgeon from health care–related sources (emergency room, insurance company, and PCP), with the highest percentage of patients (148/329, 45.0%) referred by their PCP. Correspondingly, the data reflected the generally low importance of patient-oriented advertisements, with 204 patients (62.0%) giving this factor a rating of 1 (not important). Our data indicate that patients are value-oriented, and rated insurance coverage (260/329, 79.0%) and out-of-pocket costs (189/329, 57.4%) as very important factors. Only 130 of the 329 patients (39.5%) conducted an internet search prior to their first visit. Notably, there were significant trends observed for younger patient groups believing online information to be accurate and complete, as well as having more favorable attitudes toward PRWs in providing sufficient and unbiased information (Figure 3).

Despite the rapid expansion of online information available to patients, our data indicate that patients do not use this information to actively engage in their care. This conclusion is in support of previously published findings [43,44]. Patients also did not seek to learn about provider medical knowledge, litigation, or patient satisfaction. Patient satisfaction was purported to be a quality-of-care surrogate metric, considering the complex interplay of social, demographic, cultural, and cognitive factor interactions that influence satisfaction. The multidimensional assessment of quality was lost and deemed inappropriate [21]. Rothenfluh et al [45] suggested that one reason for this may be the perceived inability to assess physician quality even if informed by available information online, demonstrating that patients differ in decision-making between hotel selection and provider selection due to reduced trust in incorporating online information about physicians. Nevertheless, we found that 40% of patients utilized internet sources for information before their clinic visit compared to only 24% of

patients reporting such use among those visiting an outpatient orthopedic clinic surveyed in 2002 [46]. Integration of online information is likely lagging in utilization, and future research should seek to delineate the causal factors or barriers.

Our data imply that surgeons should focus on their relationships with community physician referral sources. This was previously highlighted in a study on referrals to plastic surgeons [47] showing that 82% of patients felt that a recommendation from another physician was very important to moderately important, which was a statistically significant result across all age groups. Important factors influencing the choice of a foot and ankle surgeon were identified as insurance network and recommendations (family, friend, physician) [4]. Our data provide corroboratory support to these factors as important influences on patient decision-making. Further, the external validity of the findings can be compared among studies. In another study, important factors for patient selection of their surgeon and hospital for total joint arthroplasty were ranked on a 5-point Likert scale [6]. All three aforementioned reports [4,46,47] indicated that professional reputation is critical. Similarly, recommendations by other physicians and insurance companies had a significant impact on women selecting their obstetrician/gynecologist [44]. Future studies should evaluate whether there is a difference between how much patients weigh primary care versus urgent/emergent care referrals, other orthopedic surgeons’ opinions, and other medical providers in the community.

The correlation patterns found in this study were surprising and warrant attention. Age and education level have been proposed to influence health literacy, noting that patients with a graduate degree are 130 times more likely to have adequate health literacy ( $P=.01$ ) [48]. Less than college-level education was previously identified as an independent predictor of limited musculoskeletal health literacy with a relative risk of 1.40 [49]. Our data demonstrated different statistically significant associations that had nonconsequential effect sizes. Importantly, this is not the first study to report younger age to be significantly associated

with increased use and increased perceived usefulness of online information [50,51].

This survey was not without its limitations. The survey was administered to a convenience sample of limited size. Thus, the sample size of patients is underpowered, although the study was open to all patients at a large private practice setting in an anonymous fashion. Similarly, the selection bias within our sample cannot be ascertained. Another major flaw is the lack of a comparison group, which adds further sample bias. The surveys were also administered over time, with variability in practice settings, providers, and survey administrators, which could introduce recording and recall bias. Although we were unable to precisely determine the population percentage captured, the survey was administered in multiple locations and to multiple specialties of orthopedics to increase sample

diversity. Our survey is not a standardized or validated questionnaire; thus, response bias may have been introduced. Nevertheless, our goal was to describe a macroscopic phenomenon rather than to deduce a causative process.

### Conclusions

This study shows that insurance network, physician referrals, appointment availability, and office location are important to patients, whereas advertising and internet reviews by other patients are not as helpful in choosing an orthopedic surgeon. Our data do not support consensus ideas regarding consumer autonomy and patient agency in health care. Future studies may seek to identify obstacles to patients in integrating online resources for decision-making and strategies to improve health-seeking behaviors.

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### Conflicts of Interest

None declared.

Multimedia Appendix 1

Patient survey.

[[DOCX File, 23 KB - formative\\_v6i1e22586\\_app1.docx](#)]

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## Abbreviations

**PCP:** primary care physician

**PRW:** physician rating website

**SAMPL:** Statistical Analyses and Methods in the Published Literature

**STROBE:** Strengthening the Reporting of Observation studies in Epidemiology

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Original Paper

# A Digital Intervention for Respiratory Tract Infections (Internet Dr): Process Evaluation to Understand How to Support Self-care for Minor Ailments

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## Abstract

**Background:** Approximately 57 million physician appointments annually in the United Kingdom are for minor ailments. These illnesses could be self-cared for, which would potentially lower patients' anxiety, increase their confidence, and be more convenient. In a randomized controlled trial of the *Internet Dr* digital intervention, patients with access to the intervention had fewer consultations for respiratory tract infections (RTIs). Having established intervention efficacy, further examination of trial data is required to understand how the intervention works.

**Objective:** This paper reports a process evaluation of *Internet Dr* usage by the intervention group. The evaluation aims to demonstrate how meaningful usage metrics (ie, interactions that are specific and relevant to the intervention) can be derived from the theoretical principles underlying the intervention, then applied to examine whether these interactions are effective in supporting self-care for RTIs, for whom, and at what time.

**Methods:** The *Internet Dr* trial recorded patients' characteristics and usage data over 24 weeks. At follow-up, users reported whether their levels of enablement to cope with their illness changed over the trial period. The Medical Research Council process evaluation guidance and checklists from the framework for Analyzing and Measuring Usage and Engagement Data were applied to structure research questions examining associations between usage and enablement.

**Results:** Viewing pages containing advice on caring for RTIs were identified as a meaningful metric for measuring intervention usage. Almost half of the users (616/1491, 42.31%) viewed at least one advice page, with most people (478/616, 77.6%) accessing them when they initially enrolled in the study. Users who viewed an advice page reported increased enablement to cope with their illness as a result of having participated in the study compared with users who did not (mean 2.12, SD 2.92 vs mean 1.65, SD 3.10; mean difference 0.469, 95% CI 0.082-0.856). The target population was users who had visited their general practitioners for an RTI in the year before the trial, and analyses revealed that this group was more likely to access advice pages (odds ratio 1.35, 95% CI 1.159-1.571;  $P < .001$ ).

**Conclusions:** The process evaluation identifies viewing advice pages as associated with increased enablement to self-care, even when accessed in the absence of a RTI, meaning that dissemination activities need not be restricted to targeting users who are ill. The intervention was effective at reaching the target population of users who had previously consulted their general practitioners. However, attrition before reaching advice pages was high, highlighting the necessity of prioritizing access during the design phase. These findings provide guidance on how the intervention may be improved and disseminated and have wider implications for minor ailment interventions.

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## KEYWORDS

illness behavior; self-care; internet; evaluation studies; respiratory tract infection; mobile phone

## Introduction

### Background

Minor ailments are defined as nonserious health conditions that may be cared for by patients (eg, back pain, respiratory tract infections [RTIs], headache, and stomach upsets) [1]. However, an estimated 57 million unnecessary visits to general practitioners (GPs) in the National Health Service (NHS) occur every year in the United Kingdom as patients seek advice for managing these conditions [2]. The strain this places on primary care resources is well documented [3,4]; however, there is also a cost to the patient through increased anxiety, lowered confidence, and inconvenience [1]. Promoting self-care for these ailments would help alleviate the stress on both primary care and patients by helping patients understand and feel more enabled to cope with their health [3].

Many patients already use web-based resources for guidance with health issues [5]. However, credible, evidence-based interventions are needed to ensure that potentially serious infections are identified, and users are advised to consult a health care professional (HCP) when necessary. Interventions aimed solely at increasing users' knowledge regarding their illness have shown only limited effects on increasing self-care [4]. Instead, calls have been made for interventions that address barriers to self-care, such as patients feeling distressed regarding their symptoms and not knowing how to treat them [4,6]. Theoretically-based digital health interventions have the potential to address these barriers and offer the advantage of providing ongoing support at a time and place that is convenient to the user. *Internet Dr* is a digital intervention that supports appropriate self-management of RTIs [7]. The intervention content is theoretically underpinned and contains tailored advice on self-caring for RTI symptoms, as well as a symptom checker to identify serious illnesses, including meningitis and sepsis [6] (see the *Intervention* subsection in the *Methods* section for more details). The content was designed to address previously identified barriers to self-care: (1) uncertainty regarding the need for medical treatment and (2) distress caused by the symptoms [4,6].

A randomized controlled trial (RCT) of *Internet Dr* was conducted over the winters of 2012 and 2013, with 3044 participants recruited randomly from lists of all patients registered at a selection of general practices in southern England. Users who had access to the intervention had fewer GP consultations for an RTI compared with those in the control group (239/1574, 15.18% vs 304/1664, 18.26%; multivariate

risk ratio 0.71, 95% CI 0.52-0.98;  $P=.04$ ), despite both groups having an equivalent occurrence of illnesses [7]. This means that more users in the intervention group decided to self-care for their symptoms. In addition to GP visits, self-reported scores for the patient enablement index (PEI) were also collected as an outcome measure at follow-up to capture the psychological benefits for patients using the intervention [8]. The PEI items asked users to reflect on perceived changes that occurred as a result of having participated in the study; for example, "thinking about the kinds of symptoms we have asked about in this study, compared with before you took part in this study, do you feel you are able to help yourself: same or less; better; much better?" Having previously focused on the intervention's impact on health service use [7], a process evaluation of the RCT data is required to understand the psychological changes and behavioral engagement with the theoretically underpinned content of the intervention that led to the intervention group's increased ability to self-care.

### Objectives

Process evaluations aim to provide insight into the parts of an intervention that work, for whom, and under what conditions [9,10]. This may be achieved by examining the underlying intervention mechanisms that are anticipated to lead to positive outcomes and the impact of context on the implementation of an intervention [9,10]. Logic models are often used to map the intervention content, theoretical underpinning, anticipated mechanisms of action, and outcomes [11], thereby identifying core research questions or hypotheses to address within a process analysis [12]. By explaining the mechanisms and effects of context, process evaluations have the potential to inform future intervention development and dissemination and advance our understanding of intervention theory [9,10].

Quantitative usage data collected automatically during interactions with a digital intervention (ie, log data) have the ability to provide a rich source of metrics for usage analyses [13-16]. Although widely used, broad, summative measures of usage, such as time spent or number of pages or components viewed in an intervention, have been criticized for their inability to explain how usage leads to positive outcomes [15,17-20]. In addition, the breadth of potential usage metrics available means that there is a danger that inferential analyses that examine all of these variables will produce results that do not relate meaningfully to the theoretically designed intervention architecture and are therefore unable to offer specific practical and actionable recommendations to optimize future intervention designs [18]. A clear rationale for choosing usage metrics is

necessary to understand what is being measured and what can be inferred from analyses [19,21,22]. On that basis, arguments have been made to identify usage metrics that are meaningful to the intervention rather than data dredging [15]. This means determining types or patterns of usage that are specific to an intervention's structure and the target behavior and are able to examine usage of theory-based content. For example, by isolating usage of a specific component [15,18]. For example, by isolating the use of a specific component or set of pages aimed at improving users' self-efficacy for carrying out a target behavior, it is possible to examine the relationships between having viewed that component, reported changes in self-efficacy, and behavioral outcomes.

The framework for Analyzing and Measuring Usage and Engagement Data (AMUsED) [15] was developed to support systematic usage analyses of digital interventions by guiding researchers through 3 stages of planning and carrying out analyses. Stage 1 focuses on familiarization with the intervention architecture, including content, structure, and data collection. Through a list of generic questions in the first section of stage 2, researchers identify available metrics with which to measure usage, covering both summative measures (eg, number of times the intervention was accessed, completing the intervention, and amount of time spent) and more in-depth measures (eg, type, frequency, and completion of theoretically-based content). Researchers are then encouraged to consider these variables alongside the information from stage 1 and identify usage metrics that are relevant to the intervention structure, theory-based content, and target behavior and that are most likely to provide insight into how the intervention was effective and may be improved and implemented. Sections 2 and 3 of stage 2 then address how these metrics may be used in inferential analyses with self-report measures for user characteristics and target behaviors or outcomes. Stage 3 focuses on planning compatible data collection to ensure that analysis using appropriate analytical software is both possible and less onerous. The framework has previously been used to shape data collection for other digital interventions [15]; however, this process evaluation reports the first application to a usage analysis.

In line with the Medical Research Council guidance, this paper reports the process evaluation of the *Internet Dr* RCT, including a detailed usage analysis structured by the AMUsED framework [15]. The aims of the evaluation are (1) to identify measures of usage that are meaningful to the intervention and (2) to examine which parts of the intervention worked, for whom, and at what time. These results will generate guidance on how the design, implementation, and dissemination of *Internet Dr* can be improved but will also have generic implications for guiding the successful design and development of other digital interventions promoting self-care for minor ailments.

## Methods

### Internet Dr Trial Design

An open, pragmatic, parallel-group RCT of the *Internet Dr* digital intervention had been previously conducted [7]. After completing web-based enrollment in the study and baseline measures, participants were randomized using

computer-generated random numbers to either the intervention group who had access to the website or the control group who did not. Having completed outcome measures at 24 weeks, participants in the control group were able to view the intervention. The full details of the *Internet Dr* RCT and findings from the primary analysis are available in the study by Little et al [7]. The study was registered with a trial registration number of ISRCTN91518452, and ethics approval from the South West Medical Research Ethics Committee, United Kingdom Health Departments' Research Ethics Service, was obtained.

### Participants

Adults (aged  $\geq 18$  years) registered with GPs within NHS Primary Care were recruited for the RCT by postal invitation. Patients with severe mental health problems or terminal illnesses were excluded. Participants needed to have access to the internet, with only 1 participant per household taking part. The process evaluation only examines participants who were randomly allocated to the intervention group and therefore had access to the intervention during the 24-week trial period.

### Process Evaluation Design

A plan for conducting a complete process evaluation of data collected during the *Internet Dr* RCT was designed and conducted in line with the Medical Research Council guidance [12] using the AMUsED framework [15]. On the basis of the AMUsED framework checklists, the intervention's structure, theoretical underpinning, and data collection points were collated (stage 1; [Multimedia Appendix 1](#) [7,8,22-29]). All available usage metrics were considered in relation to the information in stage 1 to ascertain the types of usage that would be most meaningful to the intervention (stage 2, section 1; [Multimedia Appendix 2](#)). A comprehensive list of research questions was then generated to examine associations between the meaningful measures of usage, user characteristics, and outcomes (stage 2, sections 2 and 3; [Multimedia Appendix 2](#)). The questions were refined based on the logic model (see the *Intervention* section). The most appropriate analytical tools for examining the research questions were selected, and the necessary data preparation was considered (stage 3; [Multimedia Appendix 3](#)).

The process evaluation team combined expertise in psychology, primary care, statistical analyses, and computing. A total of 4 team members were previously unfamiliar with the intervention. The other 4 researchers had been involved in various stages of the *Internet Dr* development and primary outcome evaluation of the trial [7] and advised on the intervention content, logic model, and data capture processes and analyses. The first author (SM) had previously developed the AMUsED framework for application in process evaluations but was not familiar with the *Internet Dr* intervention.

### Measures

Participants were requested to complete web-based baseline measures at the start of the trial, interim questionnaires every 4 weeks on RTI occurrence, and outcome measures at 24 weeks. Actual GP visits before and during the trial were collected after 1 year from participants' GP records. Log data for individual

users and sessions were collected during the trial (eg, pages accessed, time spent, and order of pages viewed).

Modifiable psychological characteristics thought to underlie decisions to self-care were measured at baseline and follow-up to capture any changes over the trial period that may help to explain outcomes (theory of planned behavior [TPB] [22]: attitudes and norms; perceived behavioral control (PBC); and beliefs regarding the necessity of HCPs: health locus of control [23] and Krantz Health Opinion Survey [24]). Trait anxiety (Health Anxiety Inventory [25]) and intentions to use and follow intervention advice (TPB) [22] were measured at baseline. Experiences of accessing and using the intervention were collected at follow-up (Problematic Experiences of Therapy Scale [PETS]; [26]), along with the psychological outcome measure of how much users felt their ability to cope with an RTI had changed over the course of the trial (PEI; [8]). Full details of the psychological measures and response items are available in [Multimedia Appendix 4](#) [8,16,19, 22-24].

## Internet Dr Intervention

### Overview

*Internet Dr* is a web-based digital intervention developed using LifeGuide software (University of Southampton) [30]. All participants were encouraged to log in as soon as they received the invitation letter to the study from their GPs. Having completed trial enrollment and baseline measures, participants allocated to the intervention group were able to access the entire intervention immediately and at any point throughout the study. In addition to completing the interim questionnaires, users were encouraged to log in again if they experienced an RTI. The

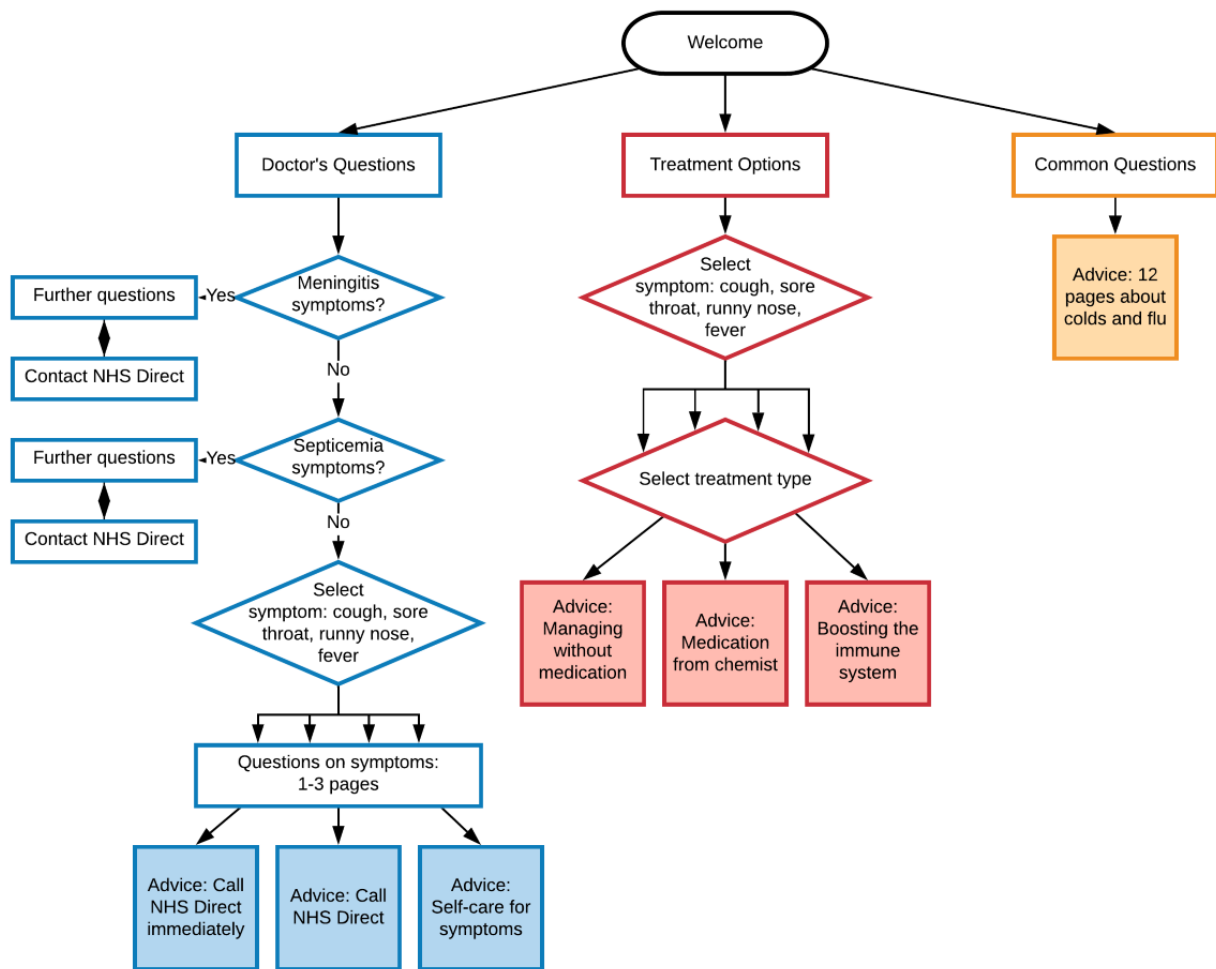
intervention was developed between 2008 and 2009 before the widespread use of smartphones.

### Intervention Content

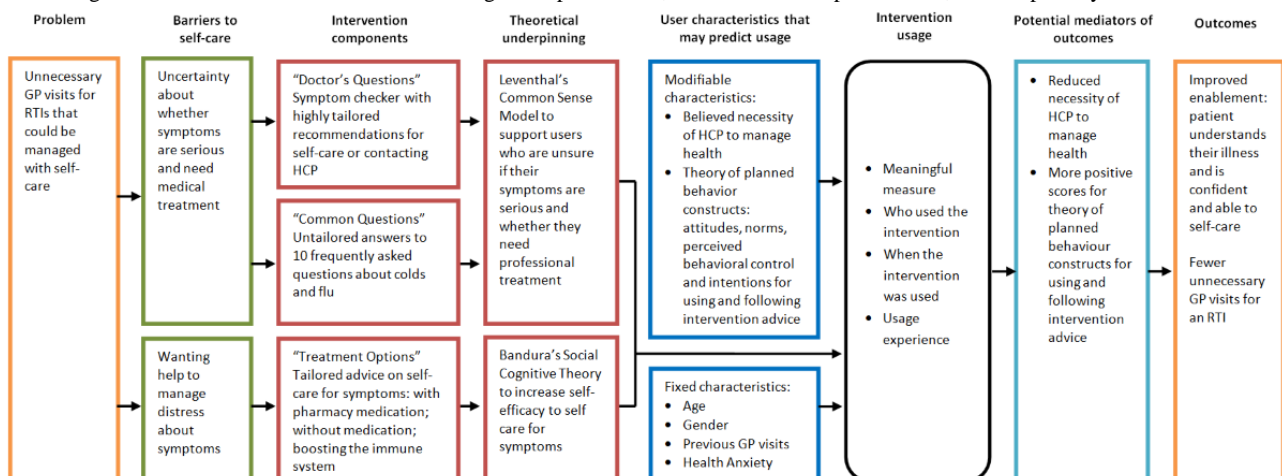
*Internet Dr* comprises 3 theory-based components offering varying levels of tailored advice (Figures 1 and 2). Full details and examples of content are available in the study by Yardley et al [6]. The *Doctor's Questions* component contains a symptom checker with detailed questions regarding users' symptoms. On the basis of these answers, users are shown 1 of 3 tailored advice messages: (1) "Your symptoms could be a sign of a serious condition that needs urgent care, ring NHS Direct immediately"; (2) "You should contact NHS Direct for further advice"; and (3) details on how to self-manage symptoms with a recommendation to revisit the website should their symptoms not improve or deteriorate further. NHS Direct was a triage phone service where patients were advised whether they needed to visit a hospital or their GP for their symptoms, which has since been replaced by NHS 111. Where patients are recommended by NHS Direct to contact their GP, this information is not automatically transferred to the patient's GP notes. This component of the intervention ensures that users with potentially serious infections receive the required treatment. The *Common Questions* component provides answers to 10 frequently asked questions regarding RTIs (eg, "how can I tell if my symptoms are due to a cold or flu?"). Questions of interest are chosen by the user; however, there is no tailoring in the answers provided. Both components are informed by Leventhal's common sense model of self-regulation of health and illness [27] and aim to support users who are unsure whether their symptoms are serious and they need medical treatment.



**Figure 1.** Page flow of the 3 components in Internet Dr leading to advice pages. Oval: start; rectangle: input pages; diamond: decision pages; shaded: advice pages; arrows: direction of movement. NHS: National Health Service.



**Figure 2.** Logic model for Internet Dr intervention. GP: general practitioner; HCP: health care professional; RTI: respiratory tract infection.



The *Treatment Options* component supports users in managing any distress they have regarding their symptoms. The content is informed by Bandura's social cognitive theory [28] to increase users' self-efficacy in managing their symptoms independently. This section offers tailored advice on self-managing an RTI dependent on the symptom selected and preferred type of treatment (ie, without medication, medication from pharmacy,

and boosting the immune system). Although this component offers advice based on the type of treatment selected by the user, it is less tailored than *Doctor's Questions*, where the advice is specific to the individual and their need to consult the NHS.

Although each component is structured around a psychological theory and aimed at a specific barrier to self-care, the advice

pages draw upon common behavior change techniques [31]. These include instructions on how to perform the behavior, information regarding health consequences, and regulation through pharmacological support and by reducing negative emotions.

### **Intervention Structure**

All 3 intervention components are designed such that users are required to navigate through specific pages before reaching the RTI management advice (Figure 1). However, each component is structured differently with varying numbers of prerequisite pages, therefore, requiring differing levels of effort to access advice. For example, because of the high level of tailoring required for the symptom checker, a user may view up to 10 pages of questions within *Doctor's Questions* before reaching an advice page. In contrast, users accessing *Common Questions* need only view 1 page before accessing advice. The advice pages are designed to be standalone, such that viewing a single page from any component may provide the user with the necessary support for self-care.

### **Intervention Logic Model**

The logic model illustrates the barriers to self-caring for RTI symptoms that are suggested to influence unnecessary GP visits (Figure 2). Use of the theoretically underpinned content was anticipated to change modifiable characteristics underlying those barriers to self-care, leading to increased levels of enablement. For example, the constructs of the TPB (Figure 2) [22] were measured to capture attitudinal and normative beliefs regarding using and following the intervention advice.

On the basis of the logic models, the following are hypothesized:

- Hypothesis 1: Meaningful usage of the intervention is associated with higher levels of enablement.
- Hypothesis 2: Baseline user characteristics predict meaningful intervention usage.
- Hypothesis 3: Changes in modifiable user characteristics mediate the relationship between meaningful usage and enablement.

### **Statistical Analysis**

All analyses examined data from only the intervention group. The LifeGuide Visualization Tool (University of Southampton) [32] was used to examine which pages had been accessed, at what point in the trial, and the number of users who had viewed

them. Statistical analyses were conducted using SPSS for Windows (version 24; IBM Corp). All validated scales were used and scored according to the published guidance. Higher scores are indicative of positive change in all measures. Changes in scores for modifiable characteristics were calculated by subtracting individuals' scores at baseline from their scores at follow-up. The frequency distribution of scores for constructs was visually assessed for normality; where these were inconclusive, Kolmogorov-Smirnov tests were performed. All scales were nonnormally distributed except for change scores. As each advice page was designed to be effective in isolation, as opposed to having an additive effect, a dichotomous categorical variable for users who viewed or did not view advice pages was calculated. All analyses were 2-tailed. Owing to a data collection error, it was not possible to analyze responses for the TPB construct of attitudes to using and following the advice at baseline and follow-up.

The distribution of scores and residuals for the PEI was positively skewed. Therefore, regression analyses were not possible for the PEI. Subsequently, 95% CIs were conducted to examine mean differences (MDs) in enablement based on usage and point biserial Spearman  $\rho$  correlation coefficient to examine the relationships between changes in user characteristics and enablement. Differences in scores for PETS based on usage were also examined using 95% CIs. Logistic regression was used to examine whether user characteristics at baseline predicted usage. Simple linear regression analyses were performed to examine whether usage predicted changes in modifiable characteristics.

## **Results**

### **Intervention Group Characteristics**

A total of 31 general practices invited 43,769 patients to take part in the RCT. Of these 43,769 patients, 3044 (6.95%) consented to take part. Of the 3044 patients, 121 (3.98%) participants left their practice over the course of the study, leaving a total of 2923 (96.02%) users; of the 2923 participants, 1491 (51.01%) were in the intervention group, and 1432 (48.99%) were in the control group (Table 1). The patients' GP notes showed that 18.04% (269/1491) of people in the intervention group had visited their GP for an RTI in the year before the study. Over the course of the trial, 57.14% (852/1491) of participants in the intervention group reported having an RTI.

**Table 1.** User characteristics and psychological measures collected on the web and usage data (N=1491).

Measure	Baseline		Follow-up	
	Values, n (%)	Values, mean (SD; range)	Values, n (%)	Values, mean (SD; range)
<b>User characteristics</b>				
Age (years)	1490 (100)	56.78 (13.52; 18-89)	— <sup>a</sup>	—
Female	816 (54.77)	—	—	—
<b>Psychological measures</b>				
Health anxiety	1491 (100)	8.20 (4.65; 0-34)	—	—
<b>TPB<sup>b</sup></b>				
Subjective norm	1387 (93.02)	9.07 (2.85; 0-14)	833 (55.87)	8.50 (2.72; 0-14)
PBC <sup>c</sup>	1426 (95.64)	10.20 (2.85; 0-14)	831 (55.73)	8.07 (3.63; 0-14)
Intentions	1445 (96.91)	9.37 (3.40; 0-14)	—	—
Health locus of control	1487 (99.73)	13.90 (5.12; 0-21)	962 (64.52)	13.54 (5.05; 0-21)
Krantz Health Opinion Survey	1490 (99.93)	27.45 (9.15; 0-49)	966 (64.79)	27.35 (8.98; 0-49)
<b>PETS<sup>d</sup></b>				
Made symptoms worse	—	—	458 (30.72)	4.34 (0.88; 1-5)
Uncertain how to use intervention	—	—	458 (30.72)	4.37 (0.95; 1-5)
Doubts about intervention efficacy	—	—	458 (30.72)	4.03 (1.08; 1-5)
Practical problems	—	—	458 (30.72)	4.19 (0.96; 1-5)
PEI <sup>e</sup>	—	—	952 (63.85)	1.86 (3.03; 0-12)
<b>Summative usage data</b>				
Number of log-ins	—	—	1491 (100)	4.86 (2.87; 0-18)
Time spent (minutes)	—	—	1491 (100)	4.68 (6.57; 0-44.58)
Number of pages viewed	—	—	1491 (100)	10.10 (10.99; 0-81)
<b>Meaningful usage data</b>				
Viewed any advice	—	—	616 (41.32)	—
Viewed Doctor's Questions advice	—	—	244 (16.37)	—
Viewed Treatment Options advice	—	—	297 (19.92)	—
Viewed Common Questions advice	—	—	372 (24.95)	—

<sup>a</sup>Not collected.

<sup>b</sup>TPB: theory of planned behavior.

<sup>c</sup>PBC: perceived behavioral control.

<sup>d</sup>PETS: Problematic Experiences of Therapy Scale.

<sup>e</sup>PEI: patient enablement index.

## Describing and Defining Usage

### *What Type of Usage Is Meaningful to the Intervention?*

Summative measures of usage for the number of log-ins, time spent on the intervention, and number of pages viewed were examined (Table 1). The number of log-ins includes completing interim questionnaires every 4 weeks (when intervention content may not have been viewed). The number of pages viewed and time spent on the intervention varied depending on the size and required interaction for each component (Figure 1). In addition, the only intervention pages that contained theory-based behavioral change techniques were the advice pages in each of

the 3 components, meaning that only users who viewed an advice page received support in self-caring for their symptoms. On this basis, having viewed an advice page from any of the components was considered a meaningful way of examining usage.

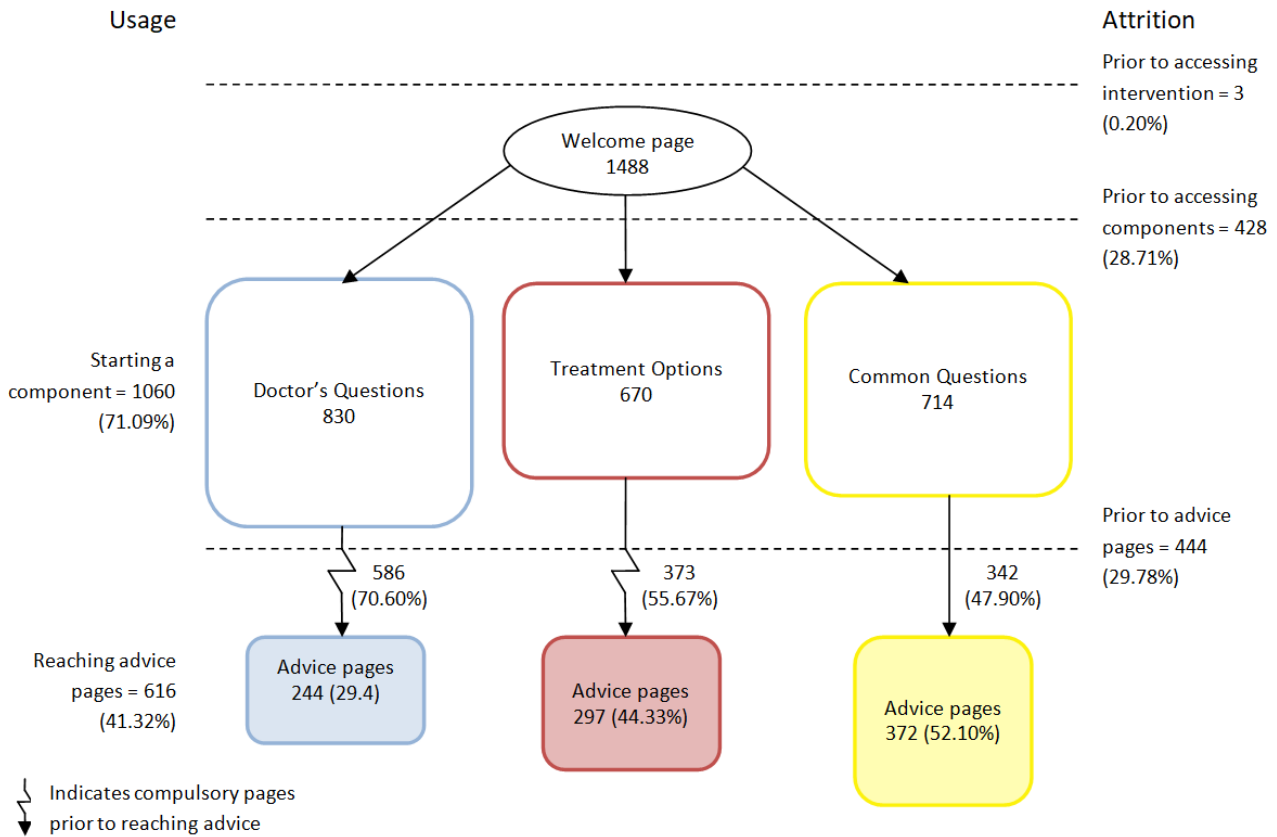
### *How Many People Reached Advice Pages and When Were They Viewed?*

Approximately 42.32% (616/1491) of users viewed at least one of the advice pages (Figure 3; Table 1). For views by component, a total of 913 views indicated that almost half of the 616 users viewed >1 component (297/616, 48.2%). The level of attrition before accessing the 3 components (428/1491,

28.71%) was similar to the attrition within each component before reaching an advice page (444/1491, 29.78%). *Doctor's Questions*, the component with the most pages, was accessed by most users and saw the highest attrition. Of the users who

viewed advice pages, the highest proportion (478/616, 77.6%) did so during their first log-in, having just completed the baseline questionnaire.

**Figure 3.** Numbers of users reaching or leaving components and advice pages.



**Did Usage Experiences Differ for Users Who Viewed or Did Not View Advice Pages?**

Scores for PETS [23] at 24 weeks revealed that users who had not viewed advice pages were more likely to report that the intervention made their symptoms worse (MD 0.260, 95% CI 0.100-0.420); they were uncertain regarding how to use the intervention (MD 0.289, 95% CI 0.116-0.462); and they experienced more practical problems that prevented them from accessing the intervention, such as forgetting or being too tired or busy (MD 2.57, 95% CI 0.082-0.431). Users who had viewed advice pages and those who had not held equivalent positive beliefs regarding the efficacy of the intervention (MD 0.161, 95% CI -0.038 to 0.361).

**Testing the Logic Model**

**Hypothesis 1: Viewing Advice Pages Predicts Increased Enablement**

Users who viewed an advice page were more likely to report increased understanding and ability to cope with their illness as a result of having participated in the study compared with users who did not view advice pages (Table 2). When examined by individual components, the difference in enablement scores between users who viewed an advice page from *Treatment Options* and those who did not was great enough to be practically significant.

**Table 2.** CIs comparing scores for enablement at follow-up between users who did or did not view advice pages (n=952).

Component viewed	Not viewed advice pages		Viewed advice pages		Mean difference (95% CI)
	Values, n (%)	Values, mean (SD)	Values, n (%)	Values, mean (SD)	
Any	532 (55.9)	1.65 (3.10)	420 (44.1)	2.12 (2.92)	0.469 (0.082 to 0.856)
Doctor's Questions	785 (82.5)	1.78 (3.04)	167 (17.5)	2.22 (2.97)	0.432 (-0.074 to 0.938)
Treatment Options	755 (79.3)	1.68 (2.99)	197 (20.7)	2.55 (3.08)	0.875 (0.402 to 1.348)
Common Questions	683 (71.8)	1.79 (3.12)	269 (28.3)	2.04 (2.79)	0.258 (-0.170 to 0.686)

### **Hypothesis 2: Baseline User Characteristics Predict Viewing Advice Pages**

Users were more likely to view advice pages if they had stronger intentions to use and follow the website advice and stronger

beliefs in their ability to self-manage their illness (Table 3). The number of times a user had visited their GP for an RTI in the year before the trial was the strongest predictor for viewing advice pages. Other characteristics measured at baseline were not predictive of viewing advice pages.

**Table 3.** Variables predicting viewing or not viewing advice pages.

Predictors	$\beta$ (SE)	Wald test ( <i>df</i> )	<i>P</i> value	Odds ratio (95% CI)
Age	-.003 (0.004)	0.5 (1)	.47	0.997 (0.988-1.005)
Gender	-.037 (0.118)	0.1 (1)	.75	0.963 (0.764-1.215)
Health anxiety	.020 (0.012)	2.7 (1)	.10	1.020 (0.996-1.045)
<b>Theory of planned behavior</b>				
Subjective norms	-.008 (0.023)	0.1 (1)	.72	0.992 (0.948-1.037)
PBC <sup>a</sup>	.021 (0.028)	0.6 (1)	.44	1.022 (0.967-1.079)
Intentions	.064 (0.023)	7.5 (1)	.006	1.066 (1.018-1.116)
Health locus of control	.011 (0.013)	0.8 (1)	.37	1.011 (0.987-1.036)
Krantz Health Opinion Survey	.018 (0.007)	6.7 (1)	.009	1.018 (1.004-1.032)
Past general practitioner visits	.300 (0.078)	14.9 (1)	<.001	1.349 (1.159-1.571)

<sup>a</sup>PBC: perceived behavioral control.

### **Hypothesis 3: Changes in Modifiable User Characteristics Mediate the Relationship Between Viewing Advice Pages and Enablement**

Viewing advice pages did not predict changes in any of the measured modifiable user characteristics over the trial period (norms:  $F_{1,784}=0.117$ ;  $P=.73$ ; PBC:  $F_{1,798}=1.089$ ;  $P=.30$ ; health locus of control:  $F_{1,957}=0.142$ ;  $P=.71$ ; Krantz Health Opinion Survey:  $F_{1,964}=1.037$ ;  $P=.31$ ). Changes in these modifiable characteristics do not mediate the observed association between viewing advice pages and enablement.

Strengthened normative beliefs (ie, that friends and family support using and following intervention advice) and increased perceived ease of using and following the advice over the trial period were positively correlated with enablement ( $r_s=0.140$ ;  $P<.001$  and  $r_s=0.269$ ;  $P<.001$ , respectively). No relationships were observed between enablement and changes in reported dependence on HCPs (health locus of control:  $r_s=0.024$ ;  $P=.47$ ; Krantz Health Opinion Survey:  $r_s=0.003$ ;  $P=.91$ ).

## **Discussion**

### **Principal Findings**

This paper presents a process evaluation of data previously collected in an RCT of the *Internet Dr* intervention designed to enable users to appropriately self-care for RTIs [7]. The aims of the evaluation were to identify meaningful measures of usage (ie, types or patterns of interaction that are relevant to the structure and theory-based content of the intervention) with which to undertake a systematic process analysis and to examine the parts of the intervention that worked, for whom, and in what context.

This evaluation provides a clear example of when summative measures of usage (eg, number of log-ins and time spent on the intervention) would not provide the fine-grained details necessary to understand how the intervention worked; instead, it identifies usage metrics that are relevant to the structure and theory-based content of *Internet Dr*. With regard to the number of log-ins, these include users who logged in to complete interim study questionnaires as well as users who were accessing the intervention. Therefore, inferential analyses using the number of log-ins would capture users' engagement with the trial as well as with the intervention. Alternatively, if the number of pages viewed had been analyzed and found to be associated with increased enablement, it is unclear what this would have meant or how it may be applied to improve the intervention. Each of the components varied in size, so that users who chose the *Doctor's Questions* component may have viewed 5 pages and then left the component without having reached any advice on self-caring (Figure 1). In comparison, if users who visited the *Common Questions* component also viewed 5 pages, they would have been able to access 4 pages of advice. Without knowing what the content of the pages is, the number of pages viewed provides little insight into how users experienced increases in enablement or for improvements to the website. Instead, as the advice pages are the only content aimed at supporting users to self-care for their illness, viewing advice pages from the different components was identified as the most meaningful metric with which to analyze the use of the intervention. Users who viewed any advice page were more likely to report higher levels of enablement at 24 weeks compared with users who did not. Although this effect was fairly small, when analyzed by individual components, it was apparent that viewing an advice page from *Treatment Options* led to a practically significant increase in enablement. Therefore, viewing an advice page represents the minimal type and amount



of usage required to improve outcomes and may be described as *effective engagement* with the intervention [18].

The 3 components were initially accessed by similar volumes of users, with almost half accessing >1 component. This suggests that offering a variety of content may be useful to maximize the number of users who reach the key features of an intervention. Most users (478/616, 77.6%) who viewed advice pages did so during their first log-in, having just completed the baseline questionnaire. Given that this figure represents more than half of all users in the intervention group who reported having an RTI during the 24-week trial (852/1491, 57.14%), it is unlikely that everyone accessing advice was experiencing an RTI at that precise time. Most if not all users will have experienced RTIs in the past and become familiar with any symptoms they found challenging. This prior experience could have supported *well* users to engage fully with the intervention and access pertinent advice without having to experience the symptoms at that point. This would also be the case for many other common ailments, which suggests that promoting intervention usage when users are well would be effective for self-caring for future minor ailments, as seen with RTIs.

As past behavior is typically a strong predictor of future behavior [33], and previous GP visits reinforce a patient's decision to return to the GP in future [1], it was anticipated that users who had consulted their GP for an RTI in the year before the study would be less likely to use the intervention and view advice pages. However, the process analysis shows the reverse to be true, with these target users being more likely to view advice pages. As using *Internet Dr* has already been shown to lower the number of GP visits [7], it is probable that reaching these users was key to achieving this.

Viewing advice pages is important for increasing users' enablement to self-care, with *Treatment Options* advice showing the greatest impact. However, users' characteristics measured across the study provide only a limited explanation of the psychological changes that led to better enablement. *Internet Dr* content is underpinned by social cognitive theory (*Treatment Options*) and Leventhal's common sense model [27] (*Doctor's Questions* and *Common Questions*). The TPB was selected, along with measures of beliefs regarding the necessity of HCPs to manage illness to measure psychological changes across the study. Azjen cites Bandura's definition of self-efficacy as the basis for the construct of PBC within the TPB [34]. Therefore, users who accessed *Treatment Options* content based on social cognitive theory were expected to report increased PBC; however, this effect was not found. Bandura [35] stipulates the use of measures of self-efficacy with social cognitive theory, and considering that PBC encapsulates several constructs [36], a general self-efficacy measure may be preferable for future studies of this nature [37]. Since the development of *Internet Dr* in 2008, further research has identified additional barriers to self-care (eg, perceptions of illness severity, not considering alternative options, and cost implications of paying for unprescribed medication [4]). Although these were not intentionally targeted within *Internet Dr*, the increases in enablement and the lower GP visits suggest that the theoretically underpinned content may have been effective in addressing some of these additional barriers. Future research, including

measures of user characteristics that better reflect these barriers, may provide a more in-depth explanation of the association between usage and enablement.

In addition to examining users who viewed advice pages, it is also important to consider that approximately two-thirds of users in the intervention group did not access any advice pages. The first point of attrition for these users occurred at the *Welcome Page*, with just under one-third of users not progressing any further (Figure 3). An explanation for this might be that many of these users were not ill at the time and intended to return to the intervention if they experienced an RTI. However, these findings suggest that using advice pages when users are well can still be of benefit. Users who did not view advice pages were also more likely to report practical barriers to usage (eg, too tired or busy and forgetting). Applying these findings to future dissemination means that patients can be encouraged to access the intervention at a time that is convenient to them and not have to wait until they are experiencing symptoms. This could be reiterated to users by adding a message to the *Welcome Page*.

The second incidence of attrition occurred within the components, with almost another one-third of users starting a component but not reaching an advice page. The highest proportion of this attrition occurred in the *Doctor's Questions* component, which is the largest component. This section includes a compulsory symptom checker with up to 10 pages of questions necessary in any intervention for minor ailments to ensure that serious infections in need of urgent medical attention are identified. Although these questions could not be omitted, the format and layout could be amended to minimize the burden on the user and subsequent attrition. For example, streamlining content by combining pages or motivating users to continue by including page numbers or breadcrumbs to show progress and location may have lowered attrition. Interestingly, these compulsory pages were not raised as a concern in qualitative evaluations conducted during the development phase [6]. This highlights the ability of process evaluations to establish design precedents from post hoc data analysis, such as ensuring that users are motivated and able to access the active ingredients of interventions with minimal effort.

## Limitations

Scores for increased enablement were low, with most users selecting *same or less* (0), which probably reflects that most users have experienced and successfully self-cared for RTIs previously. This is supported by the finding that users who had failed to self-care before the study were more likely to use advice pages. The PEI scoring was problematic as there were only 3 response options available, which did not allow users to distinguish between no change and deterioration in enablement. The resultant skew in scores meant that regression analyses were inappropriate for examining variables predicting enablement. Recent studies have measured PEI using Likert scales of  $\geq 5$ , allowing for multiple, finer-graded levels of response [38,39].

The purpose of this study was to examine the psychological outcomes of intervention users and to explain the effectiveness of the intervention. As a result of the problematic PEI scoring,

we considered examining the relationship between the usage of advice pages and the behavioral outcome of GP visits. However, this was not possible for several reasons. Almost half of the users who had viewed an advice page accessed advice from >1 component, and some users viewed several advice pages within a component, meaning that it was not possible to match the advice received to the action taken. In addition, most users had accessed advice before becoming ill. Finally, users who were advised to contact NHS Direct may have been recommended by NHS Direct to contact their GP; however, this was not captured in either self-report data or patients' GP notes.

Initial RCT uptake by patients was 6.95% (3044/43,769), suggesting that participants were more willing to engage in this type of research and may not be representative of the wider population. Therefore, participant and nonparticipant characteristics were compared for the RCT analysis, and as the index for multiple deprivation showed that participants were less deprived than the wider population, the RCT results were controlled for this variable. However, as the process evaluation was a secondary analysis of the data collected in the RCT, identifiable details (ie, home address) were removed from usage data; as a consequence, it was not possible to control for possible effects that lower levels of deprivation may have had on behavioral engagement.

*Internet Dr* was developed and trialed >10 years ago, and since that time, digital intervention technology has advanced considerably. In addition to the recommendations from the usage analysis, before further dissemination activities are undertaken, the intervention would need further testing and development to

ensure that current accessibility guidelines are met and the content is mobile friendly.

## Conclusions

The findings from the process evaluation demonstrate the advantages of using systematic methods for analyzing digital intervention usage. By identifying specific metrics that are meaningful to the intervention structure, theory-based content, and target behavior, it was possible to examine how the intervention was effective, for whom, and in what context, and to provide specific recommendations for improving intervention design and implementation. Inferential analyses of usage identified that viewing advice pages from the *Internet Dr* intervention is effective at increasing the enablement of self-care for the symptoms of RTIs. Having identified content that is crucial for behavior change, this provides the opportunity to ensure that prior compulsory pages are streamlined to maximize the number of users reaching these *active ingredients*, thereby minimizing attrition. However, streamlining within components does not necessarily mean reducing the number of components available as users used the choice. These findings suggest that viewing advice pages before having an RTI encourages users to self-care for future symptoms. This means that for *Internet Dr*'s dissemination, users may be encouraged to access the intervention at their convenience rather than wait for the occurrence of an illness. The intervention was effective at reaching the target population of users who had previously failed to self-care for their symptoms and consulted their GP. Taking these findings into consideration, *Internet Dr* provides a model for future digital interventions aiming to increase self-care for other minor ailments.

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## Conflicts of Interest

None declared.

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### Multimedia Appendix 1

Analyzing and Measuring Usage and Engagement Data framework, stage 1 checklist: familiarization with the data. Completed for Internet Dr.

[\[PDF File \(Adobe PDF File\), 1279 KB - formative\\_v6i1e24239\\_app1.pdf\]](#)

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### Multimedia Appendix 2

Analyzing and Measuring Usage and Engagement Data framework, stage 2 checklist: selecting use variables and generating research questions. Completed for Internet Dr.

[\[PDF File \(Adobe PDF File\), 1175 KB - formative\\_v6i1e24239\\_app2.pdf\]](#)

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### Multimedia Appendix 3

Analyzing and Measuring Usage and Engagement Data framework, stage 3 checklist: preparation for analysis. Completed for Internet Dr.

[[PDF File \(Adobe PDF File\), 718 KB - formative\\_v6i1e24239\\_app3.pdf](#)]

#### Multimedia Appendix 4

Psychological measures collected on the web at baseline and follow-up.

[[PDF File \(Adobe PDF File\), 848 KB - formative\\_v6i1e24239\\_app4.pdf](#)]

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## Abbreviations

**AMUsED:** Analyzing and Measuring Usage and Engagement Data



**GP:** general practitioner  
**HCP:** health care professional  
**MD:** mean difference  
**NHS:** National Health Service  
**NIHR:** National Institute for Health Research  
**PBC:** perceived behavioral control  
**PEI:** patient enablement index  
**PETS:** Problematic Experiences of Therapy Scale  
**RCT:** randomized controlled trial  
**RTI:** respiratory tract infection  
**TPB:** theory of planned behavior

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Original Paper

# The Challenges in Designing a Prevention Chatbot for Eating Disorders: Observational Study

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## Abstract

**Background:** Chatbots have the potential to provide cost-effective mental health prevention programs at scale and increase interactivity, ease of use, and accessibility of intervention programs.

**Objective:** The development of chatbot prevention for eating disorders (EDs) is still in its infancy. Our aim is to present examples of and solutions to challenges in designing and refining a rule-based prevention chatbot program for EDs, targeted at adult women at risk for developing an ED.

**Methods:** Participants were 2409 individuals who at least began to use an EDs prevention chatbot in response to social media advertising. Over 6 months, the research team reviewed up to 52,129 comments from these users to identify inappropriate responses that negatively impacted users' experience and technical glitches. Problems identified by reviewers were then presented to the entire research team, who then generated possible solutions and implemented new responses.

**Results:** The most common problem with the chatbot was a general limitation in understanding and responding appropriately to unanticipated user responses. We developed several workarounds to limit these problems while retaining some interactivity.

**Conclusions:** Rule-based chatbots have the potential to reach large populations at low cost but are limited in understanding and responding appropriately to unanticipated user responses. They can be most effective in providing information and simple conversations. Workarounds can reduce *conversation errors*.

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**KEYWORDS**

chatbot; eating disorders; digital mental health; prevention; intervention development

## Introduction

### Eating Disorders Prevention

Eating disorders (EDs) are serious psychiatric disorders associated with high morbidity and mortality, marked

psychosocial impairment, and poor quality of life [1]. A recent meta-analysis found EDs prevalence rates of about 8% in women in the Western world, as well as evidence that these disorders are prevalent worldwide [2]. However, fewer than 20% of individuals who develop EDs receive treatment [3,4]. EDs prevention plays a vital role to help bridge the treatment gap.

Fortunately, a number of risk factors for EDs onset have been identified, including internalization of the thin-body ideal and having many weight and shape concerns [5-7]. Weight and shape concerns and internalization of the thin-body ideal affect many young women. In one study, about 23% of college-age women had elevated levels of weight and shape concern that put them at risk for EDs [3]. Therefore, prevention of EDs is of utmost importance given the prevalence and low treatment rates of affected individuals. Interventions designed to target the highest risk groups have been shown to reduce risk factors and even onset [7-9]. For instance, a recent meta-analysis found a 38% decrease in incidence in the intervention groups compared with controls with small to moderate effects on EDs symptoms and risk factors, with most of the evidence coming from internet-based studies [8].

On the assumption that internet-based programs can provide easy and convenient access to EDs prevention, we developed a cognitive behavior-based program called Student Bodies (C). Human-moderated (guided) versions of Student Bodies have been shown to be associated with moderate improvements in ED-related attitudes, including reductions in negative body image and the desire to be thin [9-12]. Human moderators helped reinforce the use of the program by providing support and feedback. When comparing a moderated and an unmoderated version of the Student Bodies program, it was found that some guidance and encouragement from a human moderator improved outcomes [13]. However, providing human moderation to prevention programs incurs cost and is not a viable approach to reaching large populations who might benefit from EDs risk reduction.

### Chatbot Development

As such, we considered ways to provide *automated moderation* and specifically considered whether a chatbot could provide some automated interactivity, mirroring 1 aspect of human moderation. Chatbots are computer programs that can provide information and simulate human conversations [14]. Chatbots are widely used in the United States for several activities (eg, Siri, Alexa, or service centers) [15]. In recent years, many chatbots have been developed to provide psychoeducational and mental health interventions [16]. Chatbots also have the advantage of being delivered via mobile devices. As of 2019, 96% of American adults aged between 18 and 29 years owned a smartphone [17], smartphone users have an average screen time of 3 hours 10 minutes per day [18], and millennials spend nearly 50 minutes each day texting [19]. Research has found that, relative to an internet browser-based program, a chatbot-based program was associated with higher ease of use and increased response rate [20,21]. While chatbots in various forms are becoming widespread, few studies have evaluated their effectiveness in the prevention of mental health problems [14,22,23].

Chatbots can be developed in several ways [24-26]. One approach is to write out the basic conversations, including responses to user inputs, and then continue to refine the conversations based on user and chatbot inputs. In other words, it is necessary to develop a hand-curated, rule-based chatbot. An advantage of this is that the responses can be prescribed

and controlled by the investigators. A disadvantage is that the conversations are predefined and thus limited. Another basic approach is to use artificial intelligence to generate responses in which the chatbot learns responses based on exemplar data [27]. Exemplar data for generative chatbots can be formed through prior chatbot interactions and can be curated through both user and expert ratings [28]. Generative chatbots work by mimicking the semantic patterns of the pre-established narrative text on which it is trained. An advantage is that conversations can be dynamic and fluid, adopting a wide repertoire, but it requires large, curated databases as well as considerable technical expertise. In addition, many chatbots have retrieval-based algorithms running to identify potential user inputs with authored text (ie, sometimes called intent-matching). In mental health chatbots, they can be used in areas outside the scope of the core content, such as suicidality [29,30].

Unfortunately, most researchers and providers who might consider the benefit of developing a chatbot do not have the resources to develop an artificial intelligence-based chatbot. However, rule-based chatbot authoring programs are becoming available and can be used without extensive programming experience (eg, Rasa [31] and Google's DialogFlow [32]). Such an approach also represents a reasonable first-line approach to the initial development of a chatbot for a specific purpose. Therefore, we decided to use this approach to create a chatbot for Student Bodies in an effort to develop a scalable and low-cost resource for those in the United States who might benefit from Student Bodies. Our goal is to create an automated version of the program called the Body Positive program. Body Positive is moderated by a chatbot called Tessa (TM), developed by a private mental health chatbot company, X2AI.

The development of EDs prevention chatbots is in its infancy. A systematic review in 2019 found that only 1 out of 41 mental health chatbots targeted EDs [33]. Since the publication of the 2019 systematic review, Beilharz et al [34] published a paper on the acceptability and feasibility of a chatbot that provides psychoeducation and coping skills targeting people with body image and eating concerns. Despite increasing attention on the use of chatbots for mental health treatment and prevention, there is relatively little information in the literature about the process of developing and refining mental health-related rule-based chatbots. This could be of great value for those designing such chatbots in the future. Therefore, the objective of this study is to share our examples of challenges and workarounds in designing and refining a rule-based EDs prevention chatbot that targets young adult women at risk of developing an ED, to be evaluated in a separate randomized trial.

## Methods

### Body Positive

Body Positive is an EDs prevention program delivered by a chatbot, Tessa, that targets women between the ages of 18 and 30 years who are at risk for developing an ED. Body Positive was designed to be tested in a randomized controlled trial, the results of which were published in a separate paper [35]. The procedures and materials used in this study were approved by the institutional review board of Palo Alto University. All

procedures performed in this study were in accordance with the ethical standards of the 1964 Declaration of Helsinki and its later amendments or comparable ethical standards.

Body Positive was modified from the original Student Bodies [10,36] prevention program. The final version of Body Positive consisted of an introduction and 8 sessions. The introduction covered information about the program, privacy, protocol for crisis, and the limitations of the chatbot (eg, not moderated by a person in real time and will say things that may seem off). The 8 conversations covered the core content of the original Student Bodies program, which included content that addressed challenging the thin-body ideal, media literacy, 4Cs (comparisons, conversations, commercials, and clothing), healthy eating, critical comments, exercise, bingeing, and maintenance [13]. One common strategy for developing chatbots is to use a rule-based approach in which investigators create and modify the scripts and algorithms that drive the chatbot's conversation [37]. This is the approach we followed. These conversations were programmed into a chatbot, and the chatbot initiated each conversation in a predetermined order. Participants were encouraged to complete 2 conversations a week.

The chatbot that delivered and moderated Body Positive was fully automated. In addition to the Body Positive-specific modules, there were other pre-existing modules (ie, a crisis module and a module that was deployed if cursing was detected) and functions (ie, opting out of program reminders and recognizing and responding to questions) available from the wider X2AI chatbot platform that were triggered based on keywords (eg, "Unsubscribe" or "?") in users' comments. Chatbot conversational dynamics were meant to mimic natural text-based conversations. For example, the chatbot sent a message, or sometimes a few messages in succession, and then the users would respond, as instructed in the introduction, to continue the conversation. The communication was synchronous, as the chatbot was designed to respond to each of the user comments within seconds.

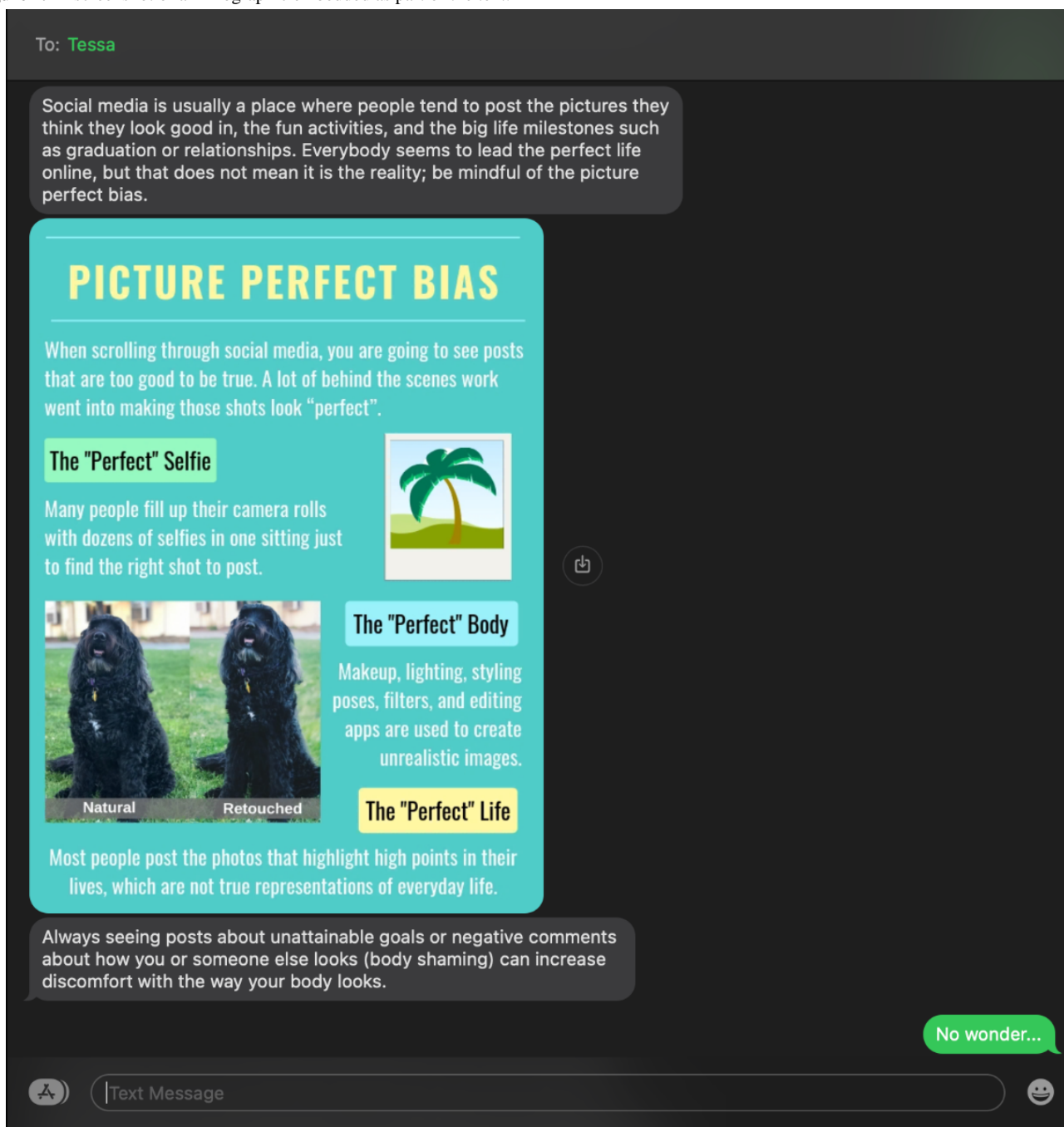
## Guiding Principles for Chatbot-Specific Content Development

There were several general principles that guided the process of modifying the Student Bodies content for the interactive chatbot platform.

First, the length of each chatbot response was kept short to align with the texting culture. The standard SMS text message character limit was 160 characters. Therefore, each chatbot response was ideally fewer than 80 characters for short responses or 160 characters for longer sentences. To improve readability, only a maximum of 3 short responses or 1 long response would be sent in a row to keep new content visible on most phone screens without scrolling. A challenge was to provide an adequate discussion of the topics at hand within such word limitations. To help reinforce ideas and to break up *walls* of text, we created a series of infographics (Figure 1) covering material discussed in the sessions that were incorporated in the conversations. Infographics were embedded as part of the SMS text messages where users could view immediately without clicking any links. We encouraged users to take screenshots for later review.

Second, the chatbot responses were designed to convey support and warmth and to be appropriate for most users. We achieved this by providing reinforcement, encouragement, and supportive language. The conversations were designed to be interactive, such that a user could respond to an open-ended question with a sentence. The chatbot also used emojis, in addition to infographics, with the goals of making the program more interesting and aligning with current texting culture or standards [38]. The chatbot had a proprietary artificial intelligence algorithm that detected the valence (positive, negative, and unsure) of user responses, which allowed us to deliver the nuanced responses of warmth and support appropriately.

**Figure 1.** A screenshot of an infographic embedded as part of the text.



Our first priority was to author a rule-based, interactive chatbot (as opposed to a program driven by artificial intelligence), focusing on creating interactivity. We anticipated that we would need to continue to improve the conversations over time, following the process described in subsequent sections. Once this pilot program is evaluated and widely deployed, if proven effective, we would be able to generate more transcript exemplar data. It would then be possible to further improve the core program by using machine learning and related tools.

### Participants

Participants were recruited through web-based social media platforms, such as Facebook and Instagram advertisements, working with Instagram influencers, physical flyers posted on university campuses and other public community settings, and

referrals through the National Eating Disorders Association web-based screen [39] or other ongoing EDs research studies.

A total of 210 participants completed a web-based screening survey [40]. The screen sought informed consent, baseline data, and eligibility. The inclusion criteria included being aged between 18 and 30 years, identifying as female, and screening as at risk for an ED. Participants were excluded if they did not meet the age or gender criteria, were not at risk for an ED, or screened positive for a clinical or subclinical ED. Participants who screened positive for an ED were provided with referral information, including information on how to access the National Eating Disorders Association web-based treatment provider database and helpline. When participants reached out to the chatbot via either Facebook Messenger or SMS text



messaging, the chatbot asked for their user ID and then initiated the introduction conversation.

In addition, 2199 participants accessed the chatbot via either Facebook Messenger or SMS text messaging through social media recruitment. Users did not have to pay to access the chatbot.

## Measures

### *Eating Disorder Risk*

EDs risk was determined using the Weight Concerns Scale [41], a 5-item self-report questionnaire that assesses weight and shape concerns, which has been shown to be a robust indicator of EDs risk [42]. There are three 5-point questions, one 4-point question, and one 7-point question that are transformed to yield a total score range of 0 to 100. High risk was defined as a score of 47 or above on the Weight Concerns Scale, indicating high weight and shape concerns. EDs risk was measured at all time points.

### *Eating Disorder Screen*

ED diagnosis, an exclusion criterion, was measured using the Stanford-Washington University Eating Disorder (SWED) screen [43]. The SWED screen has been shown to have acceptable sensitivity (from 0.90 for anorexia nervosa to 0.55 for purging disorder) and specificity (from 0.99 for anorexia nervosa to 0.78 for subthreshold binge ED) for identifying an ED diagnosis [43,44]. ED diagnosis was measured using SWED screen at baseline only.

### *Transcript Review*

The research team monitored the chatbot's performance by reviewing the transcripts between the chatbot and users at least once a month. Over 150,000 responses (105,000 from the chatbot and 52,129 from users) were reviewed to identify bugs, chatbot responses that were erroneous or problematic, and conversations that did not flow smoothly. Transcripts were reviewed and evenly divided among 7 authors, who were mental health professionals and supervised and trained graduate and undergraduate students in psychology. Transcripts were reviewed monthly between December 2019 and May 2020. Each reviewer identified possible bugs that needed to be fixed and chatbot responses that needed to be improved. We did not create a *threshold* response or rubric but relied on reviewers' judgment that the conversation should be reviewed by the group. Reviewers would present their transcript review findings to the group, focusing on issues that would negatively affect user experience. These issues and possible solutions were then discussed in weekly team meetings. Discussions and changes were monitored and tracked to ensure that they had been implemented. The chatbot content authoring platform was straightforward and accessible, which allowed the research team to easily and independently (ie, without the assistance of the technology partner) make iterative changes to the content and create fixes for minor bugs. In addition, the technology partner was responsive to troubleshooting technical glitches. The research team met with representatives from the company regularly for consultation and to implement major modifications and bug fixes.

### *Time Costs of Transcript Review*

In general, each reviewer was given about 4000 to 5000 lines of transcript (including chatbot informational messages and user comments) each month, which required  $\leq 2$  hours to review. The total time devoted to transcript review was  $\leq 60$  hours over 6 months. In addition, eight 1-hour research meetings were held to review the transcripts and brainstorm solutions. Additional time was also required to implement these changes.

Consistent with Mohr et al [45], our general approach was not to change any of the core content or activities of the program but to improve the users' experience by fixing bugs and reducing problematic chatbot responses through transcript review. Thus, the following section aims to address the problems and challenges we faced, namely, how to provide appropriate reinforcement; how to respond to users' questions; and challenges with comprehensibility, context awareness, and technical issues.

## Results

### Overview

Between September 7, 2019, and May 31, 2020, we received 52,129 user comments from 2409 unique users who responded to the chatbot with at least one message. Participants were recruited from multiple sources. In this study, some interacted with the chatbot anonymously. As a result, demographic data for the entire sample were not reported. From March 10, 2020, onward, after many changes were made, we reviewed 26,305 lines of user comments and found only several minor errors that did not negatively impact users' experience.

### How to Provide Reinforcement

#### *Challenge*

Authoring appropriate responses to nearly all user comments is one of the biggest challenges in creating a chatbot. For instance, our initial goal in creating the chatbot was to provide encouragement to continue with the program through positive responses, for example, "Great!" and "Wonderful!" While the positive responses were appropriate for many user responses, these positive responses did not work for some interactions. For example, when the chatbot asked, "Do you want to commit to NO FAT TALK, say for the next month?" The user replied, "Haha." The prescribed response was "Wonderful! You might want to let your friends know that you are committed to NO FAT TALK for the next month." We also found that positive responses unexpectedly reinforced harmful behaviors at times. For example, the chatbot prompted, "Please share with me a few things that make you feel good about yourself. For example, your humor, grace, personality, family, friends, achievements and more!" The user replied, "I hate my appearance, my personality sucks, my family does not like me, and I don't have any friends or achievements." The chatbot responded by saying, "Keep on recognizing your great qualities! Now, let's look deeper into body image beliefs." See [Table 1](#) for additional examples.



**Table 1.** Additional examples of inappropriate chatbot reinforcement responses.

Issues	Examples	Solutions
Reinforcing potentially harmful behaviors	<ul style="list-style-type: none"> <li>• Chatbot: Now, please take a moment to write about when you felt best about your body?</li> <li>• User 1: I have never felt good about myself.</li> <li>• User 2: When I was underweight and could see my bones</li> <li>• User 3: When I was skinnier I felt better because I could do more. I felt really good about my body when I went to the gym 5-6 days a week.</li> <li>• User 4: I feel best about my body when I ignore it and don't think about it at all</li> <li>• Chatbot: It is awesome that you can recognize a moment when you felt confident in your skin, let's keep working on making you feel this good more often.</li> </ul>	<ul style="list-style-type: none"> <li>• Use of AI<sup>a</sup> valence detection to deliver nuanced responses that match the tone of users' comments (eg, positive, unsure, or negative)</li> <li>• Replacing nonspecific positive responses with neutral statements</li> </ul>
Inappropriate standardized positive response	<ul style="list-style-type: none"> <li>• Chatbot: This next exercise will help you learn to appreciate the many other aspects of yourself. Take a minute to write down a few things that make you feel good about yourself. For example, your humor, grace, personality, family, friends, achievements and more!</li> <li>• User 1: I don't have anything</li> <li>• User 2: Ummmmm I actually kinda hate myself so we're not going to get very far there. I think I'm a selfish piece of crap.</li> <li>• User 3: I can't think of anything.</li> <li>• Chatbot: Keep on recognizing your great qualities! Now, let's look deeper into body image beliefs.</li> </ul>	<ul style="list-style-type: none"> <li>• Use of AI valence detection to deliver nuanced responses that match the tone of users' comments (eg, positive, unsure, or negative)</li> <li>• Replacing nonspecific positive responses with neutral statements</li> </ul>

<sup>a</sup>AI: artificial intelligence.

### Solution

To avoid reinforcing harmful comments, nonspecific and positive responses, for example, "Great!" and "Wonderful!" were mostly removed and replaced with more neutral statements while maintaining a warm tone. For example, the chatbot asked, "Share with me what you can say to yourself to minimize harmful comparisons." The user replied, "Try to focus on the good things you have in common with others." The chatbot responded, "Okay, keep challenging your thoughts when you compare yourself to others unrealistically."

In addition to rewriting 1 standard positive chatbot response for the prompt that asked users to think of positive qualities about themselves, we added more nuanced responses to capture potential negative or ambivalent user comments. For the abovementioned example (eg, "I hate myself..."), the statement, "Sometimes it is difficult to remember the good qualities that you possess. You might consider something positive that someone who knows you well would say about you," was added as a response to encourage and validate users who may be struggling with the prompt and to help users better engage with the content.

The following example highlights the complexity of crafting a positive response that "always works." The chatbot asked, "What is a small healthy eating habit goal you would like to set up before you start your next conversation?" One user replied, "Don't eat." The chatbot said, "Take a moment to pat yourself on the back for doing this hard work, <<USER>>!" The chatbot was later updated to, "Thanks for taking the time to think about this, <<USER>>!" The updated language was specific to

reinforcing the effort put into engaging in the exercise while not directly reinforcing the problematic response, that is, potential food restriction. However, the problematic response, that is, not eating, was not addressed. With many more responses, it would be possible to train the AI to identify and respond better to problematic responses.

### Lesson Learned

It is difficult to write prescribed responses that are appropriate to all the varied comments that users make in response to chatbot questions. Praise words designed to respond to user activities may inadvertently reinforce harmful behaviors.

### How to Respond to Users' Questions

#### Challenge

The script of the chatbot was designed to focus on EDs prevention, and it was unable to handle users' questions or comments that required additional information than what was scripted. For example, the chatbot asked, "Are you willing to take this challenge ['Post a photo that captures something you love about yourself to one of your social media pages with no filters or retouching and use the caption, I am proud of \_\_\_\_']?" The user replied, "Not in this quarantine." The chatbot said, "It is okay that you don't feel ready yet to share an image with all your friends, maybe you can start by posting in a way that is only visible for you or your closest friends, like in a private snapchat story." Even though the chatbot's response was broad and perhaps considered appropriate, it could not address the quarantine comment directly. See [Table 2](#) for additional examples.

**Table 2.** Additional examples of inappropriate chatbot responses regarding users' questions.

Issues	Examples	Solutions
Ignoring users' questions	<ul style="list-style-type: none"> <li>Chatbot: "Now let's think about how you can make the Four C's have a less negative, and rather a more positive impact on your body image."</li> <li>User: "How can I do that?"</li> <li>Chatbot: "I don't yet know how to answer that, but I will do my best to learn as we continue to talk. If you rephrase your response, it will help me help you."</li> <li>Chatbot: "Now let's think about how you can make the Four C's have a less negative, and rather a more positive impact on your body image."</li> </ul>	Redirect users back to the scripted content and acknowledge limitations of chatbot
Unable to provide a response	<ul style="list-style-type: none"> <li>Chatbot: "Take your time with BP to get the most out of our conversations. I recommend that you have two conversations with me a week so that you finish BP in about a month."</li> <li>User: "Okay. So this is the program that I will check in with you about. Do I message you first? Are there reminders/checkpoints?"</li> <li>Chatbot: "I don't have an answer to that yet. Let me think about it for a bit and we can keep chatting in the meantime."</li> </ul>	Redirect users back to the scripted content and acknowledge limitations of chatbot

### Solution

New responses were drafted to redirect users to the scripted content and acknowledge that there was no good answer at the moment. Examples included, "I'll be honest, I'm not sure how to best answer that question right now. Until I do, respond to my previous message to the best of your ability." "I'm still learning so I don't have a good answer for that yet. However, I want to give you an opportunity to reply to my last message."

### Lesson Learned

Rule-based chatbots have a minimal ability to be spontaneous and flexible. Users should be informed of the limitations of the chatbot and be provided realistic expectations.

### Comprehensibility

#### Challenge

Some users did not respond to the chatbot's open-ended prompts, contrary to the expectation that they would type their answers in the chat. The original open-ended questions began with prompts such as, "think about..." or "write down..." Some users responded to the prompt by typing out their comments as expected. However, some users responded to the prompt by

simply saying "done," "Should I type them?" or "I wrote some stuff down." As the prompts did not explicitly ask users to type their answers out in the chat, we were unable to determine if "done" or "okay" meant that the users were disengaged or, alternatively, that they did engage with the prompt but did not explicitly write their answers in the chat (as suggested by this user's comment: "I wrote some stuff down").

Another challenge is that the chatbot's responses may be misinterpreted at times. One of the prompts was "Can you think of people that you find attractive who are happy and who are not thin?" If the user replied "no," the chatbot would say "This is a common misinterpretation." We noticed that this exchange generally worked well when a user simply replied with "no." However, we observed a few comments such as these: "They are reality if you look around at our society. This is why CBT is dumb. There's no room for being a realist and certainly no room for cynicism" and "Yes but being fat is not healthy." If users responded with more than a simple "no," the response, "This is a common misinterpretation," could have been easily misunderstood by the user. Users may have thought that the chatbot was saying that the content of their comment was a common misinterpretation, which was not what we intended to communicate. See [Table 3](#) for additional examples.

**Table 3.** Additional examples regarding comprehensibility of chatbot responses.

Issues	Examples	Solutions
Insufficient instructions	<ul style="list-style-type: none"> <li>Chatbot: "Another idea: a lot of people have decided to commit themselves to 'NO FAT TALK' about themselves or others. NO FAT TALK can be helpful for all of us. Do you want to commit to NO FAT TALK, say for the next month?"</li> <li>User: "What is no fat talk?"</li> <li>Chatbot: "I may have an answer for you in time, but the right response is not coming to me at the moment. Let's take a step back."</li> </ul>	Rewrite prompts to be more explicit and specific
Unable to provide clarifications	<ul style="list-style-type: none"> <li>Chatbot: "Okay! You have probably noticed that you are full when you feel satisfied, lack interest in food, or feel like eating slower. Often when people are distracted or under stress, they stop paying attention to their body and overeat. If you do find yourself overeating, remember to pay attention to your body's signals."</li> <li>User: "So do I eat when I'm hungry or 3 meals a day and two snacks?"</li> <li>User: "Because those aren't the same"</li> <li>Chatbot: "Here is a tool to help you assess when you are hungry or full: The hunger scale. Feel free to save the image to your phone and review it later! It can serve as a good reminder about how to assess your level of hunger and your need for more (or less) food during the day."</li> </ul>	Rewrite prompts to be more explicit and specific

**Solution**

To minimize the likelihood of misinterpretation, prompts were rewritten to be more specific. Prompts such as “think about...” were changed to “please share with me...” to be more explicit about asking users to type their answers in the chat. Other ambiguous responses were also rewritten to be more specific, for example, “It is a common misperception that you can’t be happy and attractive without being thin.”

**Lesson Learned**

Chatbot responses could be misinterpreted. Authoring explicit and foolproof chatbot responses helps to improve comprehensibility.

**Context Awareness**

**Challenge**

The chatbot sometimes misunderstood users because it took users’ comments literally, without considering the context or tone. For example:

Chatbot: Think of a recent conversation where negative body talk came up. Please share with me what you could do next time to avoid it or respond differently...

User: I will let my mind move on and recognize I’m only hurting myself with these conversations.

Chatbot: I am concerned, <<user>>. Have you had any recent thoughts about taking your life?

User: No.

Chatbot: That is good to hear, <<USER>>. I just want to make sure you are safe! I won’t keep you if you need to run. Do you want to stop talking?

User: No.

The conversation continued in a loop for 10 more lines before the user said, “I broke the bot.” The user then ended the conversation and did not return. The phrase “hurting myself” triggered the chatbot’s crisis module from X2AI’s broader system. Throughout the study, the crisis module was triggered 9 times. The chatbot failed to understand that the user was not implying self-harm and the comment was not an actual risk situation.

Another example was, “Think of a recent conversation where negative body talk came up...” The user said, “I could change the subject.” The chatbot said, “Got it, we can do something different. Hi there. My main purpose right now is to support you as you work through the Body Positive program...” The user said, “No I meant that’s how I would respond.” What should have happened was that the chatbot should have treated this as a regular comment and moved on to the next line. However, the chatbot interpreted “change the subject” as a command to leave the conversation without knowing that the user meant changing the negative body talk conversation in response to the prompt. See [Table 4](#) for additional examples.

**Table 4.** Additional examples regarding context awareness.

Issues	Examples	Solutions
Misunderstanding user’s use of swear word in the context of a quote	<ul style="list-style-type: none"> <li>• Chatbot: Please share a little bit about someone in your life who has been known to make critical comments about your body and how you might use PERC to respond to them.</li> <li>• User: My brother likes to laugh about my tummy. Usually I’d say f...k you and laugh at his tummy instead.</li> <li>• Chatbot: That’s not so nice to hear. Can we continue respectfully?</li> <li>• User: Yes?</li> </ul>	Only the essential content and crisis module were active to minimize disruptions
Did not respond to potentially inappropriate response	<ul style="list-style-type: none"> <li>• Chatbot: What’s one way you can reduce triggers related to clothing?</li> <li>• User: Be a nudist</li> <li>• Chatbot: I hear you, keep thinking of ways you can reduce triggers as we continue through Body Positive, alright?</li> </ul>	Only the essential content and crisis module were active to minimize disruptions

**Solution**

We disabled the chatbot’s ability to recognize and respond to trigger words that are irrelevant to Body Positive in order to focus the chatbot on content delivery and minimize interruptions. For example, the chatbot was modified to ignore trigger words such as “change the subject.” We decided to keep the crisis module active, as it might identify a “true crisis,” but there remains the possibility that this module could be triggered in error.

**Lesson Learned**

Ruled-based chatbots are limited in interpreting complex comments because they do not always delineate the context. Until natural language processing technology reaches maturity,

keeping only the essential content and modules helps to minimize disruptions.

**Technical Issues**

**Challenge**

We encountered several technical issues, such as the chatbot being occasionally unable to verify a user’s ID and incorrectly categorizing positive and negative answers, as well as issues such as conversation loops, opt-out glitches, conversation routing errors, and reminder errors (see [Table 5](#) for examples). These technical issues often lead to user frustration and, at times, dropouts. Some of the glitches were caused unexpectedly as we made modifications to the chatbot. For example, the opt-out malfunction occurred only after we implemented a system-wide reminder to users who did not input an ID in mid-January 2020.

**Table 5.** Examples of technical issues encountered.

Errors or glitches	Examples
Occasionally unable to verify user ID	<ul style="list-style-type: none"> <li>• Chatbot: Hi, did you end up taking the eligibility survey for this study?</li> <li>• User: Yes i did</li> <li>• Chatbot: Okay, if you have a User ID #, please enter it so you can get started!" and "Okay, were you enrolled in this study?"</li> <li>• Chatbot repeated this loop twice</li> <li>• User finally entered ID: &lt;&lt;USER ID&gt;&gt;</li> <li>• Chatbot asked "Okay, were you enrolled in this study?" 5 more times</li> <li>• User did not return</li> </ul>
Categorized positive and negative comments incorrectly	<ul style="list-style-type: none"> <li>• Chatbot: Are you willing to take this challenge?</li> <li>• Users: No, sorry</li> <li>• Chatbot mistakenly categorized the comment as a positive answer, saying: "Great! Posting about positive body image will not only bring authenticity to your post but might also be a positive reminder for the people who follow you."</li> <li>• It should have been categorized as a negative response and responded with, "It is okay that you don't feel ready yet to share an image with all your friends, maybe you can start by posting in a way that is only visible for you or your closest friends, like in a private snapchat story."</li> </ul>
Conversation loops	<ul style="list-style-type: none"> <li>• User: I finished the list of commands already</li> <li>• Chatbot: I hear you, &lt;&lt;USER&gt;&gt;. My main purpose right now is to support you... Let's go back to BP, okay?</li> <li>• User: Bye</li> <li>• Chatbot sent out the list of conversation commands</li> <li>• User: I have a question</li> <li>• Chatbot: I hear you, &lt;&lt;USER&gt;&gt;. My main purpose right now is to support you... Let's go back to BP, okay?</li> <li>• User: I have a question Tessa</li> <li>• Chatbot sent out the list of conversation commands again</li> <li>• User: So if I tell you something are you the only person that'll know</li> <li>• Chatbot: I hear you, &lt;&lt;USER&gt;&gt;. My main purpose right now is to support you... Let's go back to BP, okay?</li> <li>• User: "Omg," "F...k this," "Bye"</li> <li>• Chatbot: Talk to you later</li> <li>• User: Hmu when u get a brain</li> </ul>
Opt-out glitch (users were not able to stop the chatbot from sending them messages. The unsubscribe function was an integral part of the chatbot that allowed users to opt-out.)	<ul style="list-style-type: none"> <li>• Chatbot: Hey, have you had a chance to complete the eligibility survey for this study?</li> <li>• User: STOP</li> <li>• Chatbot: "I'm sorry &lt;&lt;USER&gt;&gt;," "It sounds like our discussion is not very helpful right now. Would you like to try something else?"</li> <li>• User: "STOP," "GO AWAY," "NO MORE MESSAGES"</li> <li>• Chatbot: It sounds like you prefer that I no longer contact you first. Is that correct?</li> <li>• User: Correct</li> <li>• Chatbot: I understand &lt;&lt;USER&gt;&gt;. You can always reach back out if you change your mind.</li> <li>• Chatbot: Hi there! Have you completed the eligibility survey for this study?</li> <li>• User: F...king opt out you piece of shiy</li> <li>• Exchange went on for 18 more lines before user dropped out</li> </ul>
Occasionally unable to respond to users' commands	<ul style="list-style-type: none"> <li>• User: BPC2 (upon recognizing BPC2, chatbot is supposed to start conversation 2)</li> <li>• One hour later. User said, "are you there?"</li> <li>• Chatbot: Of course! What would you like to talk about?</li> <li>• User: BPC2</li> <li>• Chatbot: Are you ready to start conversation 2?</li> <li>• (Conversation continues correctly)</li> </ul>
Conversation routing Error	<ul style="list-style-type: none"> <li>• Chatbot: ...But in fact, these influencers are paid for promoting these products or brands.</li> <li>• Chatbot: Sorry I got a little too confused there, is it OK if I start over this conversation?</li> <li>• User: Yes</li> <li>• Chatbot: Should we pause our chat for today?</li> <li>• User: Can we talk more?</li> <li>• Chatbot: "Alright, we can continue..." "What feeling would you like to focus on now?"</li> <li>• User: BPC2</li> <li>• Chatbot: Are you ready to start conversation 2?</li> <li>• Same mistake happened again before user restarted the conversation</li> </ul>

Errors or glitches	Examples
Reminder errors	<ul style="list-style-type: none"> <li>• Chatbot: Hi, did you end up taking the eligibility survey for this study?</li> <li>• User: I took it awhile ago.</li> <li>• Chatbot asked, Okay, were you eligible for the study?</li> <li>• User: Yes. Why?</li> <li>• Chatbot: "I'll be honest, I'm not sure how to best answer that question right now. Until I do, respond to my previous message to the best of your ability." "Okay, were you enrolled in this study?"</li> <li>• User: Yes</li> <li>• Chatbot then asked a few more questions...</li> <li>• User: I'm really confused. I met the criteria and received my number.</li> <li>• User then entered "BPC2" twice and was able to start conversation 2</li> </ul>

### Solution

It is difficult to identify all possible technical issues in advance, and thus, identifying technical issues and bugs requires an ongoing review of chatbot transcripts. Systematic and continued review of the transcripts eventually identified most of the bugs, which were then fixed. Importantly, we prioritized addressing technical issues that repeatedly and negatively affected user experience, that is, issues that hampered users' ability to move along the program and increased user frustration and dropouts. Changes in many of these bugs required assistance from the company's engineers to address backend issues.

### Lessons Learned

Bugs are to be expected and need to be monitored. Iterative changes may also generate new and unintended bugs. At times, we found that fixing certain bugs was beyond our expertise and required support from the technology partner. As such, a good working relationship between content developers and technology partners, with clear expectations of both parts, is critical. Identifying and addressing all the bugs can be expensive. We prioritized addressing bugs that negatively affected the user experience.

### Discussion

#### Principal Findings

The goal of this paper was to share our lessons learned through the process of developing and refining an EDs prevention chatbot. Through transcript review, we identified several problems and limitations that are likely to be common with most rule-based mental health chatbots. We implemented various workarounds until we found no further usability issues. We did not provide quantitative data to demonstrate that making these iterative changes might improve program effectiveness because we believe that the iterative changes were important only in terms of face validity. In the absence of these data, the most compelling arguments for making the changes are that doing so might reduce the number of individuals who leave the program because of "frustration," examples of which are provided in [Table 5](#), as well as to avoid compromising the face validity of the chatbot to users. It can be assumed that a negative experience with digital mental health intervention in some cases can potentially demoralize, prevent, or delay help-seeking behaviors. Therefore, optimization is valuable.

### Lessons Learned

Chatbots may be the most effective in providing simple information and interactions. The number of possibilities—and errors—increase exponentially as conversations lengthen and increase in complexity. Until the next chatbot technology breakthrough, the challenge of using a straightforward, rule-based chatbot to address complex body image issues and EDs risk factors remains. In the hope that the development of EDs chatbots can be catalyzed, here are our lessons learned and general recommendations.

First, a regular review of chatbot transcripts is necessary to identify bugs and inappropriate conversations. We believe regular review is necessary even when the program has been *finalized*, as it is possible that technical issues or issues impacting user experience could be introduced unexpectedly after a change is made. This recommendation is consistent with [Beaudry et al \[21\]](#), who noted that significant time and costs are incurred in developing and maintaining mental health chatbots.

Second, having access to chatbot authoring tools to fix minor bugs and to make minor content changes is critical. Complex fixes can be left to platform engineers. A good working relationship with the technology provider is essential for such interdisciplinary collaborations.

Third, it is important to keep track of all changes made in the implementation, from enrollment procedures and recruitment methods to uptake, engagement, helpfulness ratings, and outcome, as well as rationale to determine how effectiveness metrics may be impacted by these various changes. Several guidelines have been published [\[46\]](#). Data should also be collected on potential explanatory variables, such as baseline motivation.

We focused on increasing interactivity and feedback, implementing straightforward intervention approaches, and minimizing the use of longer conversations. However, in doing so, the program would not replicate the "deeper" levels of human-directed conversations that occurred in the [Kass et al study \[13\]](#). Given that conversational errors increase exponentially with more complex interactions, using our approach would be challenging to address complicated topics. Instead, if the chatbot proves effective, the next step would be to use deep learning approaches, for instance, running the chatbot in large populations using more questions and recommendations to generate exemplar data such that the



information can be used to generate an artificial intelligence-driven chatbot to create a better conversation.

It is also worth noting that X2AI includes some generic monitoring functions, for example, to identify suicidal behavior and valence detection, in their system-wide chatbot platform. As such, our chatbot should be considered as a hybrid model (a rule-based chatbot with features of artificial intelligence).

### Limitations

Our method has some limitations. Most notably, we do not know if the iterative changes to the chatbot are necessary from the user's perspective or if they improve the user experience. From our team's perspective, the changes were justified in terms of face validity. Future studies should investigate the impact of improving conversations on users' experiences and the

effectiveness of the program. Second, we did not determine agreement among reviewers based on the number or type of problems identified. However, as our goal was to make the chatbot responses more appropriate, we continued the process until we found no usability errors. Finally, demographic data of the entire sample were not available. Thus, it is unclear how generalizable the results are to other samples.

### Conclusions

Rule-based chatbots have the potential to reach large populations at low cost in providing information and simple interactions but are limited in understanding and responding appropriately to unanticipated user responses. Workarounds can reduce *conversation errors* and minimize user frustration to preserve the face validity of the content.

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### Authors' Contributions

WWC, CBT, and EEFC contributed to the original drafting and design of the paper. NCJ contributed to the data analysis. All authors provided substantial contributions to the conception, design, acquisition of data, and critical drafting and revision of the paper for important intellectual content. All authors approved the final paper to be published.

### Conflicts of Interest

None declared.

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## Abbreviations

**ED:** eating disorder

**SWED:** Stanford-Washington University Eating Disorder

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Original Paper

# Toward Data-Driven Radiation Oncology Using Standardized Terminology as a Starting Point: Cross-sectional Study

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## Abstract

**Background:** The inability to seamlessly exchange information across radiation therapy ecosystems is a limiting factor in the pursuit of data-driven clinical practice. The implementation of semantic interoperability is a prerequisite for achieving the full capacity of the latest developments in personalized and precision medicine, such as mathematical modeling, advanced algorithmic information processing, and artificial intelligence approaches.

**Objective:** This study aims to evaluate the state of terminology resources (TRs) dedicated to radiation oncology as a prerequisite for an oncology semantic ecosystem. The goal of this cross-sectional analysis is to quantify the state of the art in radiation therapy specific terminology.

**Methods:** The Unified Medical Language System (UMLS) was searched for the following terms: *radio oncology*, *radiation oncology*, *radiation therapy*, and *radiotherapy*. We extracted 6509 unique concepts for further analysis. We conducted a quantitative analysis of available source vocabularies (SVs) and analyzed all UMLS SVs according to the route source, number, author, location of authors, license type, the lexical density of TR, and semantic types. Descriptive data are presented as numbers and percentages.

**Results:** The concepts were distributed across 35 SVs. The median number of unique concepts per SV was 5 (range 1-5479), with 14% (5/35) of SVs containing 94.59% (6157/6509) of the concepts. The SVs were created by 29 authors, predominantly legal entities registered in the United States (25/35, 71%), followed by international organizations (6/35, 17%), legal entities registered in Australia (2/35, 6%), and the Netherlands and the United Kingdom with 3% (1/35) of authors each. Of the total 35 SVs, 16 (46%) did not have any restrictions on use, whereas for 19 (54%) of SVs, some level of restriction was required. Overall, 57% (20/35) of SVs were updated within the last 5 years. All concepts found within radiation therapy SVs were labeled with one of the 29 semantic types represented within UMLS. After removing the *stop words*, the total number of words for all SVs together was 56,219, with a median of 25 unique words per SV (range 3-50,682). The total number of unique words in all SVs was 1048, with a median of 19 unique words per vocabulary (range 3-406). The lexical density for all concepts within all SVs was 0 (0.02 rounded to 2 decimals). Median lexical density per unique SV was 0.7 (range 0.0-1.0). There were no dedicated radiation therapy SVs.

**Conclusions:** We did not identify any dedicated TRs for radiation oncology. Current terminologies are not sufficient to cover the need of modern radiation oncology practice and research. To achieve a sufficient level of interoperability, of the creation of a new, standardized, universally accepted TR dedicated to modern radiation therapy is required.

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**KEYWORDS**

terminology; semantic interoperability; radiation oncology; informatics; medical informatics; oncology; lexical analysis; eHealth

## Introduction

### Background

It is a globally accepted concept that data-driven medicine leads to better, safer, and more affordable care. In addition, it is perceived that it is not achievable without the free exchange of data among all members of a health care enterprise [1-3]. From a technical perspective, we have witnessed significant advances in the last decade. More than 160 exabytes of data are seamlessly exchanged among different systems via the internet every day [4]. At its core, internet communication relies on standardized data formats, such as Internet Message Format, XML, and JavaScript Object Notation. Security is ensured through robust encryption algorithms and authentication services, such as the OAuth protocol. Various industries have used the advantages of digitalization to simplify, accelerate, and standardize their work processes. However, data interoperability in health care has yet to reach its full potential [3].

The surge of health care digitalization in the United States during the last decade, supported by 36 billion dollars of government stimulation packages, failed to deliver on the promise of health care advancements. Mainstream media describe the current state of eHealth care records in the United States as an “unholy mess” [5,6]. Conversely, reports on software failures, safety, and security issues in scientific journals are scarce because of entrenched secrecy policies and so-called *gag* clauses that prevent physicians and researchers from publishing [7]. Furthermore, this flawed digitalization has resulted in a dramatic rise in burnout symptoms among health care workers. At least one serious symptom of burnout is recorded in 70% of physicians, a situation that is partly attributable to problems with software usability, user-unfriendly interfaces, one-size-fits-all software approaches, and foremost—to the lack of interoperability [1,8].

Contemporary health care information systems require multiple low-level manual operations, such as copy-pasting information from one interface to another, which often results in erroneous and repetitive work. Furthermore, the lack of interoperability, along with other design issues, is recognized as one of the main reasons for preventable medical errors, preventing the efficient conduct of clinical research and medical education [9-13].

The Healthcare Information and Management Systems Society defines interoperability as the ability of different information systems, devices, and applications to access, exchange, integrate, and cooperatively use data in a coordinated manner within and across organizational, regional, and national boundaries. Furthermore, interoperability is divided into four distinct levels: foundational, structural, semantic, and organizational. The American Standard Code for Information Interchange, Unicode (an information technology standard for the consistent encoding, representation, and handling of text), World Wide Web Consortium, and Health Level Seven govern foundational and structural interoperability levels. Transfer protocols and file

formats used in communication are well established and standardized [14].

Organizational interoperability concerns policies, laws, regulations, and ethical considerations that span from individual actors, across health care facilities and service providers, all the way to state and international levels. The interoperability levels mentioned above are difficult to influence within a daily clinical or research routine. Foundational and technical standards necessary for clinical data exchange are well covered by the Fast Healthcare Interoperability Resources [15], a set of rules describing data formats and elements for exchanging electronic health records. Organizational interoperability refers to the willingness and ability of organizations to transfer data, which in health care are heavily regulated by the authorities that are hard to influence (by ordinary clinicians or researchers).

The semantic interoperability (SI) level is important for patients and clinicians. SI, as defined by the Healthcare Information and Management Systems Society, is a property of systems that share data with unambiguous meanings. More precisely, SI is defined as the underlying models and codification of the data, including the use of data elements with standardized definitions from publicly available value sets and coding vocabularies, providing a shared understanding and meaning to the user [16,17]. Clinical dictionaries, terminologies, or coding systems are structured lists of terms and phrases paired with their definitions or, eventually, codes. Their purpose is to describe the care and treatment of patients unambiguously. Recently, new types of lexical resources, such as ontologies and graph analytic tools, have emerged. They play a significant role in knowledge organization and management, for example, in genome-based research or enterprise business development [18,19].

### Objective

The need for standardized communication in radiation oncology has been well recognized and described by several authors and groups [20-22]. However, little is known about the availability of dedicated radiation oncology lexical resources. This study aims to evaluate the current state of radiation oncology-specific terminology as a prerequisite for data-driven radiation oncology.

## Methods

### Goals

The primary goal of the project was to quantitatively evaluate existing radiation therapy-specific source vocabularies (SVs) available in the Unified Medical Language System (UMLS). Secondary goals were the lexical analysis of SVs and qualitative analysis, which was done to verify whether the existing terminology resources (TRs) were sufficient to cover radiation therapy needs.

### Definition of TRs

There is no clear distinction between existing terminology and lexical resources that can be acquired via literature or general



internet research. For this project, we defined TR as any comprehensive resource found within UMLS SVs, such as a vocabulary, taxonomy, thesaurus, coding system, ontology, or any other type.

## Material for Research

UMLS [23] was used as the basis for this study. To the best of our knowledge, UMLS is the most comprehensive repository of biomedical terminologies developed and maintained by the United States National Library of Medicine [23]. It consists of 216 vocabulary items (last reviewed: May 4, 2020) in English (151/216, 70% of content) and other languages that contribute to a total of 15,479,756 concept names and synonyms. After individual registration and acceptance of an individual licensing agreement (by NC), UMLS-registered users can search content through an HTML, a web-based graphical user, or an application programming interface. Data records are accessible for download in JavaScript Object Notation format.

## Methodology

We aimed to cover the terms specific to radiation therapy. To maximize sensitivity and specificity we searched UMLS on June 15, 2020, for the following terms: *radiation therapy*, 6030 concepts; *radiotherapy*, 479 concepts; *radiation oncology*, 58 concepts; and *radio oncology*, 0 concepts. In total, 6567 concepts were retrieved and exported, together with metadata in the JavaScript Object Notation format. We designed a denormalized database to facilitate further analysis. For this work, we downloaded the following data points from the UMLS server:

- Unique concept identifier—a code value that uniquely identifies a single concept;
- Route Source—an entity that has authored the TR;
- Name—a string chosen to represent the concept as a whole;
- Definition of a concept:
  - Atoms—the smallest unit of naming in a source (a specific string with specific code values and identifiers from a specific source);
- Semantic type—a category of a concept assigned by the UMLS.

We analyzed all SVs according to the route source, number, author, location of the author, license type, lexical density of TR, and semantic types.

The data on TR authors were searched within the UMLS website or by general internet search (via Google) if the data were not available. We recorded the country where the legal residence of the authors was registered in the official state company register. *International organization* was defined as an institution drawing membership from at least 3 states and having activities in several states.

Licensing was categorized into two main groups: free TR, where no use restriction applied, and restricted TR, where any use was limited under conditions specified in the license agreement. Further evaluation of licensing types and terms of use was beyond the scope of this study.

*Word* is defined as a combination of characters representing a spoken sound that can be uttered in isolation with objective or practical meaning. The lexical density of a TR serves as a measure of the structure and complexity of communication. It is defined as the ratio of the total number of words that describe all concepts within a TR and the number of unique words used to describe the concepts. The word propagation index was used as a measure of the importance of a word and was expressed as the number of SVs that contained this word.

Data processing and lexical analysis were performed using Python (version 3.7; Python Software Foundation) and Python library Natural Language Toolkit (version 3.5).

The systematic review of other biomedical terminology services and repositories, such as Open Biological and Biomedical Ontology Foundry [24] or BioPortal [25], was beyond the scope of this work.

## Results

### Overview

A total of 6567 concepts were retrieved from UMLS. After the removal of duplicate entries, 6509 unique concepts were selected for further analysis.

The concepts were distributed across 35 SVs. The median number of unique concepts was 5 per SV (range 1–5479 concepts per TR). Of the SVs, 14% (5/35) contained 94.59% (6157/6509) of all the concepts. The SVs were International Classification of Diseases, Tenth Revision Procedure Coding System (5479/6509, 84.18% of concepts), Systematized Nomenclature of Medicine-Clinical Terms (United States; 326/6509, 5.01% of concepts), Current Procedural Terminology (142/6509, 2.18% of concepts), MedDRA (115/6509, 1.77% of concepts), and MEDCIN (95/6509, 1.46% of concepts). The remaining 5.41% (352/6509) of concepts were contained in 86% (30/35) of SVs. All data are presented in [Multimedia Appendix 1](#).

The SVs were created by 29 individual authors. The US National Library of Medicine was the author of (4/29, 14%) SVs. The National Center for Health Statistics and the Centers for Medicare and Medicaid Services, National Cancer Institute Enterprise Vocabulary Services, and the College of American Pathologists or International Health Terminology Standards Development Organization contributed 7% (2/35) of SVs each. Other 26 authors contributed with 3% (1/35) SV each. An overview of SVs is presented in [Multimedia Appendix 2](#).

### Vocabulary Sources

The authors of the SVs were predominantly legal entities registered in the United States (25/35, 71%), followed by international organizations (6/35, 17%) and legal entities registered in Australia (2/35, 6%), the Netherlands, and the United Kingdom (1/35, 3%). Of the total SVs, (16/35, 46%) did not have any restriction on use, whereas the remaining (19/35, 54%) SVs had some level of restriction. Of the 35 SVs, 20 (57%) were updated within the last 5 years ([Multimedia Appendix 3](#)).

All concepts found in RT SVs were labeled with one of 29 semantic types ([Multimedia Appendix 4](#)), which accounted for

21.8% (29/133) of all semantic types available in UMLS. Of the total concepts, 94.05% (6122/6509) were classified by UMLS as terms describing a *therapeutic or preventive procedure* according to the scheme for classification of semantic types.

After removing the *stop words*, the total number of words for all SVs was 56,219, with a median of 25 unique words per TR (range 3-50,682). The total number of unique words in all SVs was 1048, with a median of 19 unique words per vocabulary (range 3-406). The lexical density for all concepts in all SVs was zero (0.02 rounded to 2 decimals; [Multimedia Appendix](#)

5). Median lexical density per unique TR was 0.7 (range 0.0-1.0). The median maximal length of all concepts expressed as the total number of words for all TR was 8 (range, 3-28). The median minimal length of all concepts expressed as the total number of words for all TRs was 3 (range 1-10). All results are shown in [Table 1](#).

Of the total words, 677 were unique to only one TR, whereas four words were present in multiple SVs: *radiation* was present in 31, *therapy* in 28, *radiotherapy* in 18, and *procedure* in 11 SVs. We did not identify any TR specifically dedicated to radiation therapy.

**Table 1.** Properties of source vocabularies.

Vocabulary resource	Total number of all words	Total number of unique words	Lexical density of the vocabulary resource	Average length of the concept	Median length of the concept	Maximal length of the concept	Minimal length of the concept
ATC <sup>a</sup>	5	5	1.0	5	5	5	5
CCS <sup>b</sup>	3	3	1.0	3	3	3	3
CHV <sup>c</sup>	3	3	1.0	3	3	3	3
ICD10AMAE <sup>d</sup>	12	12	1.0	6	6	7	5
ICD9CM <sup>e</sup>	7	7	1.0	4	4	5	2
MTHICD9 <sup>f</sup>	9	9	1.0	9	9	9	9
NANDA-I <sup>g</sup>	4	4	1.0	4	4	4	4
NCL_CPTAC <sup>h</sup>	3	3	1.0	3	3	3	3
SNM <sup>i</sup>	7	7	1.0	7	7	7	7
PCDS <sup>j</sup>	9	8	0.9	9	9	9	9
NIC <sup>k</sup>	34	30	0.9	11	8	18	8
ICD10CM <sup>l</sup>	9	7	0.8	5	5	5	4
ALT <sup>m</sup>	25	19	0.8	8	8	14	3
ICD-10 <sup>n</sup>	25	19	0.8	6	5	14	2
CCPSS <sup>o</sup>	7	5	0.7	4	4	4	3
ICNP <sup>p</sup>	6	4	0.7	3	3	3	3
PDQ <sup>q</sup>	27	18	0.7	5	6	8	3
ICD10AM <sup>r</sup>	29	19	0.7	6	6	7	4
ICPC2ICD10ENG <sup>s</sup>	19	12	0.6	3	2	5	2
MSH <sup>t</sup>	52	32	0.6	3	3	4	2
SPN <sup>u</sup>	24	14	0.6	5	5	6	4
CSP <sup>v</sup>	7	4	0.6	4	4	4	3
HCPCS <sup>w</sup>	97	54	0.6	14	13	22	10
SNMI <sup>x</sup>	71	36	0.5	6	7	8	5
MTH <sup>y</sup>	265	132	0.5	4	4	23	1
HL7V3.0 <sup>z</sup>	46	20	0.4	7	6	10	4
NCI Thesaurus	279	115	0.4	4	4	14	1
Read Codes	61	22	0.4	4	3	5	3
MEDCIN	488	175	0.4	5	5	10	2
UMD <sup>aa</sup>	312	97	0.3	5	5	9	2
SNOMEDCT_US <sup>ab</sup>	1420	406	0.3	4	4	10	2
LOINC <sup>ac</sup>	365	96	0.3	8	8	19	2
MedDRA <sup>ad</sup>	409	84	0.2	4	4	8	2
Current Procedural Terminology	1398	228	0.2	10	9	28	3

Vocabulary resource	Total number of all words	Total number of unique words	Lexical density of the vocabulary resource	Average length of the concept	Median length of the concept	Maximal length of the concept	Minimal length of the concept
ICD10PCS <sup>ae</sup>	50,682	175	0.0	9	9	15	2
Median	25	19	0.7	5	5	8	3
Minimal	3	3	0.0	3	2	3	1
Maximal	50,682	406	1.0	14	13	28	10

<sup>a</sup>ATC: Anatomical Therapeutic Chemical Classification System.

<sup>b</sup>CCS: Clinical Classifications Software.

<sup>c</sup>CHV: Consumer Health Vocabulary.

<sup>d</sup>ICD10AMAE: International Classification of Diseases and Related Health Problems, Tenth Revision, Australian Modification, Americanized English Equivalents.

<sup>e</sup>ICD9CM: International Classification of Diseases, Ninth Revision, Clinical Modification Entry Terms.

<sup>f</sup>MTHICD9: Metathesaurus Names International Classification of Diseases, Ninth Revision, Clinical Modification Entry Terms.

<sup>g</sup>NANDA-I: NANDA-I Taxonomy.

<sup>h</sup>NCL\_CPTAC: Clinical Proteomic Tumor Analysis Consortium.

<sup>i</sup>SNM: The Systematized Nomenclature of Medicine, Second Edition.

<sup>j</sup>PCDS: Patient Care Data Set.

<sup>k</sup>NIC: Nursing Interventions Classification.

<sup>l</sup>ICD10CM: International Classification of Diseases, Tenth Revision, Clinical Modification.

<sup>m</sup>ALT: Alternative Billing Concepts.

<sup>n</sup>ICD-10: International Classification of Diseases, Tenth Revision.

<sup>o</sup>CCPSS: Clinical Problem Statements.

<sup>p</sup>ICNP: International Classification for Nursing Practice.

<sup>q</sup>PDQ: Physician Data Query.

<sup>r</sup>ICD10AM: International Classification of Diseases, Tenth Revision, Australian Modification.

<sup>s</sup>ICPC2ICD10ENG: International Classification of Primary Care-International Classification of Diseases, Tenth Revision Thesaurus.

<sup>t</sup>MSH: Medical Subject Headings.

<sup>u</sup>SPN: Standard Product Nomenclature.

<sup>v</sup>CSP: CRISP Thesaurus.

<sup>w</sup>HCPCS: Healthcare Common Procedure Coding System.

<sup>x</sup>SNMI: The Systemized Nomenclature of Human and Veterinary Medicine.

<sup>y</sup>MTH: Metathesaurus Names.

<sup>z</sup>HL7V3.0: Health Level Seven version 3.0.

<sup>aa</sup>UMD: Universal Medical Device Nomenclature System.

<sup>ab</sup>SNOMEDCT\_US: The Systematized Nomenclature of Medicine-Clinical Terms, US Edition.

<sup>ac</sup> LOINC: Logical Observations Identifiers, Names, Codes.

<sup>ad</sup>MedDRA: Medical Dictionary for Regulatory Activities.

<sup>ae</sup>ICD10PCS: The International Classification of Diseases, Tenth Revision, Procedure Coding System.

## Discussion

### Principal Findings

To the best of our knowledge, this is the first study to evaluate the state of standardized SVs dedicated to radiation therapy. Although our search of UMLS retrieved a large number of unique concepts distributed across 35 SVs, none of them was identified as a dedicated TR for radiation oncology. However, such a dedicated TR, providing standardized terms for modern radiation therapy and being widely adopted, is a prerequisite for achieving interoperability. The existing SVs are concentrated on describing different radiation therapy techniques, most probably for reimbursement coding purposes.

An important milestone in the standardization of radiation therapy communication was published by the International Commission on Radiation Units and Measurements report 50, 62, and 83. The International Commission on Radiation Units and Measurements 83 provides the information necessary to standardize techniques and procedures and harmonize the prescribing, recording, and reporting of intensity-modulated radiation therapy. The most significant achievements were made in the recommendation of the definition, selection, and delineation of the radiation therapy volumes along with dose prescription to the volumes and dose-volume reporting recommendations [22]. However, the International Commission on Radiation Units and Measurements 83 does not go beyond a high-level abstract and conceptual description of the target

and risk volumes, whereas the specific anatomy of the patient was not subject to standardization.

Furthermore, the American Society for Radiation Oncology (ASTRO) and the American Association of Physicists in Medicine have recognized the need for a unified and standardized terminological approach to radiation therapy. Members of both societies published several papers and recommendations concerning standardized approaches in naming conventions for radiation therapy [13,20,26-28].

The authors of the ASTRO white paper, published in 2016, have argued that the standardized terminology approach in dose prescription will facilitate accurate communication among providers to support safe practice and guide product developers in creating software consistent with the best standard of practice [21]. To avoid common pitfalls of standardization efforts [29], the working group limited their efforts to standardize the central prescription items concerning how the prescribed dose is specified. They suggested standardization of key elements for prescription, such as treatment site, delivery method, dose per fraction, fraction number, total dose, and a special field named *other elements*. They commented on the previous work of other groups such as the American College of Radiology–ASTRO Practice Parameter for Radiation Oncology [28], the ASTRO Accreditation Program for Excellence Standard [27], and ASTRO recommendation for documenting intensity-modulated radiation therapy [26]. The authors of the white paper rightfully argued that although thoughtfully developed, the proposals will be hard to implement in the modern environment. Some items are not sufficiently precise, and other concepts are difficult to define as our field evolves.

The most challenging and intellectually demanding process is the formalization of treatment sites. Frequently, radiation therapy volumes span several distinct anatomical entities and consist of numerous anatomical regions. For example, treatment volumes for head and neck cancer traditionally consist of macroscopic tumors or former tumor sites that span several anatomical entities of the digestive tract and respiratory organs. In malignancies of pelvic origin, it is common to have part volumes extending to the abdominal region or lower extremities (eg, paraaortic volumes or partially in the upper extremities in vulvar cancer). Large tumors of any histology, such as sarcomas or metastatic diseases, sometimes create geometric forms that are very difficult to intuitively define using standard anatomical descriptors, such as lymph node levels or anatomical organ boundaries. An additional level of complexity is added through time-dependent changes in volume shapes and the introduction of subvolumes, which receive a different dose synchronously (eg, simultaneous integrated boost).

Further important work in the domain of RT vocabulary standardization has been done by the American Association of Physicists in Medicine Task Group 263. Their 2018 published report provides a detailed overview of scientific literature, previous achievements, contemporary practice, and some future directions related to nomenclature standardization [20]. The main output of this report is the development of a nomenclature system for target volumes, organs at risk, and dose-volume

histogram metrics with the goal of straightforward adoption in current practice. In contrast to all previous initiatives for structure standardization, this nomenclature was developed by an assembly of stakeholders in radiation oncology, including multiple societies (eg, ASTRO, the European Society for Radiotherapy and Oncology, and others), disciplines, and vendors, ensuring broad endorsement and use of the nomenclature. A major drawback of this approach was the intention to primarily accommodate and serve the manufacturers of radiation therapy software and hardware, and not patients or physicians. By doing so, we are risking repeating the major historical mistakes, which have brought us to our current position. Patients, physicians, or payers must have clearer and understandable naming conventions designed according to their needs.

In this light, we must consider the newest development in the legislative environment in the United States formalized in the 21st-Century Cures Act, signed into law on December 13, 2016, which is designed to help accelerate medical product development and bring innovations and advances to patients who need them faster and more efficiently. The act finally results in the ONC's Cures Act Final Rule, which supports seamless and secure access, exchange, and use of eHealth information. However, good initiatives and their formulation within legal boundaries sometimes collide with reality. The last surge of digitalization in the United States ended in the complete lockdown of information within vendor software. Furthermore, this led to a phenomenon popularly known as a *death by a thousand clicks* [5], which resulted in a health care crisis and unprecedented burnout rate among physicians [8].

We acknowledge the limitations of this study. As the most important limitation, we acknowledge the missing review of ontological repositories such as BioPortal or OBO Foundry. Furthermore, we reviewed only UMLS. It is possible that there are some TRs in other languages that we are not aware of. Despite this limitation, we believe that this analysis provides a realistic overview of the current state of terminologies developed specifically for radiation oncology. Cross-sectional analysis is important, even if negative.

## Conclusions

Cancer is still one of the leading causes of death and morbidity globally, and oncological research comprises approximately one-quarter of the complete biomedical clinical research portfolio [30]. Radiation oncology will be used in at least 50% of cancer patients for treatment or palliation, is an important contributor to survival and symptom control, and is an essential part of streaming toward precise and personalized medicine [31,32]. However, without meaningful digitalization and high data availability, we may not achieve the desired effects. To achieve the promise of digitalization in the clinical environment, we need SI in practice [1]. The basis for SI is shared TR. We need to establish an agile, productive, and progressive way for communication among all actors in radiation therapy and beyond through the development of dedicated radiation therapy-specific virtual reality.



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## Authors' Contributions

NC was responsible for the design of the study. ASW helped with data classification and preparation. NC prepared the data and created a draft of the manuscript with MP and EVB. DMA critically reviewed the manuscript and provided significant inputs. All other authors evaluated the results together with NC and contributed to the writing of the manuscript sufficiently to be stated as coauthors. All authors have reviewed and approved the final version of the manuscript.

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## Conflicts of Interest

NC is the founder of a Wemedoo AG, Sumpfstrasse 24, 6312 Steinhausen, Switzerland, a clinical information company. However, there are no conflicts of interest related to this work.

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### Multimedia Appendix 1

A complete database used for analysis.

[[XLSX File \(Microsoft Excel File\), 240 KB - formative\\_v6i1e27550\\_app1.xlsx](#) ]

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### Multimedia Appendix 2

Overview of the source vocabularies.

[[DOCX File , 19 KB - formative\\_v6i1e27550\\_app2.docx](#) ]

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### Multimedia Appendix 3

A number of lexical resources published according to last year's update.

[[DOCX File , 144 KB - formative\\_v6i1e27550\\_app3.docx](#) ]

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### Multimedia Appendix 4

A number of terms per Unified Medical Language System semantic type category.

[[DOCX File , 116 KB - formative\\_v6i1e27550\\_app4.docx](#) ]

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### Multimedia Appendix 5

A number of words per source vocabulary.

[[DOCX File , 131 KB - formative\\_v6i1e27550\\_app5.docx](#) ]

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## Abbreviations

**ASTRO:** American Society for Radiation Oncology  
**SI:** semantic interoperability

**SV:** source vocabulary

**TR:** terminology resource

**UMLS:** Unified Medical Language System

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Original Paper

# A Transdiagnostic, Emotion Regulation App (Eda) for Children: Design, Development, and Lessons Learned

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## Abstract

**Background:** Digital interventions, including mobile apps, represent a promising means of providing effective mental health support to children and young people. Despite the increased availability of mental health apps, there is a significant gap for this age group, especially for children (aged 10-12 years). Research investigating the effectiveness and development process of child mental health apps is limited, and the field faces persistent issues in relation to low user uptake and engagement, which is assumed to be a result of limited user involvement in the design process.

**Objective:** This study aims to present the development and design process of a new mental health app for children that targets their emotion regulation abilities. We describe the creation of a new interdisciplinary development framework to guide the design process and explain how each activity informed different app features.

**Methods:** The first 2 stages of the framework used a variety of methods, including weekly classroom observations over a 6-month period (20 in total); public engagement events with the target group (N=21); synthesis of the existing evidence as part of a meta-analysis; a series of co-design and participatory workshops with young users (N=33), clinicians (N=7), researchers (N=12), app developers (N=1), and designers (N=2); and finally, testing of the first high-tech prototype (N=15).

**Results:** For the interdisciplinary framework, we drew on methods derived from the Medical Research Council framework for complex interventions, the patient-clinician framework, and the Druin cooperative inquiry. The classroom observations, public engagement events, and synthesis of the existing evidence informed the first key pillars of the app and wireframes. Subsequently, a series of workshops shaped and reshaped the content and app features, including games, psychoeducational films, and practice modules. On the basis of the prototype testing sessions, we made further adjustments to improve the app.

**Conclusions:** Although mobile apps could be highly suitable to support children's mental health on a wider scale, there is little guidance on how these interventions could be designed and developed. The involvement of young users across different design activities is very valuable. We hope that our interdisciplinary framework and description of the used methods will be helpful to others who are hoping to develop mental health apps for children and young people.

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**KEYWORDS**

mHealth; participatory design; emotion regulation; interdisciplinary development; child mental health

## Introduction

### Background

It has been estimated that approximately 10%-20% of children and young people worldwide experience mental health problems, making it one of the leading causes of disability in this population [1,2]. Addressing the rising number of mental health problems in young people is a major public health concern. International studies indicate that >60% of young people do not have access to adequate (or any) treatment [3], highlighting the urgent need for innovative approaches to tackling this problem. Mental health apps present a promising means of addressing this challenge by making mental health support more widely accessible to young people. Our research team developed a new mental health app that aims to support children (aged 10-12 years) by enhancing their emotion regulation skills. Difficulties with emotion regulation are seen in a wide range of mental health problems, and recent evidence suggests that enhancing emotion regulation in children and adolescents is related to improvements in mental health regardless of the type of disorder or intervention [4]. To date, guidelines and studies on the development of mental health apps for children are lacking. This study aims to fill this gap.

### Digital Mental Health Landscape for Youth

Although it has been suggested that digital mental health interventions can be efficacious in both preventing and treating mental health problems in young people (aged  $\geq 12$  years) [5-7], recent systematic reviews found that in comparison to the adult literature, research investigating the effectiveness of digital interventions for children and young people is lagging [7,8]. Only a few mental health apps have been designed and tested specifically for young people (aged  $\geq 12$  years); however, even fewer are available for children aged  $< 12$  years. The latest systematic reviews identified only 2 mental health apps for children, thereby highlighting the significant evidence gap and limited availability of suitable digital interventions for this age group [7,9]. Despite these considerable limitations, digital interventions are expected to be highly accepted by young people because of the high degree of anonymity they provide. Furthermore, they are cost-effective and, if designed appropriately, are highly applicable across different contexts [10].

Most available mental health apps have low uptake and engagement levels [11,12], which are considered essential to securing their effectiveness [13,14]. Various methods have been suggested to increase engagement levels with digital interventions, including the involvement of users in the development and design process as part of user-centered design methods. A recent review of 30 studies and another meta-review of 21 studies demonstrated that most digital mental health interventions, which targeted children and young people, neglected the use of such methods, which is reflected in the highly uniform design across these interventions, where psychoeducation often represents the main intervention component [15,16]. In terms of specific mental health apps for children (aged  $< 12$  years), we were unable to identify any app

that involved target users during the development and design stages, thereby further emphasizing the importance of this paper.

A closer look at the digital mental health landscape indicates that most interventions draw on evidence-based treatments that target specific symptoms or diagnoses [17,18]. Initially, the recycling approach of taking existing interventions and transferring them to digital platforms helped the field to move forward quickly; however, this approach has increasingly been criticized as it provides little room for innovation and improvement [17]. Chandrashekar [19] summarized the key features of highly effective and engaging mental health apps and specifically highlighted components targeting transdiagnostic mechanisms. Transdiagnostic mechanisms are not specific to one disorder but are present across different mental health problems. The focus on transdiagnostic mechanisms has also enhanced traditional psychotherapeutic approaches in the past [20,21]. One such mechanism that has been repeatedly emphasized as a highly promising treatment and prevention target is emotion dysregulation.

### Emotion Regulation as an Intervention Target

Deficits in emotion regulation—or the ability to monitor, evaluate, and modify one's emotional reactions to accomplish one's goals [22]—have been identified as a risk and maintenance factor for mental ill health. Developmental research has demonstrated that higher emotion dysregulation in children is associated with greater mental health difficulties concurrently and later in life. Recent meta-analyses have indicated that interventions that effectively reduce emotion dysregulation in children also reduce psychopathological symptoms, irrespective of the intervention type or clinical diagnosis [4,23]. With respect to our target group, that is, children aged 10 to 12 years, the latter is of particular importance, as high comorbidity rates are common in this group and symptom presentations are often not clear-cut.

The transdiagnostic approach has also been deemed suitable for mental health prevention programs. Forbes et al [24] recently highlighted that targeting transdiagnostic factors in mental health prevention has the potential to activate a range of related, beneficial developmental cascades, such as social or academic development. Furthermore, they argued that transdiagnostic approaches reduce the burden on schools, for whom it is difficult to provide a multitude of short-lived programs, each trying to tackle a different problem [24].

To the best of our knowledge, there is currently no app intervention that targets emotion regulation as a transdiagnostic factor in late childhood (aged 10-12 years), although this period has been highlighted as a critical stage in achieving maximum impact in terms of youth mental health prevention [25]. Moreover, in the United Kingdom, late childhood (ages 10-12 years) is characterized by the transition from primary to secondary school, which is frequently experienced as stressful by children, thereby strengthening the case for an intervention that supports children before and during this transition period [26].



## This Paper's Objectives

With respect to the existing limitations in the field, we present the development process of a new, transdiagnostic mental health app for children, which puts the young user group in the center of the design process. To achieve this, we have created a new development framework that draws on methodologies from the fields of psychology, human–computer interaction (HCI), and user design. In the following sections, we (1) describe the interdisciplinary design, development, and refinement process; (2) take the reader through the different stages and research activities; (3) describe the various app features and explain how they were informed by the research activities; and finally, (4) share important lessons that were learned and considerations for future activities.

## Formulation of Our Interdisciplinary Development Framework

### Developing a Complex Digital Intervention

The present mental health app is considered a complex intervention as it involves multiple, interconnected, and interacting components [27,28]. In line with that, we used the first 3 stages of the Medical Research Council (Figure 1) framework for complex interventions to guide the development and evaluation process of the present mental health app. We first explored relevant theories and existing evidence to identify promising intervention components. In the next stage, the research team focused on identifying the underlying mechanisms that might influence the preferred outcome to incorporate them in the design of the intervention. This paper focuses primarily on the early development and design stages to address existing gaps in the literature. Therefore, we only present the research activities of the first 2 stages, as depicted in Figure 2. The findings of the third stage, the exploratory trial, are published elsewhere [29].

**Figure 1.** Medical Research Council framework for complex interventions.

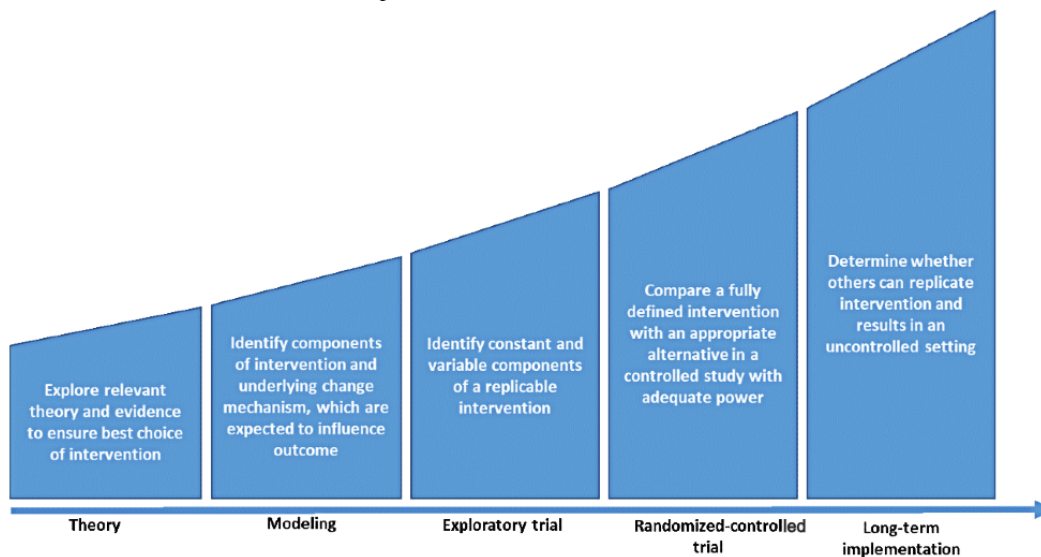


Figure 2. Development framework and research activity outline of the present app.

	Stage I: Theory		Stage II: Modeling		Stage III: Exploratory trial	
Objectives	<ul style="list-style-type: none"> <li>Understand problem and context</li> <li>Involve users in design process</li> <li>Identify existing evidence</li> <li>Identify key components of logic model</li> <li>Generate ideas for basic wireframes</li> </ul>		<ul style="list-style-type: none"> <li>Involve children and practitioners in design</li> <li>Accommodate different design goals</li> <li>Review and adjust wireframes</li> <li>Test, develop, adjust low- and high-tech prototype</li> </ul>		<ul style="list-style-type: none"> <li>Evaluate acceptability and usability</li> <li>Explore use in classroom context</li> <li>Improve and optimize app intervention</li> <li>Explore facilitators and barriers to evaluating app within classroom</li> </ul>	
Research team	Public engagement events		Systematic review and meta-analysis		Co-design workshops	
	Classroom observations	Organizing workshops	Combining and mediating feedback from stakeholders	Facilitating idea generation, adjustment, and iterative re-design	Prototype testing	Combining and mediating feedback from stakeholders
Users	Public engagement events		Co-design workshops		Prototype testing	
Clinicians	Workshops to gather feedback on content ideas		Workshops to gather feedback on content ideas			
Teacher/School	Classroom observations		Co-design workshops		Prototype testing	
App developer/Designer	Idea generation workshop		Idea generation, adjustments, and iterative redesign			
Outcomes	<ul style="list-style-type: none"> <li>Young preferences for MH app</li> <li>Logic model (draft)</li> <li>Systematic review and meta-analysis</li> </ul>		<ul style="list-style-type: none"> <li>Ideas for games and modules</li> <li>Content of animation videos</li> <li>Wireframes</li> </ul>		<ul style="list-style-type: none"> <li>Finalizing animations</li> <li>Decision on low-tech prototype content</li> <li>Development of high-tech prototype</li> </ul>	
Participants	<ul style="list-style-type: none"> <li>Young people (n=21) and Teachers</li> <li>Psychologists (n=7, male 1, female 6)</li> <li>Parents (n=4)</li> <li>App developer (n=1, male) and Designer (n=2, female)</li> <li>Researchers (n=7, male 1, female 6)</li> </ul>		<ul style="list-style-type: none"> <li>Children (n=48) and Teachers (n=4, female)</li> <li>Psychologists (n=7, male 1, female 6)</li> <li>App developer (n=1, male) and Designer (n=1, female)</li> <li>Emotion regulation researchers (n=5)</li> </ul>		<ul style="list-style-type: none"> <li>Testing of high-tech prototype</li> <li>Adjustments</li> <li>Trial ready prototype</li> </ul>	
					<ul style="list-style-type: none"> <li>Exploratory trial outcomes and learnings</li> </ul>	
					<ul style="list-style-type: none"> <li>Children interviews (n=19)</li> <li>Children surveys (n=132)</li> <li>Teachers (n=6)</li> <li>Researcher (n=2)</li> </ul>	

### Designing a Complex Digital Intervention

Although the Medical Research Council framework provides valuable guidelines for the development and evaluation of complex interventions, it provides little information on the design of intervention components [30]. Hence, we drew on 2 frameworks rooted in the fields of HCI and user-centered design.

The patient–clinician–designer framework provides guidance on how to structure the design and content creation process of digital interventions for mental illness [31]. It aims to meet the complex requirements when designing user-centered interventions for mental illnesses by taking into account different perspectives (ie, patient vs clinician) and design goals. It describes how 5 key principles, based on user-centered design methodology, can be applied in the design process and divides it into four design phases: (1) understanding the illness and its challenges, (2) involving users in the design, (3) mediating co-design activities between users and professionals, and (4) accommodating different evaluation goals.

With respect to our target user group, that is, children at the end of primary school (aged 10–12 years), we decided to incorporate the Druin [32] cooperative inquiry framework, which provides specific techniques for involving young users in the design process of technologies and is widely used in the field. This framework highlights the importance of involving children as partners in the whole process instead of merely letting them test an almost finished prototype or end product. Druin [32] emphasizes the benefits of conducting fieldwork (ie, contextual inquiry) first, as it allows researchers to detect relevant contextual information, including patterns of activities, ways of communication, and other artifacts. In addition, it has been reported that discussing design features in the relevant context (eg, school and home) makes it easier for children to express ideas and provide suggestions [33]. Finally, the framework calls

for the importance of visualizing ideas through low- and high-tech prototypes, as this offers children more concrete ways to elaborate on ideas and reject or refine them.

### Present Development Framework

We combined the 3 frameworks outlined above, which allowed us to take a highly interdisciplinary approach (Figure 2). For each stage of the development process, we used a unique set of methodologies derived from different disciplines. The research team was involved in all the activities as a linking point and served as a mediator between different stakeholders.

The research team comprised 5 child and adolescent mental health researchers, of whom 2 have extensive experience in conducting digital health research (BM and JEC), 1 has a background in clinical psychology (BM), and 4 have extensive experience in designing, delivering, and evaluating school mental health programs (JD, JEC, PP, and HAB). A total of 3 authors (BM, JEC, and JD) are part of an international training network on technology-enabled mental health systems for young people, with experts from different disciplines (ie, computer sciences, psychology, medicine, data privacy, and design), who were consulted throughout the process. BM also has extensive training in applying HCI and user experience (UX) techniques. Figure 2 depicts the stakeholders involved at each stage, including app developers, clinicians, UX and graphic designers, young people, teachers, and parents.

## Methods

### Stage 1: Identifying Theory, Evidence, and Challenges

#### Objectives

As shown in Figure 2, this stage focuses on understanding the context and the problem at hand. We generate initial ideas with key stakeholders and test the feasibility of potential research

activities for stage 2. Furthermore, we summarize the existing evidence to create the underlying logic model of the intervention, including its active ingredients and expected outcomes [34].

### Activities and Data Analysis

In line with our framework, we conducted (1) multiple classroom observations, (2) a systematic review and meta-analysis to summarize the evidence for existing psychological interventions and their effectiveness in enhancing emotion regulation skills in youth, and (3) 2 consultation groups with young people. Notes and materials (ie, drawings, sticky notes, outcomes of exercises, and reflective notes) produced during (1) classroom observations and (2) consultation groups were analyzed using reflexive thematic analysis as described by Braun and Clarke [35,36]. BM manually coded the data, detailing inductive descriptive codes by highlighting and categorizing similar phrases, words, or patterns across the data. This was done in NVivo 11 (QSR International NVivo) or Microsoft Excel (further specified in the following sections). Themes were created using mind-mapping exercises and refined through discussions with all authors. Occasionally, we also

involved app developers, designers, and clinicians, as specified below.

### School Visits and Classroom Observations

Familiarization with the user and their environment as part of a fieldwork exercise is a central tenet of the cooperative inquiry framework. Clinical research has also shown that the identification of user resources within the intervention context is a significant determining factor of an interventions' effectiveness [37].

Schools are considered key players in youth mental health provision [38,39]. We collaborated closely with 2 schools for this project, resulting in weekly school visits across a 6-month period, with a total of 20 observations. This allowed us to identify common challenges that children and teachers face, especially in relation to emotion dysregulation and resulting behavioral difficulties (eg, not being able to concentrate, disrupting the teaching process, and distracting other children). We became familiar with their everyday practices and issues related to the school setting and gained valuable insights into what children and teachers do to manage difficult emotions at school (Table 1).

**Table 1.** Outcomes and implications based on school observations.

Observations	Design implication and goals
Teachers and children use different devices, including tablets, PCs, and smartboards, during lessons.	Web-based app that can be accessed from different devices
Children try different strategies that help them in the classroom. Sometimes, these are agreed with the teacher.	Let children create a list of <i>tools</i> , which contains personal strategies and provides suggestions
Children struggle to draw on strategies when they have very intense emotions. Some teachers direct children in need to a quiet corner.	Add a function that gives quick access to guided strategy to provide in-the-moment support
Children are familiar with breathing exercises and time-outs.	Guided relaxation, breathing, and mindfulness exercises
Children report on certain situations in which they find it difficult to regulate their emotions and where this impedes their goals.	Integrate children's stories as examples in content to make it more relevant to the target group
Teachers use a range of strategies, some that help specific individuals when needed and some that they apply to the whole class.	Design an intervention that can be used with the whole class, as well as for individual children

The lead author (BM) was able to observe different lessons, classes, and teachers in both schools. BM took notes during the observations and reflective notes afterward. BM was also able to ask teachers about their understanding of emotion dysregulation, its role in the classroom, and how children and teachers managed situations where children experienced intense feelings. During the school visits, teachers and children most frequently mentioned 1 strategy to manage emotion dysregulation in the classroom: the use of quiet corners or so-called *time-out zones*.

Time-out zones are defined areas in the classroom where students are directed when they show difficult behavior, struggle to concentrate, or distract other pupils in class. Some classrooms were divided into different zones, representing different types of support (eg, zones closer to the front to facilitate concentration and zones closer to the back for time-outs). The time-out zones often included a sofa or pillows to sit on, and children had access to books and other tools to help them calm down. On the basis of this observation, storing a tablet with the

app intervention in the time-out zone seemed to be a suitable approach to implement the app in the classroom context.

Children reported that they themselves or together with a teacher had identified strategies to manage difficult feelings, such as playing with putty, stepping outside, reading a book, or listening to music in a quiet corner. This list of emotion regulation strategies inspired the implementation of the digital toolbox in the app see *Intervention Description* below).

Although insights from the school visits significantly influenced some design concepts in the app, the collaboration with the schools also helped us access parents and other professionals who we were able to consult on parent-teacher days about the app.

### Public Consultation Groups

A total of 2 consultation groups were conducted as part of a patient and public involvement (PPI) event. Participants were recruited through the center's network and existing collaborations with other third-sector child mental health organizations. Organization leads contacted young people or

their parents who previously consented to be contacted for PPI events.

The PPI events involved 21 *young research advisors* aged between 12 and 19 years and had an even distribution of female and male participants. The term *young research advisor* is a special term that is used to describe a group of young people who have been service users themselves and received specific training that prepares them to work with researchers. The research team worked with this specific group, despite them being slightly older than the target group, because of their prior training and experience of working with researchers. This had a number of benefits. They were familiar with common research processes and had an existing relationship with the workshop facilitators, which secured good engagement. This allowed us to ask questions that were more complex and receive direct feedback on specific workshop activities.

The young advisors were reimbursed for their time in line with the organization's internal arrangements. The lead author and 2 PPI leaders who were familiar with young advisors facilitated the workshops.

1. Each PPI event included an icebreaker exercise, an introduction to the topic (eg, mental health and digital interventions), and a discussion of the following questions:

2. What is mental health for you, and how do you take care of it?
3. How can technology support young people's mental health or emotion regulation?
4. What are young people's perceived barriers to and facilitators of the use of mental health apps?
5. How can research involve children and young people in the design process of mental health technology?

For some exercises, the groups were split into smaller teams first, where they brainstormed together and collected ideas on big sheets of paper. Subsequently, each group presented their ideas and discussed them with a larger group. BM was present at each PPI event to observe participants, ask follow-up questions, and take notes. Materials produced as part of the PPI groups (ie, drawings and notes resulting from exercises) and written notes by the lead author were thematically analyzed [35,36]. On the basis of the identified themes, a list of *do's and don'ts* for mental health apps was developed (Table 2). If the young advisors had suggested possible solutions in the workshop, they were included; however, the research team also consulted the app developer and graphic designer afterward to identify possible solutions (marked with *a* in Table 2).

**Table 2.** Identified *do's* and *don'ts* for mental health apps based on patient and public involvement group.

Please do	Please avoid	App solution
<b>Accessibility</b>		
<ul style="list-style-type: none"> <li>• Available across devices</li> <li>• Affordable for a young person</li> <li>• Available offline</li> </ul>	<ul style="list-style-type: none"> <li>• Advertisement</li> <li>• In-app purchases</li> <li>• Too much data or Wi-Fi</li> </ul>	<ul style="list-style-type: none"> <li>• Web-based app<sup>a</sup></li> <li>• No costs</li> <li>• Data or Wi-Fi for first-time log-in and updates<sup>a</sup></li> </ul>
<b>Engagement</b>		
<ul style="list-style-type: none"> <li>• Interactive, games, and tracking</li> <li>• Social connection and community</li> <li>• Make use of users' feedback and provide relevant updates</li> </ul>	<ul style="list-style-type: none"> <li>• Push notifications</li> <li>• Dead website or app</li> <li>• Information or text only</li> </ul>	<ul style="list-style-type: none"> <li>• Selection of games</li> <li>• Digital agent for interaction</li> <li>• Multimedia content</li> <li>• Feedback option in the app</li> </ul>
<b>Design</b>		
<ul style="list-style-type: none"> <li>• Customizable features</li> <li>• Age appropriate (language and design)</li> <li>• Intuitive and easy to use</li> </ul>	<ul style="list-style-type: none"> <li>• Childish</li> <li>• Clunky</li> <li>• Text only</li> </ul>	<ul style="list-style-type: none"> <li>• Customizable features</li> <li>• Designed and tested by users</li> </ul>
<b>Data and technology</b>		
<ul style="list-style-type: none"> <li>• Use cloud service to limit storage space</li> <li>• Transparent data tracking</li> <li>• User control over data or tracking</li> <li>• Data security and privacy</li> </ul>	<ul style="list-style-type: none"> <li>• Requires too much data</li> <li>• Crashes or is slow</li> <li>• Hidden data tracking</li> </ul>	<ul style="list-style-type: none"> <li>• Google Analytics provides insight for general use of app content<sup>a</sup></li> <li>• No individual data tracking through app<sup>a</sup></li> </ul>
<b>Mental health-specific</b>		
<ul style="list-style-type: none"> <li>• Teach and educate</li> <li>• Increase understanding</li> <li>• Opportunity to practice</li> <li>• Facilitate social connectedness</li> <li>• Signposting to services</li> </ul>	<ul style="list-style-type: none"> <li>• Signposting only</li> <li>• Text only</li> </ul>	<ul style="list-style-type: none"> <li>• Content that educates and increases understanding</li> <li>• Practice modules</li> <li>• Digital agent to feel socially connected</li> <li>• Signposting</li> </ul>

<sup>a</sup>Suggested by the app developer.

### Considerations and Design Implications

The patient-clinician-designer and cooperative inquiry framework recommend the inclusion of target users directly into the design process. We explored the usability of potential co-design methods with this group before using them in workshops with younger, untrained children. However, the PPI participants were significantly older (aged 12-19 years) than the expected user group, which might explain some of the difficulties that we faced when working with younger children in the co-design workshops (see *Co-design Workshops* section).

### Systematic Review and Meta-analysis

We conducted a systematic review and meta-analysis that aimed to understand potential intervention mechanisms, best practices, and suitable intervention components, as well as ways of measuring emotion regulation in youth [4]. We identified 21 studies, of which 9% (2/21) included some type of digital intervention. The results demonstrated a significant lack of technology-based interventions for youths and provided insights into the evidence base of existing psychological interventions and their impact on emotion dysregulation. Given the lack of any technology-based intervention for emotion regulation in our review, we had to rely on prior evidence that primarily

focused on face-to-face interventions. A meta-regression suggested that changes in emotion dysregulation are associated with changes in psychopathology [4].

With respect to intervention components, the evidence was strongest for cognitive behavior therapy (CBT) approaches. We created an overview of the different intervention components (eg, psychoeducation, mindfulness, and attention bias modification), which subsequently formed the first basic tenets of the app (Table 3). CBT models and theories (eg, thought-feelings-behavior triangle) informed the content of a series of animated videos, which served as psychoeducational components. The animations also discussed strategies that are commonly used in CBT interventions to enhance emotion regulation, such as problem solving, cognitive restructuring, mindfulness, and relaxation. A more detailed description of the intervention components identified in the systematic review can be found in the study by Moltrecht et al [4].

In contrast to existing interventions and the limitations identified in the systematic review, the present app puts a greater focus on adaptive emotion regulation processes, as evidence from developmental studies suggested that the lack of adaptive emotion regulation in early childhood is associated with increased emotion dysregulation later in life [40].



**Table 3.** Design implications based on systematic review.

Findings	Design implications and goals
CBT <sup>a</sup> interventions have the strongest evidence for face-to-face as well as digital interventions.	Integrate CBT concepts into the app, for example, psychoeducation about feelings, behavior, and thoughts
Interventions that improve emotion regulation also improve mental health.	Integrate exercises that enhance emotion regulation, for example, mindfulness
Emotion literacy, understanding, and differentiation are linked to better mental health.	Enhance children’s emotional literacy and understanding
Adaptive and positive emotion regulation are associated with less emotion dysregulation.	Include games that increase positive emotions and introduce adaptive emotion regulation strategies (eg, teach adaptive strategies)

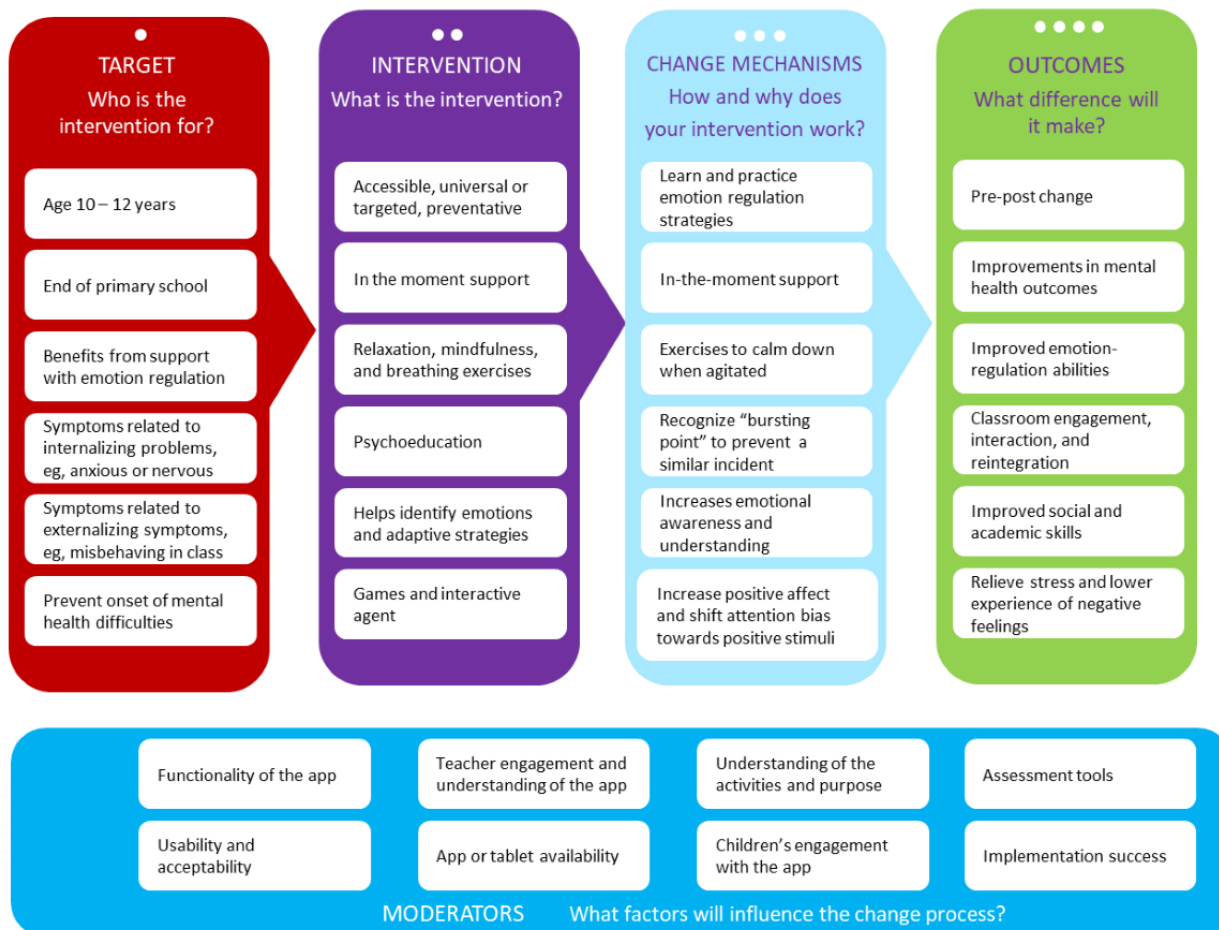
<sup>a</sup>CBT: cognitive behavioral therapy.

### Design Implications of Stage 1

On the basis of the stage 1 findings, we outlined the different intervention components, change mechanisms, moderators, and outcomes in a logic model (Figure 3). The logic model was developed to clarify the conceptual and logical underpinnings

of complex interventions used in child mental health services [34]. On the basis of our logic model and the outcomes of the PPI groups and school observations, initial wireframes were created by an app designer and developer. Furthermore, we decided on key criteria for the technology underlying the app (see the technology specifications in the following sections).

**Figure 3.** Stage 1 logic model of app intervention.



### Stage 2: Modeling and Design

#### Objectives

Stage 2 focused on involving children and other key stakeholders, including teachers, clinicians, researchers, the app developer, and designers, in the design and modeling process. This included the identification of key modules in the app, as

well as the development of content and design of each module, such as psychoeducational content, games, and exercises.

#### Activities, Data Analysis, and Resulting Design Formulations

Stage 2 comprised a highly iterative process, combining the results of the PPI events (Table 2) and co-design and participatory workshops, followed by 3 testing sessions to make

final design decisions and test the functionality and usability of the prototype. The combined use of PPI and user-centered design methods is highly recommended for the development of complex interventions [41]. Ethical approval to conduct these workshops was obtained from the University College London research ethics board (number 11701/001). We conducted 3 co-designs (N=15) and 3 participatory workshops (N=18) across 2 primary schools with 33 children (aged 10-12 years). Although specific demographic data, including the age and gender of the children, were not collected, the researcher team noticed that there was a slightly greater number of girls present in the workshops. Each workshop was conducted by the lead author and accompanied by a teacher.

The lead author took notes during each workshop and produced reflective notes afterward. Materials and notes produced during the workshops were coded manually and organized using mind-mapping exercises. Following this, a Microsoft Excel sheet was created to provide an overview of all items raised in the workshops. Each item was discussed with the app developer and designer to identify whether and how they could be integrated into the app. Each item in the Microsoft Excel sheet was color coded accordingly as follows: *green*=can be done, *orange*=might be possible or alternative suggestion to be tested in next workshop, and *red*=on hold or technology or design do not allow for this. On occasion, other stakeholders were involved, such as clinicians, to provide feedback on specific modules; their involvement is described in more detail in the respective sections.

### Co-design Workshops

The first co-design workshop introduced children to the project and their role as cocreators. After an icebreaker exercise, we explored what children knew about mental health and emotions, including what strategies they used in different emotion-eliciting situations. The first workshop did not involve specific wireframes, as the focus for this stage was to explore freely with children what activities and potential app features could help them regulate their feelings.

Children wrote down what feelings they knew (on sticky notes) and identified which feelings they found most difficult to regulate. Children reported that intense negative and positive emotions had a negative impact on their behavior in school (eg, “When I am super excited, I cannot concentrate” or “when I am angry, I don’t want to do stuff.”). In relation to this, children shared personal stories of situations that tended to elicit strong feelings in them either at school or at home.

On the basis of the children’s suggestions, we created a list of day-to-day strategies, which included strategies such as the following: *playing web-based games*, *listening to music*, *drawing and painting*, *watching something funny on YouTube*, *playing with my pet*, and physical activities such as *cycling or football with friends*. As a next step, we discussed the activities that could be supported through the app. The final list was then used to create overarching categories, which formed the core components of the app: (1) games to play, (2) something to relax, and (3) something to watch.

Going forward, we focused on these components as key modules while linking them to the stage 1 findings. For the games module, we created a list of possible games with the children. They frequently mentioned existing popular video games (eg, *Fortnite*) but also referred to other apps such as music making, coloring in, drawing in sand, and fast reaction games. In discussion with the app developer, each item was marked as *possible*, *alternative game*, or *not possible*. Complex games with multiple levels, requiring frequent updates, large amounts of data, or needing high resolution were discarded, as they conflicted with other design goals, such as (1) slowing down the app, (2) requiring too much data, or (3) not being suitable for a small mobile device. Owing to this, we had to exclude game ideas suggested by children, such as coloring in, music making, taking care and raising a pet, and a reaction game where the user smashes eggs by hitting them.

Simultaneously, the research team screened the literature to identify existing evidence for any of the games suggested or other games that have been developed in other contexts for this age group.

We asked the children what activities they found to be relaxing. Many suggested mindfulness and breathing exercises, which they had learned about at school. Others suggested *watching something on the web* or *listening to music*. This led to the idea of including music, or sound features, and encouraged us to make animated videos that could guide children with mindfulness and breathing exercises.

For the *watch* modules, we decided to develop a series of animated films. The storylines were inspired by children’s reports on their emotion-eliciting situations and the associated feelings, thoughts, and behaviors (eg, having a fight with a friend and not being able to concentrate in class). The stories were complemented with theories grounded in CBT (eg, the behavior–thoughts–feelings triangle) so that they could serve as a psychoeducational component. The scripts and screens were developed by a clinical psychologist and an animator who specializes in communicating mental health concepts to the public. Drafts of the films were reviewed by clinicians (N=7) who worked with children and in schools and a group of researchers specializing in child emotion regulation (N=5). Both provided feedback on the scripts and the visual presentation of the content and helped to ensure that they were in line with current evidence and guidelines. Any changes to the script or content were presented to children in subsequent workshops to ensure that they were age appropriate and that children could identify with it.

For the second and third workshops, wireframes and potential screen designs were printed on A3 paper based on the 3 core modules. Children were provided with pens, stickers, and sticky notes to add ideas for new features and review existing features. In contrast to the Druin [32] reports, but in line with recent observations by Jones et al [42], some children seemed to struggle with the creation of visual representations for potential app functions. It seemed as if they could not visualize how something that was drawn on paper could later be transferred to an app. As a result, some children were hesitant to draw their ideas and preferred to describe them. Therefore, we decided to

build a basic but high-tech prototype for subsequent workshops, which seemed to make it easier for children to provide suggestions for existing and new app features.

### Participatory Workshops

We asked the children to provide feedback on the high-tech prototype that we developed based on the outcomes of the co-design workshops. In comparison to the low-tech paper prototypes, the high-tech prototype made it significantly easier for children to find their role in the process and provide suggestions for and against potential app features.

During the participatory workshops (N=18), children raised the need for a feature that provided in-the-moment support. They reported that it was difficult to remember helpful strategies when they experienced strong feelings. Following this, a *help button* was added, which children could press when they were experiencing strong emotions and could not remember the tools or strategies available to them.

Moreover, children suggested that it would help them if they could tell the app how they felt, and it told them in return what they could do about their feelings (“Can I tell it how I feel and it tells me what to do?”). This possibility was first explored through a chatbot function, whereby children could tap on an animated agent on the home screen to open a chat window. When we tested this feature in subsequent workshops, it became evident that some children thought that they were speaking to an actual person (ie, “Who is on the other side?”). Therefore, we decided against the chatbot function for this age group, as it involved potential risks, for instance, if a child needed urgent help and tried to access it through the chatbot. Although the chatbot function presents an exciting opportunity for engaging

children with the app, developing it further was beyond the scope of this research. Hence, we decided to replace the chatbot with a *check-in function*. With this feature, children could select a feeling from a list to indicate their emotional state, and in return, the app would provide suggestions on what to do. This feature was considered a safer alternative by clinicians and researchers and required less complex functionality and development time (see *The Check-in Function* below).

For the check-in function, an initial list of 12 feelings was created based on the most common feelings that children reported in the first round of the co-design workshops. We designed a set of images, each representing 1 of the 12 feelings. We tested the validity by showing children the images without a description and letting them rate what emotions were represented. On the basis of the children’s feedback, the images were further adjusted. Children also highlighted important emotions that were missing; therefore, the list was extended. The final list aimed to reflect a full range of feelings, ranging from emotions with positive or neutral valence to negative valence, as well as different levels of arousal. For instance, *feeling excited* represents an emotion of positive valence and high arousal, whereas *feeling grateful* is a state of positive emotional valence but low arousal.

Consequently, the functionality of the animated agent was reduced to two main functions: (1) *tell me something*, which activated a random selection of jokes or funny facts that were expected to increase the level of engagement and perceived level of interaction with the app, and (2) the *check-in* function, as presented above.

A summary of all items raised in the workshops and the resulting changes to the app are presented in [Table 4](#).

**Table 4.** Observations and design implications based on participatory design workshops.

Observations and feedback	Implications, solutions, and actions
<ul style="list-style-type: none"> <li>Games to play and feel happy</li> </ul>	<ul style="list-style-type: none"> <li>We created a list of games to discuss with the app developer.</li> <li>Solutions and suggestions were tested and further adjusted with children in the next workshop.</li> </ul>
<ul style="list-style-type: none"> <li>Children suggested breathing and mindfulness exercises, which they knew from school.</li> </ul>	<ul style="list-style-type: none"> <li>We developed animated videos to guide them through exercises.</li> </ul>
<ul style="list-style-type: none"> <li>Children would like a feature to create music.</li> <li>Children listen to music to relax.</li> </ul>	<ul style="list-style-type: none"> <li>Music making feature conflicted with the usability of the app.</li> <li>We added music and sounds to the relax module.</li> </ul>
<ul style="list-style-type: none"> <li>Children frequently reported watching videos as a way of calming down, relaxing, being happy, and distracting themselves.</li> </ul>	<ul style="list-style-type: none"> <li>We created video content for watch modules.</li> </ul>
<ul style="list-style-type: none"> <li>“Can I tell it how I feel and it tells me what to do?” indicated that children would like some guidance and support in difficult situations and with specific feelings.</li> </ul>	<ul style="list-style-type: none"> <li>We explored the chatbot function, which was then replaced with the check-in function.</li> </ul>
<ul style="list-style-type: none"> <li>Children requested in-the-moment support when feelings were too intense.</li> </ul>	<ul style="list-style-type: none"> <li>We added an easy-to-reach help button to the home screen of the app. Once pressed, a stop and breathe sign covered the whole screen, which is followed by a guided breathing exercise.</li> </ul>
<ul style="list-style-type: none"> <li>Children thought that they were talking with a real person in chat.</li> </ul>	<ul style="list-style-type: none"> <li>We replaced the chatbot with a check-in function.</li> </ul>
<ul style="list-style-type: none"> <li>Children liked to interact with the digital agent and wanted more of that.</li> </ul>	<ul style="list-style-type: none"> <li>We kept the digital agent and added interactive features.</li> </ul>
<ul style="list-style-type: none"> <li>Children reported watching and listening to funny things to feel better.</li> </ul>	<ul style="list-style-type: none"> <li>We asked children for jokes and fun facts and added these to the animated agent, which was in line with our goal of increasing opportunities for interaction.</li> </ul>
<ul style="list-style-type: none"> <li>Speech bubbles of agent too fast</li> </ul>	<ul style="list-style-type: none"> <li>We increased the length of time of the speech bubbles.</li> </ul>
<ul style="list-style-type: none"> <li>The onboarding process required more colors and options</li> </ul>	<ul style="list-style-type: none"> <li>We added background colors and a selection of different color themes.</li> </ul>
<ul style="list-style-type: none"> <li>Explainer on how to use the app</li> </ul>	<ul style="list-style-type: none"> <li>We added stars to highlight different functions in the app for first-time users. This was discarded as it was too complex to adjust the position of the stars on the screen for different screen sizes.</li> <li>We added a short explainer video as part of the onboarding process.</li> </ul>

## Prototype Testing

The prototype was tested in another primary school with 15 children across 3 workshops. During these workshops, broad design features, such as the flow of screens, as well as more detailed design questions regarding language and use of colors, were discussed. The schools provided tablets, which allowed us to test the functionality of the app across different devices and the school’s technology infrastructure (eg, access to Wi-Fi and digital safety policies of the school). The teacher was present at each workshop.

At the beginning of the workshops, children were informed about the purpose of the app but were not given any instructions on how to use the app. This allowed us to observe whether the current design was intuitive enough for children to use it without much explanation. Children were encouraged to speak out loud their thoughts while navigating through the app. A researcher

observed the children and took written notes about the ways in which they explored the app to identify pitfalls, popular items, technical difficulties, and features that they did not discover on their own. Following this, children received an in-depth introduction and were asked to be technology detectives who helped us find any glitches and errors. All children were encouraged to provide honest feedback and suggestions concerning the usability of the app and how it could be improved.

BM took part in each workshop, asked follow-up questions, and took notes. After each workshop, BM made reflective notes and asked teachers about their observations. The data were organized in a Microsoft Excel spreadsheet according to specific app functions. The spreadsheet was used to discuss each item with the app developer and designer, who subsequently adjusted the app. A summary of the items raised and adjustments made is provided in [Table 5](#).

**Table 5.** Observations and implications following prototype testing.

Observations and feedback	Design implications and actions
<ul style="list-style-type: none"> <li>Difficulties with certain functions dependent on different uses of browsers</li> </ul>	<ul style="list-style-type: none"> <li>Test the web-based app across different browsers and devices</li> </ul>
<ul style="list-style-type: none"> <li>The screen and design did not adjust correctly for devices of different sizes.</li> </ul>	<ul style="list-style-type: none"> <li>Test with different screens and devices</li> </ul>
<ul style="list-style-type: none"> <li>Animated videos were sometimes slow.</li> </ul>	<ul style="list-style-type: none"> <li>Improve video quality</li> <li>Make them available offline</li> </ul>
<ul style="list-style-type: none"> <li>Add personalized tools to the tools list</li> <li>Differentiate between in-class and out-of-class tools list, as some tools, for example, go outside, were not suitable for the classroom context</li> </ul>	<ul style="list-style-type: none"> <li>Children can mark favorite tools in the list.</li> <li>Two tabs for different contexts</li> </ul>
<ul style="list-style-type: none"> <li>Problems with log-in.</li> <li>Children either did not have an email address or forgot log-in details.</li> </ul>	<ul style="list-style-type: none"> <li>Add different log-ins for quick classroom access and use at home</li> </ul>
<ul style="list-style-type: none"> <li>Music did not stop when leaving the module</li> </ul>	<ul style="list-style-type: none"> <li>App developer checks stop and pause functions, and music and videos automatically pause when leaving a module</li> </ul>
<ul style="list-style-type: none"> <li>Some of the games did not start.</li> </ul>	<ul style="list-style-type: none"> <li>App developer adjusts underlying technology</li> </ul>

## Results

### Intervention Design and Evidence Base: Technical Specifications

The intervention was developed as a responsive web-based app to increase the accessibility of the app, as it allows users to access it from different mobile devices, desktop computers, and smartboards. Although it works across multiple platforms, it was optimized for tablets, as children are more likely to have access to tablets at school and at home [43].

The app is delivered through a browser, meaning over-the-wire updates could be pushed out instantly, and the app uses advanced HTML5, cascading style sheets level 3, and JavaScript (ECMAScript 6) techniques to render a smooth and performant UX. The underlying development platform used was Meteor.js, a full-stack Node.js application development framework, hosted on a resilient Amazon Web Services Elastic Compute Cloud-2 instance with a MongoDB database hosted via MongoDB Atlas. The app only requires an internet connection when users access it for the first time, after which it can be saved to the home screen. This feature was chosen to mitigate risks that the

intervention could not be accessed in the case of reduced or limited Wi-Fi.

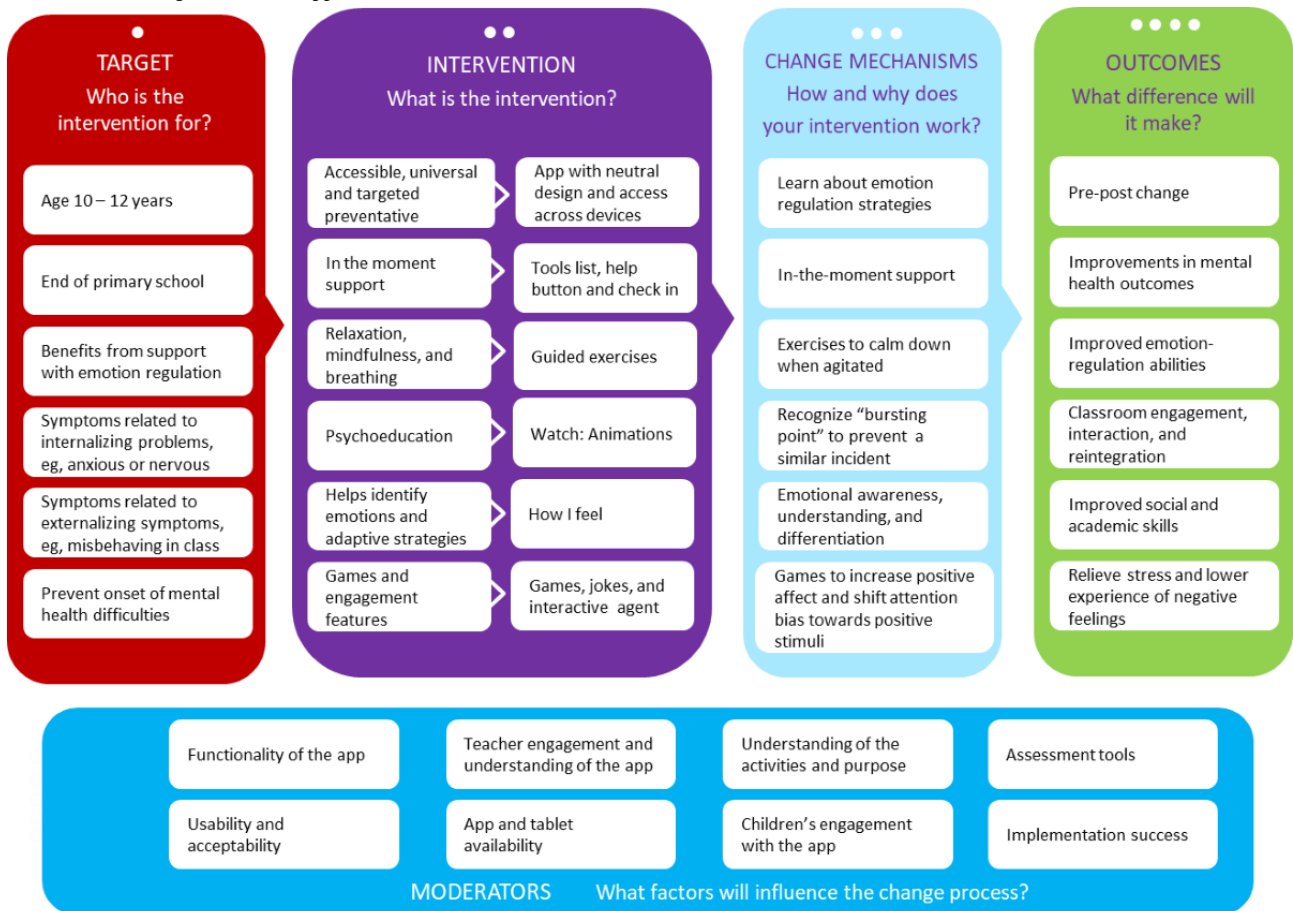
The app offers two different types of log-ins: a guest log-in and a registered account log-in. The guest-log-in serves the following purposes: (1) new users can explore the app without having to register, (2) children without an email address can use the app, and (3) it allows for easy and fast access. The second log-in allows users to set up a personal account registered through an email address and password. The app only remembers personalized features (eg, design features) when users access it through their personal account. The app does not store any individual user data and adheres to existing general data protection regulations.

### Intervention Description

The latest version of the intervention includes four modules: play, relax, watch, and tools. The different modules provide users with opportunities to learn, practice, and develop their emotion regulation skills. The content is presented through audio tracks, images, animated films, and games. On the basis of the activities and findings outlined above, we adjusted the logic model further (Figure 4).



Figure 4. Finalized logic model for app intervention.



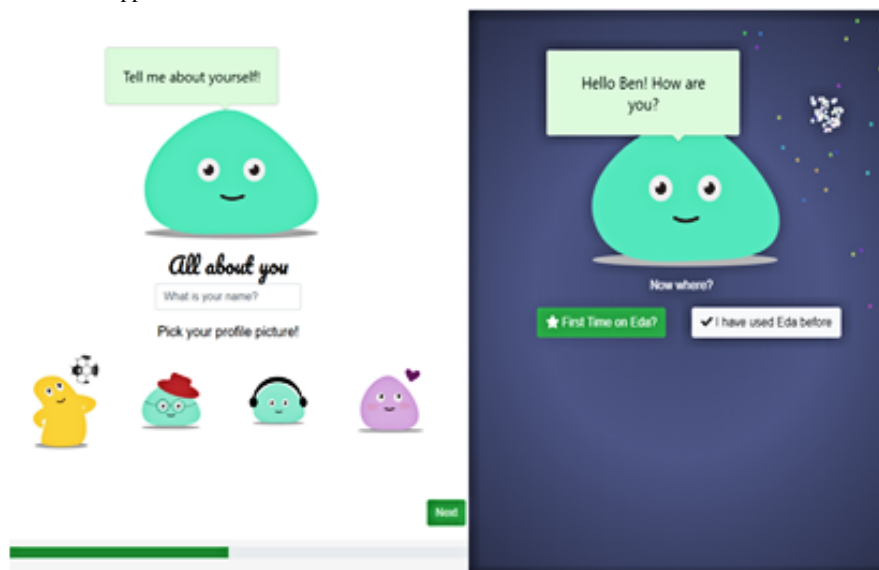
## Onboarding Process and Home Screen

### Overview

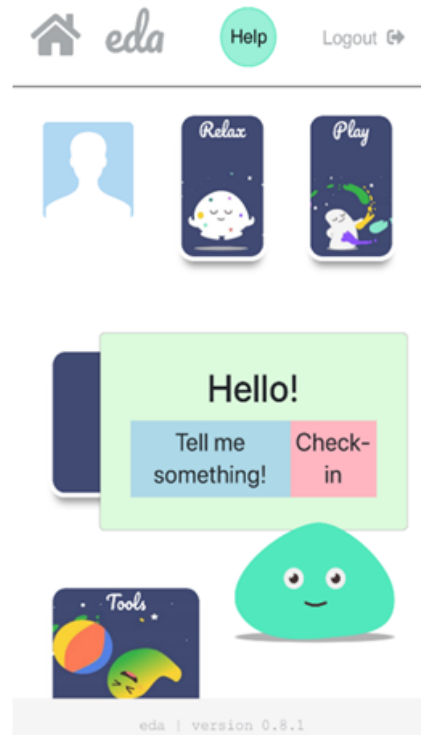
First-time users go through an onboarding process before they reach the home screen of the app. During this process, they learn about the purpose of the app, provide account details (eg, username), and select a preferred color scheme and profile

picture (Figure 5). After the onboarding process, the user enters the home screen, where Eda, an animated digital agent, greets them with their chosen username. Eda encourages them to explore the app or tap on its body to open the *check-in* or *tell me something* functions. The latter activates a random selection of jokes or funny facts to increase the level of engagement with the app (Figure 6).

Figure 5. Onboarding screens of the app.



**Figure 6.** Home screen of the app with 4 main modules and the digital agent.



### ***The Digital Agent***

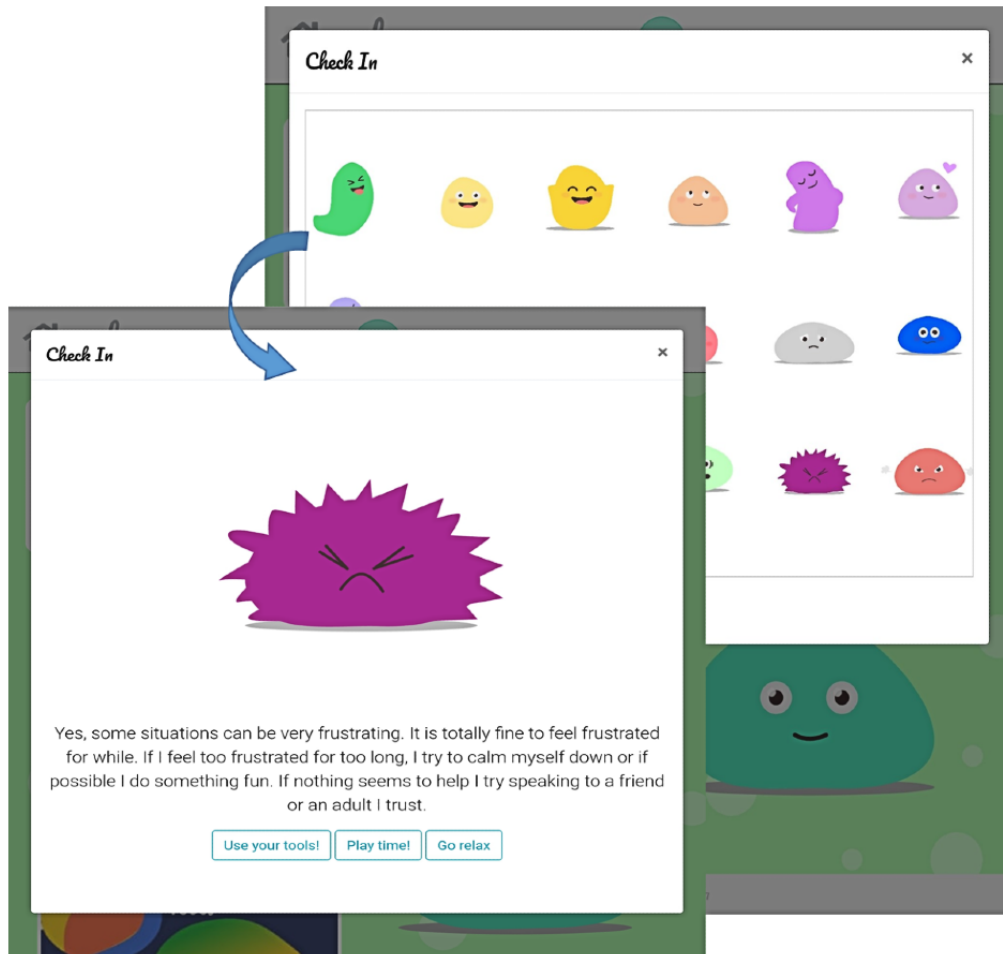
We aimed to design Eda as a gender-neutral, animated agent who accompanies the user through the different modules in the app. This feature was added based on the children's requests to have someone to turn to in situations where strong emotions are experienced. In addition, research has shown that the use of animated agents can facilitate the experience of having a personal relationship, which in turn increases long-term engagement with a digital intervention [44]. The digital agent was designed as a moving (or *wobbling*) blob with big, blinking eyes to add a human feel to it, which is hoped to enhance a feeling of connectedness and engagement in the user [45].

### ***The Check-in Function***

The *check-in* function (Figure 7) displays a set of 18 different feelings to the user. When the user selects a specific feeling, a

new window opens up that provides more information about the chosen feeling and provides suggestions regarding potentially helpful emotion regulation strategies. Where appropriate, cross-links to other modules in the app are provided (eg, relax) so that the user has the opportunity to immediately apply or practice these strategies. This approach is in line with past research that has structured emotions along the 2 dimensions of arousal (high vs low) and valence (positive vs negative) [46]. It has been suggested that internalizing symptoms are associated with the primary experience of low-arousal emotions, whereas externalizing symptoms are linked to high-arousal emotions [47]. We believe that this function not only meets the children's initial requests but can also help them expand their emotional literacy and emotion differentiation skills, which has been linked to better mental health and is therefore in line with the purpose of the present app [48-50].

Figure 7. Check-in function in the app.

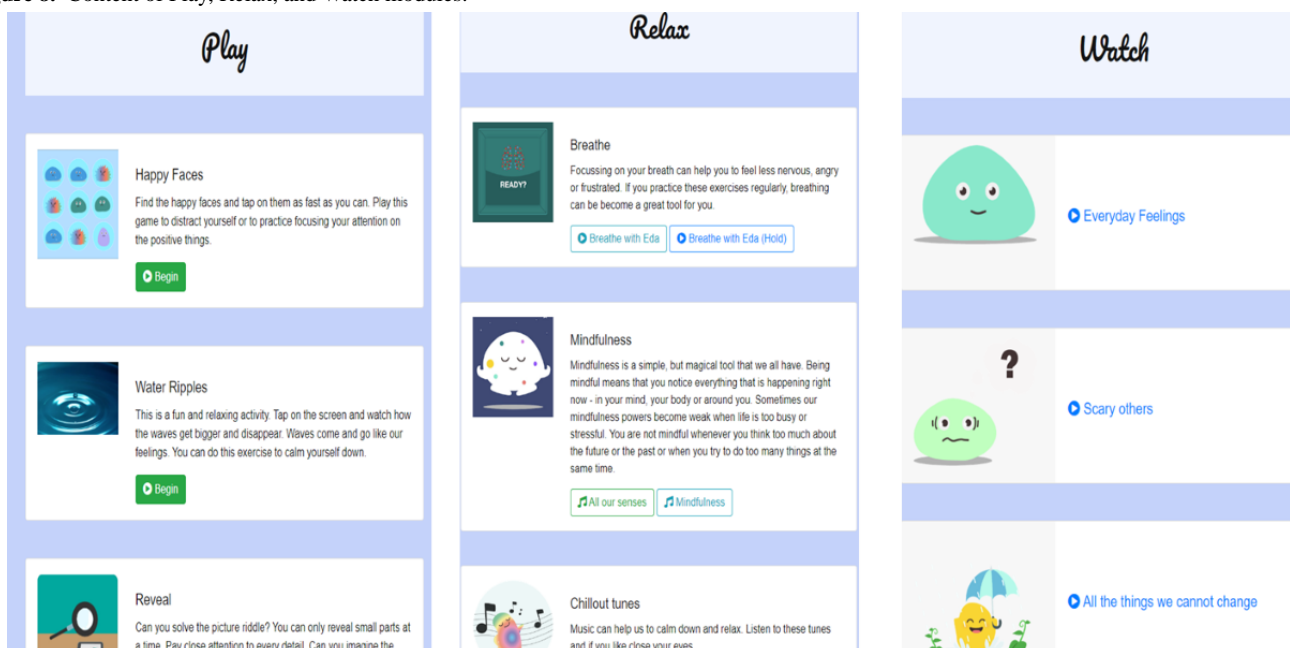


**Education and Practice Modules**

Users can access 1 of the 4 main modules (Figure 8) manually via the home screen or by selecting an emotion in the check-in

function, which subsequently forwards the user to one of the practice modules.

Figure 8. Content of Play, Relax, and Watch modules.



## Play

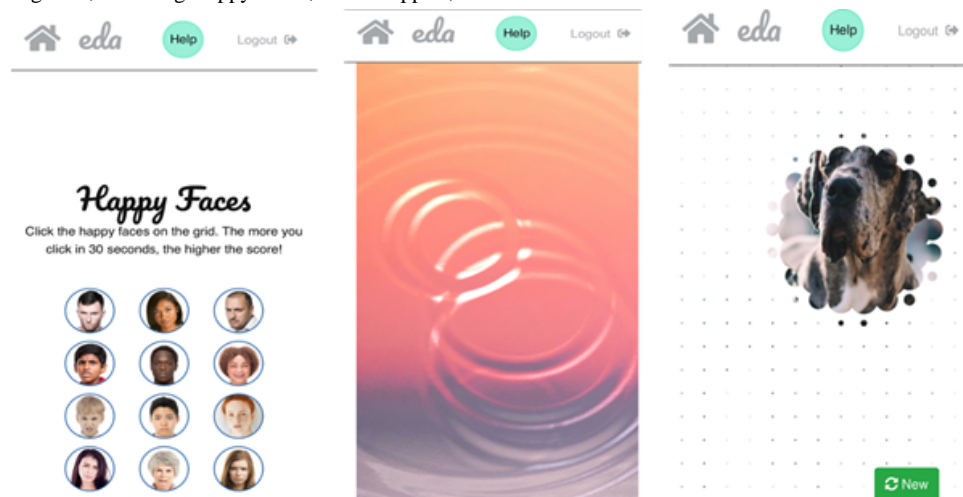
This module contains 3 games (Figure 9). In the first game, *Happy Faces*, the user must identify 1 happy face among 12 neutral or angry faces. This design was chosen because research shows that search tasks such as these can result in an attention bias shift toward positive stimuli, which in turn increases the likelihood of experiencing more positive emotions [51]. During one of the workshops, some children suggested that the game should have a second level of increased difficulty by animating the faces so that they move over the screen like balloons. In discussions with the app developer, this specific feature was considered too complex for the present version of the app but will be further explored in the future.

The second game, *Water Ripples*, presents a colorful picture with an animated water surface. By tapping the screen, the water animation creates circular waves that slowly expand to the sides of the screen. The design evolved from the co-design workshops, where children reported that drawing in sand or water drops had a calming effect on them. Furthermore, it resembles a

commonly used mindfulness exercise, in which individuals imagine their emotions as waves that come and go [52].

The third game, *Reveal*, shows a colorful picture that is covered by a white layer. By touching the layer with a finger, parts of the white layer disappear and reveal sections of the underlying picture. The user is encouraged to guess the theme or object of the underlying picture. Although there was no specific psychological theory to guide the design of this game, especially in the context of a mental health intervention, research has shown that games such as the ones chosen here foster engagement [53]. Furthermore, games have been shown to increase positive affect and well-being, although more research is needed to identify which specific aspects initiate the change and whether or how this might differ for different users [54,55]. When testing this game with the children for the first time, it became evident that they (1) wanted to know whether they identified the correct underlying picture and (2) that adding a point or reward system for correct answers could further increase their engagement with this game.

**Figure 9.** Overview of games, including Happy Faces, Water Ripples, and Reveal.

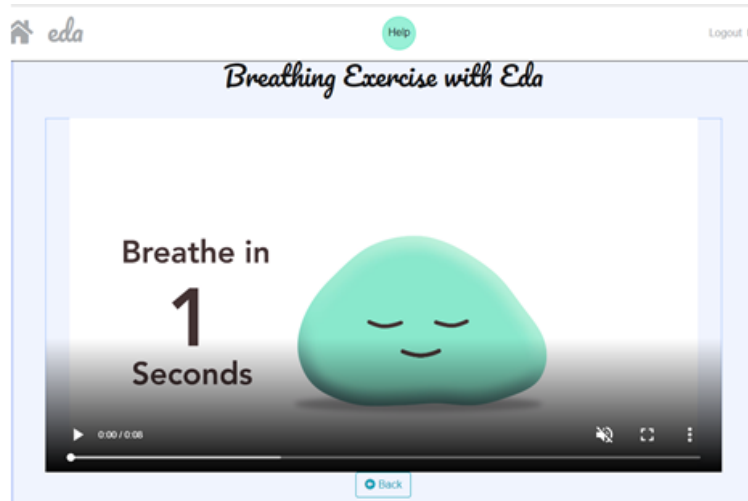


## Relax

The relax module was inspired by the school observations and reports from children during the workshops, which indicated that most schools already used breathing and mindfulness methods; hence, many children were already familiar with relaxation exercises. In line with this, increasing evidence shows that mindfulness interventions enhance emotion regulation and exert positive effects on mental health and well-being [56,57].

The relax module contains 3 sections that encourage the user to actively engage in some type of relaxation or mindfulness exercise. The user can choose from video animated breathing exercises (Figure 10), audio-guided mindfulness exercises, and a selection of calming sounds (eg, guitar or rain). The decision to include sounds or relaxing music was based on the children's suggestions in the workshop, as well as classroom observations, where teachers used music to keep children concentrated during a task.

Figure 10. Screenshot of guided breathing animation.

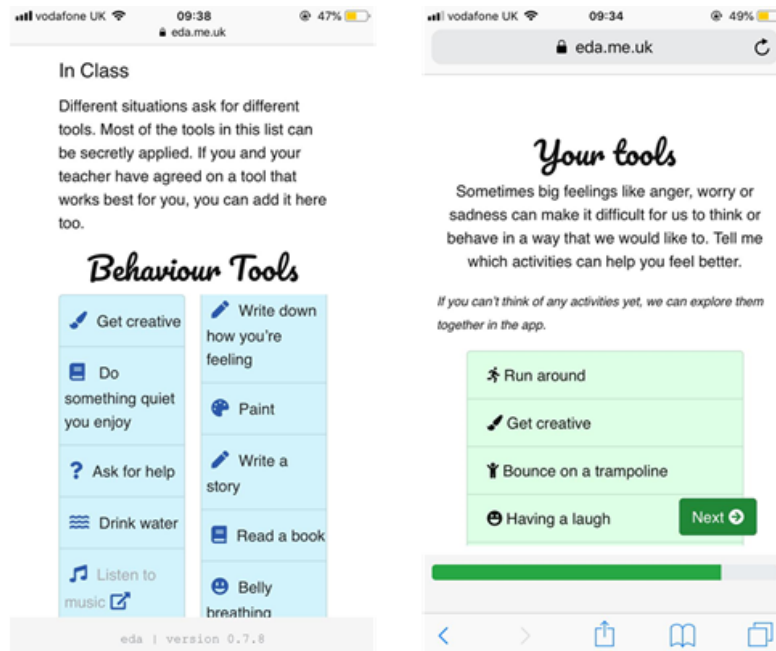


**Tools List**

The tools module evolved from conversations with children who indicated that they used different methods to regulate their emotions; some of these methods were developed with the help of a teacher. Thus, the tools module comprises a list of behavioral and cognitive strategies that are expected to help with intense emotions (Figure 11). The list is divided into a general tools list that can be referred to outside of the classroom (eg, doing something fun and getting support from a friend) and a specific list suitable for the classroom (eg, going to the quiet zone).

With respect to existing evidence demonstrating that the lack of and limited access to appropriate emotion regulation strategies contributes to mental health difficulties, it was expected that giving users easy access to these tools would positively influence their emotion regulation abilities [58]. Furthermore, research has shown that early school years represent a crucial time for children to expand their repertoire of emotion regulation strategies, including cognitive and behavioral strategies [59]; hence, it was assumed that the tools list could positively support this development.

Figure 11. Tools list feature showing different tools for different contexts and personalized tools.



**Watch**

This module contains animated psychoeducational films to improve users' understanding of emotions, emotion regulation strategies, and how thoughts and behaviors influence emotional experiences. This is achieved by explaining commonly applied CBT principles in simple terms and by introducing some of the

more complex emotion regulation strategies, such as cognitively restructuring one's thoughts (ie, cognitive reappraisal) or mindfulness [60,61]. Research has shown that CBT-based interventions successfully improve a variety of psychopathological symptoms, even if delivered through technology-based platforms [15]. Furthermore, the results of the systematic review demonstrated that CBT-based



interventions were effective in improving emotion regulation difficulties in youths.

### **Help Function**

This function was included based on the children's requests to have more in-the-moment support when they experience high levels of negative emotions, which can prevent them from engaging in adaptive decision-making.

Therefore, by clicking on the help button, a series of emotion regulation methods are presented to the user (ie, stop what you are doing, count to 3, and breathe), who is instructed to follow them until the initial emotional reaction decreases to allow for more adaptive actions. This functionality is also in line with research indicating that the duration of an emotional experience is influenced by the type of emotion regulation strategy used [62]. It was expected that the help function would support children to distract themselves from emotion-eliciting stimuli. Distraction is an emotion regulation strategy that has been shown to quickly decrease the levels of negative emotions [63,64]. Similarly, the use of distraction strategies to regulate intense emotions is a substantial part of dialectic behavioral therapy, which has been shown to effectively support individuals with severe emotion regulation problems [65,66].

## **Discussion**

### **Principal Findings**

Mobile apps for children represent a promising pathway for providing effective mental health support; however, there is a significant lack of mental health apps for this age group (ages 10-12 years) [7,9]. Only recently, the self-management intervention ReZone was developed for children (aged 10-15 years) with the aim of reducing internalizing and externalizing symptoms [67]. Early findings suggest that the app was perceived as helpful by pupils; however, findings from a proposed randomized controlled trial have not yet been published. In addition, Hides et al [68] developed a new music app to enhance emotion regulation in adolescents, and their initial findings with young people (N=169; aged 16-25 years) suggested that the app could potentially enhance emotion regulation; however, further testing is required to determine its effectiveness.

As highlighted above, for many mental health apps for children, information on the design and testing process is not available [7]; hence, we address this gap by describing and sharing our development and design process as we continue to develop the app further.

### **Strength, Limitations, and Lessons Learned**

A significant strength of the present development process is the inclusion of children and young people at every stage. Owing to existing collaborations, we were able to involve young advisors (aged 12-19 years) in the early stages of our project, which had numerous benefits. However, the inclusion of slightly older participants in the PPI events may have also contributed to some of the issues we experienced in the workshops with younger children. We believe that the work with young advisors was very valuable but want to highlight that the involvement

of the target users should be a priority when designing new digital interventions.

By combining methodologies from different fields, we adopted a highly interdisciplinary approach, the lack of which has been highlighted as a significant limitation in existing digital mental health interventions. We hope that in doing so, we increased the potential for sufficient user engagement while also providing a sound evidence base for the content of the intervention [12,15]. Despite our best efforts, it was not possible to have all the different experts in one room for the workshops. This can be particularly difficult in research that includes vulnerable populations, where additional safeguarding regulations are in place. Such access constraints affecting the work of HCI researchers and designers with vulnerable groups have been highlighted before [69]. In our project, the lead researcher was already trained to work with children and had easier access to the target group. To facilitate our interdisciplinary approach, BM undertook additional training to familiarize herself with the methods from the different disciplines and consulted experts from other fields before and after each activity. Throughout the development process, the lead author served as a linking point for all stakeholders and tried to gain and share everyone's views and opinions. Although in an ideal scenario, experts from different fields would be conducting the workshops together, we believe that we took the best possible approach by training the lead researchers in interdisciplinary methods and having regular consultations with experts from the respective fields.

Although the inclusion of various experts and stakeholders in the process is a significant strength of our development framework, we believe that this aspect could be further improved by developing a decision-making tool with all stakeholders beforehand. Such a tool could be consulted whenever contradicting design goals from different stakeholders need to be addressed. Our team did not develop such a tool, and final decisions were made by the research team, which may have resulted in unwanted biases.

The collaborative approach with schools had various benefits, as it ensured regular access to the user group and helped us identify context-specific design goals at an early stage. Furthermore, the research team was able to conduct all the design workshops within the school context, as recommended in the cooperative inquiry framework [32]. However, during the workshop activities, the research team noticed that children who were reported to show the most emotional and behavioral difficulties at school were also less engaged in the workshop. The research team had the impression that some of these vulnerable children may have engaged more in a different context. Going forward, we would suggest speaking to these children outside of the school context or choosing different workshop activities so that all voices can be taken into account. Furthermore, in most cases, the teachers decided which children would join the workshop activities. This could have caused an unwanted bias, as previous research suggests that adults were less likely to choose children with certain characteristics (ie, less sociable, externalizing symptoms, and lower academic competencies) [70]. In relation to that, it should be noted that the research team did not collect specific demographic or other sensitive category data, which could be useful in interpreting

current but also future use data. Collecting data on participant characteristics can provide insights into other mental health risk factors (eg, existing mental health problems, living status, and ethnicity), which can help in comparisons among different user groups that may be of the same age but have different mental health profiles. Therefore, we suggest that future research should collect relevant participant data during the early design stages.

Teachers contributed tremendously with their views and expertise. However, they had very limited time available, and their role as intervention deliverers has not yet been fully addressed at this stage. We suggest conducting more classroom observations with a specific focus on teachers' roles and needs to adjust the app accordingly. This could also be explored as part of an exploratory feasibility trial, which we suggest as a next step to develop and evaluate the present app further. We suggest a series of exploratory feasibility trials to uncover and iron out the remaining technology and design issues. Moreover, with respect to one of the greatest limitations of today's digital mental health interventions [12], we suggest that the next stages need to focus primarily on usability, engagement, and implementation of the present app before any effectiveness testing.

Throughout the development process, we noticed a tension between finding the right balance between guaranteeing an adequate evidence base for each feature of the intervention and

leaving enough room for creativity and innovation of new features. We strongly agree that evidence-based and evidence-informed concepts are of significant importance; however, there seems to be a common misconception that one can only achieve *evidence-based innovation* by *transforming* evidence-based nondigital interventions into digital ones [17]. We would like to encourage the field to free itself from this notion as it can significantly hinder us from reaching the actual potential of digital mental health interventions [71]. In relation to this, we would like to refer the readers to the findings of our exploratory trial [29], where we discuss promising future directions for the present app.

## Conclusions

Digital interventions that target transdiagnostic mechanisms such as emotion regulation have the potential to support young people's mental health on a wider scale, regardless of the level or type of symptoms that they experience. Currently, little guidance exists on how to develop such transdiagnostic digital interventions for children. We highlight the existing limitations in the field and present a new approach to address them in this project. By developing a new interdisciplinary development framework, we were able to incorporate methods from different fields. Although more research is needed to evaluate and further improve this app, we hope that sharing our insights and lessons learned in this paper will be a helpful guide to others.

## Acknowledgments

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## Authors' Contributions

BM conducted this research as part of her PhD at the Anna Freud Center and University College London. She received funding for this study from the European Union's Horizon 2020 program under the Marie Skłodowska-Curie grant agreement (grant 722561). BM was involved in conceptualizing, data collection, data analysis, writing, editing, and reviewing the manuscript.

PP, JD, and JEC supervised BM during her PhD and were involved in conceptualizing and designing the study, writing, editing, and reviewing the manuscript.

HAB conducted her PhD alongside BM and was involved in conceptualizing, writing, editing, and reviewing the manuscript.

## Conflicts of Interest

The app development company and the authors have no financial gains from the app. The app development company contracted the project. The costs resulting from this project were covered by BM's PhD scholarship, as stated above. The project formed part of BM's independent PhD research; therefore, the intellectual property rights of the content of the app lie with the first author.

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## Abbreviations

**CBT:** cognitive behavior therapy

**HCI:** human-computer interaction



**PPI:** patient and public involvement

**UX:** user experience

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Original Paper

# A Remote Health Coaching, Text-Based Walking Program in Ethnic Minority Primary Care Patients With Overweight and Obesity: Feasibility and Acceptability Pilot Study

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## Abstract

**Background:** Over half of US adults have at least one chronic disease, including obesity. Although physical activity is an important component of chronic disease self-management, few reach the recommended physical activity goals. Individuals who identify as racial and ethnic minorities are disproportionately affected by chronic diseases and physical inactivity. Interventions using consumer-based wearable devices have shown promise for increasing physical activity among patients with chronic diseases; however, populations with the most to gain, such as minorities, have been poorly represented to date.

**Objective:** This study aims to assess the feasibility, acceptability, and preliminary outcomes of an 8-week text-based coaching and Fitbit program aimed at increasing the number of steps in a predominantly overweight ethnic minority population.

**Methods:** Overweight patients (BMI >25 kg/m<sup>2</sup>) were recruited from an internal medicine clinic located in an inner-city academic medical center. Fitbit devices were provided. Using 2-way SMS text messaging, health coaches (HCs) guided patients to establish weekly step goals that were specific, measurable, attainable, realistic, and time-bound. SMS text messaging and Fitbit activities were managed using a custom-designed app. Program feasibility was assessed via the recruitment rate, retention rate (the proportion of eligible participants completing the 8-week program), and patient engagement (based on the number of weekly text message goals set with the HC across the 8-week period). Acceptability was assessed using a qualitative, summative evaluation. Exploratory statistical analysis included evaluating the average weekly steps in week 1 compared with week 8 using a paired *t* test (2-tailed) and modeling daily steps over time using a linear mixed model.

**Results:** Of the 33 patients initially screened; 30 (91%) patients were enrolled in the study. At baseline, the average BMI was 39.3 (SD 9.3) kg/m<sup>2</sup>, with 70% (23/33) of participants presenting as obese. A total of 30% (9/30) of participants self-rated their health as either *fair* or *poor*, and 73% (22/30) of participants set up ≥6 weekly goals across the 8-week program. In total, 93% (28/30) of participants completed a qualitative summative evaluation, and 10 themes emerged from the evaluation: patient motivation, convenient SMS text messaging experience, social support, supportive accountability, technology support, self-determined goals, achievable goals, feedback from Fitbit, challenges, and habit formation. There was no significant group change in the average weekly steps for week 1 compared with week 8 (mean difference 7.26, SD 6209.3; *P*=.99). However, 17% (5/30) of participants showed a significant increase in their daily steps.

**Conclusions:** Overall, the results demonstrate the feasibility and acceptability of a remotely delivered walking study that included an HC; SMS text messaging; a wearable device (Fitbit); and specific, measurable, attainable, realistic, and time-bound goals within an ethnic minority patient population. Results support further development and testing in larger samples to explore efficacy.

**KEYWORDS**

mHealth; Fitbit; SMART goals; texting; health coach; mobile phone

## Introduction

### Background

Approximately 52% of the adults in the United States live with at least one chronic disease, and 27% have multiple chronic diseases [1]. These estimates exclude obesity, which affects approximately 42% of the adults in the United States [2]. Physical activity is an important component of self-management for the most prevalent chronic diseases in the United States, such as hypertension, diabetes, asthma, and obesity [3,4]. Despite the benefits of physical activity in managing and preventing chronic disease, the rates of physical inactivity are considerable. Within the United States, rates vary by racial and ethnic groups, with 32% of Hispanic adults being physically inactive, followed by 30% of non-Hispanic Black adults and 23% of non-Hispanic White adults [5]. Even fewer reach the recommended levels of at least 150 minutes per week of moderate to intense aerobic activity (eg, brisk walking) [3]. A growing body of literature suggests that physical activity has a dose effect on health, with those who are the least active experiencing the greatest benefits [6,7]. Therefore, physically inactive individuals may experience significant health benefits by increasing the number of steps they walk [8,9].

Interventions designed to increase physical activity among people with chronic diseases in primary care have historically shown mixed results [10]. However, in 2010, the emergence of consumer-based wearables that track physical activity presented new approaches to address this problem [11,12]. Consumer-based wearables are devices that provide immediate, real-time, quantitative feedback on steps in addition to a variety of additional functions and parameters depending on the make and model [13]. Building upon the capacity to self-monitor as an important component of behavior change theory, physical activity interventions designed with wearables have increased in number over the past few years [12,14,15]. Typically, these patient-oriented interventions include a wearable device with some type of human support delivered by a combination of telephonic, SMS text messaging, and in-person sessions that were either one-on-one or group-based [12,16-19].

A total of 2 recent meta-analyses of physical activity interventions with wearables have reported small effect sizes overall, with some increase in daily steps. Lynch et al [15] identified 21 studies that met the initial criteria; however, heterogeneity was quite extensive across the studies. The results of a subset of 9 studies that included a comparison group suggested that wearables contributed to an approximate increase of 500 steps/day. A second meta-analysis conducted by Franssen et al [20] focused exclusively on wearable activity tracker-based interventions in patients with a range of chronic cardiometabolic diseases. The results of this analysis suggested an average increase of 2100 steps/day following the interventions [20]. Neither analysis explored the impact of participants' demographic characteristics on the response to the interventions.

In fact, with few exceptions, studies evaluating wearables have not described the racial and ethnic backgrounds of the participants [21]. Those that do report this information typically have a small representation from these groups [22]. This is problematic considering that racial and ethnic minorities and those with lower socioeconomic status likely have the most to gain from increased engagement in physical activity.

### Objectives

The aim of this study is to pilot-test an 8-week text-based walking program with physically inactive, ethnic minority patients within a primary care setting. The primary outcomes included feasibility and acceptability. A mixed methods research approach was used, which included a summative evaluation that offered qualitative information on the patients' experiences. The number of steps measured by Fitbit was analyzed as an estimate of the change in physical activity.

## Methods

### Participant Recruitment

Patients were recruited as a convenience sample within an internal medicine outpatient clinic that was part of an urban academic medical center serving a predominantly ethnic minority patient population. The research staff members were present in person. Recruitment relied on physicians and clinic staff who were aware of the study activities and referred patients presenting for a regularly scheduled appointment at their own discretion. However, they were asked to refer patients who were English-speaking, overweight, and healthy enough to increase their walking activity. As such, the sample was one of convenience. Once referred, the research staff screened patients for eligibility as follows: (1) self-reported that they engaged in <150 minutes of moderate to intense physical activity a week [23], (2) aged 21-65 years, (3) comfortable communicating in English, (4) not currently or planning to be pregnant, (5) had physician clearance to walk, (6) owned a smartphone with unlimited text messages, (7) sent text messages, (8) had no serious mental health issues, and (9) BMI >25 kg/m<sup>2</sup>. Only 1 participant per household was allowed to be recruited. Interested and eligible participants provided written informed consent. The consent informed patients that if an emergency arose, they should seek medical care directly and not rely on SMS text messaging the health coach (HC). All participants received the intervention. The enrollment goal was 30 participants.

### Fitbit and SMS Text Messaging Platform Setup

After completing an interviewer-administered demographic survey, participants received a Fitbit Charge 2 or Charge 3 and training on the device. The research staff downloaded the Fitbit app onto participants' smartphones using a study-designated Gmail account. The Fitbit device was synchronized to the Fitbit app. Patients' mobile phones and study identifiers were entered into Mytapp, a 2-way SMS text messaging platform used to

communicate and set goals with patients. Mytapp is a custom-designed research platform that uses Fitbit's web application programming interface to securely obtain physical activity data on participants (heart rate, steps, and battery status). Mytapp only provides a simple interface to visualize Fitbit data in graphical form at the time of request. No Fitbit data are ever stored on the Mytapp server. When HCs use Mytapp, they are able to view the most recent Fitbit data available on demand (based on the last time the user synchronized their Fitbit device).

All communication over the 8-week intervention period was transmitted through text messages sent on Mytapp. Text messages sent by the HCs were in free form. Participants were informed that replying with *STOP*, *QUIT*, or *END* would automatically block Mytapp from sending further messages without requiring contact from the research team. Participants who wished to withdraw from the study needed to explicitly indicate so in text or contact a research member.

### Health Coaches

Participants were assigned to 1 of the 3 HCs who were research team members unaffiliated with the clinic. The lead HC was an experienced health psychologist (LS), who formally trained two other coaches on all study activities, including integration into the primary care clinic, patient recruitment and technology setup, Mytapp platform use, and the goal-setting process that supported participants setting their own goals. Coaches were responsible for tracking their panel of patients and monitoring the text messages daily.

### Goal-Setting Activities

Goal-setting followed the specific, measurable, attainable, realistic, and time-bound (SMART) goal framework. Participants were instructed that they would exchange a series of text messages with the HC to set a new step goal using the SMART goal framework each week. This was explained to patients in person at the time of recruitment and used in the process of setting the goal for week 1. They also received a handout that explained the SMART goal process in a low literacy language. To confirm that the messaging platform was successfully linked to their mobile phone, the staff set up the first goal through a text message with the patient. Finally, patients were told the name of their HC before leaving the clinic. Assignment to 1 of the 3 HCs was nonrandom. Within 1 hour of the patient leaving the clinic, the assigned HC was notified of a new patient and their first goal. Within 24 hours, the HC sent a text message to the patient with an introduction and welcome while confirming the set goal.

### Ethics Approval

The study was approved by the institutional review board at the University of Illinois at Chicago (institutional review board protocol number: 2016-0772).

### Intervention

All participants received the intervention in this pilot study. The walking program used 3 behavior change strategies found to be effective in increasing physical activity, including goal-setting, biofeedback, and prompts or cues to action [24].

Increased daily steps were theorized to be driven by individuals setting their personal SMART goal, which outlined explicit elements to increase success, such as time and location for walking, along with the number of steps. Participants set goals that they felt were realistic and achievable. HCs assisted the participants' assessment of this by assessing their confidence in reaching the goal on a scale from 0 to 10. Goals rated <8 were revised to increase the confidence of the participants. Fitbit devices provided immediate real-time feedback on steps, with HCs supporting the feedback through SMS text messaging, which reinforced the participants' goals as well as offering cues to action. In addition, the HC provided supportive accountability and social support for goal attainment.

For 8 weeks, the assigned HC sent text messages related to walking goals (eg, "Only 500 more steps to reach your goal for today!"). The participant set a new SMART goal with HC support each week via SMS text messaging. Goal-setting was expected to require several text message exchanges that could extend over a day or more. If the participant did not get a new goal set up within the 7-day week window, the subsequent week window began once the new goal was set. The HCs sent a minimum of 5 text messages each week. Additional text messages from the HC responded to patient-initiated text messages, troubleshoot synchronizing failures with the Fitbit, or reminded the participants to charge their Fitbit batteries.

### Intervention Fidelity and Safety Monitoring

To ensure HC fidelity to using the SMART goal framework with participants, HCs met weekly to review all text message exchanges. A psychologist with previous experience in the goal-setting framework reviewed the text messages with the team. Feedback and discussion focused on ensuring that all aspects of the SMART framework were addressed. In addition, standardized approaches to addressing goal-setting text messages were reviewed, with a focus on participants who had a delay in responding. Engagement in the program was defined as setting at least six goals over 8 weeks. Fitbit use was defined as participants having steps recorded within a 24-hour period in the Fitbit app. At enrollment, participants were instructed not to rely on the HC or SMS text messaging for medical emergencies. The HCs were instructed to report any concerning text message to the head psychologist immediately.

### Outcome Measures

The feasibility was assessed using several parameters. A fundamental indicator was the number of patients referred to the program, the number of patients who completed eligibility screening, and the number of patients who enrolled in the study. Engagement was operationalized as the number of weeks out of 8 weeks when a text message goal was set. The goal for engagement was 7 out of 8 weeks. Although no specific goal was set, the number of text messages sent and received by each participant and HC served as an additional descriptor of engagement. All text messages were stored in Mytapp. Retention was defined as the number of participants who set a goal in the last week of the program. Feasible retention was set at 80% for this pilot study. The feasibility of using the Fitbit trackers and Mytapp text messaging platform was assessed by maintaining a log of issues that arose during all phases of the program.

The acceptability of the program was assessed through a summative evaluation using qualitative methods and a 9-item standardized semistructured interview following the 8-week program. The summative evaluation addressed participants' experiences with the program, including their motivation to participate, the goal-setting process, the frequency of SMS text messaging, Fitbit devices, and HCs. Research assistants conducted interviews in person or by telephone, depending on the patient's availability. The interviews were audio recorded and transcribed using written notes. After the interview, the participants received a monetary compensation of US \$50 for their time and retained their Fitbit device after the study.

Preliminary exploratory outcomes included average daily steps and duration of physical activity categorized as sedentary, lightly active, or moderately to vigorously active times (in minutes) as recorded in the Fitbit app. The pilot study was not powered to detect differences in the outcomes.

### Analysis

Descriptive statistics were calculated for demographic characteristics and the average number of text messages sent by the participants. Exploratory statistical analysis of the Fitbit data was performed using SAS (version 9.4; SAS Institute). After ensuring that the Fitbit step data were normally distributed, a paired *t* test (2-tailed) was conducted on the average weekly steps for weeks 1 and 8. Daily steps over time were explored using a linear mixed model accounting for repeated measures, similar to the methods outlined in the study by Polgreen et al [25]. The duration of the study began at enrollment and continued until the end of the study period (ie, after 8 weeks) or study dropout. Participants who had a significant positive or negative association between steps and days were categorized as having an increase or decrease in daily steps, respectively. Those who had no significant association between steps and days were categorized as having no change in daily steps. The patient's average weekly steps were plotted across 8 weeks. The average of these values for all patients within each category (ie, whether they had an increase, decrease, or no change in their daily steps) was also plotted across 8 weeks. Changes in the average length of sedentary, lightly active, and moderately

to vigorously active time in minutes from week 1 to week 8 were evaluated using a paired *t* test, with 95% CIs also reported. Analyses of whether patient demographics and patient engagement were associated with being categorized as having increased daily steps were conducted using Fisher exact test because of small cell sizes. All statistical tests were evaluated at a significance level of 5%. Missing data were handled in a conservative manner by assigning 0 steps walked that day for days where steps were missing. This conservative assumption was based on the patient population self-reporting low physical activity levels.

Qualitative data from summative evaluation were coded and managed using QDA Miner Lite (version 5; Provalis Research) [26]. A total of 2 coders and a qualitative expert read all the interviews before the meeting to develop a coding scheme using thematic analysis. A total of 5 interviews were independently coded by the 2 coders, followed by reviewing and refining the codes by the qualitative expert. The coders independently applied the coding to the remaining interviews. Subsequently, the coders and the expert met to review all codes, resolve any discrepancies, and identify relevant themes.

## Results

### Baseline Characteristics

Participants were recruited from May 2019 to August 2019. Participant demographics and baseline characteristics are shown in [Table 1](#).

Of the 30 participants, 23 (77%) participants were women and were aged on average 47 years (SD 9.6 years). A total of 80% (24/30) of participants were African American, and 17% (5/30) were Hispanic or Latino. A total of 20% (6/30) of participants reported a yearly household income <US \$20,000, and 37% (11/30) of participants reported high school as their highest level of education. At baseline, the average BMI was 39.3 kg/m<sup>2</sup> (SD 9.3 kg/m<sup>2</sup>) and 77% (23/30) of the participants were considered obese (BMI≥30 kg/m<sup>2</sup>) [27]. A total of 30% (9/30) of participants self-rated their health as either *fair* or *poor*.



**Table 1.** Demographic and baseline characteristics (N=30).

Characteristics	Value
<b>Baseline BMI, mean (SD)</b>	39.3 (9.3)
Overweight (25.0 kg/m <sup>2</sup> >BMI<30 kg/m <sup>2</sup> ), n (%)	5 (18)
Obesity class 1 (30 kg/m <sup>2</sup> >BMI<35 kg/m <sup>2</sup> ), n (%)	7 (25)
Obesity class 2 (35 kg/m <sup>2</sup> >BMI<40 kg/m <sup>2</sup> ), n (%)	2 (7)
Obesity class 3 (BMI≥40 kg/m <sup>2</sup> ), n (%)	14 (50)
Age (years) at enrollment, mean (SD)	47.1 (9.6)
Gender (female), n (%)	23 (77)
<b>Race, n (%)</b>	
African American or Black	24 (80)
Hispanic or Latino	5 (17)
White and non-Hispanic	1 (3)
<b>Health insurance, n (%)</b>	
Health Maintenance Organization or Preferred Provider Organization	19 (63)
Medicare	2 (7)
Public aid or Medicaid	9 (30)
<b>Employment, n (%)</b>	
Worked full-time for pay	18 (60)
Worked part-time for pay	5 (17)
Disabled and unable to work	3 (10)
Out of work or unemployed	3 (10)
Retired	1 (3)
<b>Highest level of education, n (%)</b>	
High school diploma or General Educational Development	12 (40)
2-year certificate or associate degree	9 (30)
College graduate	9 (30)
<b>How would you describe your health? n (%)</b>	
Excellent	1 (3)
Very good	7 (23)
Good	13 (43)
Fair	8 (27)
Poor	1 (3)
<b>Marital status, n (%)</b>	
Married or living with partner	9 (30)
Divorced or widowed	3 (10)
Single, never married	18 (60)
<b>Yearly household income (US \$), n (%)</b>	
<19,999	6 (20)
20,000-49,999	9 (30)
50,000-69,999	8 (27)
≥70,000	6 (20)
Refused to answer	1 (3)

## Feasibility

### Recruitment and Retention

A total of 33 patients were referred by primary care physicians to the research staff. All 33 patients were screened for eligibility, of which 1 patient was ineligible because of the age criteria and 2 patients were not interested after screening. In total, 91% (30/33) of patients were enrolled in the study. The study's retention rate was 93% (28/30), exceeding the minimum 80% threshold. One individual withdrew from the study after week 6. Another individual stopped responding to the text messages from the HC starting week 4 and was withdrawn per established protocol. One individual lost their Fitbit device after week 4 but participated in the summative evaluation. Two of the first patients recruited received a Fitbit Charge 3, which the research

staff were unable to synchronize to the participants' mobile phone app or with the Mytapp app. As a result, HCs were not able to monitor the steps for these 2 patients. However, they set up weekly step goals with the HCs through SMS text messaging and self-monitored their daily steps on their Fitbit devices for the entire study. Charge 2 models were used on all subsequent participants without initial synchronizing problems.

### Engagement Through SMS Text Messaging

As the 2 patients who withdrew from the study contributed to <2 weeks of goal-setting text messages, they were excluded from the SMS text messaging analysis (decided a priori).

The average number of weekly text messages sent by 28 patients and their HCs each week is shown in [Table 2](#).

**Table 2.** Average weekly text messages sent by patients and coaches across 8 weeks (N=28)<sup>a</sup>.

Week	Patients, mean (SD)	Health coaches, mean (SD)
1	11 (5.9)	14.9 (7.4)
2	10.9 (7.7)	14.2 (8.5)
3	7.8 (5.4)	11.1 (5.5)
4	7.1 (3.9)	11.3 (5.3)
5	5.6 (3.1)	8.8 (4.7)
6	6.9 (5)	9.5 (4.7)
7	6.6 (4.4)	9.2 (5.2)
8	6.7 (3.3)	9.2 (3.6)

<sup>a</sup>Two patients were excluded from this analysis because they contributed to <2 weeks of goal-setting text messages.

The average number of text messages sent by HCs was significantly greater than the number sent by the participants ( $P=.02$ ) as expected. HCs sent reminder and motivational text messages that did not require a response. Interestingly, the difference remained fairly stable across time with HCs sending, on average, 3 to 4 more text messages than the participants, despite the average decrease over time for both groups. There were 73% (22/30) of patients who set at least seven goals across the 8 weeks, with 47% (14/30) patients setting a goal every week. A total of 13% (4/30) of patients set 6 goals, 3% (1/30)

of patients set 5 goals, and 10% (3/30) of patients set 3 goals or less.

### Acceptability

A total of 93% (28/30) of participants completed the exit interview, which lasted between 15 and 30 minutes. Owing to availability, telephone interviews were completed with 3 participants. [Textbox 1](#) shows a summary of the 10 key themes that emerged when participants were asked to describe their experience with the pilot program and exemplary quotes.

**Textbox 1.** Themes and quotes from qualitative interviews of patient experiences with the pilot program.

<p><b>Patient motivation</b></p> <ul style="list-style-type: none"> <li>• “I also wanted to walk more to help with my anxiety and depression.” [Female participant, aged 42 years]</li> <li>• “I wanted to lose weight. I didn’t like how much I weighed. I wanted someone to keep me accountable.” [Female participant, aged 41 years]</li> <li>• “[I wanted] to exercise more, keep moving; be a little bit healthier. The study helped me to achieve that.” [Male participant, aged 55 years]</li> </ul> <p><b>Convenient texting experience</b></p> <ul style="list-style-type: none"> <li>• “It was more convenient for me. I didn’t have to take time from work to set those goals and go all the way to go into a location to talk to a HC or have to have a long conversation to talk to a HC because it was like between the time I was going to work or getting ready to start work, so I was able to text back.” [Female participant, aged 48 years]</li> </ul> <p><b>Social support</b></p> <ul style="list-style-type: none"> <li>• “I felt like I was really connected to a person that was supporting me and encouraging me to continue to take my steps.” [Female participant, aged 48 years]</li> </ul> <p><b>Supportive accountability</b></p> <ul style="list-style-type: none"> <li>• “When you are only accountable to yourself, you can blow [the goal] off; but when you are accountable to someone else...I don’t want her (the HC) to see I am not doing anything” [Male participant, aged 55 years]</li> <li>• “If I got so caught up with my everyday workload, and I checked my phone with the coach...it triggered me to touch bases with the HC...the texting and communication kept me kind of focused on the goals even though I had a lot of distractions.” [Female participant, aged 58 years]</li> </ul> <p><b>Technology support</b></p> <ul style="list-style-type: none"> <li>• “When my Fitbit wasn’t syncing she [the HC] would reach out” [Female participant, aged 34 years]</li> </ul> <p><b>Self-determined goals</b></p> <ul style="list-style-type: none"> <li>• “...the understanding [and] acceptance if the goal went down or went up or whatever, it was all up to me.” [Female participant, aged 42 years]</li> <li>• “I knew you (the HC) was going to be texting me to see what my goal was, and I tried to think of it before, so I was ready, but it was hard sometimes.” [Female participant, aged 45 years]</li> </ul> <p><b>Achievable goals</b></p> <ul style="list-style-type: none"> <li>• “Everything was accomplishable and reasonable. It (the step goal) was realistic. You [the HC] always said make it something that you know you can succeed. You weren’t really giving me something high and big that I might struggle with.” [Female participant, aged 45 years]</li> <li>• “No one was pressuring you to go higher or lower. I really enjoyed that.” [Female participant, aged 33 years]</li> </ul> <p><b>Feedback from Fitbit device</b></p> <ul style="list-style-type: none"> <li>• “I never paid attention to how many steps I took. So, with this [the Fitbit], it made me focus or pay attention.” [Female participant, aged 49 years]</li> <li>• “It was cool to see how many steps I got and to try to get some more.” [Male participant, aged 44 years]</li> </ul> <p><b>Challenges</b></p> <ul style="list-style-type: none"> <li>• “The texting didn’t give a push. It was a little push because you are talking to someone, but it wasn’t like someone yelling at you to work out. Hands-on is always better. But the texting is fine; it’s just not hands-on.” [Male participant, aged 48 years]</li> </ul> <p><b>Habit formation</b></p> <ul style="list-style-type: none"> <li>• “Usually I wouldn’t do it [walking]. But now it’s a habit, and if I don’t see the texts, I have the Fitbit.” [Female participant, aged 45 years]</li> </ul>
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Nearly all participants expressed that they enrolled in the study with a desire to improve their health, increase their physical activity, or lose weight. Some were curious about their daily step count. Although most appreciated the ability to control the goal they set each week, 3 participants experienced the self-setting goals to be challenging and commented that they would have liked the HC to set the goals. Importantly, many participants commented that they felt their goal could be reached successfully. Setting realistic goals was 1 component within the SMART goal framework, thereby supporting the fidelity of

the goal-setting process. The participants identified a few barriers to study involvement. Almost half indicated that their busy schedules hindered their ability to send back a text message to the HC immediately. As a result, lag periods between receiving text messages from the HCs and responding to them were common, ranging from hours to days. When the content is related to goal-setting, HCs typically sent another text message the following day. However, many text messages did not require responses; therefore, the delay was of little consequence. The participants also noted some problems related

to the technology. One Fitbit band broke and was replaced quickly but required the participant to travel to the study site to pick it up. A few participants experienced synchronizing issues among the Fitbit, mobile app, and text messaging platform. Furthermore, 2 participants noted that while sending a text message to an HC was convenient, they preferred face-to-face or verbal communication, pushing them directly to work out harder. In addition, patient-reported barriers to attaining step goals included forgetting to put the Fitbit device on in the morning, not adhering to their goals on the weekends, and acute health-related problems. Finally, suggestions for improving the program included adding reminders to eat healthily, providing goal suggestions, and incorporating mutual competitiveness among participants.

In addition to the 10 themes, participants noted additional behavior changes related to focusing on their step goals. Examples include self-reported weight loss, perceived improvement in chronic health conditions, and overall increased health consciousness. Despite the fact that the program did not have any content related to other health behaviors, some mentioned that they had increased fruit and vegetable consumption or decreased late night eating. One participant reported that she started walking with her husband to gain benefits from increased activity.

### Safety

One safety issue required follow-up. A text message from 1 participant mentioned that they were unable to meet their step goals because of *pain from* falling. This was immediately reported to the lead HC who contacted the participant. The participant had fallen in their backyard completely unrelated to walking as part of the program. The pain was from twisting an ankle that the participant reported was minor. No further action was required, and the participant was working on step goals within 2 days.

### Exploratory Analysis of Fitbit Steps Data

Fitbit data from all 30 participants were included in the analyses. There was no significant change in the average weekly steps for week 1 compared with the average weekly steps for week 8 (mean difference 7.26, 95% CI -867.5 to 882.0). The linear mixed model showed that there were 17% (5/30) of participants who had a significant increase and 20% (6/30) of participants who had a significant decrease in their daily steps. The remaining 61% (17/30) of participants showed no change in their daily steps. There were no statistically significant changes in average weekly sedentary minutes (mean difference -17.6, 95% CI -67.8 to 32.6), average lightly active minutes (mean difference -3.37, 95% CI -28.8 to 22.1), and average vigorously active minutes (mean difference 6.79, 95% CI -3.4 to 17.0) from week 1 to week 8 among the cohort of participants. There was no association between baseline demographic characteristics and increase in their average daily steps. Similarly, there was no association between engagement (measured by the number of text messages) and increase in their average daily steps. The average weekly steps across the 8-week program for patients who increased and decreased their steps over time can be seen in [Multimedia Appendices 1 and 2](#).

## Discussion

### Principal Findings

The feasibility and acceptability of a walking program designed around remote text-based goal-setting with an HC was supported among a sample of ethnic minority patients with chronic health problems, including overweight and obesity. The sample was diverse in terms of self-reported health status, including approximately one-third with fair or poor health status. Patients' interest in the study was extremely high, with 91% (30/33) of those referred by their physician successfully enrolled in the study. Patients were able and willing to engage in SMS text messaging with the HC to set walking goals using the SMART framework over 8 weeks. Poststudy interviews suggested that participation was driven by motivation to improve their health both psychologically and physically. The salience of this motivation may have been heightened by the fact that patients were approached after an appointment with their primary care provider, which serves as a call for action to some patients [28,29].

Overall retention and text message engagement compared favorably with other studies. A recent meta-analysis of 35 studies testing wearables in people with cardiometabolic diseases reported an 87% mean retention (range 63%-100%) [12]. These studies ranged in length from 4 to 52 weeks, with 60% of the studies between 4 and 16 weeks. Despite continued engagement in this pilot study, the frequency of SMS text messaging decreased over time. However, given that the decrease in the frequency of SMS text messaging by the participants was consistently 3 to 4 SMS text messages less than the HCs frequency of SMS text messaging by the HCs, it is possible that the decrease was related to increased efficiency in applying the SMART goal framework. Future studies may explore this hypothesis by intentionally varying the frequency of HC text messages across time to assess whether this impacts the frequency of SMS text messaging by the participants.

Consistent with other reports, some Fitbit challenges had to be overcome [30]. Initially, participants were offered the choice of a Fitbit Charge 2 or Charge 3. However, research staff were unable to synchronize Charge 3 for 2 of the first 3 participants, and subsequent participants all received Charge 2 without setup issues. Occasional lags occurred when synchronizing the Fitbit with the app and text messaging platform. Some participants needed reminders to charge the device. This was facilitated by HCs monitoring the battery levels and sending text message alerts before the battery discharged. Having the HCs trained to address synchronizing or charging problems was important, as was training the participants when they received the Fitbit. A total of 2 participants had previous experience with Fitbit devices. However, the use of Fitbit devices and SMS text messaging was deemed feasible and acceptable in this population of socioeconomically diverse, ethnic minority samples.

This study is not alone in aiming to increase walking among people with chronic diseases by integrating a wearable (Fitbit) and health coaching [31]. However, this study is among the first to include a population that is disproportionately affected by

chronic diseases and has unequal access to health technology. The sample comprised 97% ethnic minorities, of which 82% were clinically obese ( $BMI \geq 30 \text{ kg/m}^2$ ) [27], and 30% had fair or poor self-reported health status. Despite the fact that existing evidence suggests that reaching moderate to vigorous activity levels are important, for many, this goal may simply be unrealistic. As noted by others, it is important to explore the impact of increased physical activity regardless of the intensity, particularly in individuals with physiological compromise because of chronic diseases [12,32,33].

This pilot study focused on refining a program by exploring its feasibility and acceptability. It was not designed or powered to explore the changes in the number of steps. Therefore, it is premature to draw conclusions regarding the efficacy of the program. However, HCs and text message content conveyed that some patients struggled to meet their goals because of acute health-related issues unrelated to the walking program. In such cases, HCs encouraged the participants to do only what they felt comfortable doing, regardless of their goal that week. In these cases, the HC checked in frequently to understand whether the health issue resolved and supported the participants' return to walking goals when the participant felt better. Future work to develop this program would benefit from capturing patient health information at baseline and throughout the program to understand how health impacts participation in walking and guide adjustments in goals.

In understanding the experience of the participants, the most common theme that surfaced in the summative evaluation was social support and supportive accountability provided by the HC through the text messages. This suggests that the HC was a well-liked and important component of the program. In addition, almost two-thirds of the patients appreciated the convenience of SMS text messaging, which may have helped overcome certain barriers when it comes to engaging with an HC in real time (ie, appointments required for telephonic, in-person, or remote meetings). The asynchronous nature of SMS text messaging allowed both the patient and HC to freely respond on their own terms. This is highlighted where almost half of the patients indicated that their busy schedules hindered their ability to send back a text message to the HC immediately.

### Limitations

The generalizability of the study results is limited by several factors. The sample is not representative of the primary care

populations. Recruitment was dependent on primary care physicians referring interested patients to the research staff. This process may have introduced selection bias. Nevertheless, as in previous research, our pilot study was able to successfully recruit by incorporating practitioners' involvement [34]. In addition, the study used a within-person design and was not designed or powered to compare changes in the number of steps. Detailed medical histories were not obtained; therefore, the relationships among specific health conditions, goals, and steps cannot be explored. Over half ( $n=17$ ) of the participants averaged 5000 steps per day in the first week, which may have been impacted by knowing that an HC would be monitoring their steps (ie, Hawthorne effect) or by having a novel Fitbit. Regardless, the range of steps was consistent with previous reports of step count among older patients or those with comorbidities or disabilities [9]. Finally, the continued development of the program must consider factors that may influence its dissemination and implementation in other settings. For example, the HCs in the study were trained research members. Not all primary care clinics have in-house HCs or clinical staff with the capacity to execute the key features of the program. Therefore, future work will need to consider factors, such as program effectiveness and adaptability as well as organizational characteristics that might influence its impact [35].

### Conclusions

The acceptability and feasibility of this remotely delivered walking intervention was supported among physically inactive underserved populations with chronic health conditions, such as obesity. Specifically, 91% (30/33) of the patients who were offered the study agreed to participate. Complete Fitbit and SMS text messaging data were collected from 93% (28/30) of the participants, with no adverse outcomes reported. Responses to the qualitative summative evaluation highlighted the convenience of remote delivery and social support experienced through the study. The results of the study support the inclusion of low-income and populations of color in the design of remote health interventions. Future research using a larger sample size and randomized control design is required to explore the efficacy of the approach to alter steps or perhaps, more importantly, to explore the impact on health outcomes and quality of life.

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### Authors' Contributions

MHS and LKS contributed to writing the manuscript. MHS, LKS, NAN, and IG analyzed the data. BSG provided clinical expertise. BZ was the principal investigator of the grant. All authors provided critical feedback and helped shape the research, analysis, and manuscript.



## Conflicts of Interest

None declared.

### Multimedia Appendix 1

Average weekly steps for patients who increased their steps over time. The patient, noted with an asterisk, requested to withdraw during week 6.

[PNG File , 118 KB - [formative\\_v6ile31989\\_app1.png](#) ]

### Multimedia Appendix 2

Average weekly steps for patients who decreased their steps over time. Patient LKS08, noted with an asterisk, lost their Fitbit after week 4. Patient NAN14, noted with an asterisk, stopped responding to the text messages from their health coach starting week 4.

[PNG File , 150 KB - [formative\\_v6ile31989\\_app2.png](#) ]

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## Abbreviations

**HC:** health coach

**SMART:** specific, measurable, attainable, realistic, and time-bound

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Original Paper

# Prediction of Age-Adjusted Mortality From Stroke in Japanese Prefectures: Ecological Study Using Search Engine Queries

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## Abstract

**Background:** Stroke is a major cause of death and the need for nursing care in Japan, with large regional disparities.

**Objective:** The purpose of this study was to clarify the association between stroke-related information retrieval behavior and age-adjusted mortality in each prefecture in Japan.

**Methods:** Age-adjusted mortality from stroke and aging rates were obtained from publicly available Japanese government statistics. A total of 9476 abstracts of Japanese articles related to symptoms and signs of stroke were identified in Ichushi-Web, a Japanese web-based database of biomedical articles, and 100 highly frequent words (hereafter referred to as the Stroke 100) were extracted. Using data from 2014 to 2019, a random forest analysis was carried out using the age-adjusted mortality from stroke in 47 prefectures as the outcome variable and the standardized retrieval numbers of the Stroke 100 words in the log data of Yahoo! JAPAN Search as predictive variables. Regression analysis was performed using a generalized linear mixed model (GLMM) with the number of standardized searches for Stroke 100 words with high importance scores in the random forest model as the predictive variable. In the GLMM, the aging rate and data year were used as control variables, and the random slope of data year and random intercept were calculated by prefecture.

**Results:** The mean age-adjusted mortality from stroke was 28.07 (SD 4.55) deaths per 100,000 for all prefectures in all data years. The accuracy score of the random forest analysis was 89.94%, the average error was 2.79 degrees, and the mean squared error was 13.57 degrees. The following 9 variables with high importance scores in the random forest analysis were selected as predictive variables for the regression analysis: male, age, hospitalization, enforcement, progress, stroke, abnormal, use, and change. As a result of the regression analysis with GLMM, the standardized partial regression coefficients ( $\beta$ ) and 95% confidence intervals showed that the following internet search terms were significantly associated with age-adjusted mortality from stroke: male ( $\beta=-5.83$ , 95% CI  $-8.67$  to  $-3.29$ ), age ( $\beta=-5.83$ , 95% CI  $-8.67$  to  $-3.29$ ), hospitalization ( $\beta=-5.83$ , 95% CI  $-8.67$  to  $-3.29$ ), and abnormal ( $\beta=3.83$ , 95% CI 1.14 to 6.56).

**Conclusions:** Stroke-related search behavior was associated with age-adjusted mortality from stroke in each prefecture in Japan. Query terms that were strongly associated with age-adjusted mortality rates of stroke suggested the possibility that individual characteristics, such as sex and age, have an impact on stroke-associated mortality and that it is important to receive medical care early after stroke onset. Further studies on the criteria and timing of alerting are needed by monitoring information-seeking behavior to identify queries that are strongly associated with stroke mortality.

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**KEYWORDS**

stroke; age-adjusted mortality; search engine query; Japan; random forest; generalized linear mixed model; search engine; GLMM; information-seeking behavior

## Introduction

### Research Background

In Japan, approximately 106,000 people die from stroke per year, making it one of the leading causes of death [1]. Furthermore, stroke, a cerebrovascular disease, is at 15.1%, the second leading reason for the need for nursing care, following dementia, at 18.7% [2]; additionally, some of these patients develop dementia, an organic sequela of stroke. The increase in the number of people in need of nursing care not only affects patients' quality of life, but also causes problems, such as the burden of nursing care on caregivers [3]. In addition, Japan's social and economic losses, such as increased social security costs [4] and productivity losses due to the inability of caregivers to work in the labor market [5], are significant. Thus, stroke and dementia prevention are important for the prevention of conditions requiring nursing care.

Due to advances in treatment methods, such as the administration of tissue plasminogen activator and thrombus recovery therapy, stroke has become a disease with an improved prognosis and reduced sequelae if treated promptly after onset [6]. However, regional differences in the outcome of stroke treatment have been reported [7], and it is important to understand the causes of such differences to reduce health disparities and extend healthy life expectancy.

### Prior Work

The area of research known as infodemiology, which uses user-contributed health information to improve public health, has attracted attention in recent years [8,9]. Several ecological studies have reported an association between the behavior of seeking stroke-related information on the internet and stroke incidence or mortality. Walcott et al [10] reported that in the United States, the web search interest level of common queries used to identify signs and symptoms of stroke and to educate people about stroke correlates with the relative stroke prevalence. Kumar et al [11] described a correlation between the relative search volume of queries related to cardiovascular disease and the burden of cerebrovascular disease mortality in the United States and Australia [11]. Furthermore, an association between the normalized search volume for stroke and stroke-related queries and the incidence of stroke has been reported in Malaysia [12]. These studies also suggest that internet search behavior is associated with the tendency for stroke to be more common in winter because of the nature of the disease [11,12].

In addition to stroke, other major causes of death, such as cancer and heart disease, have also been reported to be associated with internet search behavior. Hospitalization rates for coronary heart disease are associated with the number of search requests for

symptoms experienced by these patients, especially chest pain [13], and cancer incidence and mortality are associated with the search volume of cancer types normalized to the total Google search volume [14].

### Motivation for This Study

Stroke-focused ecological studies have been conducted in the United States, Australia, and Malaysia [10-12], but have not been reported in Japan before. In Japan, stroke is a major cause of death and the need for long-term care; thus, equivalent studies are needed. In addition, clarification of the relationship between information retrieval behavior and stroke may enable real-time regional monitoring, leading to early detection and treatment of patients affected by stroke and the resolution of regional disparities [7].

### Aim of This Study

The purpose of this study was to clarify the association between stroke-related query retrieval behavior and age-adjusted mortality in each prefecture in Japan and to assess the impact of each query on age-adjusted mortality from stroke using regression analysis. Based on these findings, this study provides suggestions to improve decision-making processes in public health.

## Methods

### Search Queries Related to Stroke Signs and Symptoms

To identify search queries most likely to be related to stroke, 100 frequently occurring words were extracted from the abstract of Japanese academic papers related to stroke. The abstracts were retrieved using Ichushi-Web [15], a fee-based, web-based database of medical literature in Japan. A total of 9476 abstracts from original articles containing the keywords "stroke" and "signs and symptoms" were included (Table 1). Since we considered that words with statistically significant associations to stroke may have a higher predictive accuracy, to improve their extraction, unnecessary information, such as the citations list and the conflicts of interest declaration, was not included. Furthermore, the abstract of the academic paper, which represents the authors' key messages, was judged to be sufficient.

Morphological analysis was performed on these 9476 abstracts and 100 frequently occurring words (hereafter referred to as the Stroke 100 words) were identified (Multimedia Appendix 1). In the morphological analysis, an ipadic-NEologd dictionary (mecab-ipadic-NEologd) was used as a dictionary, and the words included in the stop word list provided by Apache Subversion (Apache Software Foundation) [16], as well as the words "abstract", "introduction", "method", "result", and "conclusions" (depending on the data to be analyzed), were excluded.



**Table 1.** Retrieval strategy for abstracts in Ichushi-Web and search results.

Strategy number	Retrieval strategy	Number of search results
1	Stroke <sup>a</sup>	134,111
2	Signs and symptoms <sup>a</sup>	1,162,123
3	1 and 2	36,640
4	Original articles in 3 whose abstracts could be downloaded	9476

<sup>a</sup>Abstracts containing these keywords were retrieved. Synonyms of keywords found in a thesaurus search were also included in the retrieval strategy. No field restrictions were used.

## Outcome Variables

Age-adjusted mortality from stroke by prefecture in Japan was used as the outcome variable. Age-adjusted mortality rates were calculated using the direct method based on the number of stroke deaths extracted from vital statistics provided by the Japanese government [1], and the total population was derived from population estimates or the national census. The reference population used for age adjustment was the 1985 model population, in accordance with Japanese practice [17]. These data can be obtained from e-Stat [18], a portal site that compiles Japanese government statistics. For variables used in the analysis, data from all 47 prefectures were combined vertically for the 6 years from 2014 to 2019 and analyzed as a variable with a sample size of 282 (47 prefectures×6 years).

## Predictive Variables

For the identified Stroke 100 words, we extracted the number of search requests in the 47 prefectures from 2014 to 2019 using search log data from Yahoo! JAPAN Search, one of the major search engines in Japan. Since the actual number is strongly affected by words with consistently high search volumes and the population size of the prefecture, the number of searches were converted to a standardized characteristic score as a predictive variable based on equation (2). UU is the number of unique users.



## Control Variables

As control variables, the data year, prefectures, and the aging rate for each prefecture were used. The data year variable included the 6 years from 2014 to 2019, with values converted from 1 to 6 in ascending order. The prefecture variable included all 47 prefectures in Japan and was converted to a numerical value where each prefecture from north to south was assigned a number from 1 to 47. The aging rate for each prefecture was calculated using the population census or population estimate statistics, and the ratio of the population aged 65 years or older was used.

## Statistical Analysis

A random forest regressor analysis was performed using age-adjusted mortality from stroke as the outcome variable and the Stroke 100 words as predictors. The data were divided into 70% training data and 30% test data; the modeling was conducted with the training data, and the evaluation of the model was conducted with the test data. In the modeling, 3-fold cross-validation was performed, and the hyperparameter was tuned using grid search. The hyperparameter settings used in the grid search are shown in [Textbox 1](#). For the model with the best parameters, the accuracy score was calculated. In addition, high-importance variables were identified using the Gini importance score, and predictive variables for regression analysis were selected.

Regression analysis using a generalized linear mixed model (GLMM) was performed because it was not possible to determine which queries were associated with age-adjusted mortality from stroke in prefectures in the random forest regression. First, the Pearson correlation coefficient and variance inflation factor (VIF) were calculated for age-adjusted mortality from stroke, prefectural variables, data years, aging rates, and queries as predictors selected in the random forest analyses, and it was confirmed that no problems arose from multicollinearity. In the GLMM, age-adjusted mortality due to stroke was used as the outcome variable, queries selected in the random forest analysis were used as predictors, the aging rate and data year were used as control variables, and the random slope of data year and random intercept were calculated by prefecture.

To estimate the parameters, simulated draws from the posterior were obtained for each parameter using the Markov chain Monte Carlo (MCMC) method [19,20]. Then, Rhat was calculated to confirm the convergence of the simulation. Rhat is an index of divergence among chains; in the case of 3 or more chains, a value of 1.1 or less is by convention considered to indicate convergence.

Analyses were performed using the scikit-learn Python library (Python Software Foundation) and the open-source statistical software R, version 3.6.2 (R Foundation for Statistical Computing). The Rstan package was used for parameter estimation by MCMC.

**Textbox 1.** Hyperparameter values used to tune the random forest regression by grid search.

- Number of trees in the forest (n\_estimators): 10, 20, 30, 40, 50, 60, 70, 80, 90, 100, 110, 120, 130, 140, 150, 160, 170, 180, 190, 200
- Bootstrap: True, False
- Function to measure the quality of the split (criterion): mean squared error (MSE), mean absolute error (MAE)
- Maximum depth of the tree (max\_depth): 10, 20, 30, 40, 50, 60, 70, 80, 90, 100, None
- Number of features to consider when looking for the best split (max\_features): Auto, Square root, log2
- Minimum number of samples required to be at a leaf node (min\_samples\_leaf): 1, 2, 4
- Minimum number of samples required to split an internal node (min\_samples\_split): 2, 5, 10

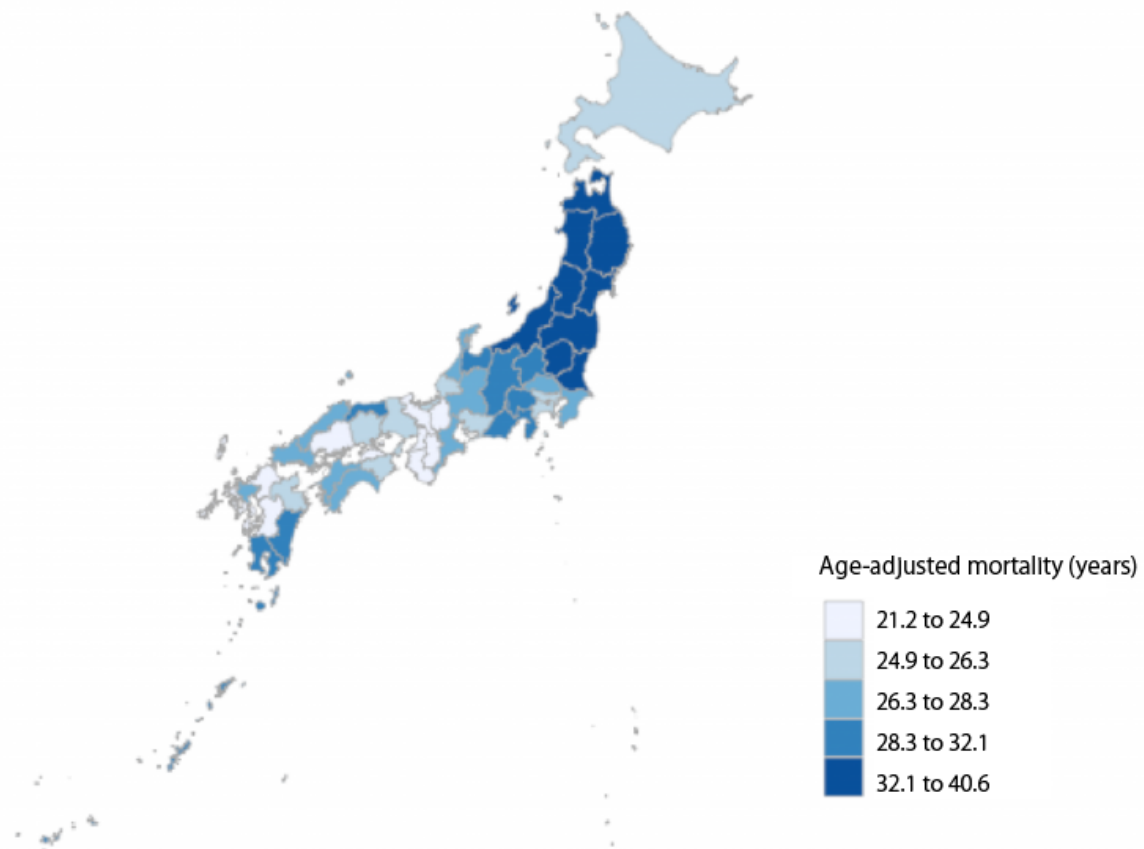
## Results

### Characteristics of Government Statistics from e-Stat

The overall mean age-adjusted mortality from stroke was 28.07 (SD 4.55) deaths per 100,000 for all prefectures in all data years. The average for each data year (in deaths per 100,000) was

30.62 (SD 4.49) in 2014, 29.40 (SD 4.41) in 2015, 28.28 (SD 4.04) in 2016, 27.68 (SD 4.22) in 2017, 26.60 (SD 4.28) in 2018, and 25.87 (SD 4.34) in 2019. The averages by prefecture are shown in [Figure 1](#). The overall mean aging rate (expressed as a percentage) was 29.10 (SD 3.04) for all prefectures in all data years.

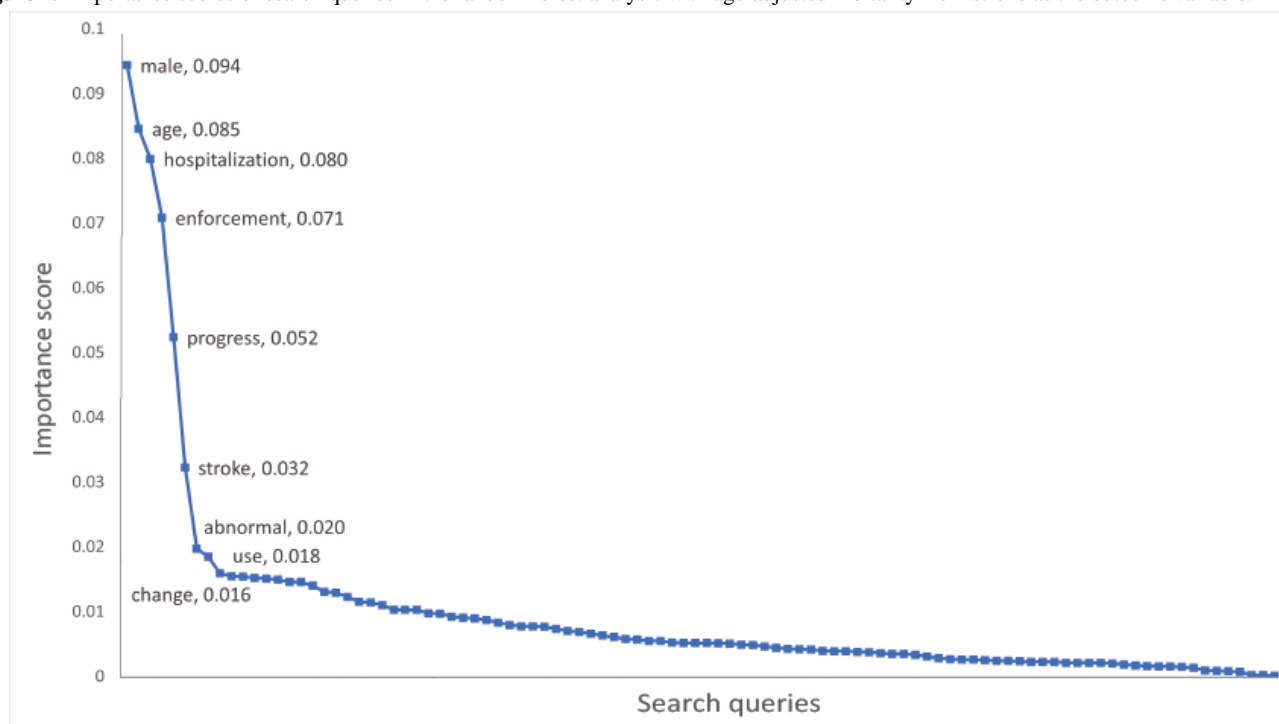
**Figure 1.** Average age-adjusted mortality from stroke between 2014 and 2019 in Japan by prefecture.



### Results of the Random Forest Analysis

The accuracy score of the random forest regression was 89.94%, the average error was 2.79 degrees, and the mean squared error (MSE) value was 13.57 degrees. The best hyperparameters were as follows: n\_estimators=40, bootstrap=True, criterion=MSE, max\_depth=80, max\_features=auto, min\_samples\_leaf=4, and

max\_samples\_split=10. To identify the variables that contributed to the prediction, importance scores were calculated as shown in [Figure 2](#). A total of 9 variables with a high importance score were selected as predictive variables for the regression analysis: male, age, hospitalization, enforcement, progress, stroke, abnormal, use, and change.

**Figure 2.** Importance scores of search queries in the random forest analysis with age-adjusted mortality from stroke as the outcome variable.

### Results of the Regression Analysis With the Generalized Linear Mixed Model

The Pearson correlation coefficients and VIF values for the variables used in the regression analysis are shown in [Table 2](#). Of the absolute values of the correlation coefficient, the minimum and maximum values were 0.00 and 0.77, respectively, and the respective VIF values were 1.00 and 2.41. This suggested the absence of multicollinearity, and all variables were used in further analyses as predictors and control variables.

As a result of the regression analysis using the GLMM ([Figure 3](#), [Table 3](#)), the standardized partial regression coefficients ( $\beta$ ) and 95% confidence intervals showed that the following internet search engine queries were significantly associated with age-adjusted mortality from stroke: male ( $\beta=-5.83$ , 95% CI  $-8.67$  to  $-3.29$ ), age ( $\beta=-5.83$ , 95% CI  $-8.67$  to  $-3.29$ ), hospitalization ( $\beta=-5.83$ , 95% CI  $-8.67$  to  $-3.29$ ), and abnormal ( $\beta=3.83$ , 95% CI  $1.14$  to  $6.56$ ). Finally, the Rhat values, the number of effective samples representing the strength of autocorrelation, and Monte Carlo standard error suggested that the MCMC algorithm achieved convergence for all parameters.

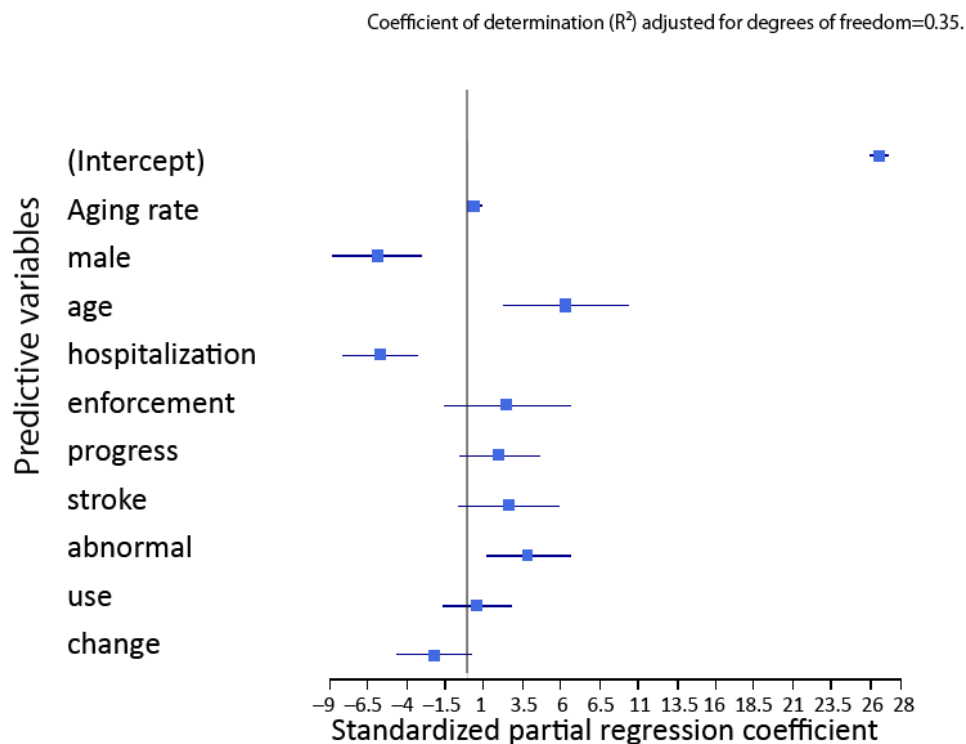
**Table 2.** Correlation coefficients and variance inflation factors (VIFs) among variables in the generalized linear mixed model.

Variable	V1	V2	V3	V4	V5	V6	V7	V8	V9	V10	V11	V12	V13
<b>V1. Age-adjusted mortality</b>													
<i>r</i>	1.00	-0.47	-0.35**	0.12	-0.26**	0.22**	-0.23**	0.27**	0.23**	0.07	0.10	0.11	-0.12
P value	N/A <sup>b</sup>	<.001	<.001	.04	<.001	<.001	<.001	<.001	<.001	.25	.09	.06	.05
VIF	N/A	1.29	1.14	1.02	1.08	1.05	1.06	1.08	1.05	1.00	1.01	1.01	1.01
<b>V2. Prefecture</b>													
<i>r</i>	-0.47	1.00	0.00	0.06	-0.15*	-0.48**	-0.29**	-0.35**	-0.46**	-0.32**	-0.37**	-0.33**	-0.31**
P value	<.001	N/A	>.99	.29	.01	<.001	<.001	<.001	<.001	<.001	<.001	<.001	<.001
VIF	1.29	N/A	1.00	1.00	1.02	1.30	1.09	1.14	1.26	1.12	1.15	1.12	1.11
<b>V3. Data year</b>													
<i>r</i>	-0.35**	0.00	1.00	0.35**	0.03	-0.04	0.11	-0.12*	-0.05	-0.12*	-0.05	-0.02	-0.05
P value	<.001	>.99	N/A	<.001	.59	.50	.06	.04	.44	.04	.45	.77	.37
VIF	1.14	1.00	N/A	1.14	1.00	1.00	1.01	1.01	1.00	1.02	1.00	1.00	1.00
<b>V4. Aging rate</b>													
<i>r</i>	0.12	0.06	0.35**	1.00	-0.47**	-0.27**	-0.27**	-0.29**	-0.34**	-0.32**	-0.33**	-0.43**	-0.45**
P value	.04	.29	<.001	N/A	<.001	<.001	<.001	<.001	<.001	<.001	<.001	<.001	<.001
VIF	1.02	1.00	1.14	N/A	1.28	1.08	1.08	1.09	1.13	1.12	1.12	1.23	1.25
<b>V5. Male<sup>a</sup></b>													
<i>r</i>	-0.26**	-0.15*	0.03	-0.47**	1.00	0.52**	0.74**	0.43**	0.43**	0.66**	0.66**	0.51**	0.69**
P value	<.001	.01	.59	<.001	N/A	<.001	<.001	<.001	<.001	<.001	<.001	<.001	<.001
VIF	1.08	1.02	1.00	1.28	N/A	1.38	2.19	1.22	1.22	1.77	1.79	1.35	1.90
<b>V6. Age</b>													
<i>r</i>	0.22**	-0.48**	-0.04	-0.27**	0.52**	1.00	0.60**	0.76**	0.69**	0.71**	0.73**	0.63**	0.67**
P value	<.001	<.001	.50	<.001	<.001	N/A	<.001	<.001	<.001	<.001	<.001	<.001	<.001
VIF	1.05	1.30	1.00	1.08	1.38	N/A	1.56	2.37	1.89	2.02	2.11	1.67	1.79
<b>V7. Hospitalization</b>													
<i>r</i>	-0.23**	-0.29**	0.11	-0.27**	0.74**	0.60**	1.00	0.44**	0.42**	0.62**	0.65**	0.50**	0.66**
P value	<.001	<.001	.06	<.001	<.001	<.001	N/A	<.001	<.001	<.001	<.001	<.001	<.001
VIF	1.06	1.09	1.01	1.08	2.19	1.56	N/A	1.25	1.22	1.63	1.73	1.33	1.77
<b>V8. Enforcement</b>													
<i>r</i>	0.27**	-0.35**	-0.12*	-0.29**	0.43**	0.76**	0.44**	1.00	0.77**	0.64**	0.62**	0.67**	0.50**
P value	<.001	<.001	.04	<.001	<.001	<.001	<.001	N/A	<.001	<.001	<.001	<.001	<.001
VIF	1.08	1.14	1.01	1.09	1.22	2.37	1.25	N/A	2.41	1.70	1.64	1.81	1.34
<b>V9. Progress</b>													
<i>r</i>	0.23**	-0.46**	-0.05	-0.34**	0.43**	0.69**	0.42**	0.77**	1.00	0.53**	0.59**	0.66**	0.54**
P value	<.001	<.001	.44	<.001	<.001	<.001	<.001	<.001	N/A	<.001	<.001	<.001	<.001
VIF	1.05	1.26	1.00	1.13	1.22	1.89	1.22	2.41	N/A	1.40	1.54	1.76	1.42
<b>V10. Stroke</b>													
<i>r</i>	0.07	-0.32**	-0.12*	-0.32**	0.66**	0.71**	0.62**	0.64**	0.53**	1.00	0.66**	0.56**	0.59**
P value	.25	<.001	.04	<.001	<.001	<.001	<.001	<.001	<.001	N/A	<.001	<.001	<.001

Variable	V1	V2	V3	V4	V5	V6	V7	V8	V9	V10	V11	V12	V13
VIF	1.00	1.12	1.02	1.12	1.77	2.02	1.63	1.70	1.40	N/A	1.78	1.46	1.53
<b>V11. Abnormal</b>													
<i>r</i>	0.10	-0.37**	-0.05	-0.33**	0.66**	0.73**	0.65**	0.62**	0.59**	0.66**	1.00	0.65**	0.61**
P value	.09	<.001	.45	<.001	<.001	<.001	<.001	<.001	<.001	<.001	N/A	<.001	<.001
VIF	1.01	1.15	1.00	1.12	1.79	2.11	1.73	1.64	1.54	1.78	N/A	1.72	1.60
<b>V12. Use</b>													
<i>r</i>	0.11	-0.33**	-0.02	-0.43**	0.51**	0.63**	0.50**	0.67**	0.66**	0.56**	0.65**	1.00	0.58**
P value	.06	<.001	.77	<.001	<.001	<.001	<.001	<.001	<.001	<.001	<.001	N/A	<.001
VIF	1.01	1.12	1.00	1.23	1.35	1.67	1.33	1.81	1.76	1.46	1.72	N/A	1.50
<b>V13. Change</b>													
<i>r</i>	-0.12	-0.31**	-0.05	-0.45**	0.69**	0.67**	0.66**	0.50**	0.54**	0.59**	0.61**	0.58**	1.00
P value	.05	<.001	.37	<.001	<.001	<.001	<.001	<.001	<.001	<.001	<.001	<.001	N/A
VIF	1.01	1.11	1.00	1.25	1.90	1.79	1.77	1.34	1.42	1.53	1.60	1.50	N/A

<sup>a</sup>The italicized variables are those with high importance scores in the random forest regression analysis with the Stroke 100 words.  
<sup>b</sup>N/A: not applicable.  
 \*P<.05, \*\*P<.01.

**Figure 3.** Results of the generalized linear mixed model with age-adjusted mortality from stroke as the outcome variable.





**Table 3.** Standardized partial regression coefficient and 95% confidence intervals for the generalized linear mixed model with age-adjusted mortality from stroke as the outcome variable.

Predictive variable	Standardized partial regression coefficient ( $\beta$ )	95% CI
(Intercept)	26.6	26.08 to 27.20
Aging rate	0.34	0.18 to 0.87
Male	-5.83	-8.67 to -3.04
Age	6.31	2.32 to 10.34
Hospitalization	-5.69	-8.06 to -3.29
Enforcement	2.49	-1.52 to 6.54
Progress	1.99	-0.50 to 4.60
Stroke	2.63	-0.66 to 5.88
Abnormal	3.83	1.14 to 6.56
Use	0.55	-1.66 to 2.75
Change	-2.13	-4.55 to 0.21

## Discussion

### Principal Findings

The accuracy score of 89.94% in the random forest regression and the average error of 2.79 degrees indicate that a stroke-related query can predict age-adjusted mortality from stroke in each prefecture in Japan with high accuracy.

The regression analysis using the GLMM showed that the search terms “male” and “hospitalization” were associated with prefectures with low age-adjusted mortality from stroke, whereas the keywords “age” and “abnormal” were associated with prefectures with high age-adjusted mortality from stroke. Because the stroke risk increases with age and women tend to live longer, the absolute number of stroke events is higher in women [21]. However, the age-adjusted mortality rate is higher in men [22], and men tend to experience stroke at a younger age [23]. It is inferred that queries such as “male” and “age” became significant due to sex differences in stroke epidemiology. Moreover, because stroke outcome mainly depends on the time it takes to detect an abnormality early and to receive appropriate treatment, search terms such as “abnormal” or “hospitalization” may have been significant in our model. However, it is necessary to carefully examine the confounding factors of these significant queries, and it is desirable to analyze the mixed search of multiple queries and design a study that can demonstrate causality.

### Comparison With Prior Work

The results of the random forest analysis clarified that stroke was included in the query with a high importance score and that the query concerning the disease was associated with the age-adjusted death rate in Japan, confirming previous research in other countries [10-12]. In contrast to previous studies, this study was novel in that it extracted high-frequency words from abstracts related to stroke and analyzed the association between search behavior for a wide range of queries and age-adjusted

mortality from stroke. As a result, queries such as “male”, “age”, and “hospitalization”, in addition to disease name and symptom, were confirmed to have a significant association with stroke-related mortality. Furthermore, in this study, we extracted high-frequency words from the abstracts of academic papers, but it may be possible to obtain more realistic results by analyzing high-frequency words extracted from the records of stroke patients.

### Limitations

This study has several limitations. Since this is an ecological study, it is possible to assess each region, but the impact on individuals living in the region cannot be determined. However, to address public health issues, it may be important to identify high-risk regions for stroke based on internet queries and alert the residents of those regions. Therefore, further studies on the criteria and timing of alerting based on information-seeking behavior are needed. In addition, considering the seasonal variation in age-adjusted mortality and the research number of stroke-related queries, the unit of analysis in this study was each prefecture in Japan with a large population. However, in order to propose specific administrative measures, it is desirable to conduct a more detailed analysis by region, such as by area classification based on the status of emergency transport and medical services.

### Conclusion

Stroke-related search behavior was associated with age-adjusted mortality from stroke in each prefecture in Japan. Query terms that were strongly associated with age-adjusted mortality rates of stroke suggest the possibility that individual characteristics such as sex and age have an impact on stroke-associated mortality and that it is important to receive medical care early after stroke onset. Further studies on the criteria and timing of alerting are needed by monitoring information-seeking behavior to identify queries that are strongly associated with stroke mortality.

## Acknowledgments

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## Authors' Contributions

KT was responsible for conceptualization of the study, formal analysis of the data, writing of the manuscript, and funding acquisition. SF was responsible for data curation, validation, and supervision.

## Conflicts of Interest

SF is an employee of the Yahoo! Japan Corporation, a Japanese internet company that provides Yahoo! JAPAN Search services. Data obtained by these services were analyzed in this study. The company had no influence on the study design, the results, or the decision to publish the findings.

## Multimedia Appendix 1

Search queries related to the stroke signs and symptoms from the abstracts in Ichushi-Web.

[DOC File , 111 KB - formative\_v61e27805\_app1.doc ]

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## Abbreviations

**GLMM:** generalized linear mixed model

**MAE:** mean absolute error

**MCMC:** Markov chain Monte Carlo

**MSE:** mean squared error

**Stroke 100:** 100 frequently occurring words that were extracted from the abstract of Japanese academic papers related to stroke

**VIF:** variance inflation factor

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Original Paper

# Understanding Adoption and Preliminary Effectiveness of a Mobile App for Chronic Pain Management Among US Military Veterans: Pre-Post Mixed Methods Evaluation

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## Abstract

**Background:** The Veterans Health Administration Pain Coach mobile health app was developed to support veterans with chronic pain.

**Objective:** Our objective was to evaluate early user experiences with the Pain Coach app and preliminary impacts of app use on pain-related outcomes.

**Methods:** Following a sequential, explanatory, mixed methods design, we mailed surveys to veterans at 2 time points with an outreach program in between and conducted semistructured interviews with a subsample of survey respondents. We analyzed survey data using descriptive statistics among veterans who completed both surveys and examined differences in key outcomes using paired samples *t* tests. We analyzed semistructured interview data using thematic analysis.

**Results:** Of 1507 veterans invited and eligible to complete the baseline survey, we received responses from 393 (26.1%). These veterans received our outreach program; 236 (236/393, 60.1%) completed follow-up surveys. We conducted interviews with 10 app users and 10 nonusers. Among survey respondents, 10.2% (24/236) used Pain Coach, and 58% (14/24) reported it was easy to use, though interviews identified various app usability issues. Veterans who used Pain Coach reported greater pain self-efficacy (mean 23.1 vs mean 16.6;  $P=.01$ ) and lower pain interference (mean 34.6 vs mean 31.8;  $P=.03$ ) after (vs before) use. The most frequent reason veterans reported for not using the app was that their health care team had not discussed it with them (96/212, 45.3%).

**Conclusions:** Our findings suggest that future efforts to increase adoption of Pain Coach and other mobile apps among veterans should include health care team endorsement. Our findings regarding the impact of Pain Coach use on outcomes warrant further study.

**KEYWORDS**

mobile health applications; pain; veterans; usability

**Introduction**

Chronic pain is a leading cause of disability [1] and poses a significant, costly problem [2] among US adults, including veterans of the US military. In fact, veterans suffer from pain at disproportionately high rates compared with the general population [3]. Reports suggest that nearly two-thirds of veterans experience pain [3], with even greater pain prevalence observed among certain veteran cohorts [4-6]. This pain experience leads to negative consequences including functional impairment [7], increased stress and mental health concerns [8,9], substance abuse [8,9], risky opioid use [10], impaired sleep [9], decreased quality of life [11], and increased health care utilization [12]. Accordingly, safe and effective strategies are needed to help veterans manage pain.

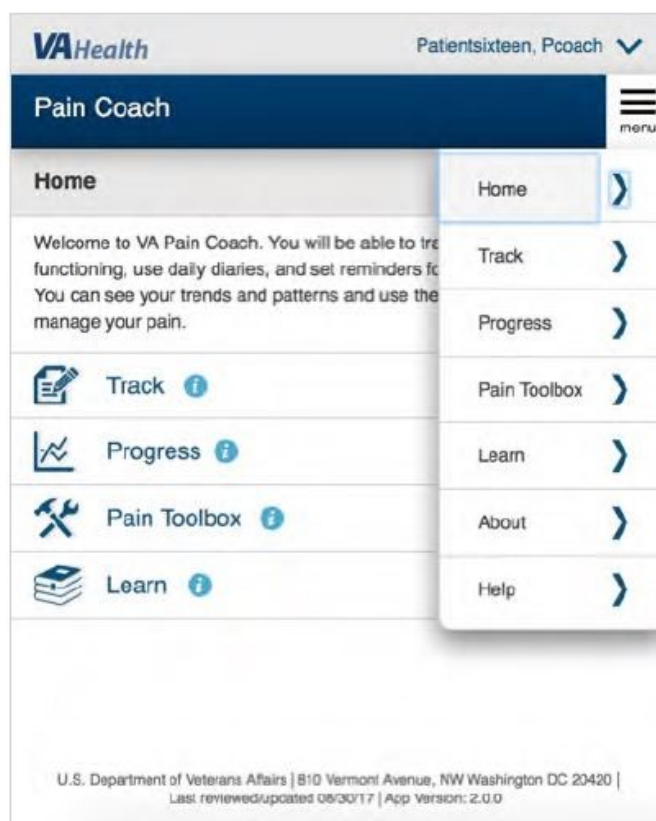
In recent years, national guidelines for the management of chronic pain have recommended use of nonpharmacological pain management strategies over medications (ie, opioid analgesics) [13], including US Veterans Health Administration (VA) and Department of Defense Clinical Practice Guidelines that suggest frontline treatment options such as behavioral therapy, activity-based therapy, and some nonopioid medications [14]. In line with these guidelines, the VA health care system is committed to identifying non-medication-based pain

treatment options and self-management support for veterans who experience chronic pain.

Mobile health apps are a platform for providing accessible self-management tools to patients, and a number of apps are being developed to help individuals manage pain [15-19], including by the VA's Office of Connected Care (OCC). Recently, the OCC developed the VA Pain Coach mobile health app as a tool to support veterans in managing chronic pain and related care. Through the app, veterans can reference educational resources about pain, including pain management techniques and tools besides medications; track and monitor their pain through a daily pain diary and monthly check-in; and review tables and graphs of changes in their pain level over time [20]. The data that veterans enter into the app are viewable by VA care team members through VA care team-facing apps. A screenshot of the VA Pain Coach app interface, which is a web-based (rather than native) app, is included in Figure 1.

Mobile health apps like VA Pain Coach have great potential for helping veterans communicate with their care team members and self-manage their health. Recent literature suggests that veterans are interested in using mobile health tools [21,22]; however, the adoption of such tools has been limited to date [22,23]. The objective of this evaluation was to evaluate early user experiences with the Pain Coach app and preliminary impacts of app use on pain-related outcomes.

**Figure 1.** VA Pain Coach interface.





## Methods

### Design

Beginning in summer 2019, we completed a sequential, explanatory, mixed methods, multisite evaluation of the Pain Coach app, wherein we first collected and analyzed quantitative data and subsequently, qualitative data. Specifically, we administered mailed surveys at 2 time points, with an outreach program in between, and then conducted semistructured interviews with a purposive sample of veterans who responded to the surveys.

### Recruitment and Data Collection

We recruited veterans with a chronic pain diagnosis, including veterans who either used or did not use opioid therapy, from 3 geographically dispersed VA Medical Centers located in the Western and Southeastern regions of the United States.

### Baseline Survey

We mailed the baseline surveys, along with a cover letter and a postage-paid reply envelope, to veterans beginning in August 2019. We placed follow-up phone calls to veterans who did not return a survey in the mail to maximize their opportunity to participate. A member of our team mailed veterans who completed the survey a US \$10 gift card to thank them for their time.

### Outreach Program

Veterans who completed the baseline survey subsequently received the components of an outreach program about the Pain Coach app. The components included (1) a frequently asked questions (FAQ) sheet about the Pain Coach app that veterans received in the mail, (2) a phone call to veterans from the VA National Telehealth Technology Helpdesk (NTTHD) to offer additional support and troubleshooting with the app as needed, and (3) an informational email sent to the VA care team members of these veterans explaining the Pain Coach app.

### Follow-up Survey

Beginning in February 2020, we mailed follow-up surveys to veterans who completed a baseline survey and received the outreach program components. Following the methods described in the previous section, we mailed surveys along with a cover letter and postage-paid reply envelope. We again placed follow-up phone calls to veterans who did not return a survey in the mail and compensated respondents with another US \$10 gift card.

### Semistructured Interviews

In accordance with the principles of purposive sampling, we identified a set of criteria (age, gender, geographic location, Pain Coach app use, and use of opioid therapy) with which to target our interview recruitment. We conducted interviews by telephone between April 2020 and June 2020. The interviews lasted 20 minutes to 30 minutes on average and were audio-recorded and transcribed verbatim to facilitate analysis.

## Data Collection Instruments and Measures

### Baseline Survey

We collected information on veteran sociodemographics including age, gender, race, ethnicity, relationship status, highest level of education completed, living arrangement, and self-reported health status (1=excellent to 5=poor). We measured veteran socioeconomic status by asking veterans to report how hard it is for them (and their family) to pay for basic necessities like food and heating/cooling (1=very hard to 4=not very hard). We also asked veterans to describe the technology that they own (desktop or laptop computer, tablet, cell phone).

Experience with and management of pain variables included prior-week pain intensity measured using a 10-point validated rating scale, ranging from 0 (no pain at all) to 10 (pain as bad as you can imagine) [24]. We measured pain self-efficacy using the Pain Self-Efficacy Questionnaire [25], an established 10-item scale that measures the extent to which individuals are confident that they can perform a range of activities despite their pain. We assessed pain interference with the Patient-Reported Outcomes Measurement Information System 8-item pain interference short form [26], which measures the extent to which individuals felt their pain interfered with their life and activities in the prior week. We also asked veterans to report how much pain had interfered with their sleep in the prior week (1=not at all to 5=very much). Finally, we gathered information on pain outcomes using the Pain Outcomes Questionnaire - Short Form [27], a 19-item validated scale that assesses pain-related outcomes.

### Outreach Program

The 1-page FAQ sheet about the Pain Coach app that we mailed to veterans included a summary of the purpose of the app, details about its features, and where veterans could find more information about the app. Veterans also received proactive technical support in the form of telephone calls from the VA's NTTHD in case they were having difficulty with the Pain Coach app. Callers from the NTTHD followed a script developed by our evaluation team to walk veterans through any challenges they were encountering using the app and troubleshooting to overcome those challenges. The final component of our outreach program was an informational email that briefly summarized the purpose and features of the Pain Coach app and the evaluation we were conducting, which was sent to the VA care team members of the veterans who returned our baseline survey.

### Follow-up Survey

We asked veterans to report whether they recalled receiving our outreach program components. In addition, we asked veterans to report whether they had used the Pain Coach app. Among veterans who reported having used the app, we assessed self-reported patterns of use.

We also asked self-reported app users about their experiences with and perspectives on the Pain Coach app. Questions asked veterans to report their level of agreement (1=strongly agree to 5=strongly disagree) on factors related to app usability and usefulness and whether the app helped them communicate with their VA care team about their pain. Additionally, we asked

veterans to report their level of agreement (1=strongly agree to 5=strongly disagree) on items assessing perceived impact of the app on outcomes (eg, VA Pain Coach helped me to be more engaged in my pain management). Further, we asked veterans to rate their satisfaction with the app (1=very satisfied to 5=not at all satisfied) and their likelihood of recommending the app to other veterans (1=definitely will to 5=definitely will not recommend). Among veterans who reported not having used the app, we asked them to indicate their reasons for nonuse.

We also repeated all questions from the baseline survey regarding veterans' experiences with and management of pain (please see the Baseline Survey section).

### ***Semistructured Interviews***

Our semistructured interviews with app users and nonusers followed guides and, reflective of data integration through "building" in mixed methods, included questions intended to elaborate on responses to specific survey items [28]. We asked veterans who reported having used the Pain Coach app about their perceptions of the usability and usefulness of the app, impact of using the app on outcomes and communication with their VA care team, and general perceptions of the app and suggestions for improvement. In our interviews with veterans who reported not having used the app, we asked them to elaborate on their reasons for not having used it.

### **Analyses**

#### ***Survey Data***

We analyzed survey data using descriptive statistics (means, percentages) among veterans who completed both a first and second survey. We assessed differences in key demographics (eg, age, relationship status, gender) among veterans who reported having used the Pain Coach app versus those who did not use the app using independent samples *t* tests and chi-square tests. We also examined differences in key outcomes (ie, pain self-efficacy, pain interference, pain intensity, sleep, pain outcomes) on the pre- and post-surveys for Pain Coach app users and nonusers with paired samples *t* tests. Statistical analyses were performed with STATA MP Version 14.2 software (StataCorp, College Station, TX).

#### ***Interview Data***

We analyzed interview transcripts using thematic analysis [29,30]. We first developed a code list based on topics addressed

in the interview guide and added emergent codes to the list during the coding process. We also identified exemplary quotes representative of key themes. Two team members analyzed each transcript, first reviewing the transcript independently and then meeting to discuss codes. Any identified discrepancies were resolved during these meetings until complete consensus was reached for all codes. Responses to open-ended survey questions were analyzed using similar procedures.

This work was reviewed by the Institutional Review Boards at the Edward Hines Jr. VA Hospital in Hines, IL and the VA Bedford Healthcare System in Bedford, MA and designated as program evaluation for quality improvement purposes, exempting it from further oversight (VA Handbook 1058.05).

## **Results**

### **Sample**

We invited 1668 veterans to participate in the baseline survey; we adjusted this denominator to 1507 to reflect 9 surveys that were returned as undeliverable, 3 veterans who were deceased, and 149 who declined to participate. We received responses from 393 veterans (393/1507, 26.1% response rate). These 393 veterans received our outreach program and were invited to participate in the follow-up survey; we received completed follow-up surveys from 236 veterans (236/393, 60.1% response rate). In the follow-up survey, we asked veterans if they would be willing to complete a semistructured interview to further share their perspectives on the app; 144 (15 app users and 129 nonusers) of the 236 survey respondents expressed willingness to participate in an interview, and we completed interviews with 10 app users and 10 nonusers. In the following sections, we integrate our quantitative and qualitative data, "weaving" and reporting it together according to topics [28].

### **Sample Description: Survey Respondents**

#### ***Sociodemographics***

Our sample was predominantly male (195/234, 83.3%), White (154/236, 65.3%), of non-Hispanic ethnicity (213/217, 98.2%), married or in a civil union (157/233, 67.4%), and about 64 years old, on average (Table 1). The majority had completed at least some college or vocational school or were college graduates (192/235, 81.7%) and reported being in fair (100/235, 42.6%) or poor (46/235, 19.6%) health.

**Table 1.** Demographic characteristics and technology ownership among survey respondents (n=236).

Variables	Results
<b>Sociodemographic variables</b>	
Age <sup>a</sup> (years), mean (SD)	63.5 (11.2)
Age <sup>a</sup> (years), range	28.0-87.0
Gender <sup>a</sup> : male, n (%)	195 (83.3)
Gender <sup>a</sup> : female, n (%)	39 (16.7)
Race: White, n (%)	154 (65.3)
Race: Black or African American, n (%)	69 (29.2)
Race: Asian, n (%)	2 (0.9)
Race: Native Hawaiian or other Pacific Islander, n (%)	0 (0)
Race: American Indian or Alaskan Native, n (%)	9 (3.8)
Race: Other, n (%)	4 (1.7)
Ethnicity <sup>b</sup> : Hispanic or Latino, n (%)	4 (1.8)
Ethnicity <sup>b</sup> : not Hispanic or Latino, n (%)	213 (98.2)
Relationship status <sup>c</sup> : Married or in a civil union, n (%)	157 (67.4)
Relationship status <sup>c</sup> : Not married or in a civil union <sup>d</sup> , n (%)	76 (32.6)
Education status <sup>e</sup> : high school graduate or less, n (%)	43 (18.3)
Education status <sup>e</sup> : at least some college or vocational school (1-4 years), n (%)	175 (74.5)
Education status <sup>e</sup> : Master's/professional/doctoral degree, n (%)	17 (7.2)
Living arrangement: my own apartment or house, n (%)	211 (89.4)
Living arrangement: friend's or relative's apartment or house, n (%)	19 (8.1)
Living arrangement: other <sup>f</sup> , n (%)	8 (3.4)
Financial difficulty <sup>c,g</sup> : not very hard, n (%)	110 (47.2)
Financial difficulty <sup>c,g</sup> : somewhat hard/hard/very hard/do not know, n (%)	123 (52.8)
Self-reported health status (general) <sup>e</sup> : excellent, n (%)	1 (0.4)
Self-reported health status (general) <sup>e</sup> : very good, n (%)	17 (7.2)
Self-reported health status (general) <sup>e</sup> : good, n (%)	71 (30.2)
Self-reported health status (general) <sup>e</sup> : fair, n (%)	100 (42.6)
Self-reported health status (general) <sup>e</sup> : poor, n (%)	46 (19.6)
<b>Technology ownership variables</b>	
Does own a desktop or laptop computer <sup>e</sup> , n (%)	184 (78.3)
Does not own a desktop or laptop computer <sup>e</sup> , n (%)	51 (21.7)
Does own a table computer (eg, iPad, Kindle Fire) <sup>h</sup> , n (%)	111 (48.1)
Does not own a table computer (eg, iPad, Kindle Fire) <sup>h</sup> , n (%)	120 (51.9)
Cell phone ownership <sup>i,j</sup> : smartphone <sup>k</sup> , n (%)	181 (79.0)
Cell phone ownership <sup>i,j</sup> : non-smartphone cell phone, n (%)	37 (16.2)
Cell phone ownership <sup>i,j</sup> : none, n (%)	11 (4.8)

<sup>a</sup>n=234.

<sup>b</sup><sub>n</sub>=217.

<sup>c</sup><sub>n</sub>=233.

<sup>d</sup>Engaged or in a relationship, single, separated, divorced, widowed.

<sup>e</sup><sub>n</sub>=235.

<sup>f</sup>School or dormitory, hospital or detox center, nursing home or assisted living, car or street, jail/prison.

<sup>g</sup>How hard is it for you (and your family) to pay for the very basics like food and heating/cooling?

<sup>h</sup><sub>n</sub>=231.

<sup>i</sup><sub>n</sub>=229.

<sup>j</sup>If you have multiple cell phones, select the one you use most often.

<sup>k</sup>iPhone, Android, Blackberry, Windows Phone, Symbian, or some other type of smartphone.

### Technology Ownership

The majority of respondents reported owning a smartphone (181/229, 79.0%) or non-smartphone cell phone (37/229, 16.2%) and desktop or laptop computer (184/235, 78.3%); just under one-half (111/231, 48.1%) reported owning a tablet computer.

### Sample Description: Interview Participants

Veterans who participated in our semistructured interviews were predominantly male (15/20, 75%) and 56.0 years old, on average. Just under one-half (9/20, 45%) used opioid therapy to manage their pain, and one-half (10/20, 50%) reported having used the Pain Coach app.

### Outreach Program

Among respondents, 26.3% (62/236) recalled having received informational materials in the mail about the Pain Coach app, while 51.3% (121/236) did not recall having received these materials (53/236, 22.5% were unsure). About 7.6% (18/236) recalled having spoken with someone by phone from the NTHD about the Pain Coach app, while 88.1% (208/236) reported that they did not recall speaking with anyone from the help desk (10/236, 4.2% were unsure). Finally, 11.4% (27/236) reported recalling having had communication about the Pain Coach app with their VA care team members in the past few months, while the majority did not recall such communication (193/236, 81.8%) or were unsure (16/236, 6.8%).

### Veteran-Reported Use of the Pain Coach App

Among our respondents, 10.2% (24/236) reported having used the Pain Coach app while most (212/236, 89.8%) indicated not having used the app (Table 2). We compared sociodemographic characteristics among veterans who reported having used the app and those who reported not using it. We did not find significant differences in app adoption due to gender or relationship status among veterans. However, veterans who reported using the Pain Coach app were younger, on average, than those who reported not having used the app (57.6 years vs 64.2 years;  $P=.01$ ).

Our follow-up semistructured interviews to the survey provided an opportunity to explore in more depth the motivations underlying app use. Some interviewees reported turning to the Pain Coach app as a means of tracking their pain or as part of seeking pain management strategies that could complement what they were already doing or could be alternatives to strategies that they had used previously. Others noted that their pain was chronic and ongoing and as such, were willing to try alternative approaches offered within the app to help them manage it. As one male veteran (52 years old) commented:

*I definitely have a lot of years with a lot of pain in multiple sites of my body, and I wanted to figure out what, if anything, the app could do to help.*

Some veterans also saw the app as a potential alternative to pain medications or taking pain medications throughout the day. As one female veteran (56 years old) explained:

*I suffer from migraines. I suffer from back pain, lower back pain, and other pain. I just refuse to take medication because the medication was masking the symptoms. So, I decided if I use Pain Coach, I could have something to kind of sort of guide me along the way. It was a little more user friendly than taking a pill every time you ate.*

Use of the Pain Coach app was also associated with changes that veterans were experiencing. One veteran described using the app to make sense of a type of pain he started feeling, while noting that the app might be useful for individuals who are new to managing pain in general. A male veteran (38 years old) noted:

*I think that [the VA Pain Coach app] may be beneficial for someone that is dealing with...new pain or has not heard those things before...*

Lastly, changes in an individual's pain management strategy (eg, changes in their medications) also prompted use of the app.

**Table 2.** Veteran-reported use of the Pain Coach app (n=236 survey respondents; n=24 app users).

Pain Coach app use variables	Sample proportion, n (%)
<b>Self-reported use of the VA Pain Coach app</b>	
Yes	24 (10.2)
No	212 (89.8)
<b>Which of the following best describes your use of the VA Pain Coach app?<sup>a,b</sup></b>	
I used it once but am no longer using it.	9 (40.9)
I used it more than once but am no longer using it.	7 (31.8)
I am still using it.	6 (27.3)
<b>To the best you can recall, for about how long have you been using the VA Pain Coach app? Or, if you are no longer using the VA Pain Coach app, about how long did you use it for?<sup>a,c</sup></b>	
3 months or longer	6 (26.1)
Between 1 and 3 months	4 (17.4)
Less than 1 month	7 (30.4)
1 week or less	6 (26.1)
<b>Utilization of VA Pain Coach app tools<sup>a</sup></b>	
Deep breathing	14 (58.3)
Muscle relaxation	13 (54.2)
Sleep tips	12 (50.0)
Manage thoughts	11 (45.8)
Visualization	10 (41.7)
Activity pacing	8 (33.3)
Plan a pleasant activity	7 (29.2)

<sup>a</sup> Among veterans who reported having used the app.

<sup>b</sup> n=22.

<sup>c</sup> n=23.

### Patterns of Use and Usability of the Pain Coach App

Among veterans who reported having used the Pain Coach app, 41% (9/22) used the app once, 32% (7/22) used the app more than once but discontinued use, and 27% (6/22) reported they were still using the app on their follow-up survey (Table 2). One-half or more reported using the app to support deep breathing (14/24, 58%), muscle relaxation (13/24, 54%), and sleep tips (12/24, 50%).

The follow-up semistructured interviews were an opportunity for veterans to provide feedback on features of the app they were using, including the Pain Toolbox, the section of the app that describes different pain management strategies, and the informational resources section of the app. Veterans reported benefits from this content, noting that it helped alleviate the different physical and mental burdens that pain can present, including stress and rumination that can accompany persistent pain. Still other veterans described how the Toolbox and learning resources served as a reminder of pain management techniques that they were previously aware of but had since forgotten:

*It reminded me of techniques that I had...used or I had totally forgotten about, so it was good in that aspect. [male veteran, 52 years old]*

The semistructured interviews also revealed aspects of the Toolbox and learning resources that veterans felt need to be improved. Some expressed concerns about the interface, while others noted that they did not think the content was useful or actionable beyond other health information resources available on the internet. For instance, one male veteran (54 years old) wanted to understand the rationale behind the pain management tools that were included in the Toolbox and why they might be effective at alleviating pain. In his opinion, it was a shortcoming merely to include the instructions or the how-to of the pain management tool without accompanying evidence:

*I don't know the purpose of doing them [the pain management techniques] if someone said, well this is why we want you to count to 10, because we want you to focus on "this," because obviously there is more to it than just counting to 10.*

Related to this point, other veterans felt that the presentation of general pain management strategies in the Toolbox was less effective than if they could provide a description of the pain they were experiencing so that the Toolbox could suggest



strategies based on their specific type of pain. As described by one female veteran (60 years old):

*Then they got this little tool thing, like, oh, you go to the pain Toolbox. Then, it says activity pacing, deep breathing, manage thoughts, muscle relaxation...But the thing is it doesn't ask what pain, what was the pain. You can't use all this stuff.*

### Perceived Usability

More than one-half of veterans who used the Pain Coach app reported that it was easy to use (14/24, 58.3%). One-half (12/24, 50.0%) indicated that they would have liked to have received more information on how to use the app.

Negative feedback about the app's usability shared during the semistructured interviews stemmed from its web-based platform (ie, the Pain Coach app is not a native app). Log-in issues emerged as a key usability challenge. The lengthy process to go from VA's Launchpad (the website through which veterans log into the Pain Coach app) to eventually logging into the app itself was cumbersome for some users. One male veteran (aged 54 years) commented:

*There are so many steps to even get to where you can log in...even when the system is working, it's a lot of steps just to log in to get to where you can log something in...You have to launch an app just to get to the app.*

Beyond log-in issues, veterans commented on the input-driven nature of the Pain Coach app, including the effort it takes to self-report information about one's experience of pain. Veterans wanted it to be faster and more efficient to document their pain levels. A male veteran (52 years of age) explained:

*I think as far as documenting and everything...it just could be easier, more user friendly, something quick.*

### Usefulness, Communication, and Outcomes Associated with Pain Coach App Use

#### Perceived Usefulness

Many veterans found that being able to track their pain levels in the app was useful (11/24, 45.8%). About one-third (8/24, 33.3%) found that being able to set reminders to track their pain in the app was useful and that the app helped them track how their pain was impacting other facets of their life, such as mood and sleep over time. One-quarter (6/24, 25%) of veterans who used the app reported having a better understanding of how to manage their pain because of the Pain Coach app, and 29% (7/24) stated that the app introduced them to new pain management strategies. Just under one-half of veterans (11/24, 46%) found the educational information about how they can manage pain provided in the Pain Coach app to be useful. Approximately one-third (8/24, 33%) stated that they intend to continue using the app in the future, and just under one-half (11/24, 46%) reported being satisfied with the app. More than one-half of veterans reported that they would recommend the app to other veterans (13/24, 54%).

As part of the semistructured interviews, some veterans described feeling that the app and its features fit their needs and

noted that Pain Coach can be a resource to facilitate recall of pain management strategies and to help veterans who want to learn more about how to manage their pain. Other veterans, however, felt that the amount of information to manage in the app was too much and at times, was not straightforward. A 38-year-old male veteran explained his experience this way:

*I just think it's a lot of information...too much information. ...you get agitated by trying to find different information and clicking all search feeds.*

Other veterans offered specific suggestions to improve the usefulness of the Pain Coach app's tracking features. Two key themes emerged. First, veterans suggested that it would be helpful to be able to document pain levels multiple times a day as levels fluctuate. One male veteran (54 years old) described using a different health app on his phone, which also did not allow tracking at multiple time points per day and expressed similar concerns about the Pain Coach app:

*If I can get into it numerous times a day and track what's going on, what happened, you know, it would help. But you know, for someone like myself, it's kind of a pain. Aggravating. Because at different times, I mean all day long, it's different for me.*

Second, other veterans described how being able to track what they were doing while they experienced different levels of pain would be valuable to them. This might include a data entry field where a veteran could note their activities next to their pain ratings. A female veteran aged 60 years described it this way:

*First when you...put in the pain [rating]. If they had something right there where you also have to put what activity...what type of activity you [were] doing, like a note.*

Veterans also suggested that receiving reminders to use the app and other motivational messages from the app would elevate it beyond being what could feel at times like a data entry tool. As one male veteran (aged 76 years) said:

*[If] some kind of little alarm or alert would pop up on the phone, "Hey, take your pain pills." I mean, not your pain pill, but "Take your, do your app."*

#### Communication

Among Pain Coach app users, few (2/24, 8% strongly agree; 1/24, 4% agree) reported that the app helped them communicate with their VA care team about their pain. Our semistructured interviews with app users corroborated our survey findings about Pain Coach's influence on veteran communication with their VA care team members. Our analysis revealed 2 main reasons why veterans felt the app did not help with that communication. First, several felt that their VA care team members simply lacked knowledge of the app or did not know that they were using the app. As one male veteran, aged 54 years, questioned:

*Do they [VA care team] see the app? I mean, if they see the app, they didn't tell me because I've seen them since I've logged into the app.*

Beyond care team member awareness of the app and its use, other veterans described that the limited impact of the app on

communication with their VA care team members was attributable to the quality of communication that already existed. Although some veterans reported good-quality communication with their care team members, others reported difficulties that they did not think the app would address. Veterans recognized that one of the main values of the Pain Coach app was to share information with their VA care team members; however, they questioned the point of using the app if that sharing did not happen. As one male veteran (54 years old) questioned:

*Is this something that my primary care physician is going to see and say “Well, we see your pain was up this day.” You know what I mean? Yeah, so—it is nice for me to sit here and log it in, but is it just for me? ‘Cause if it was just for me, I have a pen and a pad and a paper right next to my chair here, so I could just keep track of it myself if I wanted to.*

### Outcomes

Approximately one-fifth (5/24, 21%) of veterans reported that using the Pain Coach app helped them to be more engaged with their pain management and managing their pain was less frustrating for them because of the app (5/24, 21%); 25% (6/24) found that they were able to manage their pain more effectively because of the app.

We compared pre- and post-survey scores on veterans' self-reported experience of pain (pain self-efficacy, pain

interference, pain intensity, sleep, pain outcomes) for Pain Coach app users and nonusers using paired samples *t* tests (see [Table 3](#)). Veterans who used the Pain Coach app reported greater pain self-efficacy after using the app (after, mean 23.1 vs before, mean 16.6;  $P=.01$ ); conversely, among app nonusers, self-efficacy scores did not change from the pre (mean 22.9) to post (mean 23.0) periods ( $P=.46$ ). Moreover, while both veterans who used the Pain Coach app (mean 34.6 vs mean 31.8;  $P=.03$ ) and those who did not (mean 30.5 vs mean 28.7;  $P=.001$ ) reported lower pain interference on the post survey as compared with the pre survey, reported pain interference scores decreased more among app users (2.8-point decrease) than nonusers (1.8-point decrease). Of note, the literature indicates that a 2- to 3-point change indicates a minimally important difference on this pain interference measure [31]. In addition, veterans who used the Pain Coach app reported lower (though nonsignificant) pain intensity after using the app (after, mean 7.0 vs before, mean 7.5;  $P=.09$ ); conversely, among app nonusers, pain intensity did not change from the pre (mean 6.6) to post (mean 6.7) periods ( $P=.52$ ). Finally, both veterans who used the Pain Coach app (mean 119.5 vs mean 105.2;  $P=.04$ ) and those who did not use the app (mean 101.3 vs mean 93.3;  $P<.001$ ) reported improvements on the Pain Outcomes Questionnaire - Short Form, although scores among app users improved more than among nonusers.

**Table 3.** Comparisons of veteran outcomes from baseline to post-survey periods (n=236).

Outcome variables	App users (n=24)			App nonusers (n=212)		
	Baseline survey, mean	Follow-up survey, mean	<i>P</i> value	Baseline survey, mean	Follow-up survey, mean	<i>P</i> value
Pain self-efficacy [25]	16.6	23.1	.01	22.9	23.0	.46
Pain interference <sup>a</sup> [26]	34.6	31.8	.03	30.5	28.7	.001
Pain intensity <sup>b</sup> [24]	7.5	7.0	.09	6.6	6.7	.52
Sleep <sup>c</sup>	4.3	4.3	.50	3.9	3.9	.47
Pain outcomes (overall score) <sup>a</sup> [27]	119.5	105.2	.04	101.3	93.3	<.001

<sup>a</sup>n=212 nonusers.

<sup>b</sup>n=195 nonusers.

<sup>c</sup>n=203 nonusers.

### Reasons for Nonuse

In addition to understanding the experiences of those veterans who used the app during our evaluation period, we also gathered data from veterans who did not use the app to understand reasons for nonuse. The most frequent reason reported by veterans for not using the Pain Coach app was that their health care team

had not talked with them about it (96/212, 45.3%; [Table 4](#)). This was followed by 22.2% (47/212) of veterans reporting that they did not use the app because they were not aware of it, 16.5% (35/212) did not think it would help them manage their pain, and 16.0% (34/212) reported that they are not comfortable using apps.

**Table 4.** Reported reasons for nonuse of the Pain Coach app (n=212).

Reasons for not using the app	Sample proportion, n (%)
My health care team has not talked with me about using the app	96 (45.3)
Not aware of the app	47 (22.2)
I do not think it would help me manage my pain on my own	35 (16.5)
I am not comfortable using apps	34 (16.0)
I do not see why it would benefit me	28 (13.2)
I do not have a reliable device on which to use the app	26 (12.3)
I have concerns about entering my information in the app	21 (9.9)
I had difficulty accessing the app (eg, downloading, forgot login/password)	19 (9.0)
Not enough information about the app	14 (6.6)
I do not think it would help my health care team to manage my pain.	13 (6.1)
I do not have internet access or stable internet connection	13 (6.1)
Haven't had the time	12 (5.7)
I already have too many apps or receive too much information as it is	11 (5.2)
I do not want to share information about my pain	9 (4.3)
Limited interest in using the app	8 (3.8)
It costs too much to use the app	5 (2.4)
Needs support to use the app	4 (1.9)
Using other pain management strategies	4 (1.9)
I am already using another app to help manage my pain	3 (1.4)

Our semistructured interview data corroborated several of the key findings regarding reasons for nonuse. Limited awareness and having limited information were further described as key reasons for not using the Pain Coach app. In addition, other veterans described having limited interest in and knowledge of how to use the app, citing time pressures, other commitments, and in some cases, a sense of being overwhelmed by other electronic media. As one male veteran (72 years old) commented:

*...I deal with too much computer stuff and emails and internet things, and this [is] just one more thing that, you know, I don't need on my plate and that's why, you know, I would never really use it.*

For this same veteran, like others who reported not using the app, his lack of interest in Pain Coach also tied to his belief that its features and content could not help him manage his pain in lieu of other strategies he already tried:

*I've been through everything from physical therapy to disc fusion at this point, and so, you know, I've done all the different options. If that's what your coach thing does, it's kind of like walking through the various options to managing your pain and, you know, tracking it, then, you know, at this point I've done everything. [laugh] So, what else is there?*

Finally, several veterans who did not use the Pain Coach app explained that having members of their health care team talk with them about the app might have facilitated their willingness to try it.

*I: Okay. Great. What else would have been helpful to you in getting started to use VA Pain Coach? P: Probably, my pain management team talking to me more about it. [male veteran, 50 years old]*

*If I was able to talk to somebody, I guess, while I was already at the doctor. If, you know, that time is already set aside, somebody explain to me how it works or what the benefits of it were, it might help me be more willing to use it. [female veteran, 28 years old]*

## Discussion

### Principal Findings

Increasingly, patient-facing technologies such as mobile health apps are being used to offer pain management strategies to patients [32,33]; however, information about the adoption and impact of such apps among veterans with chronic pain is limited. In this evaluation, we used mixed quantitative and qualitative methods to examine veteran perceptions of and experiences with Pain Coach, a VA mobile health app designed to facilitate pain self-management in the veteran population. Our participants reflect the diverse experiences of veterans managing chronic pain, including those from different geographic regions and those using different pain management approaches (eg, veterans using and not using opioid therapy). Our findings revealed that a fairly "light touch" outreach program yielded limited adoption of this app among veterans and that future mobile health app implementation efforts might benefit from the integration of health care team member encouragement to maximize patient

engagement. Still, despite limited use of Pain Coach among the veterans in our sample, we identified important insights regarding usability issues, as well as encouraging, albeit preliminary, impacts of the app on increasing pain self-efficacy and reducing pain interference.

In order to facilitate app adoption among patients, awareness levels of apps must be increased. Our data revealed that traditional outreach approaches including mailed materials and phone calls appear to have limited impact among veterans in this regard. Although the FAQ sheet that we mailed to veterans about the Pain Coach app seemed to reach the greatest number of veterans in our sample, even this component was seemingly limited in its impact. Despite multiple call attempts, the technical support outreach efforts completed by the VA NTHD did not seem to reach many veterans. Furthermore, although we provided information to VA health care team members about Pain Coach and its functionality via email, veterans reported little communication with their health care team about the app.

Our findings regarding VA care team member and veteran communication about the VA Pain Coach app are particularly important. The predominant reason veterans reported not having used the app was because their care team members had not talked with them about it. This was further corroborated in our interviews with veterans, during which some participants told us that they may have been more likely to try using the app if their VA care team members had recommended it to them. The implications of these findings are significant and underscore the important role that health care team member endorsement and recommendation play in the implementation, adoption, and use of mobile health apps like Pain Coach [34]. These findings further expand on the evidence that endorsement of mobile health apps by health care providers is key to bolstering patient app adoption, including among veterans [22,35].

It is important to recognize that recommending an app to all patients may not resolve all implementation challenges either. As has been discussed in the literature, various considerations need to be made when recommending mobile apps to patients, including a patient's technical competence, potential privacy issues, and other potential online harms [36-38]. Our data further suggest other characteristics for providers to consider when determining whether a veteran might be a good candidate to use an app like Pain Coach. These include whether the individual is new to the experience and management of pain, whether they experienced some change in their pain or pain management strategies, and whether they might need a reminder of pain management strategies available to them. Similarly, those who have long-standing, chronic pain may be open to additional support to facilitate coping, thus also making them good candidates for app use.

Our evaluation further revealed insights about veteran perceptions of the usability and usefulness of the Pain Coach app. Veterans noted negative perceptions of the web-based platform of the app and in turn, the cumbersome process required to log in (a by-product of the Pain Coach not being a native app). In addition, while some veterans found the informational resources and tracking features in the Pain Coach app to be useful, participants offered suggestions for how these

features could be improved, which may be integrated into future versions of Pain Coach or other pain-focused mobile health apps. These suggestions included noting evidence to support the effectiveness of the pain management strategies detailed in the app, facilitating faster and more intuitive pain tracking, allowing users to track their pain throughout the day as opposed to once per day to account for fluctuations in pain, and including a notes field where users could indicate what they were doing when they experienced that level of pain. Veterans also indicated that they would like for the app to send them reminders and motivational messages.

Previous research focused on mobile health apps for pain management also suggests that users value being able to track their pain in the app and want to share this information with their care providers [39]. Similarly, the veterans in our evaluation recognized that one of the main values of the Pain Coach app was to share information with their VA care team members; however, they questioned the point of using the app if that sharing did not happen, and many did not feel the app facilitated communication. These perceptions could potentially be improved if veterans knew that their care team members (1) are aware of the app, (2) know that the veteran is using the app, and (3) know that the veteran is entering data into the app that are available to inform care. These findings are aligned with previous literature noting that patients want to share and discuss the data they enter into mobile health apps with their providers [40,41] and further highlight the importance of provider engagement in patient app adoption and use and subsequent impacts. In order to ensure that mobile health apps such as Pain Coach are able to effectively facilitate patient-care team communication, care team members must be aware that their patients are using such apps.

Finally, and although preliminary, our results suggested that the Pain Coach app may be effective in supporting veteran pain self-management, with users of the app in our sample reporting improved outcomes (ie, increased pain self-efficacy, reduced pain interference) after using the app. These findings are aligned with previous research suggesting that mobile health apps can effectively help individuals manage chronic pain [42] and the use of mobile health apps for pain can facilitate improved pain outcomes [43,44]. This is encouraging and further supports efforts to improve implementation of mobile health apps for pain management.

### Limitations

Our work was limited by lack of randomization and reliance on self-report data, including data on app usage, because reliable app activity log data were not available at the time this evaluation was conducted. In addition, the small number of veterans who reported using the app limits the comparisons that can be made with nonusers and generalizability beyond our sample and underscores the importance of interpreting the results, particularly those regarding impact of the app on veteran outcomes, with caution. In addition, VA Pain Coach is not a native app but rather a mobile web app accessed through an online browser; veterans may have experienced less usability concerns if they had been able to download VA Pain Coach to their personal device(s) rather than having to access a web portal



in order to log in. Future work should leverage larger samples of Pain Coach app users, as well as examine the experiences of veterans who tried the app once but did not return, to understand why and how to better support sustained use. Beyond the kind of pre-post design we utilized here, more rigorous evaluations of the effectiveness of the Pain Coach app would require prospective designs with randomization and less reliance on self-report data.

## Conclusions

The results of this evaluation have revealed that traditional outreach approaches (ie, mailed materials, phone calls) had only a marginal influence on awareness of a pain management mobile

app among a sample of veterans with chronic pain. Future mobile health app marketing and outreach efforts should be combined with health care team member endorsement, as care team members appear to have a critical role to play in promoting app adoption. Further, addressing the usability issues inherent in apps like VA's Pain Coach will only serve to advance implementation. Importantly, even though adoption of the Pain Coach app among veterans in this evaluation was quite limited, our results indicate that the app may be useful for self-management of pain (eg, increasing self-efficacy and reducing pain interference), signaling that more rigorous randomized evaluations may be warranted.

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All evaluation procedures described in this manuscript were completed in accordance with the ethical standards of the responsible committee on human experimentation (institutional or regional) and with the Helsinki Declaration.

## Conflicts of Interest

None declared.

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## Abbreviations

- FAQ:** frequently asked questions  
**NTTHD:** National Telehealth Technology Helpdesk  
**OCC:** Office of Connected Care  
**VA:** Veterans Health Administration

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Original Paper

# An Acceptance and Commitment Therapy Prototype Mobile Program for Individuals With a Visible Difference: Mixed Methods Feasibility Study

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## Abstract

**Background:** Mobile apps may offer a valuable platform for delivering evidence-based psychological interventions for individuals with atypical appearances, or visible differences, who experience psychosocial appearance concerns such as appearance-based social anxiety and body dissatisfaction. Before this study, researchers and stakeholders collaboratively designed an app prototype based on acceptance and commitment therapy (ACT), an evidence-based form of cognitive behavioral therapy that uses strategies such as mindfulness, clarification of personal values, and value-based goal setting. The intervention also included social skills training, an established approach for increasing individuals' confidence in managing social interactions, which evoke appearance-based anxiety for many.

**Objective:** In this study, the authors aim to evaluate the feasibility of an ACT-based app prototype via the primary objectives of user engagement and acceptability and the secondary feasibility objective of clinical safety and preliminary effectiveness.

**Methods:** To address the feasibility objectives, the authors used a single-group intervention design with mixed methods in a group of 36 participants who have a range of visible differences. The authors collected quantitative data via measures of program use, satisfaction ratings, and changes over 3 time points spanning 12 weeks in outcomes, including selected ACT process measures (experiential avoidance, cognitive defusion, and valued action), scales of appearance concerns (appearance-based life disengagement, appearance-fixing behaviors, appearance self-evaluation, and fear of negative appearance evaluation), and clinical well-being (depression and anxiety). Semistructured exit interviews with a subsample of 12 participants provided qualitative data to give a more in-depth understanding of participants' views and experiences of the program.

**Results:** In terms of user engagement, adherence rates over 6 sessions aligned with the upper boundary of those reported across mobile mental health apps, with over one-third of participants completing all sessions over 12 weeks, during which a steady decline in adherence was observed. Time spent on sessions matched design intentions, and engagement frequencies highlighted semiregular mindfulness practice, mixed use of value-based goal setting, and high engagement with social skills training. The findings indicate a good overall level of program acceptability via satisfaction ratings, and qualitative interview findings offer positive feedback as well as valuable directions for revisions. Overall, testing for clinical safety and potential effectiveness showed encouraging changes over time, including favorable changes in appearance-related life disengagement, appearance-fixing behaviors, and selected ACT measures. No iatrogenic effects were indicated for depression or anxiety.

**Conclusions:** An ACT-based mobile program for individuals struggling with visible differences shows promising proof of concept in addressing appearance concerns, although further revisions and development are required before further development and more rigorous evaluation.

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## KEYWORDS

mobile health; acceptance and commitment therapy; appearance; mixed methods; mobile phone

## Introduction

### Background

Visible difference refers to an unusual physical appearance caused by a congenital or acquired health condition, injury, or medical intervention [1]. Between visible skin conditions such as psoriasis and eczema, scarring from trauma or surgery, craniofacial conditions such as cleft lip and/or palate, and many other causes, approximately 1 in 60 people are estimated to live with a visible difference [2]. In the context of heightened conspicuousness and common reports of negative social reactions [3], there is a marked prevalence of appearance-related distress, most commonly in the form of anxiety (particularly social anxiety, marked by a fear of negative appearance evaluation and social withdrawal), depression, and body dissatisfaction, across a range of appearance-affecting conditions [4-6]. Although many adjust well to having a visible difference, samples of individuals with visible differences commonly show significantly higher rates of appearance-based anxiety and depression across cultures (eg, in adults with acne [7] and alopecia [8]) when compared with matched controls. With minimal specialist psychological provision available (eg, across Europe [9]), the development and testing of specialist self-help interventions are warranted. Indeed, existing self-help shows promise in addressing appearance concerns for this population [10].

### Acceptance and Commitment Therapy for Visible Differences

Acceptance and commitment therapy (ACT) offers a novel approach to the population with visible differences, with traditional cognitive behavioral therapy having dominated the research field to date [11]. ACT is a third-wave cognitive behavioral therapy in which psychological flexibility is cultivated, namely, the capacity to hold present moment awareness and acceptance of one's internal experiences while acting in ways aligned to one's personal values [12]. The psychological flexibility model holds conceptual promise for addressing appearance concerns in this group, for some of whom thoughts such as "I look strange" or "People will stare" represent a degree of objective reality, therefore being less amenable to the thought challenging approaches adopted in traditional cognitive behavioral therapy. In ACT, individuals learn to accept the presence of such unwanted thoughts and associated emotions while also detaching from their literality through an awareness of thoughts as an ongoing internal process rather than focusing on their content (via *cognitive defusion*). Concurrently, individuals clarify their personal values as guides for ongoing purposeful behavior. These values are qualities of behavior, namely, a quality that can be enacted, such as skillfulness,

honesty, and intimacy. Present moment acceptance and cognitive defusion are cultivated in ACT primarily as a means of facilitating a commitment to value-consistent activity. In combination, ACT may offer a pragmatic therapeutic approach for this population [13].

In a cross-sectional study involving individuals with a range of visible differences, researchers [14] drew from an established model of body image coping strategies [15] to investigate the role of 2 key psychological flexibility subprocesses in relation to appearance-related outcomes. The authors found that cognitive fusion (taking thoughts as factual statements to be acted on) mediated the relationship between appearance evaluation and 2 unhelpful coping strategies in the form of appearance-related life disengagement (physically avoiding situations because of appearance concerns) and appearance-fixing behaviors (eg, compulsive concealment of the visible difference). They also found that experiential avoidance (an unwillingness to remain in contact with unwanted internal experiences) partially mediated disengagement but not appearance-fixing behaviors. Cognitive fusion, experiential avoidance, and reduced committed action were also found to correlate with appearance anxiety in patients with burn scarring [16].

Recent trials offer some evidence for the efficacy of book-based ACT self-help in related clinical areas of social anxiety [17] and body dissatisfaction in the general population [18]. These interventions that are based on evidence-based ACT protocols [19,20] offer a valuable starting point for developing ACT programs for individuals with visible differences. However, modification is needed both from social anxiety interventions (eg, acknowledging that individuals with visible differences may encounter initial negative reactions to their appearance from others) and body dissatisfaction protocols, which predominantly focus on shape and weight rather than unusual appearance. To the authors' knowledge, no research investigating any other ACT self-help interventions for individuals with visible differences has been published.

### Mobile Delivery

Mobile apps offer a unique level of user functionality to facilitate everyday skills training and self-monitoring in self-help programs [21]. Real-time tailored feedback can reinforce target behaviors [22], which, for individuals with a visible difference, could include the practice of social skills training (an evidence-based component to help individuals manage difficult social encounters [23]), tailored mindfulness practices, and valued goals related to appearance concerns. Notifications can also be set to remind users to engage, a function that has been shown to improve the efficacy of mental health apps [24]. In



addition to acting as standalone interventions for individuals with mild to moderate support needs, apps can be used to augment professional interventions [25,26].

Research on existing ACT-based app interventions offers a valuable direction for designing ACT-based apps for behavior change. For example, participants who used a more complex ACT matrix health app made greater health improvements and used the app more than those who used a simpler version [27], suggesting that users may prefer a variety of novel toolbox-like activities. The involvement of key stakeholders at the design stage of an app program, including end users from the intended population and clinicians with relevant expertise, is also paramount to optimize its appeal, accessibility, and trustworthiness [28]. For this reason, the intervention investigated in this study was designed using participatory design methods involving individuals with visible differences and clinicians with relevant expertise, as detailed in a previous article [29].

Another design consideration is whether to make a mobile app self-guided or guided. In general, higher levels of professional input may confer greater efficacy [24]. However, self-guided mobile apps require fewer support resources and, therefore, are capable of reaching more users. Equally, in the field of ACT self-help studies, evidence for the superiority of guided interventions is equivocal. Selvi et al [18] found no additional benefit of guided self-help for body dissatisfaction compared with the self-guided version. Similarly, in a trial of an ACT-based social anxiety intervention delivered on the web and via an app (with equivalent content), researchers [30] found no differences between guided and unguided versions of the intervention on social anxiety outcomes. The authors proposed that mobile app features may partially compensate for the absence of a guiding therapist, for example, by providing real-time feedback during exposure tasks. However, an absence of professional oversight may heighten concerns of potential iatrogenic effects on well-being [31]. Therefore, it is important to mitigate against and test for any iatrogenic effects in the design and testing of mobile interventions.

### Goal of This Study

The aim of this study is to assess the feasibility, or proof of concept, of an ACT-based self-guided prototype mobile intervention for individuals with visible differences who experience appearance-related concerns. The prototype is delivered via a mobile-optimized web app that simulates a native

mobile app, which is consistent with the recommendation to test low-cost iterations of behavior change apps before building full-scale versions [32]. By assessing the prototype's feasibility using a mix of quantitative and qualitative methods, we aim to make subsequent modifications to develop a native app and test this via a future randomized controlled trial (RCT).

The primary feasibility objectives target user engagement and acceptability, and the secondary objective is to determine whether the program indicates clinical safety and preliminary effectiveness.

## Methods

### Participants

A sample of 36 adults was recruited between July and November 2020. The primary recruitment strategy drew from 19 UK charities that represented and supported individuals with a range of congenital and acquired appearance-affecting conditions and advertised the study to potential participants via social media, newsletters, distribution lists, and web-based events. Researchers also promoted the study on relevant Reddit subgroups with the aim of boosting the number of male participants, given the comparatively higher use of Reddit by men versus women [33].

To be eligible, participants had to self-report as having a visible difference (defined to participants as a physical appearance they considered to be significantly different from a typical appearance, with a list of example causes given). Eligibility also included currently experiencing appearance concerns, defined as psychological and/or social difficulties related to their visible differences, such as appearance-based social anxiety, low mood, and body image concerns. Participants also had to be aged  $\geq 18$  years, a UK resident, own a smartphone and have regular internet access (either through home Wi-Fi and/or cellular data), and have experience in using apps. Participants were ineligible if they acquired a visible difference from traumatic injury in the preceding 6 months because of the heightened risk of unprocessed psychological trauma, for which a self-administered intervention would be clinically inappropriate. Ineligibility also included current experience of a mental health crisis (eg, suicidality or self-harm), undergoing talking therapy, or having appearance concerns primarily related to weight or eating. The sample's mean age was 36.67 (SD 14.25) years. All other demographic characteristics are presented in Table 1.

**Table 1.** Demographic characteristics of total study sample (N=36).

Characteristics	Values, n (%)
Gender (female)	29 (81)
<b>Cause of visible difference</b>	
Skin condition (eg, alopecia, ichthyosis, psoriasis, eczema, and scarring)	20 (56)
Congenital craniofacial condition (eg, cleft lip and/or palate and craniosynostosis)	6 (17)
Other congenital conditions (eg, birthmark and inherited ichthyosis)	7 (19)
Acquired craniofacial condition (eg, facial palsy and malocclusion of jaw)	3 (8)
<b>Ethnicity and race</b>	
White	32 (89)
Mixed ethnic groups	2 (6)
Asian or Asian British	1 (3)
Black, African, or Caribbean	1 (3)
<b>Relationship status</b>	
Single	15 (42)
Married or in a civil partnership	9 (25)
Dating or living with a partner	9 (25)
Separated or divorced	2 (7)
Would rather not say	1 (3)
<b>Occupation status</b>	
Employed full time	16 (44)
Employed part time	6 (17)
Student	5 (14)
Retired	3 (8)
Unemployed	3 (8)
Unable to work	3 (8)
<b>Highest education level</b>	
Graduate degree	10 (28)
Undergraduate degree	10 (28)
Vocational qualification	10 (28)
High school	6 (17)

## The Intervention

The program *ACT It Out* comprises 6 sessions designed to take approximately 30 minutes each and be completed weekly, augmented with between-session *Skill builder* toolbox-like activities for the everyday practice of the ACT-based skills presented in session. [Textbox 1](#) shows an overview of the program content. The material was derived from a combination of the intervention research literature and stakeholder input. ACT-specific content was drawn from evidence-based protocols

for social anxiety [19] (eg, *safety mode* for threat-focused attention in public) and body dissatisfaction [20] (eg, *mindful mirror exercise*) and adapted for the population, for example, by acknowledging the possibility of unsolicited public attention in relation to social anxiety and modifying the mindful mirror script to account for participants' bodily areas of visible difference rather than their body weight and shape. Social skills training for managing difficult social interactions was informed by existing evidence-based self-help programs, for example, the study by Bessell et al [23].

**Textbox 1.** Overview of ACT It Out program content.

#### Session 1

- What *ACT It Out* is and how it works
- Choice point metaphor (toward and away moves); simple reflection on personal values
- Passengers on a bus metaphor

#### Postsession 1: Skill builders

- Recording your passengers and toward or away moves

#### Session 2

- Reviewing your passengers and toward or away moves
- Responding to your passengers (acceptance and commitment therapy social anxiety concepts of safety mode versus *ACT It Out* mode)
- Mindfulness training—your senses

#### Postsession 2: Skill builders

- Micromindfulness (text instructions)

#### Session 3

- Reviewing safety mode versus *ACT It Out* mode
- Values and taking action (values clarification and setting a simple goal for the day)
- Mindfulness training—breath and body

#### Postsession 3: Skill builders

- Tracking simple goals for the day
- Mindfulness of breath and body

#### Session 4

- Reviewing valued action (setting a simple goal for the week) and mindfulness
- Mindfulness training—breathing into intensity
- Being around people—taking control (social skills)

#### Postsession 4: Skill builders

- Tracking simple goals for the week
- Mindfulness of intense experiences
- Social skills practice

#### Session 5

- Reviewing your goal and mindfulness
- Being around people—managing negative reactions (social skills)
- Mindfulness training—mindful mirror

#### Postsession 5: Skill builders

- Social skills practice
- Mindful mirror

#### Session 6

- Reviewing your mindfulness and social skills
- Mindfulness in daily life
- *ACT It Out* long term (long-term goal setting)

#### Postsession 6: Skill builders

- Tracking long-term goals

*ACT It Out* underwent an iterative design process led by the first author (FZ), incorporating feedback from user representatives and psychological practitioners with expertise in ACT and/or visible differences. The second and third authors (OD and ER) contributed to the program’s design and testing as clinical lead and user representative lead, respectively. Examples of user-driven content incorporated into the prototype included a *human* interactive element (involving an *app guide*, the second author OD); real case examples throughout to illustrate ACT principles and offer a sense of commonality (many provided by user representatives); and accessible formatting, including large font, subtitles, and audio transcripts. Content based on clinicians’ input reflected their preferences for the inclusion of a range of established ACT metaphors used to convey important concepts, management of users’ expectations through clear information and periodic *check-ins* on the ACT model (eg, reiterating that the goal is not to directly reduce negative affect), and provision of sufficient time for behavior modification.

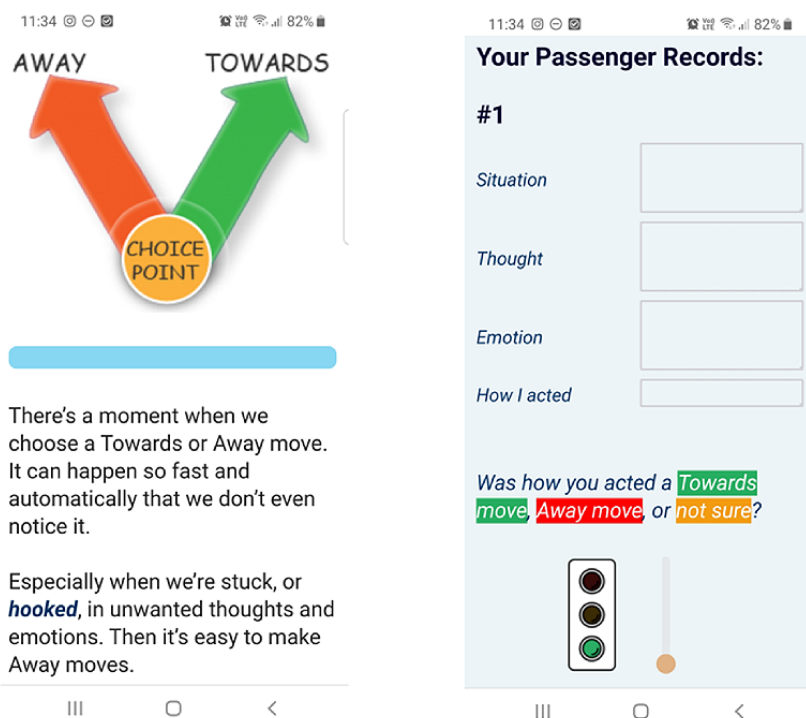
*ACT It Out* is self-guided, although the in-built *app guide* featuring in the introductory videos in each session and in tailored feedback throughout is designed to facilitate human interaction. ACT metaphors integrated into the program included *passengers on a bus* (whereby unwanted thoughts and feelings are represented by passengers on a bus), the *choice point* (in which a dichotomous choice is presented between actions that serve personal values (*toward moves*) and those that do not (*away moves*) [34]), and modified psychological flexibility *pillars* (with the different psychological flexibility subprocesses each presented as a pillar) that can be built up over time, with

the addition of self-compassion, as used in clinical practice for this population by the second author (OD) [18]. These were presented in a multimedia form via videos, pictures, and interactive exercises (as preferred by ACT clinicians [25]), along with purpose-made guided mindfulness practices. Self-monitoring of various ACT processes via single questions (eg, present moment contact), value-based goals, and social skills training was integrated throughout. Real-time behavioral recording (eg, of *toward* or *away moves*) was built into *Skill builders*, and personalized timed reminders to engage in *Skill builders* and subsequent sessions were programmed.

As new content was introduced in each session, users were encouraged to complete all 6 sessions, which would represent full completion. However, the core components of the program in the form of mindfulness (incorporating acceptance and cognitive defusion), self-compassion, value clarification, value-based goal setting, and social skills were all covered by session 4, with sessions 5 and 6 building on and consolidating these components. Completion of sessions 1 to 4 could therefore be expected to represent a cutoff for minimal completion.

Program content was delivered via the Qualtrics XM (Qualtrics International Inc) survey web app, which was constructed by the first and fifth authors (FZ and HG). Qualtrics XM is a mobile-optimized survey platform that can accommodate many native app features, such as embedded multimedia, responsive content tailored to users’ actions, and discrete *toolbox* options accessible from the home screen. Example screenshots are shown in [Figure 1](#). Text reminders were programmed to simulate push notifications.

**Figure 1.** Example *ACT It Out* screenshots.



## Design

This study adopted a single-group mixed methods design. We chose this design for its suitability to the study's objectives of user engagement, acceptability, and clinical safety and preliminary effectiveness, which together focused on assessing proof of concept before justifying native app development and more rigorous testing of a final product via a randomized design [35]. These objectives and the study design were informed by a combination of the Bowen et al [36] feasibility study design recommendations, as used in comparable mobile app feasibility trials [37,38]; the UK Medical Research Council guidance on developing and testing complex interventions [39,40]; and the Obesity-Related Behavioral Intervention Trials model for developing behavioral interventions in long-term health conditions [35]. As is the case in this study, both the UK Medical Research Council and Obesity-Related Behavioral Intervention Trials models recognize that there is often an overlap between the later objectives of the development phase, in which an intervention is refined, and the early feasibility objectives of the testing phase.

Led by this guidance, the authors used a range of mixed methods to meet the objectives. The authors aimed to assess user engagement via program adherence, duration of use, and in-program use. Acceptability was determined via satisfaction ratings and explored in greater depth through semistructured qualitative exit interviews.

To test the secondary objective of whether the program indicated clinical safety and preliminary effectiveness, we assessed changes in a range of outcomes over 3 time points. The outcomes included (1) appearance-related life disengagement and appearance-fixing behaviors as primary outcomes of targeted behavior change; (2) measures of key targeted ACT processes, cognitive fusion, and experiential avoidance, as indicated in prior research [14], as well as valued action (a targeted behavioral component of psychological flexibility); and (3) clinical well-being outcomes and secondary appearance-focused measures to test for iatrogenic effects. Clinical safety would be indicated by improvement or stability in the relevant measures and preliminary effectiveness indicated by improvement in measures. Completion rates and scale attenuation effects were also checked for measures to assess

their feasibility for use in future RCTs. In addition, qualitative interviews were used to gain a richer understanding of how participants may have experienced the program in terms of perceived psychological safety and any benefits from using the program.

## Procedure

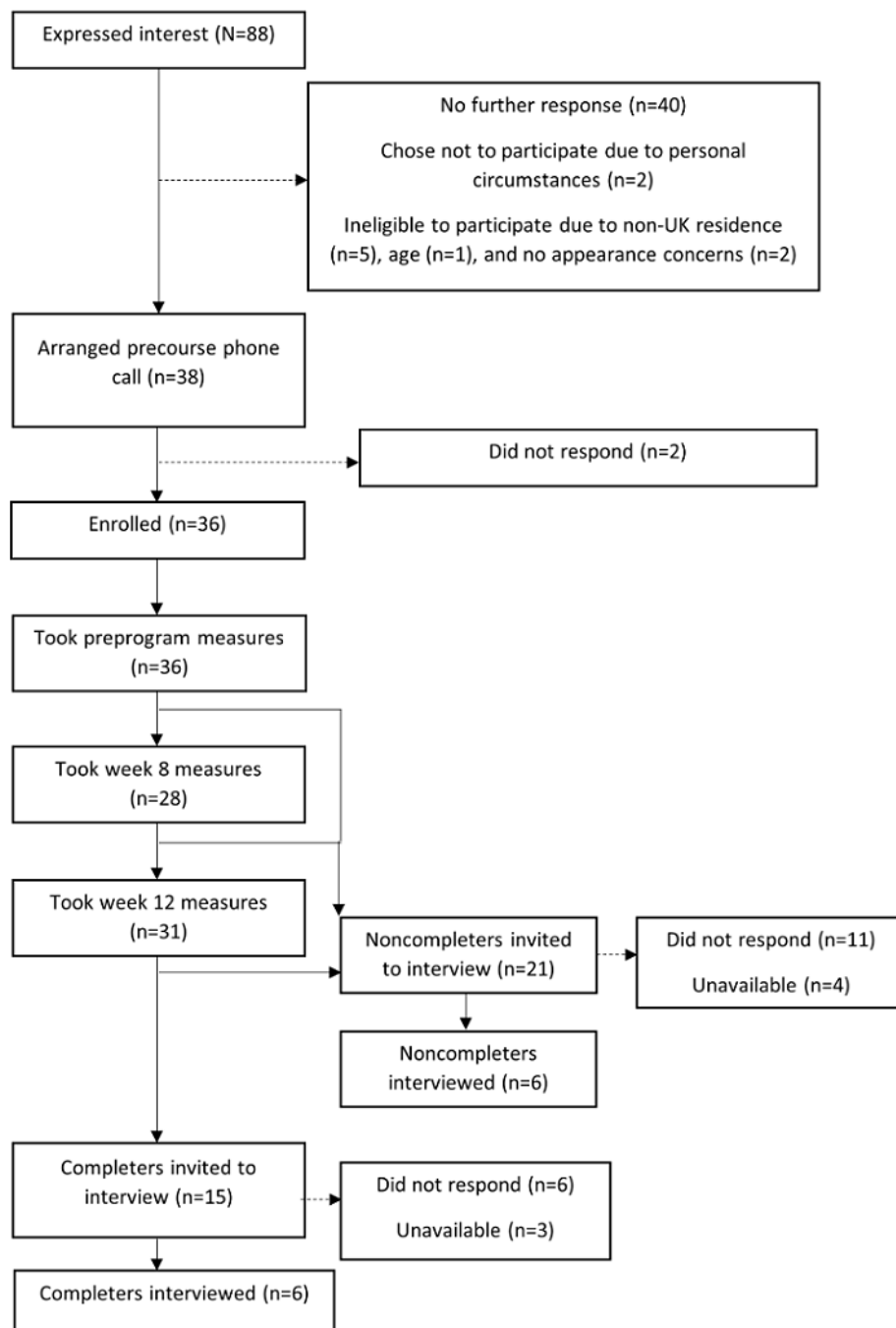
Ethical approval was granted by the university faculty research ethics committee. The first author (FZ) contacted interested individuals by their chosen method, then arranged a 15- to 20-minute orientation telephone call, in which FZ confirmed individuals' eligibility, guided participants in setting up the program, and oriented them to the platform. Before commencing the program, participants were instructed to check and complete a web-based consent checklist, followed by baseline outcome measures. Upon consent, participants were sent a £10 (US \$13.28) web-based shopping voucher to compensate for any data use costs. Outcome measures were sent to participants after 8 weeks (allowing 2 additional weeks for anticipated time slippage) and after 12 weeks, when a second compensatory £10 (US \$13.28) web-based shopping voucher was sent to completers. Access to *ACT It Out* was available to participants for 12 weeks as the authors sought to measure completion duration as part of the user engagement objective.

Semistructured exit interviews with FZ were planned for a representative subsample of up to half of the sample, including program noncompleters. Full completers were invited after the 12-week measurement, and noncompleters were invited 3 weeks after their final use of *ACT It Out* to mitigate loss in recall memory. Participants were invited via email, with the information sheet sent as an attachment. The first author (FZ) took verbal consent at the start of the interview and sent participants a £10 (US \$13.28) web-based shopping voucher following the interview (offered as a small incentive). Participant flow and dropout across the entire study are presented in [Figure 2](#).

This study coincided with the COVID-19 pandemic. In consultation with the user representative lead (third author, ER), we decided to commence the study in July 2020 when national COVID-19 *lockdown* restrictions had been eased, and study recruitment was ended when a further national lockdown was enforced in November 2020.



**Figure 2.** Diagram of participant flow, dropout, and reasons for exclusion (where N refers to the number of potential participants and n refers to a subsample of the population under study).



## Measures

### Quantitative Measures

#### User Engagement

Data embedded within the program were collected on total and session-by-session duration of use, as well as self-reported engagement with key content features, including value-based goals and mindfulness and social skills exercises. Session-by-session program adherence was monitored and recorded daily by the first author (FZ).

#### Acceptability

Satisfaction rating questions were embedded at the end of each program session, with ratings ranging from 1 (*strongly disagree*) to 5 (*strongly agree*). These questions were based on a previous feasibility trial of a web-based intervention for individuals with visible differences [41]. Participants' mean scores across all completed sessions were calculated to provide an overall satisfaction score.

### Clinical Safety and Preliminary Effectiveness Appearance Measures

The Body Image Life Disengagement Questionnaire [42] was used to measure the degree of participants' disengagement from appearance-salient activities across recreational, social, and occupational life domains because of appearance concerns. Items are rated from 1 (*has not stopped me at all*) to 4 (*stopped me all the time*). The 11-item modified version of the 10-item original version that includes a population-specific item (*use public transport*) has been used in a previous study with visibly different participants, showing good reliability [14]. Reliability in this study was good (Cronbach  $\alpha=.88$ ). The score range of the Body Image Life Disengagement Questionnaire is 1 to 4, with a lower mean score indicating greater life engagement.

The 10-item Body Image Coping Strategies Inventory–Appearance-fixing (BICSI-AF [15]) subscale assessed participants' tendency to conceal, correct, seek reassurance, and engage in social comparisons about their appearance. Items are rated between 0 (*definitely not like me*) and 3 (*definitely like me*). The BICSI-AF demonstrated good reliability and validity in college students [15] and strong reliability in visibly different populations [14,43]. Internal consistency in this study was good (Cronbach  $\alpha=.86$ ). The score range of the BICSI-AF is 0 to 3, with higher mean scores representing greater use of appearance-fixing behaviors.

The Body Esteem for Adolescents and Adults–Appearance subscale [44] measured participants' evaluation of their own appearance on 10 items. The subscale has shown good reliability and validity in young adults [45] and good reliability in samples with visible differences [14,46]. In this study, reliability was excellent (Cronbach  $\alpha=.92$ ). A total of 6 items were reverse coded, and higher scores in the range of 0 to 4 indicated a more positive appearance evaluation.

The 6-item Fear of Negative Appearance Evaluation Scale (FNAES [47]) was used to assess participants' level of concern that others would negatively evaluate their appearance. The FNAES has been shown to have good validity and reliability in college students [47], and reliability in this study was excellent (Cronbach  $\alpha=.96$ ). The scale range for the FNAES is 6 to 30, with higher scores suggesting participants' greater level of concern.

### ACT Measures

The Brief Experiential Avoidance Questionnaire [48] measured participants' level of experiential avoidance using 15 items. The scale showed strong reliability and validity in a mixed adult group [48], good internal consistency in a previous study with visibly different participants [46], and good internal consistency in this study (Cronbach  $\alpha=.86$ ). The Brief Experiential Avoidance Questionnaire scores range from 15 to 90, with higher scores indicating higher experiential avoidance.

The 7-item Cognitive Fusion Questionnaire (CFQ [49]) assessed participants' degree of cognitive fusion. The CFQ has good validity and reliability in clinical and nonclinical adult samples [49] and showed strong reliability in a visibly different population [14]. In this study, reliability was good (Cronbach

$\alpha=.86$ ). The score range of the CFQ is 7 to 49, with higher scores representing higher cognitive fusion.

The Comprehensive Assessment of Acceptance and Commitment Therapy–Valued Action subscale [50] was used to determine the extent to which participants engaged in value-oriented action, combining the traditional psychological flexibility subprocesses of value clarification and committed action. The 8-item subscale demonstrated strong reliability and validity in a variety of adult samples [51] and showed acceptable reliability in this study (Cronbach  $\alpha=.78$ ). The Comprehensive Assessment of Acceptance and Commitment Therapy–Valued Action scores range from 0 to 48, with higher scores reflecting greater valued action.

### Clinical Well-being Measures

The 14-item Hospital Anxiety and Depression Scale (HADS [52]) measured depression and anxiety in participants, with 7 items for each subscale. The HADS has well-established reliability and validity in a range of clinical and community populations [53]. In this study, internal consistency was acceptable for depression (Cronbach  $\alpha=.77$ ) and anxiety (Cronbach  $\alpha=.74$ ).

Anxiety and depression caseness on the scale range of 0 to 21 is indicated by subscale scores of 8 to 10 (mild), 11 to 14 (moderate), and 15 to 21 (severe). As the HADS alone is insufficient for a diagnosis, this study did not exclude participants scoring in the severe range. Instead, automated messages offering support contact details and a suggestion to consider whether involvement in the study was suitable were presented to any participants scoring in the severe range.

### Qualitative Measures

To explore areas related to (1) program acceptability and (2) clinical safety and preliminary effectiveness in more depth, the first author (FZ) conducted semistructured interviews via telephone, lasting an average of 27 (SD 10.0; range 14–38) minutes. The schedule explored participants' overall impression of *ACT It Out*, any aspects they particularly liked or disliked and/or found helpful or unhelpful, any notable benefits or detriments from using it, their views on the various program features, and, particularly for noncompleters, whether there were any aspects of the program that hindered adherence.

### Data Analysis

#### Quantitative Data

Frequencies and descriptive data (mean and SD) were calculated for data pertaining to user engagement and acceptability. Adherence was recorded in increments of 0.5 sessions to include partially completed sessions, which were defined as when participants completed a minimum of one-third of the relevant session without completing the full session. In exploratory analyses of the predictive effect of demographic data on user engagement, we used a binomial logistic regression model with age and education level (dichotomized into categories of higher education and high school or vocational training) as the independent variables and adherence (full completion or noncompletion) as the dependent variable. Independent sample *t* tests (2-tailed) were used to check for differences in

acceptability scores by gender and education status, and Pearson correlation coefficients were calculated to test for a relationship between age and acceptability scores.

To assess clinical safety and preliminary effectiveness, mixed model repeated measure (MMRM) analyses were used to determine the significance level of any changes in scores between baseline and week 8, baseline and week 12, and across all time points. Hedge  $g$  was calculated as corrected effect sizes for baseline to week 8 and baseline to week 12 changes because of the small sample size [54]. Scale attenuation effects were checked for each scale at all time points by assessing the percentage of participants who reported the maximum and minimum possible scores, with  $\geq 15\%$  indicating ceiling or floor effects [55]. Of the 36 participants, 8 (22%) participants did not complete week 8 measures and 5 (14%) did not complete week 12 measures. The MMRM analyses accounted for all recorded data and modeled intention-to-treat analyses. Item-level missingness was negligible: a single item was missing from the data set, and available item analysis was used to score the scale in this case [56].

### Qualitative Data

Interview data were analyzed by the first author (FZ) on NVivo software version 12 (QSR International) using thematic analysis from a primarily deductive approach; namely, themes were generated to answer the specific research questions of acceptability and preliminary effectiveness. The first author

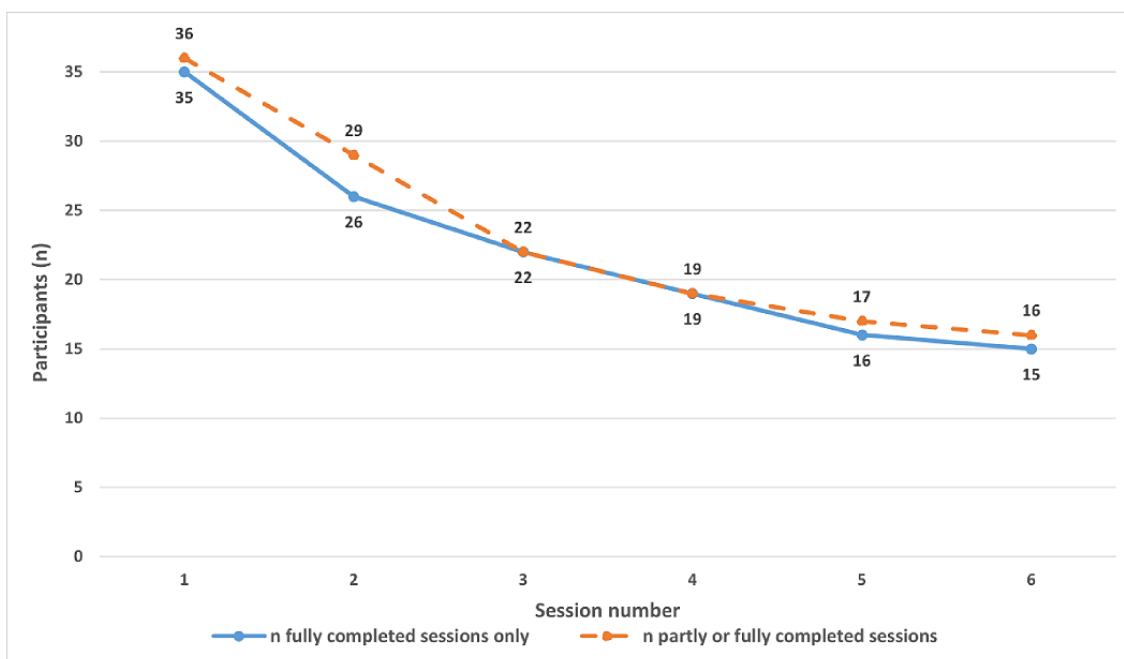
(FZ) followed the Braun and Clarke [57] six-step procedure, with minor modifications recommended by Braun and Clarke [58], as follows: (1) data familiarization through transcription, reading, and rereading; (2) generating initial codes across the entire data set; (3) generating draft themes; (4) reviewing themes by cross-referencing against coded extracts; (5) defining, refining, and naming themes; and (6) producing a report of the results and relating these findings to the research question and literature. The sixth author (HW) read a sample of interview transcripts and reviewed the first author's (FZ) analysis. Minor changes to theme descriptions were made following discussions between the authors. FZ sent a summary of these findings to interview participants for the purpose of conferring trustworthiness via member checking [59]. Approximately 19% (7/36) of participants responded and requested no changes.

## Results

### User Engagement

Out of the 6 sessions, participants completed an average of 3.32 (SD 1.85) sessions by week 8 and 3.72 (SD 2.11) by week 12. Of 36 participants, 16 (42%) completed the entire program by week 12, and 19 (53%) participants completed the suggested minimal completion cutoff of  $\geq 4$  sessions. Session-by-session adherence rates showed a slightly steeper dropout rate in the first half of the program (up to session 3), as shown in Figure 3.

**Figure 3.** Session-by-session program adherence.



A binomial logistic regression model with age and education level as predictors of adherence was statistically significant ( $\chi^2_2=12.5$ ;  $P=.002$ , with the combined predictors explaining 39.6% of the variance in the likelihood of participants completing the program (Nagelkerke  $R^2$ ). Within the model, age and education level were both statistically significant in

isolation. Higher age of participants was associated with a greater likelihood of completing all 6 sessions, and those with a high school or vocational training level of education had 9.01 times higher odds of completing the program compared with those with university-level education. Owing to the low number of male participants, gender could not be included in the binomial logistic regression model. However, although based

on a small number of male participants (7/36, 19%), the mean age of male participants was lower than that of the females (29/36, 81%; mean age: 25.57 years vs 39.34 years), and a lower proportion of males (2/7, 29%) fully completed the course compared with females (13/27, 48%), suggesting the possibility of a gender effect on completion likelihood, either in addition to or explaining the effect of age and education.

Participants spent an average of 25.7 (SD 14.67) minutes per session and 317.65 (SD 74.10) minutes in total over an average of 6.9 (SD 3.84) weeks. The engagement rates with value-based goal-setting activities are shown in Table 2. Of the 19 participants who completed session 4, 14 (74%) reported practicing the guided mindfulness of breath exercise introduced in session 3 *a few times (not daily)*; 3 (17%) reported practicing the exercise *daily*; and 2 (11%) reported *not once*. In the

following session, of the 17 participants, 13 (76%) reported practicing the mindfulness of intense experiences exercise *a few times (not daily)*, and 2 (12%) selected *daily* and *not once*, respectively. Of the 16 participants who took session 6, 12 (75%) reported practicing the final guided mindfulness practices (mindful mirror) *a few times (not daily)*, 3 (19%) reported practicing it *daily*, and 1 (6%) selected *not once*. In session 6, participants were asked which of a set of statements best described their efforts in applying the social skills they had chosen to work on in sessions 4 and 5. Of 14 responders, 7 (50%) selected “I’ve tested skills for real, and found it helpful”; 4 (29%) chose “I’ve practiced skills but struggled with it”; 2 (14%) selected “I’ve practiced skills, but not used them for real”; and 1 (7%) chose “I’ve not practiced or used skills for real.”

**Table 2.** Engagement rates with value-based goal-setting activities set in sessions 3, 4, and 6.

Goals	Participants who set a goal <sup>a</sup>		Participants who set a behavioral goal <sup>b</sup>		Example participant goal (value)	Participants who met the goal, n (%) <sup>b</sup>			
	N	n (%)	N	n (%)		Yes	No	Partly	Unknown
Goal for day (session 3)	22	20 (91)	20	18 (90)	“Allow my partner to touch my scar.” (intimacy)	10 (50)	3 (15)	5 (25)	2 (10)
Goal for week (session 4)	19	18 (95)	18	16 (89)	“Exercise at the front of gym class.” (courage)	10 (58)	2 (10)	2 (10)	4 (22)
Long-term goal (session 6)	16	5 (33)	5	5 (100)	“Eat out with friends again.” (self-care)	N/A <sup>c</sup>	N/A	N/A	5 (100) <sup>d</sup>

<sup>a</sup>Percentage of participants who set a goal is taken from participants who started the session only.

<sup>b</sup>Percentage of participants who (1) set a behavioral (rather than affective) goal and (2) rated their goal as met are taken from participants who set a goal only.

<sup>c</sup>N/A: not applicable.

<sup>d</sup>Participants were not followed up regarding the outcome of their long-term goal.

## Acceptability

### Overview

As presented in Table 3, most participants reported satisfactions with the program in terms of comprehensibility, interest, and helpfulness (although a smaller majority reported finding the

sessions helpful). Independent samples *t* tests revealed no significant differences in any of the 3 satisfaction ratings between male and female participants or in those with university level of education and high school level education. Pearson correlation coefficients showed no relationship between age and scores on any of the 3 satisfaction ratings.

**Table 3.** Average satisfaction rating scores over all completed sessions (n=30).

Satisfaction ratings	Values, mean (SD)	Scores ≥4 ( <i>somewhat agree</i> ), n (%)
Sessions were interesting	4.28 (0.59)	30 (85.7)
Sessions were easy to understand	4.45 (0.64)	31 (88.6)
Sessions helped me	3.86 (0.76)	21 (60)

Of the 36 participants, 12 (33%) participants took part in exit interviews. The mean age of the interview participants was 39.9 (SD 15.49) years. Of the 12 participants, 10 (83%) were female, 2 (17%) were male, and 11 (92%) were White. Of the 12 participants, 6 (50%) had completed all 6 sessions of the program, and 6 (50%) had not. Thematic analysis of the interviews generated 4 overall themes, with 3 relevant to program acceptability. These are presented in the following sections with illustrative quotes.

### Mobile Features Facilitated Engagement

Most participants described the program’s mobile features favorably, especially in terms of giving flexible and immediate access:

*...it felt like a little pocketbook. And just to sort of pull it out if I was waiting for my daughter to come out of work, I could just read something and it focused my mind a bit. [female, 44 years, acquired craniofacial condition]*

Participants particularly highlighted the tailored text reminders (simulating notifications) as a crucial feature in prompting the use of the program:

*I liked that this alerted you as well, you could set it to send you text messages and it reminded you to be mindful...even though I was busy with work, some of those I set them and they came through during the day and I just did them. Which I thought was super helpful.* [female, 26 years, congenital difference]

### **Engaging Content (With Room for Improvement)**

All participants felt that the multimedia elements of *ACT It Out* aided their understanding of the ACT model, although some felt these elements could be presented in a more dynamic, interactive, and clear way or more material presented visually rather than via text. Some referred to the *toward* and *away* arrows and the *pillars*, and many highlighted the *passengers on the bus* animation:

*There's like a video of the people on the bus...even though I now think about it as maybe too simple, it actually is probably quite effective because I remember it very vividly.* [female, 26 years, congenital difference]

Some participants described the content as *easy to follow* (male, 21 years, skin condition):

*Well I sound strange given I didn't complete it, but it was still very positive, the bits that I did actually do. It was very clear...the information was very sort of concise and clear.* [male, 22 years, skin condition]

Others felt improvements could be made to improve the clarity and navigation of the program:

*I wasn't sure to do these [exercises], do they get recorded [in the program] or are you just doing it for yourself? That wasn't clear enough to me I don't think.* [female, 56 years, acquired craniofacial condition]

### **Challenges to Sustained Use**

Some participants, including noncompleters, discussed the effort required to fully engage, such as needing strong motivation, self-discipline, and sufficient energy to work through the program in the face of competing demands and stressors:

*...with all the apps you've got on your phone...it's massive competition for attention and those other things like Tik Tok and Instagram, they're obviously geared towards trying to reward. And this [program] requires a lot more self-discipline and it's something that's not necessarily going to make you feel good or anything like that.* [male, 22 years, skin condition]

To place participants' views in context, it is noteworthy that they highlighted challenging personal circumstances and stressors as a barrier to engaging fully in the course, especially given that the study spanned the COVID-19 pandemic: "...when obviously the pandemic started to happen with the Coronavirus and the lockdown and then things changed at home, I just found it kind of impossible to remember to actually go on it" [female, 24 years, congenital condition].

## **Clinical Safety and Preliminary Effectiveness**

### **Overview**

Table 4 shows the results of the MMRM analyses for all outcome measures. Regarding the primary outcomes, appearance fixing significantly decreased at 8 weeks; however, improvements were lost at 12 weeks, and the opposite was found for life disengagement. Of the 2, only appearance fixing showed significant improvements over the combined time points. Hedge *g* corrected effect sizes for the primary measures ranged between 0.34 and 0.62 at premeasurement to week 8 measurement and premeasurement to week 12 measurement, suggesting small to medium effects. Changes in ACT measures were significantly favorable in all analyses, other than the valued action from premeasurement to week 12 measurement. Of the 36 participants, at baseline, 5 (14%) participants scored in the mild range for depression caseness and 5 (14%) scored in the moderate range; 3 (8%) scored in the severe range for anxiety, 11 (31%) scored in the mild range, and 7 (19%) scored in the moderate range. Overall anxiety and depression scores were significantly reduced, and although anxiety scores did not significantly reduce at week 8, the trend was toward a decrease, suggesting no iatrogenic effects from the program. Floor and ceiling effects were not detected other than for fear of negative appearance evaluation at baseline measurement, in which 17% (6/36) of participants reported the highest possible score, suggesting a higher level of concern and a possible ceiling effect.

Of the 4 themes from the interview data, 1 (25%) related to clinical safety and preliminary effectiveness.



**Table 4.** Descriptive statistics and mixed model repeated measure results for baseline to week 8, baseline to week 12, and combined time effects.

Measures	Baseline, mean (SD)	Week 8, mean (SD)	Week 12, mean (SD)	Baseline-week 8			Baseline-week 12			Combined time effect	
				F test (df)	P value	Hedge g (95% CI) <sup>a</sup>	F test (df)	P value	Hedge g (95% CI) <sup>a</sup>	F test (df)	P value
<b>Clinical well-being</b>											
HADS <sup>b</sup> -Anxiety	9.78 (3.67)	8.21 (3.79)	7.59 (3.05)	2.76 (35)	— <sup>c</sup>	0.41 (−0.91 to 0.08)	7.15 (35)	—	0.64 (0.15 to 1.13)	3.66 (35)	.03
HADS-Depression	6.33 (3.46)	4.39 (3.43)	4.39 (3.16)	5.02 (35)	.03	0.56 (0.05 to 1.06)	5.80 (35)	.02	0.58 (0.09 to 1.07)	3.67 (35)	.03
<b>ACT<sup>d</sup> measures</b>											
BEAQ <sup>e</sup>	56.83 (10.92)	50.46 (11.90)	49.26 (12.55)	4.85 (35)	.03	0.55 (0.05 to 1.06)	6.84 (35)	.01	0.64 (0.15 to 1.13)	4.23 (35)	.02
CFQ <sup>f</sup>	33.03 (6.00)	29.00 (6.10)	28.48 (6.88)	6.96 (35)	.01	0.66 (0.15 to 1.17)	8.17 (35)	.006	0.70 (0.20 to 1.19)	5.37 (35)	.007
CompACT-VA <sup>g</sup>	32.31 (7.16)	36.32 (5.98)	32.94 (5.99)	5.97 (35)	.02	0.59 (0.09 to 1.10)	0.15 (35)	—	0.09 (−0.39 to 0.57)	3.59 (35)	.03
<b>Appearance</b>											
BILD-Q <sup>h,i</sup>	2.10 (0.58)	1.77 (0.56)	1.87 (0.71)	5.27 (35)	.03	0.57 (0.06 to 1.07)	1.95 (35)	—	0.34 (0.14 to 0.83)	2.76 (35)	—
BICSI-AF <sup>i,j</sup>	1.98 (0.59)	1.68 (0.62)	1.60 (0.61)	3.91 (35)	—	0.49 (−0.01 to 1.00)	6.55 (35)	.01	0.62 (0.13 to 1.11)	3.74 (35)	.03
FNAES <sup>k</sup>	24.61 (5.49)	19.28 (7.38)	20.00 (6.63)	10.20 (35)	.002	0.82 (0.31 to 1.34)	9.4 (35)	.003	0.75 (0.26 to 1.25)	7.36 (35)	.001
BESAA-A <sup>l</sup>	1.12 (0.70)	1.68 (0.91)	1.63 (0.92)	7.23 (35)	.01	0.69 (0.18 to 1.20)	6.43 (35)	.01	0.63 (0.14 to 1.12)	5.18 (35)	.008

<sup>a</sup>Hedge *g* corrected effect size follows Cohen *d* thresholds of 0.2 to 0.49 for small effects, 0.5 to 0.79 for medium effects, and  $\geq 0.8$  and above for large effects [60].

<sup>b</sup>HADS: Hospital Anxiety and Depression Scale.

<sup>c</sup>Not available.

<sup>d</sup>ACT: acceptance and commitment therapy.

<sup>e</sup>BEAQ: Brief Experiential Avoidance Questionnaire.

<sup>f</sup>CFQ: Cognitive Fusion Questionnaire.

<sup>g</sup>CompACT-VA: Comprehensive Assessment of Acceptance and Commitment Therapy–Valued Action subscale.

<sup>h</sup>BILD-Q: Body Image Life Disengagement Questionnaire.

<sup>i</sup>Primary outcome measures.

<sup>j</sup>BICSI-AF: Body Image Coping Strategies Inventory–Appearance-fixing.

<sup>k</sup>FNAES: Fear of Negative Appearance Evaluation Scale.

<sup>l</sup>BESAA-A: Body Esteem for Adolescents and Adults–Appearance subscale.

### How the Program Helped

Relevant to clinical safety, some participants described the content as supportive and encouraging, especially the interaction from the app guide: “I came out of [a mindfulness exercise], before I read [the app guide’s] comment, thinking ‘Well that was pointless’, but then reading what she said, it was like well actually no, it’s quite difficult to do and I don’t feel so bad about it now” [female, 44 years, acquired craniofacial condition].

Most participants talked about specific ways in which using *ACT It Out* had benefited their behavior and/or self-awareness regarding their appearance. Some referred to ACT-specific content such as value-based goal setting as facilitative of

behavior change, whereas others highlighted appearance-specific content such as social skills training or a combination of the 2, such as *safety mode* behaviors like appearance comparisons:

*[ACT It Out] actually inspired me to delete Facebook. I did find that it was a massive trigger to me...I think it was the question prompts, when it said about comparing yourself to others, and it really made me think actually I do that a lot of the time. I just thought “I don’t need that in my life. Why am I spending 2 hours scrolling through Facebook, to look at other people that look perfect?”* [female, 24 years, congenital condition]

Many participants described the course content as bringing about greater self-awareness of psychological processes and their link to overt behavior:

*So I have some old habits as a result of my scarring which I didn't know were there...For example when I go for a run I'll wear a sports top, and while I'm running I touch my chest. I didn't know I did that, because I was thinking people are looking at me, so I try and move my top around and things like that, which are a bit odd. And I hadn't noticed that before until I did the app. I suppose [it was because of] those people when they gave their experiences [in ACT It Out], the little bubbles with personal experiences. That resonated with me. [female, 23 years, skin condition]*

## Discussion

### Principal Findings

The overall finding of this feasibility study was that a novel prototype mobile ACT program, *ACT It Out*, showed proof of concept for adults with visible differences who experienced appearance concerns. The results pertaining to the primary feasibility objectives of determining user engagement and acceptability support this overall finding.

In terms of user engagement, over half of the participants completed the minimum cutoff of at least 4 of 6 sessions, and full completion rates were at the upper end of the 34% to 41% range reported in a recent meta-analysis on apps for anxiety, depression, and stress, whereas the observed decline in participant adherence over time similarly follows the meta-analytical findings [61]. Combined, these findings suggest acceptable levels of adherence. The finding that higher age significantly predicted a greater likelihood of completion is of potential noteworthiness. Research findings on the influence of age on mental health app adherence are equivocal, with 3 studies included in a meta-analysis finding no relation and 1 finding older age to be associated with greater adherence [61]. Given that in this study, young interview participants made more mention of the look and feel of the prototype than older participants, it may be that the younger participants held higher expectations of the prototype's interface and were more deterred by the somewhat basic Qualtrics web app interface. This finding could also reflect the overall higher use of smartphone apps in younger people, especially in the form of social, gaming, and video apps [62], which may offer greater competition for smartphone use, as noted by a young noncompleter participant in the interviews. The apparently lower completion rates of male participants, who were also younger on average than female participants, introduce a potential alternative or additive explanation. Either way, this finding points to the importance of us gaining feedback from young and male user representatives when developing a final native app. It also poses the question of whether participants' use rates of other apps would moderate their level of engagement with the final *ACT It Out*. This could be answered in a larger trial by asking participants to self-report their broader app use. The finding that individuals with a lower level of education were more likely to complete all sessions is

also of interest. As part of the stakeholder-informed design phase of *ACT It Out*, the authors made a concerted effort to create an accessible and comprehensible intervention. As reflected by a minority of interview participants, some of the program content may potentially have been considered overly simplistic, and hence less stimulating for some. That being said, there was no difference in participants' satisfaction ratings of interest between those with university education and those with high school education. Nevertheless, offering optional *advanced* informational resources in a final app would help enrich the depth of material while retaining the intervention's comprehensibility.

Encouragingly, participants' average time spent completing sessions was consistent with the design intentions of 30 minutes per session over 6 to 8 weeks, with individual sessions completed in a mixture of single and multiple sittings, according to supplementary interview data. This tallies with the interview findings that participants valued being able to flexibly work through the program according to their schedule. The finding that most participants reported completing mindfulness practices only semiregularly aligns with the literature on mindfulness app use, for example, the study by Mikolasek et al [63]. Mindfulness practice rates may also have been hindered by the web app interface, with some interview participants discussing the challenge of navigating into target content in Qualtrics after receiving text reminders. The same issue may have contributed to the low uptake of long-term value-based goal setting, a feature accessed via *Skill builders* in the program menu rather than in session. Given apparently higher engagement with social skills training and its tangible relevance to appearance concerns, its earlier introduction in the program could potentially improve adherence.

Overall, the program was rated as acceptable, with the percentage of affirmative satisfaction ratings pertaining to comprehensibility and interest well above acceptability thresholds of 70% used in comparable app feasibility studies, for example, the study by Huberty et al [38]. The lower majority of participants rating the sessions as helpful may partly reflect the questions being delivered immediately at the end of each session, thereby giving no practice time for skills introduced in the session.

The interview data offered vital insight into participants' experience of using the program in terms of its suitability and appeal, highlighting both strengths and areas for refinement. Participants' accounts endorsed the added value of mobile-specific benefits such as tailored, immediately actionable reminders and remote, location-flexible accessibility. Most interview participants also described the content as appropriately clear, concise, and engaging for the mobile platform, a common challenge in adapting material from other self-help formats [32] (as was involved in the design process of this program). The supportive tone described by participants may reflect the importance placed on this aspect in the program's design, based on preceding stakeholder-informed design work. The need for personal effort and self-discipline highlighted by some participants may suggest that a greater degree of extrinsic reward be built into future versions of the program. This could include elements successfully used in ACT-based behavior change apps,

for example, in the study by Bricker et al [64], such as badges awarded for completed goals and sequential unlocking of features such as mindfulness exercises as users progress.

Results pertaining to the secondary objective of assessing the program's clinical safety and preliminary effectiveness are only indicative, given the possibility of artifact findings arising from demand characteristics in single-group designs [65], the small sample size, and the short-term measurement. Nevertheless, the finding that all outcomes, including primary appearance-related behaviors and ACT process measures, showed significantly favorable changes from baseline to at least one of the week 8 and week 12 time points offers encouragement for the program's potential effectiveness under more rigorous evaluation.

Importantly, for the purpose of checking for iatrogenic effects from the program, there was no increase in depression or anxiety over time. Similarly, both secondary appearance-related measures of appearance self-evaluation and fear of negative appearance evaluation, which were not directly targeted through the program's focus on valued action, improved over the 3 time points. However, the FNAES [47] used did show a signal of a ceiling effect at baseline measurement, with >15% of participants scoring the maximum fear of negative evaluation score. This indicates potential concern with its content validity and responsiveness in the target population [55] and hence requires careful consideration for use in future RCTs. The finding that improvements in valued action were lost at week 12 may be partly explained by the low uptake in long-term value-based goal setting in the final session, suggesting that the design of this feature requires close attention in the future version. Interviews also offered illustrative accounts of specific ways in which participants benefited from the program, most prominently in terms of reducing appearance-fixing behaviors (eg, engaging in hours of appearance comparisons on Facebook and habitually adjusting sportswear).

### Strengths and Limitations

A strength of the study is the comprehensive and stakeholder-focused process through which the program, *ACT It Out*, had been designed with user representatives and specialist clinicians. It is also both the first published ACT-based self-help intervention and the first mobile intervention to have been tested for adults with visible differences. The mixed methods methodology and addition of the semistructured qualitative interviews, in particular, provided useful insight into participants' experiences to inform further development not otherwise captured through data use and self-report ratings.

The limitations of this study include its co-occurrence with the COVID-19 pandemic and the potential for confounding effects on at least some data. Although data were collected during a

period of lesser restrictions, the context of participants' lives was nevertheless altered in ways relevant to common appearance concerns in individuals with visible differences. For example, the implementation of mandated mask-wearing may have offered individuals with facial differences such as cleft lip and/or palate a socially sanctioned means of concealment, and social restrictions may have similarly reduced some participants' appearance concerns because of enforced minimization of social contact. Conversely, the widespread use of video calling and conferencing platforms during the pandemic has been indicated as a source of heightened appearance anxiety for individuals with visible differences (personal communication by Professor Diana Harcourt, October 14, 2021). Therefore, the exact impact of the pandemic context on participants' data is difficult to determine. Nonetheless, the validity and reliability of certain outcome measures such as disengagement with appearance-salient activities may have been adversely affected.

The widespread disruption caused by the pandemic may also at least partly account for participants' higher-than-expected anxiety scores at baseline, as suggested by an increase in anxiety scores since the pandemic in the general UK population [66]. Some noncompleter participants also cited COVID-19-related disruption as a cause of program nonadherence in interviews, suggesting that adherence rates may have been higher under typical circumstances. Other data more centered on the content of *ACT It Out* and the experience of using it, such as satisfaction ratings and the detailed accounts collected via interviews, should be less dependent on societal conditions.

Although the sample covered a wide range of appearance-affecting conditions and ages, participants were predominantly White females, and scarring was underrepresented in the sample, limiting the study's generalizability to the visibly different population. The self-selecting nature of the interview subsample may also limit the validity of the interview findings, although half of the subsample were noncompleters, mitigating the potential for positivity bias.

### Conclusions

Despite these limitations, overall findings suggest promising feasibility of the *ACT It Out* program via adequate levels of engagement, acceptability, and indication of clinical safety and positive changes in outcomes. The study also yielded valuable direction for refinements to further enhance its potential utility. When developed further and shown to be effective under more rigorous evaluation, the program could offer a valuable standalone resource for individuals with visible differences who have mild to moderate appearance concerns, as well as a tool for specialist clinicians to use alongside psychological therapy.

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### Authors' Contributions

The Vocational Training Charitable Trust Foundation Research Team at the Centre for Appearance Research consists of Professor Diana Harcourt, Dr Amy Slater, Dr Nick Sharratt, Dr Claire Hamlet, Dr Ella Guest, Bruna Costa, Jade Parnell, Maia Thornton, and Dr Nicola Stock.

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## Conflicts of Interest

None declared.

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## Abbreviations

**ACT:** acceptance and commitment therapy

**BICSI-AF:** Body Image Coping Strategies Inventory–Appearance-fixing

**CFQ:** Cognitive Fusion Questionnaire

**FNAES:** Fear of Negative Appearance Evaluation Scale

**HADS:** Hospital Anxiety and Depression Scale

**MMRM:** mixed model repeated measure

**RCT:** randomized controlled trial

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Original Paper

# Exploring Children's Engagement in Monitoring Indoor Air Quality: Longitudinal Study

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## Abstract

**Background:** Indoor air pollution is harmful to everyone, but children are of particular concern, as they are more vulnerable to its adverse health effects from air pollutants. Although mobile technology is increasingly being designed to support monitoring and improving air quality indoors, little attention has been paid to its use by and for children. Previously, we created *inAirKids*, a child-friendly device to promote children's engagement with monitoring indoor air quality through a participatory design process. The next step is to evaluate its usability in the real world.

**Objective:** The aim of this study is to investigate how *inAirKids* affects children's understanding of and engagement with indoor air quality through a longitudinal field deployment study.

**Methods:** We deployed *inAirKids* in the homes of 9 children aged between 6 and 7 years, and investigated their use for up to 16 weeks by conducting semistructured, biweekly interviews.

**Results:** The results show that participants promptly engaged with *inAirKids* but quickly lost interest in it owing to the lack of engaging factors to sustain engagement. In addition, we identified 2 design considerations that can foster sustained engagement of children with monitoring indoor air quality: design interactivity for engaging in continuity and corporate hands-on activities as part of indoor air quality monitoring for experiential learning.

**Conclusions:** Our findings shed light on the potential to promote the engagement of children in indoor air quality as well as considerations for designing a child-friendly digital device. To the best of our knowledge, this is the first longitudinal field deployment to investigate how to engage children in monitoring indoor air quality.

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**KEYWORDS**

children; indoor air quality; mobile app; awareness; longitudinal deployment

## Introduction

**Background**

It is widely known that air quality indoors, where people spend most of their time, is essential for occupant health and comfort [1]. However, it is not commonly known that indoor air in homes and buildings is typically more polluted than outdoor air, even in large and industrialized cities [2]. As many air pollutants are colorless and odorless, it is challenging to estimate air quality conditions using bare human sensors, such as eyesight or smell [3]. Thus, many people spend most of their time inside their

homes without realizing poor air quality indoors and their association with health and well-being implications [4]

Owing to the advancement of personal and sensing technologies, smart devices are increasingly available in the market to monitor indoor air quality (IAQ). These devices have proven effective in improving IAQ, as simply making occupants aware of the IAQ levels in the homes can positively motivate their behaviors toward better IAQ [5]. However, most existing IAQ monitoring devices are optimized for interaction with adult users, which display air quality information using numeric figures, text, and graphs [6]. This trend leaves behind important household

members who can highly influence and be influenced by IAQ, the children.

Not only do children spend the majority of their time indoors. They are also most susceptible to the effects of air pollution as their lungs are still developing, and they breathe in greater volumes of air per body mass than adults [7,8]. Furthermore, children can be highly influenced by education to influence improving IAQ in their household positively. Without relevant deliberations about users' skills and cognitive abilities, the interface may cause confusion and even misunderstandings about the conveyed information [9]. As children's needs, skills, and expectations differ drastically from those of adults, a technology designed for adult users may not be suitable for children to use [10]. Therefore, it is crucial to create a tool optimized for children to promote their engagement in monitoring and improving IAQ.

We previously investigated design considerations to best convey IAQ information to children in middle childhood (aged 6-8 years) through a participatory design approach [11]. In this previous study, we had children engage in the entire design process both as informants to express opinions on interacting with the device and testers to try out the prototypes and make suggestions for improvements. This process enabled us to capture the perspectives of the child, elicit a guiding principle of designing technology for children, and create child-friendly interfaces for IAQ visualization. On the basis of the findings from that study, this paper reports our field deployment study on *inAirKids*, an IAQ monitor that provides persuasive and expressive visualization of IAQ optimized for use by children.

## Objectives

Through a longitudinal deployment study of *inAirKids*, this study aims to investigate how the IAQ visualization designed for use by children affects the understanding of and engagement with IAQ by children and what contributes to or prevents the engagement of children in monitoring IAQ.

## inAirKids: App Design and IAQ Sensing

Our system, *inAirKids*, consists of a mobile app that runs on a tablet PC as a stationary device to represent air quality indoors and outdoors graphically and an IAQ sensor (Figure 1). On the basis of the findings from our previous study [11], we created

*inAirKids*, a mobile app that runs on a tablet PC for children to check the current state of IAQ. In the design, we used a graphical metaphor of a house to visually illustrate air quality indoors and outdoors in a child-friendly manner (Figure 2).

In designing *inAirKids*, we used various graphical elements to meet the abilities, skills, and perspectives of children. First, we used simple language to explain the level of air quality so that young children who can read can easily comprehend it. The six labels to indicate different air quality states by the air quality index (AQI) of the environmental protection agency are good, moderate, unhealthy for sensitive groups, unhealthy, very unhealthy, and hazardous [12]. As some of these labels are not easy for children to understand, such as *moderate* and *hazardous*, we changed them to *not so good* and *extremely bad*, respectively. Second, we applied 6 colors from the AQI color codes to inside and outside a house graphic that directly compares the current air quality indoors and outdoors. Third, we added an animating cat that strolls inside the house to respond to different IAQs and narrate its meaning. For instance, a cat smiles and moves lively around the house when the IAQ is good, but it frowns and moves sluggishly when the IAQ is poor. Fourth, we applied relevant background images outdoors to portray air quality outside (eg, tree for good, automobile exhaust for not good, and factory chimneys for bad). Finally, clicking a cat will display a popup screen that describes the current IAQ status and suggests proper actionable interventions for children to improve the IAQ (Figure 3).

For IAQ sensing, we used an off-the-shelf sensor that continuously measures the levels of five indoor air pollutants: fine particulate matter (PM<sub>2.5</sub>), carbon monoxide, carbon dioxide, total volatile organic compounds, and nitrogen dioxide (Figure 1). This sensor transmits the measurements of these air pollutants to the server every 15 seconds. The server then sends the current IAQ level to the app every 5 minutes. The system determines the current IAQ level based on the level of air pollutants that AQI falls under as the lowest category among the 5 air pollutants. For instance, if the 5-minute average of PM<sub>2.5</sub> is 20 µg/m<sup>3</sup> and its AQI category is the lowest among the air pollutants, *inAirKids* displays IAQ as *not so good* (Figure 4 [13]).

Figure 1. Setup of inAirKids. IAQ: indoor air quality.

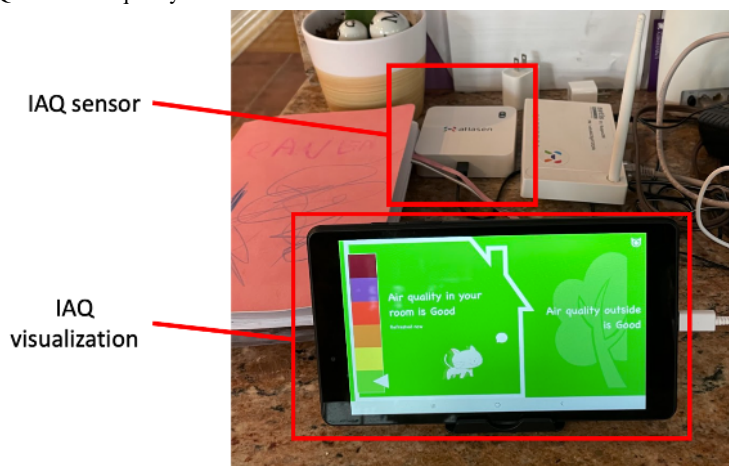




Figure 2. A set of indoor air quality visualization interfaces for inAirKids.



Figure 3. A popup screen of inAirKids that describes the current indoor air quality status with interventions.

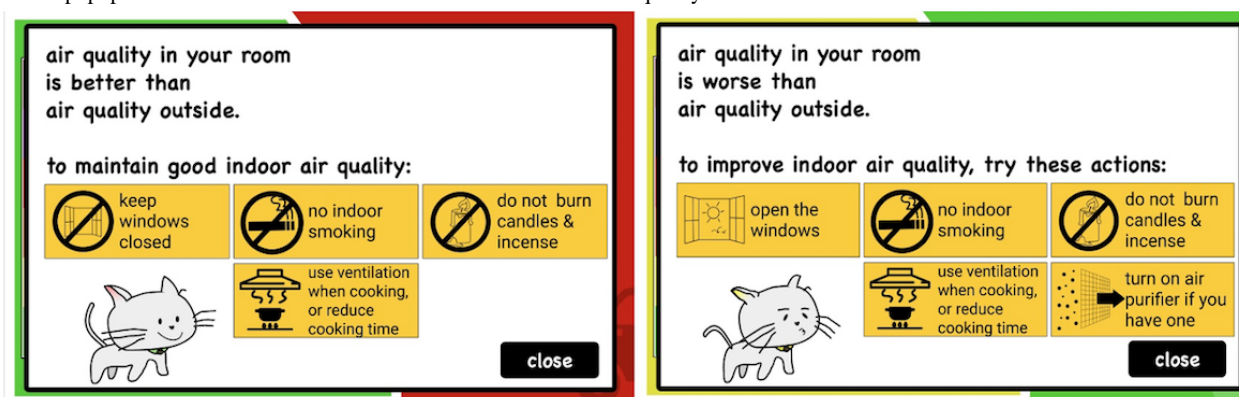


Figure 4. The air quality index category for PM2.5 (from AirNow [13]). AQI: air quality index; PM: particulate matter; USG: unhealthy for sensitive groups.

AQI Category	AQI Value	Average PM <sub>2.5</sub> Concentration (µg/m <sup>3</sup> )
Good	0 - 50	0 - 15.4
Moderate	51 - 100	15.5 - 40.4
USG	101 - 150	40.5 - 65.4
Unhealthy	151 - 200	65.5 - 150.4
Very Unhealthy	201 - 300	150.5 - 250.4
Hazardous	301 - 500	250.5 - 500.4

## Methods

### Participant Recruitment

Children aged 6-8 years and who could read were eligible to participate in the study for up to 16 weeks. We chose the age range of 6-8 years, as children in this age group begin to read and use digital devices with information written in simple languages for learning and reasoning [14]. After obtaining approval from the Rutgers institutional review board, we distributed recruitment fliers on social media and local community groups on the web for parents on Facebook, NextDoor, Reddit, Twitter, and others. The recruitment flier

included the study purpose, duration, participation criteria (children aged 6-8 years who can read), what children are asked to do, and monetary compensation. After confirming a child's age and readability, we obtained temporary consent from parents about the participation of their child in the study by phone. Parents and children provided written consent for participation during the visit of a researcher to their home for the device setup. In all, 11 children were recruited to participate in the study, 4 (36%) female participants and 7 (64%) male participants, (mean age 6.5 years, SD 0.7 years; Table 1), 4 (36%) participants of whom had withdrawn within the first few weeks of the study.



**Table 1.** Participant demographics and study duration.

ID	Age (years)	Gender	Study completion	Study duration (weeks)	Number of interviews
1	8	Female	Completed	16	8
2	7	Female	Completed	16	8
3	6	Female	Completed	12	6
4	7	Male	Completed	12	6
5	7	Male	Completed	12	6
6	6	Male	Completed	12	6
7	7	Male	Completed	12	6
8	6	Male	Withdrawn	6	3
9	6	Female	Withdrawn	6	3
10	6	Male	Withdrawn	2	1
11	6	Male	Withdrawn	2	1

## Consent and Withdrawal

### Overview

Although we obtained consent from all participants before the study, we considered consent as an ongoing process to renegotiate verbally throughout the study duration. As children are often less familiar with what research entails, they may initially wish to participate but later feel less keen as they realize what is involved in the study [15]. Alternatively, parental consent obtained as a safeguard to protect children may restrict the ability of children to participate voluntarily in research [16]. Considering all these, children need to feel comfortable ending their involvement in the research should they wish to do so from an ethical standpoint.

Among the 11 children who signed up for the study, 4 (36%) children, all aged 6 years, had withdrawn from the study within the first few weeks because they did not have or lost their interest in the study. For those who answered “I do not know” to most of our questions in the interview, we explained to feel comfortable to end their involvement in the study whenever they wanted. In all, 2 (18%) participants expressed their willingness to withdraw from the study after 1 interview, and 2 (18%) other participants did so after 3 interviews. After explaining to a parent about the right of their child to participate or withdraw voluntarily in research, we removed them from the study. We discarded all data collected from 2 (18%) children who had withdrawn after the first interview. We kept the data from the remaining participants for data analysis, which made 9 (82%) participants in total.

### Data Collection

We conducted biweekly interviews with the participants to collect qualitative data on the use of *inAirKids* by children over time. All data were collected through interviews using a videoconferencing software of the choice of the participant (eg, Skype or Zoom). In addition, we made 2 visits to the home of the participants for device setup before launching the study and its pickup after the study was complete.

### Interview Protocol

Our interview focused on the following four aspects: (1) how children initially perceive and respond to *inAirKids*, (2) how they use it in their daily lives, (3) what motivates or prevents their use of the device, and (4) how their engagement in IAQ changes over time. On the basis of this, we constructed a set of open-ended interview questions in 3 phases of the study duration to explore these spaces. The first phase focused on understanding the purpose of participating in the study, general perspectives about IAQ, and initial impressions of *inAirKids* in the first interview. The second phase focused on exploring the user experience in-depth, including patterns of using *inAirKids*, engagement in IAQ, and factors contributing to or preventing engagement of children in monitoring IAQ throughout the deployment duration, except for the final interview. Finally, the third phase focused on exploring suggestions for system improvements and reviewing the overall reflection on the use of *inAirKids* in the final interview.

### Study Procedure

Before the study started, the research team visited the home of a participant to set up *inAirKids* in the location of their preference (eg, a nightstand or a coffee table). Participants and their parents were asked to place the *inAirKids* display (a tablet PC) anywhere in the house to see it easily in their everyday lives (eg, a living room, a dining room, or a study; Figure 5). After setting up, we introduced *inAirKids* to the participants as “a device to present air quality both inside and outside of the house in real-time.” We then provided basic instructions on how to use the app. In addition, the parents of the participants filled out a survey to inform us about their basic demographic information, including the age of the child, household type, income, purpose of participation, and ethnicity. Finally, both participants and their parents were told to freely interact with *inAirKids* as much as they wanted throughout the study period. In addition, they were given contact information from the research team if they needed technical support.

**Figure 5.** The location of a tablet PC includes a side table or a television stand in a living room, on a dining table in a kitchen, and on a desk in a child's study.



During the interview, participants were told to freely use any materials (eg, pen and paper) to supplement their feelings or thoughts to facilitate their engagement in the study [17]. When they drew on a paper, we asked to show them on a screen to take a screenshot or a parent pictured and emailed them to us. When a child expressed no interest in answering questions or when a researcher had difficulty engaging them in the interview, we asked how much they liked participating in the study. We explained that they could withdraw from the study at any time and asked if they wished to terminate an interview early. Although all the interview questions were for children, we allowed the parents of the participants to join the interview and share their thoughts and opinions when they wanted. Most parents (mothers) participated in the interviews.

After the study was complete, the research team visited the homes of the participants and picked up the device. All participants were compensated with a gift card for their time up to US \$160, prorated by the duration of participation after device pickup. Participating in this study did not have any harmful consequences on the health of the participating children.

### **Study Duration**

The duration of deployment was initially planned to be 16 weeks. However, we shortened it to 12 weeks in the middle of the study, as many participants lost interest in the device as they continued using it gradually, but less significantly. Thus, 18% (2/11) of the participants completed the study for the entire 16 weeks, and 45% (5/11) of the participants completed the study for 12 weeks. We conducted interviews with each participant

every other week for the duration of the study. Thus, we conducted 8 interviews with 18% (2/11) of the participants who participated in the study for 16 weeks and 6 interviews with 36% (4/11) of the participants who participated in the study for 12 weeks. Each interview lasted between 30 minutes and 1 hour. All interviews were audio recorded and transcribed.

### Data Analysis

We analyzed the interview data using thematic analysis to reveal patterns across data sets and find significant themes through open, axial, and selective coding [18]. First, we conducted open coding to identify and code concepts significant in the data as abstract representations of events, objects, happenings, actions, and so on. The example excerpt below illustrates how one participant lost interest in using the device because of no change in the app interface. This response is coded as *bored\_of\_continuity*:

*{bored\_of\_continuity}I didn't look at the tablet at all this past week at all because nothing's changing. It's been green all the time. It's boring.{/bored\_of\_continuity}* [P2]

Next, we categorized the related concepts created by open coding into conceptual phenomena using axial coding. Phenomena refer to repeated patterns of events, happenings, actions, and interactions that represent people's responses to problems and situations. For instance, *losing\_interest* refers to a participant's loss of interest in using our app and associated factors that contribute to it. During axial coding, the open code *bored\_of\_continuity* in the example excerpt above was categorized as *losing\_interest*, as it illustrated how the participant began to lose interest in using our app. Finally, we followed the selective coding process to assemble the conceptual phenomena extracted from the axial coding. The goal of this step is to integrate all concepts by building relationships across phenomena.

## Results

### Early Phase of the Study: Positive Initial Interaction With inAirKids

Overall, we received positive feedback about the design of *inAirKids* after their initial interactions with it, as it was easy to understand the current IAQ status from its display. Except for those who withdrew, most participants engaged swiftly with *inAirKids* immediately after installation. Without much instruction, they quickly figured out how to interpret various visualization components on *inAirKids* and became aware of how different indoor activities affected IAQ differently:

*It's very easy to use. I think any kid can easily understand it. The colors are easy to understand. It's like you are good to cross the road when the traffic light turns green.* [P1]

*The color coding is nice. The instructions are very clear, so you don't really need to you know fully understand English or even science to kind of utilize it, so that's good. That's the best part about it.* [P5]

*I check it every time I come by it, like when I wake up in the morning or when I go to sleep at night. I basically do it every day. After school, before I eat breakfast, before I eat lunch, before I eat dinner. It's important to know how good or bad the air quality is so that I open the windows when it's bad.* [P2]

When we asked the participants to describe their experiences of using *inAirKids* during the early phase of the study, many dialogues were made from or reflected from the perspective of the animated cat on *inAirKids*. We implemented several visual components to illustrate the different levels of IAQ within *inAirKids*, including an animated cat, a silhouetted house, and AQI-indexed colors. Among these components, the animated cat that responds to different IAQ levels was found to be effective in drawing the participants' attention to and helping them engage in monitoring IAQ. We found that the cat served as a proxy for the participants to experience and respond to different IAQ levels indirectly, making their interaction with *inAirKids* as personified experiences, which echoes a previous work [19]:

*The first thing I notice is a cat walking to the side of the house. Every time I walk by, I see the cat. The cat has Xs on his eyes because he is sick when the air quality is not good. I like the cat because it tells us what to do and like it shows the emotions.* [P3]

*The cat is happy when the air is good. If the air wasn't as good, the cat would be sad. When it [the tablet] is red, he [the cat] walks very slow. Then when it starts to turn purple, his tail starts sticking out, his hair is down, and then his tail's wiggly, and his hair goes like that [spikey]. He gets scared when the air quality is worse. Then, we opened some windows, so the cat is not sick. Make it fresh air in the house. Then the cat doesn't feel sick anymore.* [P4]

*The cat is mad when we are cooking. He wants the air quality to be good every day. Mad kitty, he has to understand that the air quality can be bad sometimes, like when we are cooking bacon.* [P7]

Within the first few weeks, the participants swiftly noticed that cooking and opening windows are the 2 activities that significantly influence IAQ negatively and positively, respectively [20]. When these activities occurred, they fully engaged with *inAirKids* and monitored IAQ until the color of the display changed back to green—good IAQ:

*It [inAirKids] is green now. It was yellow probably an hour ago when the Airwick is on. It changed to green now because I opened the window.* [P2]

*When my mom was cooking, it becomes yellow. I was surprised because it stayed in the yellow for like five hours. We opened some windows so it can't get bad.* [P3]

*It [inAirKids] does not like the bacon smoke. I would probably say it hates it. It turned to red when my mom was frying. So, most of the time, I look at it when my mom is cooking. And I keep the kitchen door open until she's done cooking.* [P6]



## Getting Used to Using inAirKids: Prolonged Engagement in IAQ

As the study proceeded for a few weeks, we found that the participants started to develop their ways for prolonged engagement with IAQ. It was implemented primarily in two ways: soliciting the involvement of parents in improving IAQ and converting IAQ monitoring practices to art and craft activities.

## Soliciting Involvement of Parents for IAQ Improvement

One of our assumptions of this study was that, if properly informed and educated about IAQ, children can positively influence their family members to become involved in improving IAQ. Our findings confirmed this assumption. Regardless of the location of *inAirKids*, we observed that the participants were the primary users of the device and other household members, especially parents, were prompted to be involved in IAQ monitoring by the child participant.

Our findings show that the increased awareness of IAQ among children promoted their parents' inclusion and engagement in improving IAQ. When they noticed IAQ worsening, the participants actively sought the involvement of their parents in improving IAQ by telling them the IAQ status and asking them to take proper actions to reduce air pollutants. Most parents shared their experiences of their child asking, and sometimes even pestering, they took prompt action when their IAQ was not *green*. In fact, the involvement of parents was essential for IAQ improvement, as a child cannot execute IAQ interventions, such as unlocking a window to open or controlling heating, ventilation, and air conditioning appliances:

*It gives me a good sense of protection. I can tell my family when to open the windows, when to close the windows...The other day, I saw that mommy had a candle lit, so I told mommy to blow it out. It has dirt and dust in the smoke and makes it bad. I tell her that candles are bad for the air because the smoke from the candles makes the air bad. [P2]*

*He would always notice what the air quality was like and then come and tell me. Then, I would have to turn on the vent or the window. Especially when we were having construction for a couple of weeks, it was constantly turning yellow and orange. So, he was very much wanting to make sure that we were doing something about that. [Mother of P4]*

*He was trying to open the window when he saw the tablet was orange. He asked me to help him open the windows because they have the two special locks on them, so it's hard for him to open the windows. [Mother of P6]*

## IAQ Monitoring as Art and Craft Activities

Although we asked the participants nothing but to interact with *inAirKids* for the study, many participants expanded their

interaction with *inAirKids* to various hands-on art and craft activities as part of their IAQ monitoring practices. For instance, 1 participant created a journal of IAQ after using *inAirKids* for about a month. She then kept a daily record of IAQ in which she drew color-coded bugs and icons to mark different IAQ levels (Figure 6). This journaling activity had quickly become part of her daily routine, and she continued doing it for the rest of the study. This gave her extra motivation to monitor IAQ regularly, not as a passive recipient but as an active author, cocreator, and inquirer of information, which a previous work referred to as *active learning* [21]:

*I keep the journal to keep track of air quality every day. It's fine when it's green or orange, and I mark a circle. But when the tablet is red or purple, it's not good, and I draw a red spider or a purple spider. [P2]*

In addition, the participants created various drawings and crafts throughout the study period as part of their IAQ monitoring practices. It included a crafted bonfire to illustrate a source of air pollution or a drawing of air pollutants at different densities to depict different IAQ levels (Figure 7). Some of these activities were initially suggested by parents. However, most participants mentioned that they engaged in and had fun in the art and craft activities as part of IAQ monitoring.

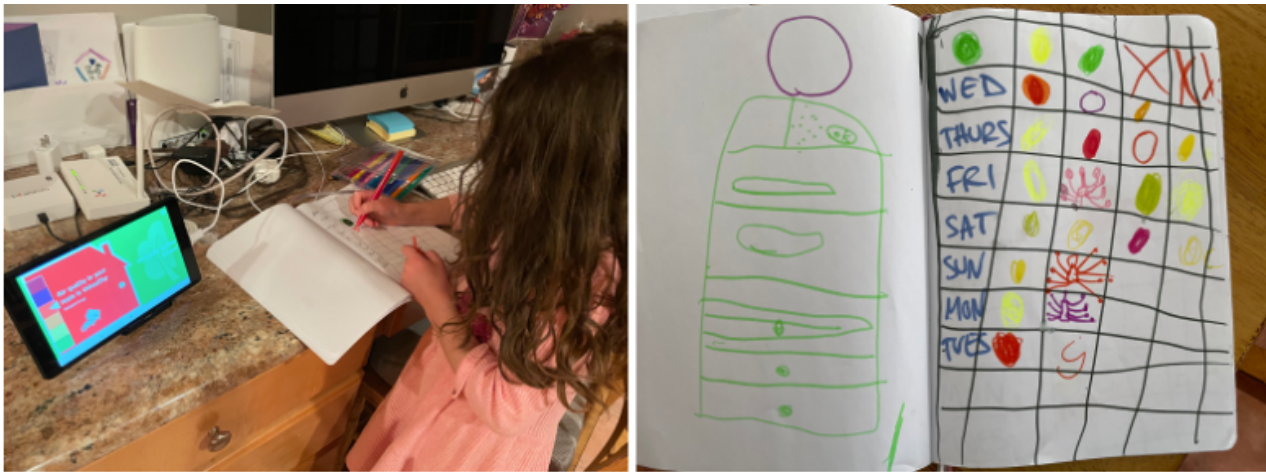
In addition, many parents expressed satisfaction with their child's learning and engaging with IAQ, which was the primary purpose of participating in this study, the desire of a parent for their child to learn about IAQ from an educational standpoint. Furthermore, these activities led to conversations and discussions about air quality between parents and children, which positively influenced and further promoted inquiries by children about air quality in general:

*We talk about stuff like air quality in the house a lot. So, it's given us another topic to talk about. She learns about stuff in school with the environment and being environmentally conscious. And this [inAirKids] adds another layer to that for her. We were having discussions that we would not have had otherwise, like what would make air quality good or bad. It gave me an opportunity to have a teachable moment with her for her to learn more about air quality and environment. [Mother of P2]*

*He asks about air quality when he goes to different places, like his grandma's house. He also asked what air quality would be like when he farts or poops. And the other day, he moved the air quality sensor to the bathroom. [Mother of P5]*

*I think it's made her aware of the terms. At six years old, it's not something that we would really be having conversations about. Now she's familiar with the term air quality, and it's been something that's ingrained in her head. [Mother of P3]*

**Figure 6.** Journaling a daily indoor air quality status (left) and a journal (right).



**Figure 7.** Art and craft activities for monitoring indoor air quality, including crafting a bonfire to depict a source of air pollution (left) and drawing air pollutant particles in different densities to illustrate different indoor air quality levels (right).



### Attenuated Interest in inAirKids: Disengagement From IAQ

As the study proceeded for several weeks, the participants exhibited a strong novelty effect on *inAirKids*. Unlike the first few weeks when the participants fully engaged with *inAirKids* for IAQ monitoring, we noticed a significant decrease in their engagement after several weeks of the study. Two key factors attributed to this phenomenon include participants' learning of IAQ change patterns over time and our focus on designing *inAirKids* to deliver IAQ changes.

### Learning the Patterns of IAQ Changes

The participants gradually learned the patterns of IAQ changes as the study proceeded. *inAirKids* enabled the participants to quickly determine two indoor activities that act as the primary source of indoor air pollution: cooking and burning candles. Once they recognized this, the onset of these activities, not *inAirKids*, triggered participants' interest in and attention to IAQ. The positive aspect is that it demonstrates the effectiveness of *inAirKids* in teaching children about primary sources of indoor air pollution. Meanwhile, it echoes a previous study about the rapid loss of interest of a child in a toy [22], showing that *inAirKids* was not successful in addressing it:

*Before she was like checking it in the morning, before breakfast, go to school, come home, get off the bus, go look at it after dinner and before bed. Now she*

*knows that if there's no cooking or candles or anything, the air quality is probably fine, and there's no reason to check. [Mother of P3]*

*He was attentive to the air quality and asked like opening the window, turning on the fan, and telling me to do that stuff like the first three or four weeks. Then, it's tapered off since then. He knows what kind of things we would be doing that would make the air quality bad. So, if there are no candles or if I'm not cooking something weird, he assumes that it's going to be green which has kind of been the case. [Mother of P5]*

In addition, the participants gradually got used to having moderate levels of IAQ. During the first few weeks, *inAirKids* displaying any color other than green prompted the participants to take immediate actions to make the color green. However, as the study continued, they became accustomed to and concerned less about the slight worsening of IAQ, such as *inAirKids*' color being yellow or orange. It is known that IAQ changes constantly and that people get used to recurrent upheavals. Thus, it is not surprising that the participants developed relaxing attitudes toward moderate levels of IAQ as the study proceeded. Meanwhile, it demonstrates that *inAirKids* was not successful in retaining the attention of the participants to the recurrent worsening of IAQ, which is crucial to enhance the overall IAQ [5]. As they learned that IAQ could worsen



somehow, the color change in *inAirKids* from green to yellow or orange was not an event to pay attention to anymore:

*It just didn't have as much of a focus. It's always either green or yellow. I think she's in a way found comfort as she's never seen it get worse either. Originally, she was like pretty hung up the first couple of times when she saw it yellow. And as she realized that sometimes it is yellow and it's not terrible, but it's okay, she didn't seem as concerned about it because I think it just became more normal to her. [Mother of P6]*

*In the beginning when it first would change, he would notice that it was yellow or orange, and he would be concerned, liked to cover his face, and asked questions like what's happened and why it is like that. And I explained to him why it's yellow and stuff. Now he's a little bit easy about it unless it would go up to red or something. Today, he might still be concerned, but if I just light a candle and it's yellow for ten minutes, it's not a big deal. [Mother of P7]*

### **inAirKids Designed to Deliver IAQ Changes**

In designing *inAirKids*, we focused on displaying the current state of IAQ in ways in which a child can easily understand and act on different IAQ statuses appropriately. To that end, we created *inAirKids* with background color changes corresponding to the current IAQ status. Then, it turned out that the IAQ of most participants' houses was mostly good. Thus, the background color of *inAirKids* remained green most of the time for most participants, except when indoor activities such as cooking or burning candles occurred. Consequently, one of the most prevalent comments we received during the later phase of the study was *inAirKids* being boring:

*I checked the tablet every day right after I'm done with my work, I come in and check on it. Now I have not looked at the tablet at all because I get bored of it. It's boring because it never changes color. The color is green all the time. [P2]*

*When the color goes up, it's interesting to see it because you can see the different colors. But it isn't as interesting because the colors never go up or down. I want to see if the tablet can get to different colors. But it never turns any color but green. When it goes to different colors, I get more excited because when it's about the same color for like a long time, it gets kind of boring. [P4]*

We intended to encourage the engagement of children in monitoring IAQ for its improvement, which took place during the early phase of the study. However, the attention of the participants moved to capturing the moment of color change in *inAirKids*, as the study proceeded. They perceived the moment of changing colors in *inAirKids* as an exciting event to capture, whether it was improving or worsening IAQ. When explaining their experience with *inAirKids* in the interviews, they were excited to share the moments they noticed color changes in *inAirKids* regardless of whether IAQ improved or worsened. In contrast, they disappointedly shared their experiences when

they did not see any color changes, even though their IAQ remained good all the time. As it was designed to highlight IAQ changes, our participants, young children, felt bored when IAQ stayed good, as the color of *inAirKids* did not change. Some participants even tried to make the color change by relocating its IAQ sensor:

*I wanted to see what the air quality in the bathroom was like because we've never put it in the bathroom, and I was happy to see the color change. Because it's not so exciting when it just keeps one color for a lot of the time, and it's cool to see the color change to a different color than green. I want to make sure that everyone's healthy in my house, but also, it's exciting to see the color change. [P4]*

*My grandma was frying, and I moved the sensor closer to the kitchen to see if the air quality would turn a different color because it would be interesting to see it turn to a different color. [P7]*

### **Suggestions for App Improvement**

In the final interview, the participants were asked to share their thoughts on improving *inAirKids* to better meet their needs. Some participants had already explored their versions of *inAirKids* as part of their hands-on arts and craft activities (Figure 8). The most prevalent response to our interview question, "What changes would you make to *inAirKids* if you would remake it?" was to add more diversity and interactivity. This aligns with the most prevalent complaint of *inAirKids* being boring.

The participants suggested adding more features to the background for diversity. We thought that an animating cat on vivid background colors would be simple yet effective in delivering IAQ information to children. However, as their interaction with *inAirKids* continued, our participants found it too simple and sought more variety in the interface. Probably because *inAirKids* illustrated a loitering cat inside a house, the participants suggested adding various other animals in various circumstances, such as a panda in the wild or a penguin and a bear in Antarctica:

*I would love to add more animations and different characters. I'd add the National Geographic background with random animals, like pandas, llamas, bears, lions, jellyfish. Or, it would be fun if there would be a way to change your background to a different setup in order to be on the moon, which you have to unlock it. [P5]*

*I want more changes in the background. I would add a flying penguin to the Antarctica background. Or, I would add a happy polar bear and an arctic hare which will follow the kid everywhere he goes in the background. [P6]*

In addition, the participants suggested implementing more interactivity to the app, especially when IAQ changes occurred. Many such suggestions were much more drastic than a simple background color change that we implemented in *inAirKids*, from wearing a mask to erupting a volcano:

*I think adding more characters like dogs or dinosaurs would make it interesting. The dog would go sniffing around and bark when the air quality gets bad. Or the dinosaur would be wearing a gas mask when the air quality would be bad so that it can help you understand it more. [P1]*

*I really want there to be like something strange or rare happens depending on how bad the air quality is. Like, the first is when the air quality is good, the cat gets elected president. And when the air quality is bad, a volcano erupts. [P5]*

**Figure 8.** Drawings of Earth with different levels of air qualities in different regions (left) and various Minecraft characters that respond to varying levels of air qualities differently (right).



## Discussion

On the basis of our findings, we discuss the considerations and lessons learned to design digital tools that would help children monitor and improve IAQ. Although our discussion centered on a mobile app for IAQ monitoring by children, we believe these considerations can be applicable to creating digital tools for educational or scientific inquiries for children in general.

### Difference Between Results in a Participatory Design and a Field Deployment

We designed the *inAirKids* interface through a robust and iterative participatory design process. The participatory design approach is a design process in which potential users, partnering with designers, are actively and directly involved in designing end user products [23]. In general, the participatory process involves brainstorming and low-tech prototyping tools to capture and demonstrate the ideas of the participants [23]. In this approach, the participants provide user-centered insight into the design, explain their difficulties with existing materials, and evaluate the interactivity [24]. Children aged between 7 and 10 years are considered ideal for participatory design because of their *emerging capacity for reflection and abstraction, and their lack of preconceptions about the design domain* [25]. Thus, the

participatory design approach has been extensively used to design technology for children [26-28] and has become one of the most prevalent usability methods in the fields of human-computer interaction for children.

All design decisions for *inAirKids* were made based on careful consideration of the child participants' feedback and comments from the participatory design. When we tested the working prototype of *inAirKids* with children, most of the feedback was positive and promising. In addition, we sought to address all issues in the interface design and usability brought up during participatory design in its development. However, we evidenced a clear sign of a novel effect as our longitudinal deployment study proceeded. Although initial feedback during the early phase of the deployment was positive, similar to those from a participatory design, responses of the participants vastly changed as their use continued. What participants praised as advantageous in participatory design disappeared quickly. Instead, many participants pointed out the shortcomings of the *inAirKids* interface as they had become used to it. Most complaints were related to the lack of interactivity and diversity of the app, which can only be captured through the extended use of a device via longitudinal field deployment.

This result provides empirical evidence regarding the real-world effects of different methodological approaches—participatory design and field deployment—in designing a digital tool. Although the consequences of the participatory design approach are invaluable to ensure the usability of a system from a user-centered perspective [25], some aspects such as a novelty effect cannot be captured from short-term user interaction. Thus, researchers and practitioners should not solely rely on study results but should also critically evaluate how the outcomes of different methodological procedures might unfold as a technology is used in the real world.

### **Incorporating Hands-on Activities in IAQ Monitoring for Experiential Learning**

Research has shown that playful and investigative activities support the engagement of children [29], which our findings echo. Although we did not ask, most participants voluntarily engaged in various hands-on art and craft activities as part of their interaction with *inAirKids*, making their practice of IAQ monitoring more fun and enjoyable. We deem this practice of *experiential learning*, in which children expand their engagement with *inAirKids* from passively receiving information to actively interpreting information through concrete hands-on experiences.

Experiential learning is a specific type of learning that connects the experiences of children to learning objects [30], thus enhancing the adaptation of new skills and knowledge [31]. Experiential learning has been shown to help students improve their understanding of scientific concepts and promote their learning interest by abstracting conceptualization from concrete actions [32,33]. Thus, children can enhance their comprehension based on their embodied experiences to construct conceptions and relationships actively while engaging in hands-on activities [34].

When creating *inAirKids*, we did not consider incorporating any hands-on activities into its use. Most existing IAQ monitoring devices have a user interface that displays air quality information using numeric figures, text, and graphs [6]. Thus, we focused on creating a child-friendly user interface with versatile graphical components and animated characters. This left behind exploring the opportunity to facilitate hands-on activities, a practice that children can engage in for a better learning experience and embodied cognition [35]. We overlooked this aspect, perhaps because we are accustomed to creating a digital tool for adults primarily to provide information. User experience with *inAirKids* might have been more positive and engaging if relevant hands-on activities were systematically implemented as part of the *inAirKids* system. Examples of such activities include providing suggestions for various art and craft activities relating to current IAQ levels, applying drawings of children to the interface to personalize an animated cat, printing out a coloring book for different IAQ levels, offering an electronic drawing board feature as part of an interface, and many more.

As toys are increasingly digitized and screen-based, it is worthwhile for researchers and practitioners to explore ways to enable children to interact simultaneously with both digital information and the physical world. Studies have demonstrated

the suitability of digital technologies, particularly mobile technologies, in facilitating experiential learning opportunities for children [33,34,36]. Our findings emphasize the importance of considering this approach for better engagement and learning by children in designing a digital tool for children's scientific and environmental inquires and beyond.

### **Designing Interactivity for Engagement in Continuity**

In general, the interface design of a personal monitoring device focuses on capturing and delivering the event of something special happening. For instance, the Fitbit vibrates if the user reaches the daily personal goal, a smoke detector beeps to alert gas leakage, and a home security system notifies when a door or window is opened unexpectedly. It is appropriate to design these devices to capture and deliver the changes, as they need to draw the attention of the users when something special happens. When designing *inAirKids*, we followed this practice by focusing on attracting the attention of a user when IAQ changes occur. To that end, we made the background color of *inAirKids* change when the IAQ level changed as its primary interactivity component.

Our findings showed that the background color change effect was played as intended. It effectively drew the attention of a user to *inAirKids* and helped children quickly apprehend their current IAQ status. However, the issue was with the frequency of its occurrence. Fortunately, the IAQ levels of most participants' houses were good most of the time, except when certain indoor activities, such as cooking, were happening. Consequently, background color changes seldom occurred. A good IAQ means that IAQ poses little or no potential to affect health, and thus, it should be perceived as favorable. In contrast, some participants felt disappointing and bored to maintain good IAQ, as they perceived the color change effect, which rarely occurs, as fun, entertaining, and exciting.

We received many requests to add more visually stimulating and animated effects to the *inAirKids* interface during the third phase of the interviews. Although these are all invaluable feedback, how to apply these requests needs to be critically reviewed. Although this can be implemented by simply adding more features when delivering something happening (eg, IAQ changing), an equally, if not more, effective approach would be to make the stable condition (eg, IAQ being good for a while) engaging and fun. We believe that the experiences of the participants with *inAirKids* were not as rich as we hoped, as our focus was on designing interactivity only for changes, which prompted the participants to engage in IAQ changes. Although it is worth further discussing whether children need to be attentive to IAQ when it is always good, it is crucial to deliberate how a different design focus can shape the user experience differently. Depending on the context of use, target users, and the purpose of a digital tool, different design foci for interactivity must be explored, including delivering changes, rendering continuity, or both.

### **Limitations**

Our findings must be evaluated in the context of several limitations. First, our sample size was small, and the attrition rate was high among younger children. Thus, our participant



pool may not be representative of the general population of children. Second, the study duration was different among different participants, which runs the risk of compromising validity. As a novelty effect is strongly related to the duration of use [37], we might have captured fewer incidences of the findings relating to a novelty effect from those who completed the study earlier. We then collected strong evidence of a novelty effect even from those who completed the study earlier, demonstrating that the novelty effect persisted earlier in the study. Third, the overall IAQ was good mostly in all participants' houses, which must have influenced how they interacted with *inAirKids* and perceived IAQ in general. If children living in more polluted areas were recruited, the results might have been different. Although we believe our findings provide valuable insights into understanding how children living in healthy indoor environments would interact with *inAirKids*, a further study is needed to investigate how children in a different sociotechnical status (eg, low-income families) or living in air-polluted regions (eg, near factories, high-traffic areas, and low-income countries) would interact with *inAirKids* and how their experience would influence engagement in IAQ differently.

## Conclusions

As time spent indoors increases in modern society, the impact of indoor environmental quality on comfort, health, and productivity of occupants also increases. With the advancement of personal computing and sensing technologies, there has been an increased interest in using sensors and smart devices to promote the engagement of occupants in monitoring and improving IAQ. However, most existing IAQ monitoring devices are optimized for interaction with adult users, leaving behind important household members who can highly influence and be influenced by IAQ, the children. We investigated how *inAirKids* affects the children's understanding of and engagement with IAQ through a longitudinal deployment study. Our findings shed light on the potential to promote the engagement of children in IAQ as well as considerations for designing a child-friendly digital device. To our knowledge, this is the first longitudinal deployment study to investigate how children engage in IAQ monitoring. We hope that our findings will encourage future studies on the engagement of children with indoor environmental quality.

## Conflicts of Interest

None declared.

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## Abbreviations

**AQI:** air quality index

**IAQ:** indoor air quality

**PM:** particulate matter

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Original Paper

# Facial and Vocal Markers of Schizophrenia Measured Using Remote Smartphone Assessments: Observational Study

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## Abstract

**Background:** Machine learning–based facial and vocal measurements have demonstrated relationships with schizophrenia diagnosis and severity. Demonstrating utility and validity of remote and automated assessments conducted outside of controlled experimental or clinical settings can facilitate scaling such measurement tools to aid in risk assessment and tracking of treatment response in populations that are difficult to engage.

**Objective:** This study aimed to determine the accuracy of machine learning–based facial and vocal measurements acquired through automated assessments conducted remotely through smartphones.

**Methods:** Measurements of facial and vocal characteristics including facial expressivity, vocal acoustics, and speech prevalence were assessed in 20 patients with schizophrenia over the course of 2 weeks in response to two classes of prompts previously utilized in experimental laboratory assessments: *evoked* prompts, where subjects are guided to produce specific facial expressions and speech; and *spontaneous* prompts, where subjects are presented stimuli in the form of emotionally evocative imagery and asked to freely respond. Facial and vocal measurements were assessed in relation to schizophrenia symptom severity using the Positive and Negative Syndrome Scale.

**Results:** Vocal markers including speech prevalence, vocal jitter, fundamental frequency, and vocal intensity demonstrated specificity as markers of negative symptom severity, while measurement of facial expressivity demonstrated itself as a robust marker of overall schizophrenia symptom severity.

**Conclusions:** Established facial and vocal measurements, collected remotely in schizophrenia patients via smartphones in response to automated task prompts, demonstrated accuracy as markers of schizophrenia symptom severity. Clinical implications are discussed.

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**KEYWORDS**

digital biomarkers; phenotyping; computer vision; facial expressivity; negative symptoms; vocal acoustics

## Introduction

Utilization of objective digital measurements of patient behavior is rapidly increasing in clinical research and practice. The

development and validation of digital measurement tools in psychiatry come with both significant opportunities and risks. Significant opportunity arises as psychiatry is undergoing a paradigm shift toward the utilization of objective markers to assess illness and disease progression [1] and toward the

widespread use of telehealth platforms for psychiatric care. This is particularly important when face-to-face medical care is not possible, such as during the COVID-19 pandemic [2-4].

Many behavioral and physiological markers are now accessible through digital technology such as wearables, mobile or web-based apps, and application programming interfaces [5]. Such advances hold promise in allowing new innovations in neuropsychiatry to truly scale in a manner where they can be used to develop and implement assessment and treatment for patients with significant psychiatric impairment [6].

Schizophrenia represents a poignant example of both the benefits and challenges of remote digital measurement. Clinical trials for schizophrenia drug development are often site-centric, requiring patients to appear physically at the site for measurement of disease severity. The need to travel to sites can restrict study populations to those that live in geographical proximity to the site, restricting access to participation and limiting patient diversity [7]. Current approaches for measurement of disease rely on clinician-administered measures that are costly and time-consuming to administer, leading to infrequent assessment. The instruments themselves are not well-aligned with current neurobiological definitions of illness [8].

Digital assessments address the practical challenges associated with in-person measurement of disease severity. Given that they can be administered remotely, they allow for assessments to occur in the patient's natural environment with reduced need for in-person consultations at a clinic. Additionally, the short length of the assessments allows for them to be administered with far greater frequency than would be possible with in-person assessments. Hence, digital assessments could provide care teams greater visibility into patient health and behavior outside the clinic with the potential to inform patient responses to treatment, or the lack thereof, earlier than would otherwise be possible [9,10]. There is a need to determine the viability of such assessment to accurately measure symptom severity when deployed in real-world settings, where differentiating between significant variability and noise can pose a challenge [11-13].

A number of behavioral characteristics of schizophrenia, such as alogia (poverty of speech) and affective flattening (diminished emotional expression or emotional withdrawal) [14], can be quantified directly using standardized tasks and coding schemes [15-19], which can be automated through use of computer vision [20] and vocal acoustic [21] machine learning models. In addition to digital measures that are directly analogous to core schizophrenia symptoms, there are a number of other acoustic measures including vocal loudness, pitch variability, fundamental frequency, and jitter, which have demonstrated validity as markers of schizophrenia [16,22-24]. These markers have demonstrated specificity as measures of the negative symptom cluster, which is of particular interest given the lack of available treatment options for negative symptoms [22].

In this study, we examine the ability to measure schizophrenia symptom severity through facial and vocal analysis using videos recorded during a remote smartphone-based assessment composed of both evoked and spontaneous prompts. We compared these measures against standard clinical assessments

of overall schizophrenia symptom severity (ie, total score on the Positive and Negative Syndrome Scale [PANSS]) as well as specific domains of positive (P total), negative (N total), and general (G total) symptoms, measured during in-person study visits [25]. We further conducted an exploratory analysis on the relationship between digital measures and individual symptoms of schizophrenia.

## Methods

### Participants

Individuals who had received a DSM-5 clinical diagnosis of schizophrenia or schizoaffective disorder and passed a telephone screening and were on a stable treatment regimen for atypical antipsychotic therapy for  $\geq 2$  months with no intent to change medication during the 2-week study were recruited as study participants. A total of 20 individuals, 15 with schizophrenia and 5 with schizoaffective disorder, were enrolled (8 male, 12 female) with an age range of 29 to 61 years ( $\mu=45$ ,  $\sigma=11$ ). A subset of 11 individuals had their diagnosis confirmed through semistructured interviews. To be included in the study, participants needed to be able to speak, read, hear, and understand the language of the study team and the informed consent form; respond verbally to questions; follow instructions; and be willing and able to participate in all study activities, including the use of smartphones for data collection.

Given that the purpose of the study was to determine whether remote assessments would be able to appropriately collect behavioral data for assessment of disease severity in patients with schizophrenia by using digital biomarkers, data from healthy controls were not included. Data on healthy controls would have allowed for assessment of whether facial and vocal digital biomarkers can distinguish healthy individuals from patients with schizophrenia. However, we felt that past work on each of the biomarkers discussed in this paper provides sufficient evidence for this claim (Table 1).

The study was conducted at the Icahn School of Medicine's Affective and Cognitive Therapeutics Research Lab and the protocol was approved by the Biomedical Research Alliance of New York.

### Data Collection

All study participants were assessed for severity of schizophrenia symptoms using both in-person clinical assessments and remote smartphone-based assessments over the course of the 14-day observational period. All data were collected over 3 months, from July to September 2019.

### In-Person Clinical Assessments

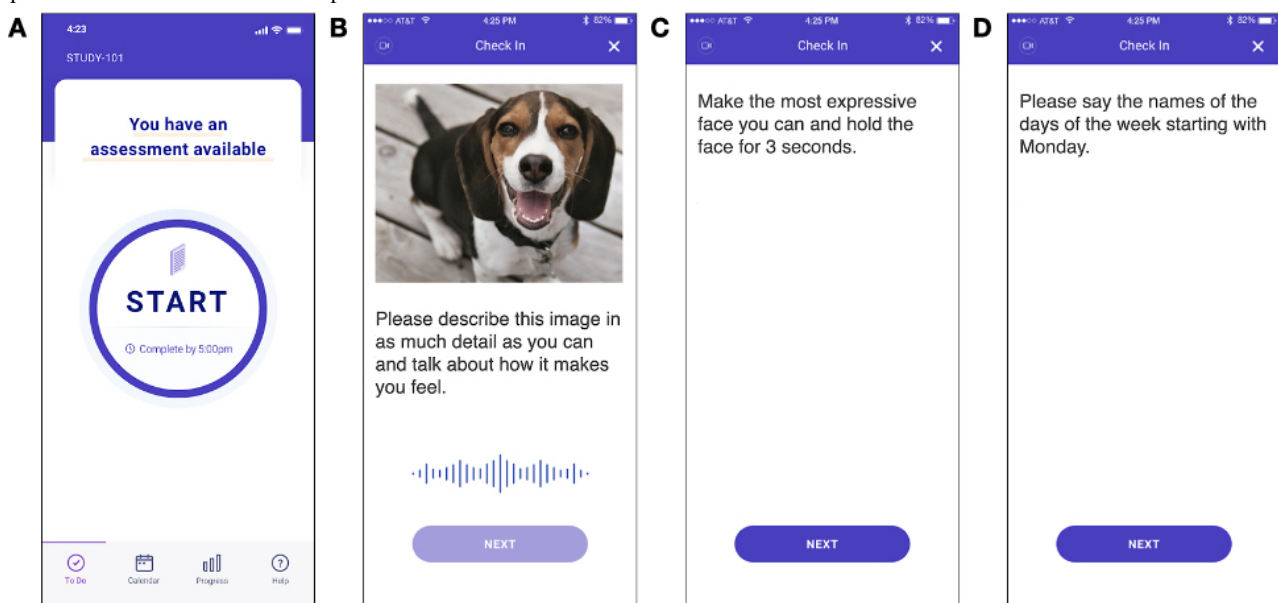
The PANSS was administered in person to all participants by a trained research team member on the first (day 1) and last (day 14) of the study. For all subsequent analyses, the PANSS scores for each study participant were averaged for the 2 time points. Given the study participants were clinically stable, averaging the two PANSS scores allowed for reduction in any noise in the measurement. Multimedia Appendix 1 shows the reliability of the PANSS scores for the two time points.

### Remote Smartphone-Based Assessments

On the first day of the study, all study participants were trained by a research coordinator on how to use the smartphone app [26] for remote data collection, which would capture video and audio data of participant behavior using the front-facing smartphone camera as they responded to on-screen prompts (Figure 1). This software has been used in clinical research for reporting medication adherence, electronic patient-reported outcomes, and ecological momentary assessments [27,28]. Participants were allowed to use their own smartphones or those provisioned to them by the study team for the duration of the

study. The assessments were taken at scheduled time points over the course of the 14 days, and the app would send a reminder to the participant at the participant's chosen daily reminder time when an assessment had become available. All participants received US \$1 per assessment they completed using a debit card that was provided to them during study enrollment. Subjects were also compensated with US \$25 for the screening visit, US \$75 for the initial training, and US \$200 at the final visit for device return (with an optional additional US \$20 reimbursement if they used their own device, to cover data costs). The assessments were designed to capture 2 main kinds of behaviors as described below.

**Figure 1.** Example screenshots from the smartphone assessment all study participants took for remote and automated collection of video and audio data. During each of the prompts, the app speaks the text displayed on the screen and awaits a verbal and visual response from the participant, all while recording video and audio from the front-facing camera and microphone. (A) Screen displayed before the participant begins the assessment. (B) Prompt for collection of free behavior in response to images, showing one example image. (C) Prompt for collection of evoked facial expression behavior. (D) Prompt for collection of evoked vocal expression behavior.



### Free Speech and Spontaneous Expressivity

Participants were shown images from the Open Affective Standard Image Set [29] and asked to describe the images and talk about how they made them feel (Figure 1B). The participants' speech and facial expressivity in response to the prompts were captured [15,16,18,19,30-32]. This assessment was conducted on days 2, 7, and 14 of the study.

### Evoked Facial and Vocal Expressions

Participants were asked separately to make the most expressive face they could and hold it for 3 seconds (Figure 1C) and then recite the days of the week out loud (Figure 1D). These prompts were selected on the basis of prior experimental tasks used to examine emotional activity and speech in schizophrenia [31,33]. The captured video and audio were used to measure facial expressivity and acoustic characteristics of voice during the evoked expressions. These assessments were scheduled on days 1, 7, and 14 of the study.

Given that the study participants were clinically stable and maintained on the psychiatric medications they entered the study on, measurements acquired from each time point of the

assessments were averaged before comparison with PANSS scores. Since we did not expect to observe significant clinical change, taking the average allows for reduction of noise and accounts for within-subject variability. [Multimedia Appendix 1](#) shows the test-retest reliability of each of the digital measures between the 2 weeks was considerable, supporting the decision to average the measures.

### Measurement of Digital Markers

Video and audio data of participant behavior collected during the remote assessments containing protected health information (PHI) were uploaded and stored using Health Insurance Portability and Accountability Act (HIPAA)-compliant backend services. These data were then processed to extract frame-by-frame measurements of behavior, generating the first level of non-PHI data. A combination of computer vision and digital signal processing tools were used for quantification of facial and vocal behavior and subsequent derivation of visual and auditory markers of schizophrenia as described below.

All analyses were conducted using Python, along with open-source tools. All digital biomarker variables analyzed were acquired through the use of OpenDBM, an open-source software

package that combines tools for measurement of facial, vocal, and movement behavior, developed partially for our study [34] and made available freely for use by all researchers.

### Measurement of Facial Expressivity

The software library OpenFace [35] was used to measure framewise facial expressivity through quantification of action units (AUs; [Multimedia Appendix 2](#)) using a computer vision-based implementation of the Facial Action Coding System. All framewise AU measurements were normalized through division by a timepoint-specific baseline value acquired at the beginning of each assessment when the participant is not presented with any stimulus. The normalization allows for correction of any inter- and intraindividual variability; this methodology has previously been demonstrated to be necessary for measurement of facial behavior using computer vision tools and for subsequent analyses of facial expressivity [36-38]. This normalization is also necessary to account for tardive dyskinesia or other movement disorders that may be present in patients receiving antipsychotics. The time point-specific baseline normalization addresses noise in facial expressivity measurements stemming from motor abnormalities. *Facial expressivity* was calculated by taking the mean framewise intensity of all AUs over the course of the video. The method for quantifying *facial expressivity* was the same for both spontaneous and evoked expressivity. For each frame of video,

OpenFace provides a confidence score denoting the likelihood that it is accurately detecting a face; only frames with a confidence score of 80% or higher were used for all downstream analyses. While OpenFace provides large amounts of information on specific AUs and emotions, in the current investigation, we focused only on *facial expressivity* because of significant evidence that patients with schizophrenia display a decrease in overall affect (eg, blunted affect) [39,40].

### Measurement of Vocal Acoustics

The software library Parselmouth [41], which is a Python implementation of the Praat software library [42], was used for measurement of all vocal acoustic characteristics. All audio analyzed was first passed through the LogMMSE noise reduction algorithm for speech enhancement [21,43].

Despite the exploratory nature of this study and given the small data sample, we attempted to be parsimonious in the selection of markers to reduce the likelihood of false discovery. Analysis of vocal markers included those that have previously demonstrated effects in studies of individuals with schizophrenia [16,23]. Each vocal marker—calculated separately during free speech and evoked vocal expressions—include *vocal intensity*, *fundamental frequency mean*, *fundamental frequency stdev*, *vocal jitter*, *harmonics to noise ratio* and *speech prevalence* [22,24,43-45]. Descriptions of these verbal acoustic features are provided in [Table 1](#).

**Table 1.** List of vocal acoustic variables extracted from audio files collected during participation in remote smartphone assessments and references to earlier work on their relevance in schizophrenia.

Variable	Description
<i>Vocal intensity</i>	Volume of participant's speech, measured in decibels, which was previously shown to be decreased in individuals with schizophrenia compared to healthy controls [30].
<i>Fundamental frequency mean</i>	Average fundamental frequency of participant speech in hertz, which has been shown to be higher in individuals with schizophrenia and decreases in response to treatment [24,44].
<i>Fundamental frequency stdev</i>	SD in fundamental frequency in hertz, which has been shown to be greater in individuals with schizophrenia [24].
<i>Vocal jitter</i>	Degree of irregularity in the frequency of the participant's speech, measured in hertz, demonstrated to be higher in individuals with schizophrenia [45].
<i>Speech prevalence</i>	Percentage of the audio file where participant speech was detected as opposed to silence; individuals with schizophrenia demonstrate increased pauses and variability in pause duration [39,46].
<i>Harmonics to noise ratio</i>	Quantification of additive noise in the participant's speech, which has been used to predict risk of psychosis, and has shown to be correlated with symptom severity in other neurological disorders such as Parkinson disease [12,47].

### Data Analysis

Both facial expressivity and vocal characteristics were assessed during free behavior following spontaneous prompts ([Table 2](#)). Facial expressivity was also assessed during evoked facial expressions and vocal characteristics were assessed during evoked vocal expression following evoked prompts. Evaluation of vocal characteristics during the evoked expression task allowed for measurement of specific characteristics that have

been previously shown to be effective measures of schizophrenia during speech (eg, *fundamental frequency mean and stdev*, *jitter*, *harmonics to noise ratio*) while also measuring speech characteristics such as amount of time spoken (ie, *speech prevalence*) [22,24,43-45]. A large number of variables can be calculated from video and audio data sources; however, the analyses presented herein were limited to features that have evidence and a theoretical basis for a relationship with schizophrenia symptom severity in the scientific literature.



**Table 2.** All variables described in Measurement of Digital Markers were calculated separately for distinct behaviors captured during the remote smartphone assessments. Each of the behaviors that were elicited and captured during the smartphone assessment and the digital markers calculated from those behaviors are listed here.

Behavior	On-screen prompt	Digital markers measured
Free behavior	Please describe what you see in this image and talk about how it makes you feel (Figure 1B)	<ul style="list-style-type: none"> <li>• Facial expressivity</li> <li>• Fundamental frequency mean</li> <li>• Fundamental frequency stdev</li> <li>• Vocal jitter</li> <li>• Harmonics to noise ratio</li> <li>• Speech prevalence</li> </ul>
Evoked facial expression	Please make the most expressive face you can and hold it for 3 seconds (Figure 1C)	<ul style="list-style-type: none"> <li>• Facial expressivity</li> </ul>
Evoked vocal expression	Please say the names of the days of the week starting with Monday (Figure 1D)	<ul style="list-style-type: none"> <li>• Fundamental frequency mean</li> <li>• Fundamental frequency stdev</li> <li>• Vocal jitter</li> <li>• Harmonics to noise ratio</li> <li>• Speech prevalence</li> </ul>

### Correlation With PANSS Subscale Scores

As the primary analysis, digital measures were correlated with overall schizophrenia symptom severity considering the PANSS total score (*PANSS Total*) along with the 3 subscales reflecting *N Total*, *P Total*, and *G Total* using Pearson's correlation. When comparing negative symptoms, we utilized the PANSS Marder Symptom Factor, which includes two symptoms that are traditionally included in the general severity score: *Motor Retardation* and *Social Avoidance and Isolation* [48].

### Correlation With Individual PANSS Items

As an additional exploratory analysis, digital measurements that demonstrated significance in relation to specific subscales were then further explored in relation to the specific symptoms that derive those subscales, correcting for multiple comparisons using a Benjamini-Hochberg adjusted *P* value [49]. This was an exploratory analysis conducted to further disaggregate the heterogeneity within the symptom scales to understand more specifically which clinical features were reflected in the digital measurement. The results from these analyses are provided in the supplementary materials and are not included in the main text.

## Results

Participation in the in-app remote assessments across participants was high (Multimedia Appendix 3).

### Correlation With PANSS Scores

#### Vocal Markers During Evoked Vocal Expression

Our results demonstrate that multiple digital measures are significantly correlated with overall *N Total* after correcting for multiple comparisons. This includes *fundamental frequency mean* ( $r=-0.64$ ; *adjusted P*=.02), *vocal jitter* ( $r=0.56$ ; *adjusted P*=.02), and *harmonics to noise ratio* ( $r=-0.61$ ; *adjusted P*=.02). Two other features trended in the hypothesized direction with *P* values of <0.1 after correction for false discovery, including *speech prevalence* ( $r=-0.47$ ; *adjusted P*=.06) and *fundamental frequency stdev* ( $r=-0.44$ ; *adjusted P*=.07; see Table 3 for full results). Importantly, the directionality of results was consistent with prior research. For example, increased negative symptom severity was reflected in decreased speech prevalence, decreased tonal qualities of speech, and increased noise to speech sounds, consistent with the literature [16,22-24].

**Table 3.** Correlation between vocal markers during evoked vocal expression and Positive and Negative Syndrome Scale (PANSS) score showed a relationship between vocal characteristics and schizophrenia symptom severity.

Variable	Negative symptom severity	Positive symptom severity	General severity	Total	Vocal intensity	Fundamental frequency stdev	Fundamental frequency mean	Vocal jitter	Speech prevalence
<b>Negative symptom severity</b>									
Pearson <i>r</i>	—								
<i>P</i> value	—								
<b>Positive symptom severity</b>									
Pearson <i>r</i>	0.452 <sup>a</sup>	—							
<i>P</i> value	.045	—							
<b>General severity</b>									
Pearson <i>r</i>	0.572 <sup>b</sup>	0.806 <sup>c</sup>	—						
<i>P</i> value	.008	<.001	—						
<b>Total</b>									
Pearson <i>r</i>	0.757 <sup>c</sup>	0.870 <sup>c</sup>	0.947 <sup>c</sup>	—					
<i>P</i> value	<.001	<.001	<.001	—					
<b>Vocal intensity</b>									
Pearson <i>r</i>	-0.091	-0.250	-0.088	-0.152	—				
<i>P</i> value	.71	.90	.72	.64	—				
<b>Fundamental frequency stdev</b>									
Pearson <i>r</i>	-0.436	-0.068	0.098	-0.090	-0.081	—			
<i>P</i> value	.07	.78	.83	.71	.74	—			
<b>Fundamental frequency mean</b>									
Pearson <i>r</i>	-0.644 <sup>a</sup>	-0.253	-0.218	-0.373	0.475	0.577 <sup>a</sup>	—		
<i>P</i> value	.02	.30	.37	.70	0.10	.02	—		
<b>Vocal jitter</b>									
Pearson <i>r</i>	0.563 <sup>a</sup>	0.229	0.122	0.293	-0.176	-0.695 <sup>c</sup>	-0.823 <sup>c</sup>	—	
<i>P</i> value	.02	.52	.93	.34	.79	<.001	<.001	—	
<b>Speech prevalence</b>									
Pearson <i>r</i>	-0.470	-0.247	-0.292	-0.362	0.611 <sup>a</sup>	0.043	0.781 <sup>c</sup>	-0.373	—
<i>P</i> value	.06	.61	.23	.38	.03	.86	<.001	.12	—
<b>Harmonics to noise ratio</b>									
Pearson <i>r</i>	-0.610 <sup>a</sup>	-0.195	-0.126	-0.297	0.154	0.773 <sup>c</sup>	0.868 <sup>c</sup>	-0.965 <sup>c</sup>	0.422
<i>P</i> value	.02	.51	.61	.43	.66	<.001	<.001	<.001	.07

<sup>a</sup>*P*<.05.<sup>b</sup>*P*<.01.<sup>c</sup>*P*<.001.

### Evoked Facial Expression

Facial expressivity demonstrated significant relationships with the overall schizophrenia symptom severity PANSS total score

( $r=-0.71$ ; *adjusted P*=.002) and on all PANSS subscales (N Total,  $r=-0.50$ ; *adjusted P*=.04; P Total,  $r=-0.63$ ; *adjusted P*=.006; G Total,  $r=-0.70$ ; *adjusted P*=.009), in a direction consistent with the literature [15,18,19,37,38] (Table 4).

**Table 4.** Correlation between facial expressivity during evoked facial expression and the Positive and Negative Syndrome Scale score showed a relationship between facial affect and schizophrenia symptom severity.

Variable	Facial expressivity	Negative symptom severity	Positive symptom severity	General severity
<b>Facial expressivity</b>				
Pearson <i>r</i>	—			
<i>P</i> value	—			
<b>Negative symptom severity</b>				
Pearson <i>r</i>	-0.500 <sup>a</sup>	—		
<i>P</i> value	.04	—		
<b>Positive symptom severity</b>				
Pearson <i>r</i>	-0.628 <sup>b</sup>	0.452 <sup>a</sup>	—	
<i>P</i> value	.01	.045	—	
<b>General severity</b>				
Pearson <i>r</i>	-0.695 <sup>b</sup>	0.572 <sup>b</sup>	0.806 <sup>c</sup>	—
<i>P</i> value	.009	0.008	<.001	—
<b>Total</b>				
Pearson <i>r</i>	-0.714 <sup>b</sup>	0.757 <sup>c</sup>	0.870 <sup>c</sup>	0.947 <sup>c</sup>
<i>P</i> value	.002	<.001	<.001	<.001

<sup>a</sup>*P*<.05.<sup>b</sup>*P*<.01.<sup>c</sup>*P*<.001.

### Free Behavior in Response to Images

Spontaneous measurement of vocal and facial expressions, as elicited by emotionally valenced images, demonstrated relationships between multiple vocal markers and the negative symptom cluster. Highly consistent with results of vocal measurements in response to evoked prompts, the following measures demonstrated significant relationships with N Total:

*fundamental frequency mean* ( $r=-0.61$ ; *adjusted P*=.04), *harmonics to noise ratio* ( $r=-0.58$ ; *adjusted P*=.03), *speech prevalence* ( $r=-0.57$ ; *adjusted P*=.03). *Vocal jitter* showed a trend in the hypothesized direction a with *P* value of <.10 ( $r=0.43$ ; *adjusted P*=.09), and *fundamental frequency stdev* did not approach significance (Table 5). In contrast to measurement after the evoked task, *vocal intensity* measured during free behavior demonstrated significance ( $r=0.50$ ; *adjusted P*=.05).

**Table 5.** Correlation between facial and vocal markers during free behavior and PANSS score showed a relationship between facial affect and vocal characteristics with schizophrenia symptom severity.

Variable	Negative symptom severity	Positive symptom severity	General severity	Total	Facial expressivity	Vocal intensity	Fundamental frequency mean	Fundamental frequency Stdev	Harmonics to noise ratio	Vocal jitter
<b>Negative symptom severity</b>										
Pearson <i>r</i>	—									
<i>P</i> value	—									
<b>Positive symptom severity</b>										
Pearson <i>r</i>	0.452 <sup>a</sup>	—								
<i>P</i> value	.045	—								
<b>General severity</b>										
Pearson <i>r</i>	0.572 <sup>b</sup>	0.806 <sup>c</sup>	—							
<i>P</i> value	.008	<.001	—							
<b>Total</b>										
Pearson <i>r</i>	0.757 <sup>c</sup>	0.870 <sup>c</sup>	0.947 <sup>c</sup>	—						
<i>P</i> value	<.001	<.001	<.001	—						
<b>Facial expressivity</b>										
Pearson <i>r</i>	0.142	-0.113	0.090	0.056	—					
<i>P</i> value	.56	.64	.83	.82	—					
<b>Vocal intensity</b>										
Pearson <i>r</i>	-0.502 <sup>a</sup>	-0.332	-0.225	-0.386	0.364	—				
<i>P</i> value	.05	.17	.83	.24	.13	—				
<b>Fundamental frequency mean</b>										
Pearson <i>r</i>	-0.606 <sup>a</sup>	-0.288	-0.268	-0.428	0.184	0.935 <sup>c</sup>	—			
<i>P</i> value	.04	.81	.27	.48	.45	<.001	—			
<b>Fundamental frequency stdev</b>										
Pearson <i>r</i>	-0.304	-0.189	-0.127	-0.225	0.179	0.581 <sup>b</sup>	0.529 <sup>a</sup>	—		
<i>P</i> value	.24	.61	.61	.50	.46	.009	.02	—		
<b>Harmonics to noise ratio</b>										
Pearson <i>r</i>	-0.584 <sup>a</sup>	-0.224	-0.097	-0.312	0.174	0.654 <sup>b</sup>	0.774 <sup>c</sup>	0.476 <sup>a</sup>	—	
<i>P</i> value	.03	.62	.97	.34	.48	.002	<.001	.04	—	
<b>Vocal jitter</b>										
Pearson <i>r</i>	0.426	0.147	0.015	0.194	-0.097	-0.541 <sup>a</sup>	-0.691 <sup>b</sup>	-0.278	-0.937 <sup>c</sup>	—
<i>P</i> value	.10	.64	.95	.50	.69	.02	.001	.25	<.001	—
<b>Speech prevalence</b>										
Pearson <i>r</i>	-0.567 <sup>a</sup>	-0.260	-0.261	-0.403	0.161	0.869 <sup>c</sup>	0.923 <sup>c</sup>	0.260	0.575 <sup>b</sup>	-0.510 <sup>a</sup>
<i>P</i> value	.03	.66	.98	.30	.51	<.001	<.001	.28	.01	.03

<sup>a</sup>*P*<.05.<sup>b</sup>*P*<.01.<sup>c</sup>*P*<.001.

## Discussion

### Principal Findings

In this study, we tested the hypothesis that facial and vocal markers of schizophrenia can be captured remotely in patients using brief automated smartphone-based assessments, and that such measures would be correlated to standard clinical measures of schizophrenia symptom severity. The measures show promise as objective and automated methods of assessing illness severity in the context of treatment development and decision-making. Prompts and vocal or facial measures that have previously demonstrated accuracy in controlled research settings were simplified and deployed as a brief assessment via a smartphone app in an observational study involving patients with schizophrenia. Our results support the ability to measure meaningful clinical markers of schizophrenia symptom severity via a brief smartphone-based assessment that captures data remotely and processes it through a back-end of machine learning algorithms to identify vocal and facial markers.

Our results demonstrate that vocal characteristics such as fundamental frequency, loudness, nonverbal vocal tones, and the prevalence of speech serve as specific markers of symptom severity—particularly for negative symptoms—in a direction consistent with previous literature, which used laboratory-based measures. The majority of these markers demonstrate a robust signal of negative symptom severity regardless of whether prompts were evoked or spontaneous.

The observation that vocal markers provide specificity as a metric of negative symptom severity has significant practical implications in clinical research and decision-making. Recent advances in the mechanistic understanding of negative symptoms have led to a number of promising pharmacological and cognitive treatments for negative symptoms of schizophrenia [50-53]. Such initiatives are important given the lack of US Food and Drug Administration–approved treatments for negative symptoms [54]. However, measures of negative symptoms to assess the efficacy of these treatments on the basis of objective measurement of behavior rather than subjective clinician observation are sparse [55-58].

Facial expressivity only demonstrated a relationship with schizophrenia symptom severity when captured using evoked prompts. This may indicate that either greater structure is needed to assess this marker remotely or that the prompts that were utilized were not a strong enough elicitation. Indeed, prior work has demonstrated that video rather than still images are stronger evocations to assess emotional variability in schizophrenia [59]. These findings suggest that care must be taken to determine the form of behavior from which facial expressivity is being quantified: facial expressivity during evoked prompts differs from facial expressivity during free behavior or in response to specific stimuli. Indeed, previous work has demonstrated how the context of behavior affects the measurements acquired [7]. In this study, we observed that facial expressivity in response to evoked prompts provides a robust signal for overall symptom severity.

### Limitations

This study presents a number of important limitations. While the primary hypotheses were supported, not all effects were consistent across prompts. Given the small sample size, it is impossible to conclude definitively which markers can be utilized to robustly assess schizophrenia symptom severity or impairment. Indeed, a number of relatively large correlation coefficients trended in the hypothesized direction but with  $P$  values of  $<.10$ , likely owing to sample size constraints. Further, despite the markers being hypothesized a priori, this work is exploratory in nature given the small sample size, limited number of assessments, and the short duration of the study. A larger assessment will be needed to replicate our findings and to assess reliability of the metrics more broadly. Additionally, the PANSS has well-documented shortcomings as a measurement tool for negative symptoms, and future work should conduct correlations with additional scales such as the Clinical Assessment Interview for Negative Symptoms or the Brief Negative Symptom Scale [60-63]. More specifically, future studies are required to individually compare specific aspects of negative symptoms with their correlates in digital measures (eg, comparison of clinician-observed blunted affect with digitally assessed facial expressivity, considering the hypothesis that greater blunted affect is correlated with reduced facial expressivity). Such studies would allow for a more direct assessment of digital assessment tools to quantify individual schizophrenia symptoms. Despite the aforementioned limitations, this study provides evidence that facial and vocal digital measures can be remotely captured in patients with schizophrenia, and that such measures demonstrate significant relationships with established measures of schizophrenia symptom severity, offering promise that these tools could be used to remotely measure and track disease severity in an objective manner.

While app-based video and audio capture utilizes a proprietary platform, this investigation utilized open-source Python-based software, available to all researchers [34]. This allows for the expansion of our study to a wider patient population, as mentioned above, and the independent validation of the methods and their implementation in this investigation by other researchers in academic and clinical research, following an open science framework for the development of digital tools for objective, accurate, and scalable measurement of disease symptoms for both mental and physical health.

### Conclusions

This study shows that facial and vocal markers, measured using computer vision and vocal analytics from video data captured remotely via a smartphone app demonstrates validity as a marker of schizophrenia and is a promising metric for negative symptom severity. Use of such technology in clinical care and clinical research settings could allow for more frequent, remotely assessed, objective measurement of disease symptoms and treatment responses in a scalable and accessible manner, which can support the development of novel treatments and risk assessment among individuals with schizophrenia.



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## Conflicts of Interest

IGL, AA, VY, and VK were employed and own shares at AiCure, LLC, at the time of the study. Authors OP, MD, MM, LS, and BH are employees of Merck Sharp & Dohme Corp, a subsidiary of Merck & Co, Inc, and may own stocks/stock options at Merck & Co, Inc. MMPR has received research grant funding from Neurocrine Biosciences Inc, Millennium Pharmaceuticals, Takeda, Merck, and AiCure. She is an advisory boardmember for Neurocrine Biosciences Inc.

### Multimedia Appendix 1

Descriptive statistics for Positive and Negative Syndrome Scale scores and digital biomarkers during free behavior.

[\[DOCX File, 7 KB - formative\\_v61e26276\\_app1.docx\]](#)

### Multimedia Appendix 2

List of facial action units (AUs) whose frame-wise intensity was quantified using computer vision; AU intensities were normalized and then combined to measure facial expressivity.

[\[DOCX File, 7 KB - formative\\_v61e26276\\_app2.docx\]](#)

### Multimedia Appendix 3

Amount of participation in the naturalistic assessments deployed through the AiCure app in the duration of the study.

[\[DOCX File, 7 KB - formative\\_v61e26276\\_app3.docx\]](#)

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## Abbreviations

**AU:** action unit

**G Total:** general severity

**N Total:** negative symptom severity

**P Total:** positive symptom severity

**PANSS:** Positive and Negative Syndrome Scale

**PHI:** protected health information

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Original Paper

# Active Use and Engagement in an mHealth Initiative Among Young Men With Obesity: Mixed Methods Study

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## Abstract

**Background:** The effectiveness of mobile health (mHealth) approaches that employ wearable technology to promote physical activity have been the subject of concern due to the declining active use observed in trial settings.

**Objective:** To better contextualize active use, this study aimed to identify the barriers and enablers to engagement in a tracker-based mHealth initiative among young men who had recently completed a 19-week residential weight loss program.

**Methods:** A mixed methods study was conducted among 167 young men who had voluntarily enrolled in the national steps challenge (NSC), an mHealth physical activity promotion initiative, following a residential weight loss intervention. A subsample of 29 enrollees with a body mass index of 29.6 (SD 3.1) participated in semistructured interviews and additional follow-up assessments. Quantitative systems data on daily step count rates were used to describe active use. Qualitative data were coded and analyzed to elicit barriers and enablers to microlevel engagement in relation to the NSC, focusing on tracker and smartphone use. We further elicited barriers and enablers to macrolevel engagement by exploring attitudes and behaviors toward the NSC. Using triangulation, we examined how qualitative engagement in the NSC could account for quantitative findings on active use. Using integration of findings, we discussed how the mHealth intervention might have changed physical activity behavior.

**Results:** Among the 167 original enrollees, active use declined from 72 (47%) in week 1 to 27 (17%) in week 21. Mean daily step counts peaked in week 1 at 10,576 steps per day and were variable throughout the NSC. Barriers to engagement had occurred in the form of technical issues leading to abandonment, device switching, and offline tracking. Passive attitudes toward step counting and disinterest in the rewards had also prevented deeper engagement. Enablers of engagement included self-monitoring and coaching features, while system targets and the implicit prospect of reward had fostered new physical activity behaviors.

**Conclusions:** Our study showed that as the NSC is implemented in this population, more emphasis should be placed on technical support and personalized activity targets to promote lasting behavior change.

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**KEYWORDS**

mHealth; physical activity; health promoting financial incentives; weight loss maintenance; young men



## Introduction

Physical inactivity has been identified as a major risk factor for noncommunicable disease, early mortality, and increasing health care costs [1-3]. An active lifestyle is considered essential to weight loss and weight loss maintenance [4-7]. To improve physical activity, interventions should be tailored, goal-oriented, and multifaceted [8,9]. Mobile health (mHealth) technologies have offered new opportunities to achieve this in clinical care [10], population health [11,12], and consumer wellness settings [13]. Moreover, the mHealth approach is thought to improve access for groups who experience stigma during physical activity, such as persons with obesity [14,15].

Clinical mHealth interventions commonly employ self-monitoring, goal setting coaching prompts, as well as games and competitions to drive the motivation to exercise [16-18]. However, strong evidence is still lacking on the effectiveness of these approaches in young adults [19,20]. Conversely, mHealth programs that feature health promoting financial incentives (HPFIs) have been shown to provide powerful extrinsic motivation in young persons and adults [21-24]. However, the moral underpinnings of offering a reward in return for health behaviors have been the subject of debate [25,26], and several studies have questioned whether HPFIs can produce sustained behavior change [27-30]. A recent paper has, however, characterized the relationship between physical activity behaviors and habits as bidirectional [31]. This means that once initiated by an HPFI [32,33], new behaviors such as activity tracking could reinforce physical activity habits and promote a virtuous cycle that persists even after the incentives have been discontinued.

One such mHealth initiative is the national steps challenge (NSC) which was first launched by Singapore's Health Promotion Board (HPB) in 2015 [34]. The NSC provided free access to a wrist-worn tracker that measured step counts and heart rate. Health points were awarded for attaining daily activity goals, and these could be converted to shopping or dining vouchers through a smartphone app, the Healthy 365 app. The system also featured back-end data linkages to accommodate 5 popular consumer tracking devices [35]. NSC incentives would lapse after 5 months, but enrollees would retain their trackers and free access to the Healthy 365 app.

In addition to its rollout to the general population, the NSC offered corporate programs to specific population groups. One such example was young men fulfilling national service obligations in the Singapore Armed Forces. During their basic training, all young men with a body mass index of 27.0 kg/m<sup>2</sup> or greater entered a 5-month residential weight loss program [36,37]. In December 2018, 1 intake of the residential program was offered to enroll in the NSC.

Many mHealth interventions experience a significant decline in active use [38], as reflected in quantitative systems data [39-41]. Decreasing [42] or insufficient engagement [43] have been cited as a possible explanation for such a decline. Current literature conceptualizes engagement with mHealth interventions as experiences and behaviors [44] that may vary between

individuals and over time [45]. To better contextualize mHealth engagement, 2 complementary levels have been proposed: an operational microlevel that comprised moment-to-moment use and a strategic macrolevel where behavior change in pursuit of behavioral goals occurred [46].

Specifically in the areas of obesity management and weight maintenance, gaps in our understanding of mHealth use and engagement remain [47]. A review of 23 studies examining technology in the management of obesity highlighted that while user experience was critical to technology acceptance [48], only 2 studies reported user satisfaction as an outcome [49].

The NSC presented a unique opportunity for our team to build on previous studies involving the residential weight loss program [50,51] and to aid our continuous efforts to promote physical activity in this group. In this mixed methods study, we therefore aimed to examine how qualitative engagement in the NSC could account for quantitative active use and discuss how the mHealth intervention might have changed physical activity behavior.

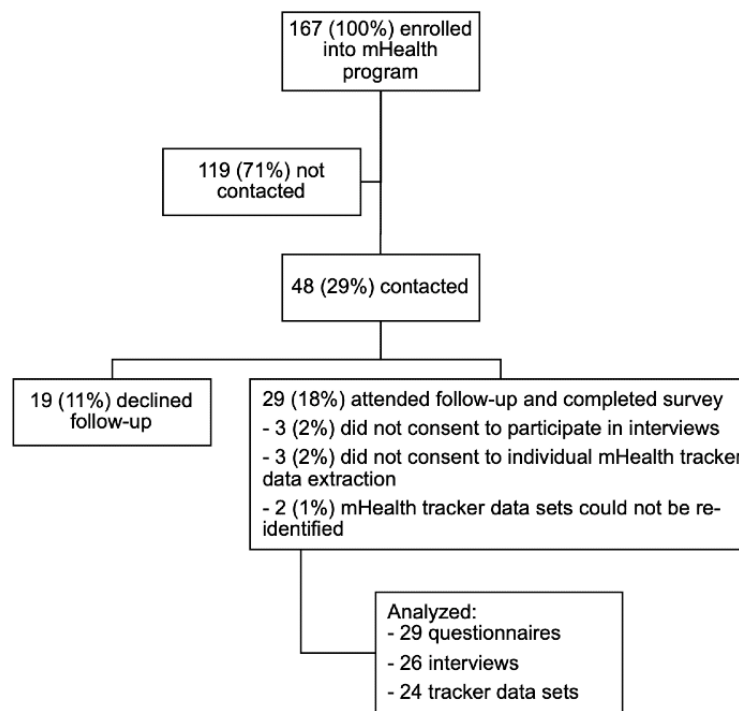
## Methods

### Study Protocol

Our mixed methods study protocol was approved by the Defence Science Organization of Singapore Armed Forces Institutional Review Board, reference 0010/2019. The quantitative component of this study examined longitudinal activity data, while the qualitative component comprised semistructured interviews. [Multimedia Appendix 1](#) summarizes the phases, procedures and products of data collection and analysis [52]. Our methodological orientation was a grounded theory approach that focused on lived experiences of study participants. We employed a concurrent triangulation of methods strategy followed by data integration to coalesce our study findings. Our research team comprised 2 male, normal-weight military physicians, 1 of whom had experience in qualitative methods. Analyses and reporting were guided by a third author with expertise in physical activity promotion.

### Study Population and Recruitment

In November 2018, 3 weeks before the end of the residential weight loss program, all 386 participants were invited to enroll in the NSC Season 4 (2018-2019) on a strictly voluntary basis. A cohort of 167 (43%) young men expressed interest and were issued the NSC tracker 2 weeks later. In June 2019, 6 months after the initial enrollment and 1 month after the official end of the NSC, the research team invited a convenience sample of 48 cohort members working in 6 different large military camp complexes to participate in our study. To be deemed eligible, they had to be at least 21 years old and provide written informed consent to complete a survey, participate in semistructured interviews, and provide their mHealth data ([Figure 1](#)). The research team reached out to potential candidates via email to their immediate superiors. Study visits were scheduled for weekday afternoons at the nearest military medical facility. Participation was strictly voluntary, and information would be handled confidentially. No honoraria were paid, but time off from work was granted for the duration of the study visit.

**Figure 1.** Recruitment for follow-up study, 6 months after enrollment into the national steps challenge.

## Quantitative Component

### Quantitative Data

HPB Singapore provided our research team week-by-week summary data for the 167 cohort members. Active use was defined as a participant who registered at least 1 day with a nonzero step count for a given week. Days with zero steps were treated as missing data and excluded from the computation of average daily step counts. For the subset of consenting study participants, HPB released individually identifiable data that reflected step counts on a day-by-day level. Our questionnaire covered basic demographic information, the Behavioral Regulation in Exercise Questionnaire (BREQ-3) [53-55] and the International Physical Activity Questionnaire Short Form (IPAQ-SF) [56].

### Quantitative Analysis

We retained HPB's definition of active use for the 167 cohort members and displayed weekly numbers of active users along with their average daily step counts graphically. To examine individually identifiable active use data more closely, we adopted a threshold of at least 1500 registered steps to indicate a valid day of active use [57]. In this group, nonvalid days of active use were treated as missing data and excluded from further reporting.

## Qualitative Component

### Interviews

Semistructured interviews followed a topic guide that was developed specifically for this study (Multimedia Appendix 2). Interviewers introduced themselves as medical professionals examining the effects of the NSC, soliciting open feedback, and exploring the lived experience. All interviews were conducted

in a private room, recorded digitally, and transcribed by members of the research team.

### Qualitative Data Management

First, 1 of the authors reviewed handwritten field notes and transcripts and coded key information according to the topic guide. In a second round of coding, interviewees' experiences using the trackers, synchronizing data, and responding to coaching prompts were coded as microlevel engagement. Interviewees' attitudes and behaviors that reflected involvement in the behavior change process (eg, related to daily goal setting, accumulation of health points, and redemption of rewards) were coded as macrolevel engagement. In a third round of coding, enablers were identified as circumstances that favored engagement or situations where engagement resulted in positive emotions or perceived benefits. Barriers were identified as circumstances that inhibited engagement or situations where engagement resulted in negative emotions or perceived loss.

### Data Triangulation, Mixing, and Integration

In a triangulation of methods [58], we produced individual timeline plots to visually validate self-reported active use and categorize the duration of active use. A "short-term user" had accumulated less than 14 weeks of active use while a "sustained user" would have recorded or reported active use that was 14 weeks or longer. BREQ-3 scores, IPAQ-SF outcomes, anthropometric measurements, and barriers and enablers to engagement were reported by category of active use. Anthropometric data were compared using unpaired *t* tests, while ordinal nonparametric BREQ-3 and IPAQ-SF data were analyzed using the Mood median test with  $P=.05$  as the chosen level of statistical significance. Integration of findings provided a coherent narrative on active use and engagement before discussing changes in physical activity behavior.

All quantitative analyses were conducted using Stata 13 (Stata Corp LLC). Qualitative data were collated and analyzed using NVivo 12 (QSR International). We used the Consolidated Criteria for Reporting Qualitative Research and the Good Reporting of a Mixed Methods Study checklists when compiling this manuscript [59,60].

## Results

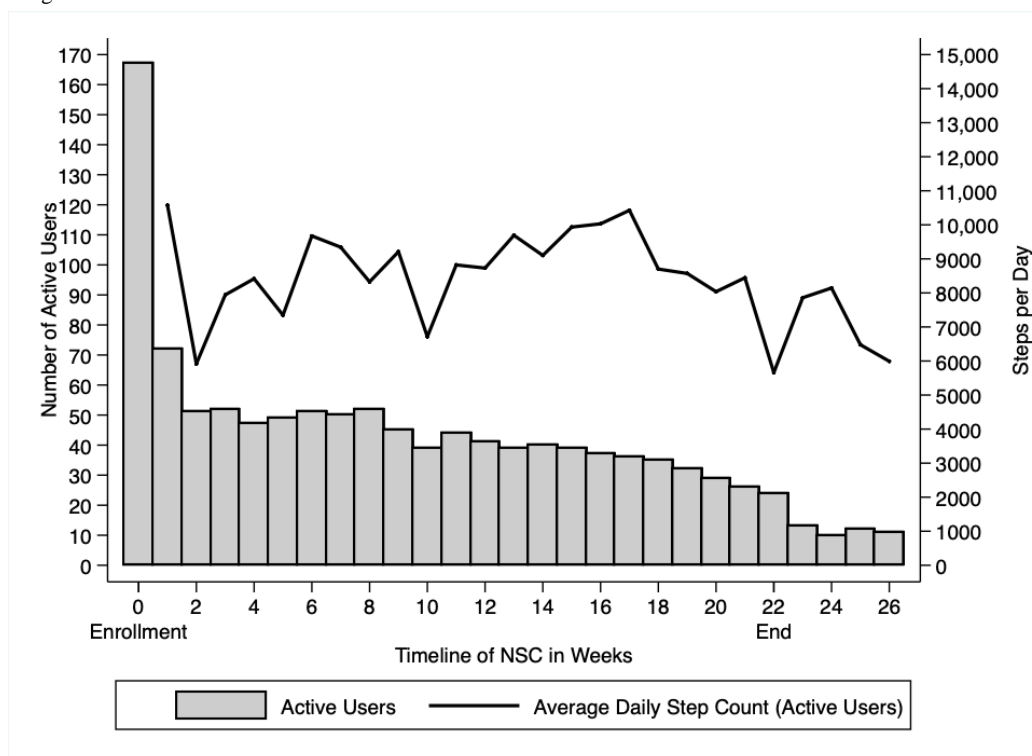
### Quantitative Results

mHealth system data showed that, in the first week, 72 (43%) of the initial 167 enrolled users were actively recording step counts on a daily basis. On average, these users had walked 10,576 steps per day (Figure 2), excluding days of inactive use

when zero steps had been registered. Thereafter, the number of active users declined steadily over the course of the NSC with only 27 (17%) of users recording any steps in the final week.

From the 48 invited users, we recruited 29 participants, 21 to 25 years old, for the follow-up visit at 6 months (Table 1). However, 3 participants (P, U, and X) did not provide informed consent to contribute tracker data, and 2 participants (J and Z) who had provided consent could not be reidentified as registered users on the NSC. A total of 24 tracker data sets were thus available for detailed quantitative reporting and analysis. Of the 1357 person-days with nonzero step counts, 1070 (78.9%) were designated as valid days of mHealth use (Multimedia Appendix 3).

**Figure 2.** Active users registered in the national steps challenge (gray bars) and their average daily step count (line) by week of enrollment. NSC: national steps challenge.



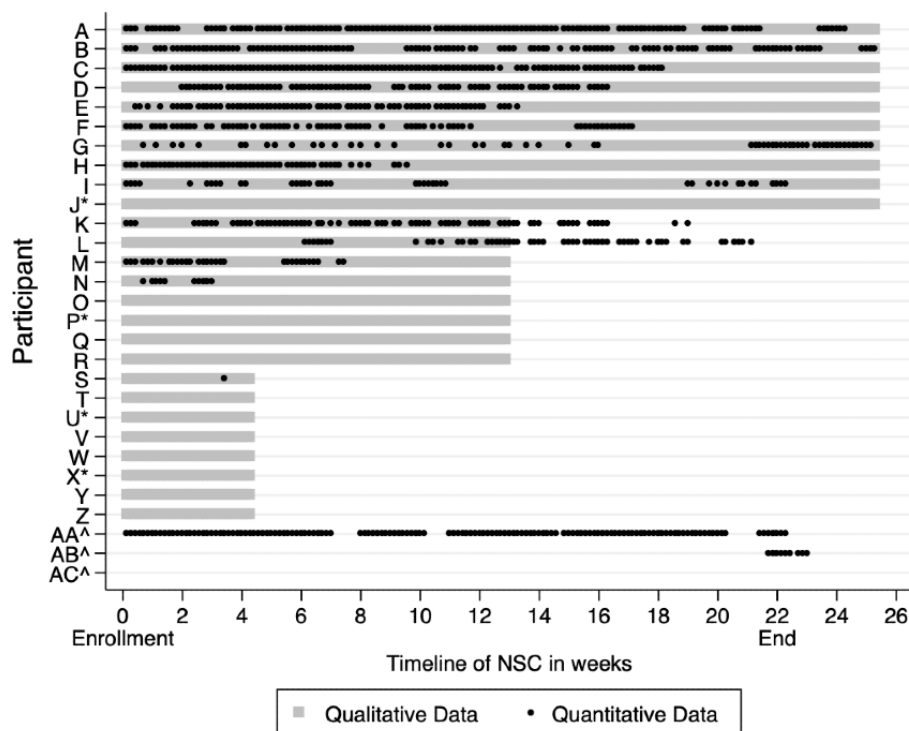
**Table 1.** Descriptive statistics for n=29 study participants.

Characteristics	Values	
	Sustained users (n=13), n (%)	Short-term users (n=16), n (%)
<b>Ethnicity</b>		
Chinese	8 (62)	11 (69)
Malay	2 (15)	1 (6)
Indian	1 (8)	2 (13)
Others	2 (15)	2 (13)
<b>Education</b>		
Technical or “O” levels equivalent	0 (0)	2 (13)
Polytechnic or “A” levels equivalent	13 (100)	14 (88)
<b>Smoking</b>		
Non-smoker and ex-smoker	9 (69)	14 (88)
Smoker	2 (15)	4 (25)

Combined quantitative and qualitative data (Figure 3) allowed us to categorize participants A to L and AA as “sustained users” while participants M to Z, AB, and AC were categorized as “short-term users.” Overall, sustained users expressed a higher level of agreement with BREQ-3 statements in the autonomous

spectrum of motivations to exercise (identified, integrated, and intrinsic), greater levels of activity recorded on the IPAQ-SF, and marginally lower levels of weight regain than those interviewees categorized as short-term users (Table 2). These differences, however, were not statistically significant.

**Figure 3.** Recorded (black dots) and self-reported (gray bars) duration of active use in n=29 participants; \* denotes participants who did not consent to or failed in the retrieval of tracker data; ^ denotes participants who declined to interview. NSC: national steps challenge.



**Table 2.** Motivations to exercise, levels of activity, and anthropometric measures for n=29 study participants.

Median measures	Overall (n=29)	Sustained users (n=13)	Short-term users (n=16)	P values
<b>BREQ-3<sup>a</sup> median score (IQR)</b>				
Amotivation	1.38 (1-2)	1.25 (1-1.5)	1.5 (1-2.5)	.26 <sup>#</sup>
External regulation	2.5 (2.25-3)	2.75 (2.5-3)	2.25 (2-3)	.14 <sup>#</sup>
Introjected regulation	3.25 (2.75-3.63)	3.25 (3-3.75)	3 (2.25-3.25)	.14 <sup>#</sup>
Identified regulation	3.75 (3.25-4.13)	3.75 (3.5-4.25)	3.25 (2.75-4)	.28 <sup>#</sup>
Integrated regulation	2.75 (2.25-3.13)	2.75 (2.25-3.5)	2.75 (2.25-3)	.74 <sup>#</sup>
Intrinsic motivation	3.25 (3-3.75)	3.5 (3.25-3.75)	3 (2.75-3.5)	.14 <sup>#</sup>
<b>IPAQ-SF<sup>b</sup> median time in min/day (IQR)</b>				
Sitting	360 (270-540)	360 (300-480)	420 (210-600)	.31 <sup>#</sup>
Walking	130 (50-385)	140 (105-350)	60 (0-420)	.71 <sup>#</sup>
MVPA <sup>c</sup>	15 (0-47)	34 (9-51)	9 (0-30)	.26 <sup>#</sup>
<b>Mean weight measures, kg (SD)</b>				
Upon entry into residential program	99.4 (11.0)	97.4 (14.0)	101 (8.0)	.40 <sup>^</sup>
Upon enrollment into NSC <sup>d</sup>	83.8 (10.4)	81.9 (13.7)	85.4 (6.6)	.38 <sup>^</sup>
At time of study	89.2 (10.2)	86.8 (12.7)	91.1 (7.7)	.26 <sup>^</sup>
<b>Mean change in weight, kg (SD)</b>				
From entry into residential program to NSC enrollment	-15.6 (4.1)	-15.5 (4.9)	-15.6 (3.4)	.94 <sup>^</sup>
From NSC enrollment to follow-up study	5.3 (4.5)	4.9 (5.6)	5.7 (3.5)	.61 <sup>^</sup>
<b>Mean BMI, kg/m<sup>2</sup> (SD)</b>				
Entry into residential program	33.0 (3.2)	32.8 (3.5)	33.2 (2.9)	.72 <sup>^</sup>
NSC enrollment	27.9 (2.9)	27.6 (3.7)	28.1 (2.3)	.64 <sup>^</sup>
Follow-up study	29.6 (3.1)	29.3 (3.8)	30.0 (2.5)	.56 <sup>^</sup>

<sup>a</sup>BREQ-3: Behavioral Regulation in Exercise Questionnaire 3.

<sup>b</sup>IPAQ-SF: International Physical Activity Questionnaire Short Form.

<sup>c</sup>MVPA: moderate-to-vigorous physical activity.

<sup>d</sup>NSC: national steps challenge.

<sup>#</sup>Using the Mood median test with the Pearson chi-squared statistic.

<sup>^</sup>Using the unpaired *t* test.

## Qualitative Results

Of the 29 participants, 3 (AA, AB, and AC) declined to participate in the qualitative segment of our study, meaning 26

semistructured interviews comprising a total of 6 hours and 27 minutes of recordings were available for analysis. An overview of barriers and enablers of microlevel and macrolevel engagement is provided in [Table 3](#).



**Table 3.** Overview of barriers and enablers elicited from n=26 interviews.

Barriers and enablers	Sustained users (n=12), n (%)	Short-term users (n=14), n (%)
<b>Microlevel barriers</b>		
Workplace safety regulations requiring clean wrists	1 (8)	3 (21)
Removal of hard objects for contact sport	2 (17)	1 (7)
Device failure, short battery life, frequent charging	2 (17)	3 (21)
Problems performing pairing of tracker with smartphone and problems synchronizing data through cellular network	3 (25)	7 (50)
Switch to a new tracker or wearable device	8 (67)	9 (64)
<b>Microlevel enablers</b>		
Use of tracker as a watch	1 (8)	5 (36)
Visualization of cumulative step counts	5 (42)	6 (43)
Convenient means of monitoring heart rate and exercise intensity	4 (33)	2 (14)
Tracker-based coaching prompts	4 (33)	3 (21)
<b>Macrolevel barriers</b>		
Passive attitude toward step count tracking	8 (67)	3 (21)
Sense of fairness or discomfort tracking incidental physical activity	1 (8)	1 (7)
Psychological pressure to make steps count, be active, or attain goals	1 (8)	1 (7)
Disinterest in the types of rewards	4 (33)	5 (36)
<b>Macrolevel enablers</b>		
Redeemed at least one reward	10 (83)	4 (29)
Desire to maximize daily health points by adopting NSC <sup>a</sup> targets	5 (42)	0 (0)
Personalized goal setting beyond system targets	5 (42)	0 (0)

<sup>a</sup>NSC: national steps challenge.

### Barriers to Microlevel Engagement

A multitude of extrinsic and intrinsic factors led to the temporary removal or abandonment of the trackers. Some users overcame technical challenges simply by using the tracker in an offline mode thus forgoing data synchronization and rewards but retaining some of the basic features such as goal setting and self-monitoring. The chief reason for device switching was personal preference, given that more advanced devices generally offered additional functionality. Several users reported difficulty linking their new devices with the Healthy 365 platform, and only 1 sustained user reported that he had accumulated health points using his new tracker.

### Enablers of Microlevel Engagement

Some users had been extrinsically motivated to don the tracker as it had become their primary means of telling time. Activity tracking and coaching features were intrinsically enabling, leading some users to report that tracking had become part of their exercise routine.

*The tracker kind of makes you conscious of what you're doing. [Q: short-term user]*

### Barriers to Macrolevel Engagement

Some users had adopted a passive mindset in relation to the mHealth system, allowing steps to accrue throughout the day

without monitoring their levels of activity. A few users only wore their trackers for structured exercise because they felt it was unfair to track incidental physical activity in the context of the NSC. Others experienced psychological pressure when using the mHealth system. Some users expressed disinterest in the rewards, and even a few sustained users felt they did not trigger any change in behavior. Other users openly questioned the morals of HPFIs.

*[Concerning] rewards, I think it really depends on the person. Do they run because they want some reward or is it because of a more personal target? ... I would say I run because I like to run, not for anything else. [J: sustained user]*

### Enablers of Macrolevel Engagement

Some sustained users internalized the NSC's daily step target by developing interim targets that they could monitor throughout the day. Some described an autonomous process of setting personal step count or intensity targets that went beyond NSC thresholds. Others would even adopt a competitive mindset, either to outdo a previous level of activity or to outperform their peers. Most users reflected on HPFIs in transactional terms. This meant that the motivation to exercise and track their levels of activity diminished once the opportunity to earn vouchers had ceased. One participant, however, felt the incentives had

outlived their purpose once he had become habituated to goal setting.

*Right now, it's kind of ingrained in me. Right now, I'm not even thinking about the vouchers. Right now, it's just keeping fit. For me that's the greatest reward.*  
[C: sustained user]

## Discussion

### Main Findings

Triangulation of methods uncovered that quantitative systems data alone painted an incomplete picture of active use among young men with obesity enrolled in the NSC. Our qualitative findings on barriers to microlevel and macrolevel engagement also demonstrated why a user might have failed to benefit from the NSC. Insights into enablers provided a mechanistic understanding of how the NSC initiated and inculcated new physical activity habits for a subset of users. Through further integration of findings, we shall now discuss the context of active use and engagement before examining how the NSC might have changed in physical activity behavior.

### Context of Active Use

Given the variety of wearable tracking systems and mHealth apps available outside the NSC, it was not implausible that users would consider switching systems [61,62]. It is possible that upgrades and patches to operating systems might have disrupted back-end data linkages. Device switching and other forms of offline use would therefore have contributed an apparent decline in quantitative active use even though the desired behaviors were still being produced [63]. Given this context, it follows that the subsequent interpretation of engagement could still be considered internally consistent despite what a strict interpretation of objective active use might have suggested [64].

### Context of Engagement

#### Self-monitoring and Goal Setting

Our findings have reinforced the notion that tracking devices on their own provided a feasible and acceptable means of self-monitoring and physical activity promotion [65]. While the NSC had prompted users to initiate, intensify, or extend physical activity [66], we suspect that generic performance targets might have also created a false ceiling in some sustained users [67]. Furthermore, it is plausible that inappropriate norms may have created negative feedback [68,69] or insecurity [70] among short-term users. Personalized goal setting, which has been a mainstay of physical activity promotion especially for weight loss maintenance, was exhibited by only a small number of users [71]. In this context, a shift in the goal setting strategy toward relative or personalized goals might enhance engagement.

#### Health Promoting Financial Incentives

At the macro level, health points had provided a virtual positive feedback loop that emulated customer loyalty program where membership, participation, and continued accrual of currency create their own intangible reward [72,73]. Even though only a minority of health points had been redeemed, interview data

suggested that the system of HPFIs had communicated and reinforced a small but tangible external benefit of being physically active [74]. It was plausible that a less transactional or more attractive HPFI strategy (eg, a lottery [75] or endowment [76]) might have elicited higher enrollment, active use, and engagement.

### Lasting Behavior Change

Self-monitoring behaviors are thought to diminish at the end of an intervention [77] while goal setting strategies are considered more durable [78]. Once HPFIs had been discontinued, some sustained users may have stopped tracking because of a loss of so-called habitual exercise instigation [79]. This means that bidirectional tracking and physical activity behaviors were still contingent on HPFIs. Alternatively, facing the prospect of a definite end point, some short-term and sustained users might have preemptively dissociated from the NSC by going offline or switching devices. These actions demonstrated an intent to extend self-monitoring and goal setting behaviors and are consistent with habit formation [80,81]. An apparent decline in active use should therefore be anticipated in population health settings.

### Study Implications

Our study focused on a segment of the population that was not only at greater risk of the effects of inactivity, but also stood to reap real benefits from behavior change interventions such as the NSC [82]. These formative research findings have already aided our continuous efforts to promote physical activity in this group. We have also identified that pervasive offline use and device switching merit further investigation. Without due consideration for these phenomena, past studies that relied on quantitative mHealth data alone to categorize users [42] or to define nonuse attrition [43] might have inadvertently introduced misclassification biases that would have reduced the overall effect size or underestimated the public health impact of the interventions in question.

### Strengths and Limitations

Objective tracker data were triangulated with subjective interview data to improve the accuracy and validity of our findings. By focusing on the barriers and enablers to engagement, we were able to examine and discuss the varied context of lived experiences engaging in the NSC.

Our study was affected by several limitations arising from the choice of study population and protocol. The participants were recruited in the context of national service, thus limiting the generalizability of our findings. By conducting semistructured interviews near the workplace, we may have inadvertently introduced information biases that would have favored public initiatives. Moreover, social desirability biases may have prevented enrollees with low mHealth use from participating in the study.

### Conclusion

Our study described how young men with obesity experienced an mHealth initiative promoting physical activity. We recognized that a decline in active use had occurred in the context of tracker abandonment, offline use, widespread device

switching, and occasional dissatisfaction with the NSC. Sustained users experienced engagement predominantly in the context of goal setting whereby HPFIs communicated the tangible benefit of a healthy lifestyle. As the NSC is implemented in this population, more emphasis should be placed on technical support and personalized activity targets to promote lasting behavior change.

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## Authors' Contributions

AWG conceived this study and performed data collection, coding, and analyses before drafting the manuscript. WCDC assisted in data collection and coding. FMR supervised the research activities and reviewed the manuscript.

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## Conflicts of Interest

None declared.

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### Multimedia Appendix 1

Phases, procedures, and products of data collection and analysis.

[[PNG File, 278 KB - formative\\_v6i1e33798\\_app1.png](#)]

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### Multimedia Appendix 2

Topic guide and associated codes for the conduct and analysis of semistructured interviews.

[[DOCX File, 28 KB - formative\\_v6i1e33798\\_app2.docx](#)]

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### Multimedia Appendix 3

Qualitative and quantitative data outlining use of the national step challenge among n=29 study participants.

[[DOCX File, 33 KB - formative\\_v6i1e33798\\_app3.docx](#)]

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## Abbreviations

**BMI:** body-mass index

**BREQ-3:** Behavioral Regulation in Exercise Questionnaire 3

**HPB:** Health Promotion Board

**HPFI:** Health Promoting Financial Incentive

**IPAQ-SF:** International Physical Activity Questionnaire Short Form

**mHealth:** mobile health

**NSC:** national steps challenge

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Original Paper

# Mobile Phone App Use Among Pregnant Women in China and Associations Between App Use and Perinatal Outcomes: Retrospective Study

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## Abstract

**Background:** Maternal and child health (MCH)-related mobile apps are becoming increasingly popular among pregnant women; however, few apps have demonstrated that they lead to improvements in pregnancy outcomes.

**Objective:** This study aims to investigate the use of MCH apps among pregnant women in China and explore associations with pregnancy outcomes.

**Methods:** A retrospective study was conducted at 6 MCH hospitals in northern China. Women who delivered a singleton baby at >28 weeks' gestation at the study hospitals were sequentially recruited from postnatal wards from October 2017 to January 2018. Information was collected on the women's self-reported MCH app use during their pregnancy, along with clinical outcomes. Women were categorized as nonusers of MCH apps and users (further divided into intermittent users and continuous users). The primary outcome was a composite adverse pregnancy outcome (CAPO) comprising preterm birth, birth weight <2500 g, birth defects, stillbirth, and neonatal asphyxia. The association between app use and CAPO was explored using multivariable logistic analysis.

**Results:** The 1850 participants reported using 127 different MCH apps during pregnancy. App use frequency was reported as never, 24.7% (457/1850); intermittent, 47.4% (876/1850); and continuous, 27.9% (517/1850). Among app users, the most common reasons for app use were health education (1393/1393, 100%), self-monitoring (755/1393, 54.2%), and antenatal appointment reminders (602/1393, 43.2%). Nonusers were older, with fewer years of education, lower incomes, and higher parity ( $P<.01$ ). No association was found between *any app* use and CAPO (6.8% in nonusers compared with 6.3% in any app users; odds ratio 0.77, 95% CI 0.48-1.25).

**Conclusions:** Women in China access a large number of different MCH apps, with social disparities in access and frequency of use. *Any app* use was not found to be associated with improved pregnancy outcomes, highlighting the need for rigorous development and testing of apps before recommendation for use in clinical settings.

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## KEYWORDS

maternal and child health; mHealth; mobile apps; retrospective study; pregnancy outcomes

## Introduction

### Background

In the past 2 decades, while maternal and child health (MCH) has greatly improved in China [1], prevention of preterm birth, neonatal asphyxia, birth defects, and low birth weight remain challenging. With mobile phone penetration growing rapidly, mobile health (mHealth) technology is being increasingly used and recognized as a tool that can improve access to, and use of, health services, including in MCH [2-6]. Thousands of MCH mobile apps are available, with millions of downloads [6-9]. Although most research in this area has focused on feasibility and acceptability studies, [9-14] mHealth could be a valuable tool for strengthening health systems [15,16].

There is evidence to support that specific apps can improve antenatal and postnatal service use [6,17-19], diet and gestational weight gain [20-22], blood glucose control in gestational diabetes [23], exclusive breastfeeding [6,24], mental health [25-28], and maternal and perinatal mortality in rural and resource-poor settings [29-31]. The main features of MCH apps include health education, pregnancy planning, engagement with care, self-monitoring, and peer support. If women engage fully with these activities throughout pregnancy, it is plausible that this could improve important perinatal outcomes. However, evidence for this is limited [32,33].

China has a fast-growing market for MCH-related apps. A 2018 survey on maternal and infant apps identified 17 apps with more than 1 million monthly active users [34]. MCH apps in China are most frequently used for sharing parenting experiences, gestation-specific knowledge and tools, baby growth records, questions and answers about pregnancy and child health, social connections, and e-commerce [35]. In an in-depth review of market MCH apps conducted in 2018, we identified more than 6000 MCH-related apps in the Android and iOS app stores. Most are commercial apps, offering multiple features; however, despite their popularity, there is no published evidence regarding their effects on pregnancy outcomes [7].

### Objective

We hypothesized that app use during pregnancy would improve women's engagement with formal maternity services and self-care and that this in turn would improve perinatal outcomes. The major objective of this study is to explore the use of MCH apps among pregnant Chinese women and explore the associations between app use and adverse outcomes at birth.

## Methods

### Study Design

This was a retrospective study investigating the associations between self-reported use of MCH apps and adverse pregnancy outcomes.

### Settings and Recruitment of Participants

Postnatal wards at 6 MCH hospitals were selected from Beijing and Hebei Province. The hospitals included 1 urban city hospital (Shijiazhuang), 4 suburban district hospitals (Huairou, Pinggu, Luquan, and Daxing), and 1 rural county hospital (Gaoyang). All women admitted to the selected postnatal ward at each study hospital were approached by a trained research physician before discharge. Women were eligible if they had delivered a singleton baby at >28 weeks' gestation during the study period (from October 2017 to January 2018) and gave consent to participate in the study. Women with severe pre-existing disease such as cardiac disease, systemic lupus erythematosus, or malignant tumors were excluded because these conditions are independently associated with poorer perinatal outcomes.

### Data Collection for Events and Exposures

A structured questionnaire was designed to ascertain use of MCH apps during pregnancy ([Multimedia Appendix 1](#)). After piloting and refinement, the final questionnaire comprised 10 items ([Multimedia Appendix 1](#)), and it took 5-8 minutes to complete. The questionnaire was administered by trained research doctors in the postnatal wards to all the eligible women after the delivery of their baby, when, being the postpartum period, they were relatively relaxed and cooperative. Considering the good compliance, participation was voluntary, with no monetary or other incentives. Antenatal and perinatal outcomes were extracted directly from medical records into a case report form by the research doctors. Data covered in the case report form included (1) medical and pregnancy history, including previous pregnancy complications and adverse outcomes; (2) maternal antenatal screening results, including height, weight, and blood pressure; and (3) pregnancy outcomes, including gestational age at birth in weeks and days, delivery mode, birth weight in grams, and pregnancy and birth complications for the women and the babies.

Several measures were taken to avoid selection bias for both app use and pregnancy outcomes. We sequentially recruited all women from 1 general postnatal ward at each study hospital to minimize selection bias. Standard training was conducted for the research doctors at each hospital regarding study protocol and quality control for data collection. The participating women and research doctors were not aware of the study hypothesis.



Regular site visits and data inspection were conducted by 2 inspectors from the research team to ensure the completeness and accuracy of outcome information in comparison with hospital records.

### Definition of MCH Apps, App Features, and User Categories

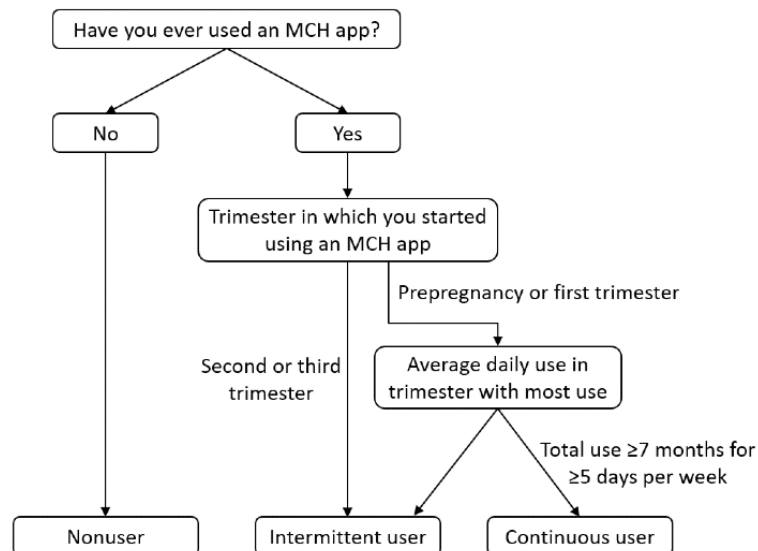
We defined an MCH app as any mobile phone app aiming to improve knowledge, behaviors, self-care, and antenatal health services use during pregnancy. Specific features of these apps include health education and promotion, physical or biodata monitoring, reminders, web-based counseling, communication, appointment making, laboratory result checking, and payments [3]. The app could be designed exclusively for use in pregnant women (MCH specialized app), or it could be a multipurpose app embedded with MCH features. We included both commercial and government and noncommercial apps.

The adopted features were counted for each app based on a previously published classification system of 23 categories [7].

The most relevant are health education, counseling, financial transactions and incentives, health status self-monitoring, reminders, appointment making, client-to-client communication, laboratory result checks, diary, shopping, games, and hospital service promotion. As most apps contained >1 feature, for the purpose of analysis, all apps were considered in aggregate.

Figure 1 shows the procedure we followed to categorize the women according to their responses to the following questions: Have you ever used an MCH app during pregnancy? When (which trimester) did you start using it? How long have you been accumulatively using the app since starting use (month)? Which trimester did you use the MCH app most? How many days did you use it every week during the most frequently used trimester? In summary, nonusers were defined as women who did not use any MCH app. App users were further categorized into continuous users if they reported using  $\geq 1$  MCH apps almost every day during the entire pregnancy and intermittent users if they reported less frequent or shorter durations of use.

**Figure 1.** The categorization of women users of maternal and child health apps. MCH: maternal and child health.



### Definitions of Outcomes

Because of the anticipated low incidence of severe adverse pregnancy outcomes, a composite adverse pregnancy outcome (CAPO) was used as the primary outcome for minimum sample size estimation and analysis. The CAPO comprised premature birth (delivery at  $\leq 37$  completed weeks of gestation), low birth weight (<2500 g), birth defects (Chinese National Criteria of Birth Defects and Tiny Deformities [36]), stillbirth (World Health Organization definition [37]), and neonatal asphyxia (experts' consensus in China [38]). The CAPO was developed as an unweighted index, with a case being defined as  $\geq 1$  of any of the aforementioned adverse outcomes assessed. The diagnosis of the individual pregnancy outcome was made by obstetricians at the participating hospitals during routine practice.

The exploratory outcomes included (1) CAPO incidence among 3 user groups (nonusers, intermittent users, and continuous users), (2) incidence of macrosomia (baby weighing  $\geq 4000$  g), and (3) incidence of each of the component outcomes of CAPO.

### Sample Size and Statistical Analysis

We estimated the CAPO rate in this population to be 15% to calculate the sample size. This was based on the reported incidences of the component outcomes of CAPO, including low birth weight (8.1%) [39], preterm birth (6.94%) [40], neonatal asphyxia (3.78%) [41], birth defects (1.92%) [36], and stillbirth (0.95%) [42], in China. Assuming that the estimated baseline CAPO rate is 15% and most participants (we assumed two-thirds) are MCH app users, at least 1800 participants (600 nonusers and 1200 overall users) would need to be recruited to explore an absolute decrease in CAPO by 5% for MCH app users compared with nonusers, with a power of no less than 80% and significance level of 5%, calculated by PASS 11 software (NCSS, LLC).

The characteristics of the participants were described as categorical variables and expressed as numbers and percentages. The proportion of women who started using an MCH app and used an app most frequently within each pregnancy trimester was described as a bar graph. The Pearson chi-square test was



performed to compare the difference in incidence of CAPO (primary outcome) and other indicators (exploratory outcomes) between MCH app users and nonusers and among the 3 app use groups. Logistic regression analysis was performed to analyze associations between the use of MCH apps and pregnancy outcomes after controlling for confounders, including hospital, age, education level, household income level, parity, gravidity, and history of cesarean section. Abortion was excluded in the model because of its strong collinearity with gravidity and parity. History of hypertension and diabetes was also excluded to avoid overadjustment because blood pressure and blood glucose level might be on the causal chain from app use to CAPO. We did not use log binomial regression and Poisson regression because of convergence issues and because the log-likelihood value cannot be further improved, respectively. Heterogeneity among the different hospitals (the 6 hospitals) and 2 hospital levels (Shijiazhang city hospital and other suburban and rural hospitals) was analyzed by examining the interaction effect of (hospital)×(app user group) and (hospital level)×(app user group), respectively, based on the logistic regression model. We conducted a complete case analysis, with no imputation for missing variables. Sensitivity analyses were conducted to determine if there was any association of app brand, gestational age when app use was started, and intensity of use (continuous daily use vs intermittent use) with CAPO and macrosomia. All data analyses were performed with SAS (version 9.4; SAS Institute).

### Ethical Approval and Informed Consent

The study protocol was approved by the ethics committee of Peking University on September 19, 2017. Verbal informed

consent was obtained from all participants included in the study. Identifiable personal information was not collected; all data were kept confidential and safe according to the internal data security policy of the George Institute for Global Health, and they were only accessible to authorized researchers.

## Results

### Characteristics of Participants

During the recruitment period, there were 1882 postnatal women admitted to the participating wards at the 6 hospitals. Of the 1882 women, we excluded 7 (0.4%) who refused participation, 10 (0.5%) who had multiple pregnancies, 13 (0.7%) who delivered at <28 weeks' gestation, and 2 (0.1%) who had severe disease, leaving 1850 women in the study. The participants were aged 18-45 years, with an average age of 29.6 (SD 4.4) years. Detailed characteristics of the participants are described in the nonuser and user (continuous and intermittent) categories in [Table 1](#).

Approximately three-fourths (1393/1850, 75.3%) of the women reported using MCH apps during pregnancy. Of the 1393 users, 876 (62.9%) were intermittent users and 517 (37.1%) were continuous users. Apart from the women at Pinggu MCH hospital, where an app was required for antenatal appointments, most of the other participants fell into the category of intermittent users. Age, education, household monthly income, gravidity, parity, history of cesarean section, and incidence of gestation diabetes differed ( $P<.001$ ) among the MCH app user groups. In general, nonusers had less education and household income, were older, and had experienced more previous pregnancies ([Table 1](#)).

**Table 1.** Characteristics of participants by maternal and child health (MCH) app user groups (N=1850).

Characteristics	Total, n (%)	Nonusers (n=457), n (%)	Intermittent users (n=876), n (%)	Continuous users (n=517), n (%)
<b>MCH hospitals<sup>a</sup></b>				
Huairou	254 (13.7)	61 (24)	141 (55.5)	52 (20.5)
Gaoyang	267 (14.4)	105 (39.3)	104 (39)	58 (21.7)
Pinggu	347 (18.8)	92 (26.5)	46 (13.3)	209 (60.2)
Luquan	243 (13.1)	32 (13.2)	188 (77.4)	23 (9.5)
Daxing	257 (13.9)	35 (13.6)	162 (63)	60 (23.3)
Shijiazhuang	482 (26.1)	132 (27.4)	235 (48.8)	115 (23.9)
<b>Age<sup>a</sup> (years)</b>				
18-24	228 (12.3)	36 (15.8)	114 (50)	78 (34.2)
25-34	1351 (73)	321 (23.8)	648 (48)	382 (28.3)
35-45	271 (14.6)	100 (36.9)	114 (42.1)	57 (21)
<b>Education level<sup>a</sup></b>				
Middle school or below	475 (25.7)	199 (41.9)	178 (37.5)	98 (20.6)
High school	451 (24.4)	101 (22.4)	235 (52.1)	115 (25.5)
College	487 (26.3)	81 (16.6)	259 (53.2)	147 (30.2)
University or above	437 (23.6)	76 (17.4)	204 (46.7)	157 (35.9)
<b>Household monthly income<sup>a</sup></b>				
<RMB ¥3000 <sup>b</sup>	331 (17.9)	119 (36)	159 (48)	53 (16)
RMB ¥3000-RMB ¥4999 <sup>c</sup>	872 (47.1)	216 (24.8)	415 (47.6)	241 (27.6)
RMB ¥5000-RMB ¥9999 <sup>d</sup>	475 (25.7)	89 (18.7)	232 (48.8)	154 (32.4)
≥RMB ¥10,000 <sup>e</sup>	172 (9.3)	33 (19.2)	70 (40.7)	69 (40.1)
<b>Gravidity<sup>a</sup></b>				
1	493 (26.6)	64 (13)	279 (56.6)	150 (30.4)
2	586 (31.7)	139 (23.7)	272 (46.4)	175 (29.9)
3	453 (24.5)	137 (30.2)	194 (42.8)	122 (26.9)
≥4	318 (17.2)	117 (36.8)	131 (41.2)	70 (22)
<b>Parity<sup>a</sup></b>				
0	695 (37.6)	84 (12.1)	364 (52.4)	247 (35.5)
1	1076 (58.2)	333 (30.9)	481 (44.7)	262 (24.3)
≥2	79 (4.3)	40 (50.6)	31 (39.2)	8 (10.1)
<b>History of cesarean section<sup>a</sup></b>				
No	1431 (77.4)	320 (22.4)	686 (47.9)	425 (29.7)
Yes	419 (22.6)	137 (32.7)	190 (45.3)	92 (22)

<sup>a</sup> $P < .001$  for differences among the subgroups based on Pearson chi-square test.

<sup>b</sup>US \$472.2.

<sup>c</sup>US \$472.2-US \$786.8.

<sup>d</sup>US \$787-US \$1573.8.

<sup>e</sup>US \$1574.

## MCH App Use

Among the 1393 MCH app users, 1003 (72%) used 1 app, 319 (22.9%) used 2 apps, and 71 (5.1%) used 3 apps during pregnancy. In total, 127 MCH apps were reported as being used. The most popular app was *Baby Tree*, which was used by 51.3% (715/1393) of the women; followed by *Meet You*, 27.6% (385/1393); *Pregnant Partner*, 10.3% (144/1393); *Daxing MCH Hospital WeChat Official Account*, 10.1% (140/1393); *Mom Bang*, 5% (69/1393); and others, 28.8% (401/1393). *Daxing MCH Hospital WeChat Official Account* is a not-for-profit applet developed by the MCH hospital and based on a social media platform, *WeChat*, and exclusively used by pregnant women registered at Daxing Hospital. The rest were commercial apps.

All the top 5 apps included health education and promotion as well as payment features. Except for *Daxing MCH Hospital WeChat Official Account*, the apps also included features related to antenatal reminders, health status self-monitoring, peer communication, counseling, and diary. Most (1136/1393, 81.6%) of the women app users used  $\geq 2$  features. The top 3 app features used were health education (1393/1393, 100%), health status self-monitoring (755/1393, 54.2%), and antenatal clinic appointment reminders (602/1393, 43.2%). [Multimedia Appendix 2](#) shows the detailed features of the 5 most frequently used apps.

Among the MCH app users, most women started using the apps quite early during the pregnancy, with approximately 1 in 5 (267/1393, 19.2%) starting before pregnancy, two-thirds (921/1393, 66.1%) starting during the first trimester, and only a small proportion (205/1393, 14.7%) starting later during the second and third trimesters. As their pregnancy progressed, women reported more frequent use of the apps. The proportion of women who reported using the app most frequently increased from 4.2% (58/1393) during prepregnancy to 24.8% (345/1393), 37.3% (519/1393), and 44.7% (623/1393) during the first, second, and third trimester, respectively.

## Association Between MCH App Use and Pregnancy Outcomes

There were 119 babies with a CAPO rate of 6.4% among the 1850 participants. Although continuous users had the lowest incidence of CAPO (26/517, 5%), no statistical difference was found for incidence of CAPO (primary outcome) between all users (88/1393, 6.3%) and nonusers (31/457, 6.8%;  $P=.73$ ) or

between nonusers (31/457, 6.8%) and intermittent users (62/876, 7.1%) or continuous users (26/517, 5%;  $P=.31$ ). Of the 9.2% (169/1850) of the babies born macrosomic, the incidence of macrosomia was similar among intermittent users (83/876, 9.5%) and continuous users (49/510, 9.6%), which, although higher than that in nonusers (37/457, 8.1%), did not reach statistical significance ( $P=.37$ ). The incidence of low birth weight was the lowest in the continuous users among the 3 groups ( $P=.04$ ), but no statistical significance was found among the groups for the other component outcomes of CAPO ([Table 2](#)).

[Table 3](#) shows the odds ratios (ORs) of CAPO and macrosomia among different MCH app users based on logistic regression analysis with adjustment for hospital, age, education level, household income level, parity, gravidity, and history of cesarean section. No significant difference was found for CAPO incidence when comparing continuous users and intermittent users and nonusers (OR 0.77, 95% CI 0.48-1.25) or comparing continuous users and nonusers (OR 0.77, 95% CI 0.42-1.42). A positive association was detected between MCH app use and the odds of delivering a macrosomic baby (OR for any app use compared with none 1.44, 95% CI 0.95-2.17, and OR for continuous app use compared with none 1.55, 95% CI 0.91-2.63); however, a null effect cannot be excluded.

The heterogeneity analyses did not show any significant findings for either CAPO or macrosomia. The  $P$  values for the interaction effect of 6 hospitals $\times$ 2 app user groups (user vs nonuser) were .75 for CAPO and .49 for macrosomia, whereas the  $P$  values for the interaction effect of 2 hospital levels $\times$ 2 app user groups (user vs nonuser) were .32 for CAPO and .31 for macrosomia.

Finally, we conducted sensitivity analyses to explore associations of app brand name ([Multimedia Appendix 2](#)), starting time, and use frequency with pregnancy outcomes, including macrosomia. No statistically significant association was detected between app use and pregnancy outcomes, although the risk of macrosomia seemed to be increased among users who used certain apps (*Mei You* vs other apps: OR 1.53, 95% CI 0.92-2.54) and among those who began using the apps at an earlier stage (pregnancy vs second and third trimester: OR 1.34, 95% CI 0.66-2.74; first trimester vs second and third trimester: OR 1.41, 95% CI 0.80-2.51; [Multimedia Appendix 3](#)).

**Table 2.** Adverse pregnancy outcomes among different app user groups (N=1850).

Adverse pregnancy outcomes	Total (N=1850), n (%)	Nonusers (n=457; user group 1), n (%)	Users			P value <sup>a</sup> (comparison between user groups 1 and 2)	P value <sup>b</sup> (comparison among user groups 1, 3, and 4)
			All users (n=1393; user group 2), n (%)	Intermittent users (n=876; user group 3), n (%)	Continuous users (n=517; user group 4), n (%)		
CAPO <sup>c</sup>	119 (6.4)	31 (6.8)	88 (6.3)	62 (7.1)	26 (5)	.73	.31
Premature birth	75 (4.1)	21 (4.6)	54 (3.9)	39 (4.5)	15 (2.9)	.50	.29
Low birth weight	34 (1.8)	7 (1.5)	27 (1.9)	23 (2.6)	4 (0.8)	.57	.04
Birth defects	22 (1.2)	3 (0.7)	19 (1.4)	12 (1.4)	7 (1.4)	.23	.48
Stillbirth	3 (0.2)	1 (0.2)	2 (0.1)	0 (0)	2 (0.4)	.73	.21
Neonatal asphyxia	9 (0.5)	4 (0.9)	5 (0.4)	4 (0.5)	1 (0.2)	.17	.31
Macrosomia <sup>d</sup>	169 (9.2)	37 (8.1)	132 (9.5)	83 (9.5)	49 (9.6)	.37	.67

<sup>a</sup>On the basis of the Pearson chi-square test.

<sup>b</sup>On the basis of the Pearson chi-square test. No pairwise Pearson comparison was conducted because no significant difference was found for overall comparison for each outcome.

<sup>c</sup>CAPO: composite adverse pregnancy outcome, defined as a case with  $\geq 1$  event of premature birth, low birth weight, birth defects, stillbirth, and neonatal asphyxia.

<sup>d</sup>Not a component of composite adverse pregnancy outcome.

**Table 3.** Odds ratios (ORs) of CAPO (composite adverse pregnancy outcome) and macrosomia among different maternal and child health app users: results of logistic regression analysis<sup>a</sup>.

Comparison	CAPO <sup>b</sup>		Macrosomia	
	OR (95% CI)	P value	OR (95% CI)	P value
User vs nonuser	1.04 (0.66-1.64)	.87	1.44 (0.95-2.17)	.09
Continuous user vs intermittent user and nonuser	0.77 (0.48-1.25)	.29	1.22 (0.82-1.82)	.32
Continuous user vs nonuser <sup>c</sup>	0.77 (0.42-1.42)	.40	1.55 (0.91-2.63)	.11

<sup>a</sup>Controlling for hospital, age, education, household income, parity, gravidity, and history of cesarean section.

<sup>b</sup>Defined as any pregnancy outcome of premature birth, low birth weight, birth defects, stillbirth, and neonatal asphyxia.

<sup>c</sup>A total of 876 intermittent users were excluded.

## Discussion

### Principal Findings

In this retrospective multicenter study in north China, we found that MCH app use is common and many women start using apps in early pregnancy. In this study, the top 3 features of apps reported were health education (1393/1393, 100%), health status self-monitoring (755/1393, 54.2%), and antenatal clinic appointment reminders (602/1393, 43.2%). However, it is notable that app use was not common to all women, with nonusers having less education, lower income, and higher age and parity compared with users ( $P < .01$ ). We did not observe any association between app use and the risk of CAPO.

Although some studies have shown that MCH app use can provide benefits, including reducing health anxiety, improving satisfaction with pregnancy care, and helping women make better lifestyle and nutritional choices [43-45], few studies have evaluated the effects of market MCH apps on pregnancy

outcomes. In this study, we did not observe any association between app use and the risk of CAPO. This could be due to several reasons. First, the download and reported use of an MCH app does not necessarily result in behavior changes. Second, as all women attending these hospitals also had access to free prenatal education sessions that target self-care and health education, any additional benefit from app use was likely to have been marginal. Third, the observational design had a weakness in balancing potential confounding factors between app users and nonusers and in controlling selection and recording bias. Fourth, heterogeneity in the association may exist among different MCH apps, different app users, different regions, and different hospital levels, which might dilute the effects of the outcome. Finally, the sample size was not powerful enough to detect the benefit of app use, although our study showed that incidences of CAPO, premature birth, low birth weight, and neonatal asphyxia were the lowest among continuous users (Table 3). A large study, especially a well-designed trial, could be a solution in terms of clarifying the effect of app use and potential heterogeneities.

Reassuringly, we did not find any evidence of harms. It is notable that none of the top 5 apps reported by the women in this study were disease- or condition-specific. It is likely that apps targeting specific behaviors where there is evidence of benefit regarding outcomes from nonapp studies could be more effective than generic apps for pregnant women. Some good examples are apps used to improve blood glucose management in women with gestational diabetes [23] and apps tracking the menstrual cycle to improve fecundability [46]. Ideally, apps should be developed using theories of behavior change, accompanied by evaluation before recommendation for general use [8].

### Use of MCH Apps

MCH apps are gaining popularity worldwide. The number of downloads for such apps has reached hundreds of millions [6-9]. However, few studies report MCH app use among pregnant women in the real world with considerations of multiple app use. In this study, we found that approximately three-fourths (1393/1850, 75.3%) of the pregnant women used  $\geq 1$  MCH apps in north China and more than one-fourth (387/1393, 27.8%) used an app every day. This popularity level is higher than that reported in other countries that promote app use, such as Jordan and South African [47,48]. Considering that more than 99% of the pregnant women in China deliver at county- or higher-level hospitals [49] and these were the target hospitals for recruitment in this study, our results on app coverage should have good representativeness for pregnant women in northern China. The high use rates we report indicate that pregnant women have a very high acceptance of MCH apps, in keeping with a market analysis conducted in China by Forward-The Economist, where adherence to MCH apps was reported as rising, with 44.1% users logging in every day in 2019 [50]. A cross-sectional study found that commercial MCH apps with more favorable user experience, in-app purchases, and in-app advertisements were more frequently downloaded [51]. However, although we observed a wide range of app functions, we are not able to comment on whether any of these helped the women in our study to achieve more downloads and sustain behavior changes.

Disparities or inequities regarding MCH outcomes between rural and urban areas and across geographical regions have been noticed and narrowed significantly by the Chinese government [52]. However, attention should be paid to emerging challenges arising from mHealth access inequities. Although mHealth technology in MCH care has spread quickly, social disparities in access and frequency of use exist and need to be dealt with. Although an association between MCH app use and improved pregnancy outcomes has not been shown, women with lower education and household income and those with more children were less likely to use apps in this study. If apps are to be used in pregnancy care pathways, programs need to ensure equitable and universal coverage. In addition, although our study did not confirm the existence of heterogeneity among hospitals and hospital levels, further exploration is still worthwhile in future studies.

### Most Common Features of MCH Apps

In this study, the mostly commonly used features of MCH apps were health education, health status self-monitoring, antenatal

appointment reminders, communication, appointment making, laboratory result checking, shopping, counseling, diary, and financial transactions. The most popular apps such as *Baby Tree* and *Meet You* offered most of these features, with the exception of the facility to make antenatal appointments or check laboratory results. These findings were similar to those we found in our market review of MCH apps and the maternal and infant industry report in 2020 [7,50]. Notably, no apps were described with decision support functions, for example, for management of gestational diabetes, healthy weight gain, exercise in pregnancy, blood pressure, and preeclampsia [53].

### App and Outcome Selection

We chose to focus on all MCH apps in aggregate, rather than specific apps, because we wanted to explore whether there were any general effects on pregnancy outcomes. There were 2 major reasons for adopting this approach. First, many pregnant women use multiple apps (in this study, 28%, 390/1393, of the women used  $\geq 2$  apps during pregnancy), making it hard to differentiate the effects of certain apps in an observational study. Second, most MCH apps have multiple and similar feature components, as shown in [Multimedia Appendix 2](#). For the purposes of this study, we therefore assumed that the effects of the apps would be similar.

Although we observed no statistical difference in CAPO between MCH app users and nonusers or among the 3 user groups, we observed a (nonsignificant) trend toward increased macrosomia with app use. Whether this can be attributed to effects secondary to behavior changes resulting from use of the apps or to these women making improved nutritional choices or whether this reflects the better social standing of the women who used the apps merits further exploration.

### Limitations

As this was a retrospective study, we were unable to control for reporting or recall bias among certain groups. As the women and the data collectors were unaware of the study hypothesis, we have assumed that any such bias would have been evenly spread among the MCH app user groups.

The observed incidence of CAPO (6.4%) at the study hospitals was much lower than what we estimated (15%), which meant that this study was underpowered to detect the difference in CAPO. In contrast, the incidence of macrosomia (9.2%) in this study was higher than previously reported in 2018 in China (2.5%) [39]. Further studies could limit the exposure to studying only the most popular apps, with prospective or randomized designs.

We have presented several exploratory analyses, including comparison of different outcome indicators among different user groups, with the purpose of guiding future studies in this area. This may have increased the chance of significant findings (type I error); we did not conduct any adjustment to control the error.

Finally, although nearly all the apps cover features regarding MCH care and we used MCH app as the general name for such apps, the evaluation was only conducted among women soon after the delivery of their baby and while they were still at the



hospital. As a result, the use of parenting features and the effect on children's health were not evaluated in this study.

## Conclusions

MCH apps are widely used among pregnant women in China, but the general effects of such apps on severe perinatal outcomes have not been well evaluated worldwide. Our retrospective study showed no significant benefit of MCH apps in improving overall adverse pregnancy outcomes. The findings on coverage of MCH apps, app adherence, and observed effect in reducing or increasing adverse pregnancy outcomes are informative for future study design and app development and upgrade.

We believe that the findings of this study have important implications for researchers, clinicians, and end users. For

researchers, the wide reach of apps among pregnant women could be a powerful tool for public health and health promotion; however, the lack of effect that we have demonstrated points to a need for further research to understand the mechanisms of action of these apps (ie, behavior change) and determine how apps can be used as a tool to strengthen delivery of maternity care. For clinicians, this paper demonstrates the high rate of app uptake among pregnant women and thus the importance of asking women about what apps they are using and signposting them to apps that are evidence-based. For end users, a signposting system to rank the clinical accuracy of apps could be valuable, although how this would work in practice in a very crowded marketplace needs to be assessed with further work.

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## Authors' Contributions

PZ designed the study. HC and JS designed the questionnaire and case report form and were responsible for training and on-site quality control. JG, HZ, MX, and CB were responsible for patient recruitment and data collection. PZ and HC drafted the manuscript under JEH's support and instruction. All authors contributed to the review and editing of the manuscript.

## Conflicts of Interest

None declared.

### Multimedia Appendix 1

Questionnaire for the use of a maternal and child health app among pregnant women.

[\[DOCX File, 32 KB - formative\\_v6i1e29644\\_app1.docx\]](#)

### Multimedia Appendix 2

Major features adopted by top 5 apps.

[\[DOCX File, 30 KB - formative\\_v6i1e29644\\_app2.docx\]](#)

### Multimedia Appendix 3

Associations of composite adverse pregnancy outcome and macrosomia with utility of maternal and child health apps among 1393 app users: results of logistic regression analysis.

[\[DOCX File, 28 KB - formative\\_v6i1e29644\\_app3.docx\]](#)

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## Abbreviations

**CAPO:** composite adverse pregnancy outcome

**MCH:** maternal and child health

**mHealth:** mobile health

**OR:** odds ratio

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Original Paper

# Remote Monitoring of Patients With Hematologic Malignancies at High Risk of Febrile Neutropenia: Exploratory Study

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## Abstract

**Background:** Febrile neutropenia is one of the most common oncologic emergencies and is associated with significant, preventable morbidity and mortality. Most patients who experience a febrile neutropenia episode are hospitalized, resulting in significant economic cost.

**Objective:** This exploratory study implemented a remote monitoring system comprising a digital infrared thermometer and a pulse oximeter with the capability to notify providers in real time of abnormalities in vital signs that could suggest early clinical deterioration and thereby improve clinical outcomes.

**Methods:** The remote monitoring system was implemented and compared to standard-of-care vital signs monitoring in hospitalized patients with underlying hematologic malignancies complicated by a febrile neutropenia episode in order to assess the feasibility and validity of the system. Statistical analysis was performed using the intraclass correlation coefficient (ICC) to assess the consistency between the measurements taken using traditional methods and those taken with the remote monitoring system for each of the vital sign parameters (temperature, heart rate, and oxygen saturation). A linear mixed-effects model with a random subject effect was used to estimate the variance components. Bland-Altman plots were created for the parameters to further delineate the direction of any occurring bias.

**Results:** A total of 23 patients were enrolled in the study (mean age 56, SD 23-75 years; male patients: n=11, 47.8%). ICC analysis confirmed the high repeatability and accuracy of the heart rate assessment (ICC=0.856), acting as a supplement to remote temperature assessment. While the sensitivity and specificity for capturing tachycardia above a rate of 100 bpm were excellent (88% and 97%, respectively), the sensitivity of the remote monitoring system in capturing temperatures >37.8 °C and oxygen saturation <92% was 45% and 50%, respectively.

**Conclusions:** Overall, this novel approach using temperature, heart rate, and oxygen saturation assessments successfully provided real-time, clinically valuable feedback to providers. While temperature and oxygen saturation assessments lagged in terms of sensitivity compared to a standard in-hospital system, the heart rate assessment provided highly accurate complementary data. As a whole, the system provided additional information that can be applied to a clinically vulnerable population. By transitioning its application to high-risk patients in the outpatient setting, this system can help prevent additional use of health care services through early provider intervention and potentially improve outcomes.

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**KEYWORDS**

remote monitoring; febrile neutropenia; temperature; heart rate; oxygen saturation; mobile health; mHealth; hematologic malignancies; hematology; malignancies; digital health; clinical outcomes

**Introduction**

Febrile neutropenia is one of the most common oncologic emergencies, accounting for approximately 5% of all cancer-related hospitalizations [1]. Moreover, it is associated with significant preventable complications including hypotension, acute renal failure, heart failure, and early mortality, as well as substantial economic cost [2,3]. Across hematologic malignancies, the risk of febrile neutropenia, and, thus, additional morbidity and mortality, is further magnified. In fact, in a prospective observational study of 120 patients with acute myeloid leukemia (AML) and acute lymphocytic leukemia (ALL) undergoing induction chemotherapy, those who became neutropenic (n=107) also experienced at least one febrile neutropenia episode (FNE) [4]. In more novel treatment regimens such as engineered cell therapies, the rate of neutropenic fever remains exceedingly high, with a recent observational analysis of 60 patients confirming an incidence of 86.7% within the first 30 days after chimeric antigen receptor (CAR) T-cell infusion [5].

Despite current guidelines and multiple risk calculators to assist in risk stratification, the majority (up to 94%) of patients with febrile neutropenia continue to be admitted to the hospital, with an even larger percentage of patients being admitted at academic centers [3,6-8]. In the era of ever-increasing health care costs, hospitalizations related to febrile neutropenia result in an excess of \$2.3 billion per year among adults and account for roughly 8% of all cancer-related costs [1]. Presumably, the persistently high rate of hospitalization is due to difficulty in risk stratification and the simultaneously high rate of preventable morbidity and mortality within this population. Thus, patients with febrile neutropenia represent a group in which there is ample opportunity for improved efficiency of care and more appropriate utilization of limited health care resources.

Recent advances in technology have made it possible to monitor a patient's key vital signs outside of a clinic or hospital setting. Within the field of oncology, these devices are being increasingly integrated into clinical care and even into oncology trials, but the great majority of remote monitoring has focused on activity, sleep, and heart rate [9-11]. Only recently have studies begun to assess the efficacy and validity of either continuous or intermittent remote temperature monitoring in neutropenic patients, but these studies have unilaterally assessed temperature via skin patch [12,13]. Our exploratory study aimed to build upon a previous remote monitoring platform developed by the UCLA Center for SMART Health by incorporating a digital infrared thermometer and a pulse oximeter with the capability to notify providers in real time of abnormalities in vital signs that could suggest early clinical deterioration. The modified mobile health platform was subsequently implemented and compared to standard-of-care monitoring in hospitalized patients with underlying hematologic malignancies complicated by an FNE in order to assess the feasibility and validity of the system.

**Methods****Remote System Development**

This institutional review board-approved (IRB#20-000303) exploratory study built upon the previously developed Sensing At-Risk Patients (SARP) platform, which consisted of a smartwatch, a software application, and a central data processing and analytics engine [14-16]. The SARP platform was initially developed to remotely monitor elderly and at-risk patients in rehabilitation facilities and at home, focusing on activity monitoring. Building up this previously validated platform, a digital infrared thermometer (AndesFit Bluetooth 4.0 Wireless Non-Contact Infrared Body/Surface Thermometer, ADF-B38A, AndesFit Health) and a pulse oximeter (AndesFit Bluetooth 4.0 Pulse Oximeter, ADF-B06, AndesFit Health) with the capability to measure heart rate and oxygen saturation were incorporated into the system to review data remotely in real time via the HIPAA (Health Insurance Portability and Accountability Act)-compliant SARP website.

**Recruitment**

We recruited patients aged 18 years or older with underlying leukemia or lymphoma admitted to the inpatient service at an academic tertiary care hospital whose course was complicated by an FNE. This included patients with newly diagnosed or relapsed/refractory disease, as well as those undergoing autologous or allogeneic stem cell transplants or CAR T-cell therapy. An FNE was defined as a temperature  $>38.3^{\circ}\text{C}$  or  $38.0^{\circ}\text{C}$  sustained over 1 hour and a concurrent neutrophil count  $<500$  cells/ $\mu\text{L}$  [17]. Patients were excluded if they were unable to comply with the additional monitoring for any reason.

The remote monitoring was implemented for 72 hours starting at the time of consent, which occurred within 24 hours of the patient's most recent FNE. Once the participant enrolled in the study, they were given the remote monitoring system, which included the thermometer, pulse oximeter, and tablet. The system remained at the patient's bedside for the remainder of the study. The health care staff, including the nursing staff and medical assistants, were instructed on the appropriate use of the remote monitoring system and performed all vital signs assessments. This instruction included an initial in-person group tutorial followed by one-on-one training and a demonstration at the time of implementation. The remote temperature and pulse oximeter assessments immediately followed the vital signs assessment using the standard hospital equipment (Phillips IntelliVue MX450), which occurred every 4 hours. At the end of the study period, the thermometer, pulse oximeter, and tablet were collected, charged, sanitized, and redistributed by the study team. The temperature, heart rate, and oxygen saturation data obtained by the health care staff every 4 hours were transmitted via Bluetooth to the tablet, which was connected by Wi-Fi and securely transmitted in real time to a secure HIPAA-compliant server. These data were automatically deidentified and could

be reviewed using unique patient identifiers on the SARP application website.

### Statistical Analysis

Statistical analysis was performed using the intraclass correlation coefficient (ICC) to assess the consistency between the measurements taken using traditional methods and those taken with the remote monitoring system for each of the vital sign parameters (temperature, heart rate, and oxygen saturation). A linear mixed-effects model with a random subject effect was used to estimate the variance components. The ICC was measured as the proportion of variance between subject measurements out of the total variance. Since measurements were taken multiple times while the patient was hospitalized, the model also included a fixed effect for time. Bland-Altman plots were created for temperature, heart rate, and oxygen saturation to further delineate the direction of any occurring bias, as well as to detect ranges where a larger difference between the two collection methods is seen. Given that subjects were monitored for up to 72 hours and measurements were taken

approximately every 4 hours during the study, it was assumed that all patients would have at least 5 measurements. Therefore, a random sample of 30 patients was estimated to produce the 2-sided 95% CI widths with an estimated range of 0.2 when the ICC is 0.80 and 0.06 when the ICC is 0.95.

## Results

### Patient Characteristics

A total of 23 patients were enrolled in the study, of which 17 patients had a confirmed diagnosis of AML and the remainder had diagnoses including ALL, multiple myeloma, diffuse large B-cell lymphoma, and blastic plasmacytoid dendritic cell neoplasm (Table 1). Of the enrolled patients, 8 were newly diagnosed and were undergoing induction chemotherapy, 7 were receiving salvage chemotherapy for relapsed/refractory disease, and 6 were undergoing either an autologous or allogeneic stem cell transplant. Two patients had recently received CAR T-cell therapy.

**Table 1.** Patient characteristics.

Characteristic	Patients (N=23)
Age (years), median (range)	56 (23-75)
Sex (male), n (%)	11 (47.8)
<b>Primary malignancy, n (%)</b>	
Acute myeloid leukemia	17 (73.9)
Multiple myeloma	2 (8.7)
Diffuse large B-cell lymphoma	2 (8.7)
Acute lymphocytic leukemia	1 (4.4)
Blastic plasmacytoid dendritic cell neoplasm	1 (4.4)
<b>Disease status, n (%)</b>	
Newly diagnosed	8 (34.8)
Relapsed/refractory	9 (39.1)
Remission	6 (26.1)
<b>Treatment, n (%)</b>	
Induction chemotherapy	8 (34.8)
Salvage chemotherapy	7 (30.4)
Allogeneic or autologous stem cell transplant	6 (26.1)
Chimeric antigen receptor T-cell	2 (8.7)

### Sensitivity and Specificity Compared to the Standard System

Upon completion of the study, the standard hospital monitoring system captured 34 temperature assessments above a threshold of 37.8 °C whereas the remote monitoring system captured 18 assessments (Table 2). With respect to the pulse oximeter, only 6 assessments had less than a threshold of 92% oxygen saturation using the hospital vital signs equipment compared to 9 assessments with the remote monitoring system. Finally, the

heart rate assessment produced 74 readings above a threshold heart rate of 100 bpm using the hospital equipment compared to 66 with the remote monitoring system. Overall, the sensitivity and specificity for capturing tachycardia above a rate of 100 bpm was 88% and 97%, respectively, using the remote system (Table 3). For temperature and oxygen saturation, the specificity was 97% and 96%, respectively. However, the sensitivity of the remote monitoring system with respect to temperature and oxygen saturation was 45% and 50%, respectively.

**Table 2.** Proportion of remotely obtained vital signs exceeding a defined threshold.

Parameter	Proportion exceeding threshold <sup>a</sup>		Agreement (%)
	Standard, n (%)	Remote, n (%)	
Temperature	34 (21)	18 (11)	88
SpO <sub>2</sub> <sup>b</sup>	6 (3)	9 (5)	95
Heart rate	74 (42)	66 (38)	93

<sup>a</sup>For temperature, a threshold of  $\geq 37.8$  °C was considered a fever. For SpO<sub>2</sub>, a threshold  $< 92\%$  was used. For heart rate, a threshold of 100 bpm was used.

<sup>b</sup>SpO<sub>2</sub>: oxygen saturation.

**Table 3.** The specificity and sensitivity of the remote monitoring system compared to standard hospital monitoring.

Parameter	AUC <sup>a,b</sup> (95% CI)	Sensitivity <sup>c</sup> (%)	Specificity <sup>d</sup> (%)
Temperature	0.898 (0.846-0.950)	45	97
SpO <sub>2</sub> <sup>e</sup>	0.964 (0.929-0.998)	50	96
Heart rate	0.990 (0.981-0.999)	88	97

<sup>a</sup>AUC: area under the curve.

<sup>b</sup>AUC was estimated using a mixed-effects logistic regression predicting temperature  $\geq 37.8$  °C and SpO<sub>2</sub>  $< 92\%$  with a fixed effect for the SARP result (as a binary predictor) and a random subject effect to account for repeated measures.

<sup>c</sup>Sensitivity is the true positive rate (ie, the proportion of patients who had a fever or low SpO<sub>2</sub> and were correctly identified as such).

<sup>d</sup>Specificity is the true negative rate (ie, the proportion of patients who did not have a fever or low SpO<sub>2</sub> and were correctly identified as such).

<sup>e</sup>SpO<sub>2</sub>: oxygen saturation.

## ICC Analysis

The calculated ICC for heart rate was 0.856, which indicated that the repeatability between the standard and remote monitoring methods is excellent (Table 4). For oxygen saturation and temperature, the ICC was 0.233 and 0.363, respectively, indicating that the repeatability was significantly lower for the

remote monitoring equipment. The Bland-Altman plots (Figures 1-3) further demonstrate repeatability by highlighting bias in the measurements obtained by the remote system compared to the standard equipment. While there was no clear bias in heart rate measurement, the remote temperature monitor was biased toward lower readings and the remote pulse oximeter was biased toward higher readings.

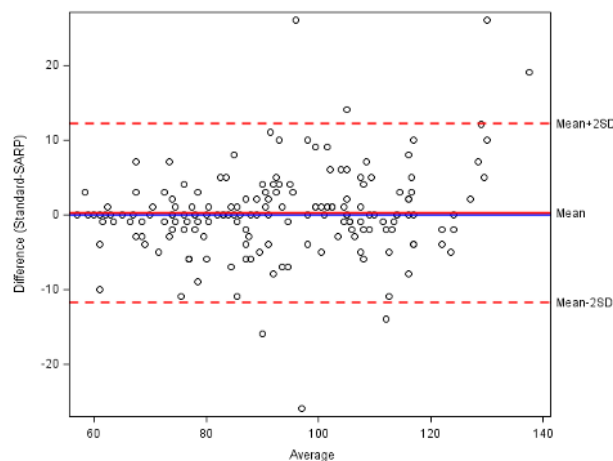
**Table 4.** Intraclass correlation coefficient (ICC) values comparing the standard system to remote monitoring.

Parameter	ICC <sup>a</sup>
Heart rate	0.856
SpO <sub>2</sub> <sup>b</sup>	0.233
Temperature	0.363

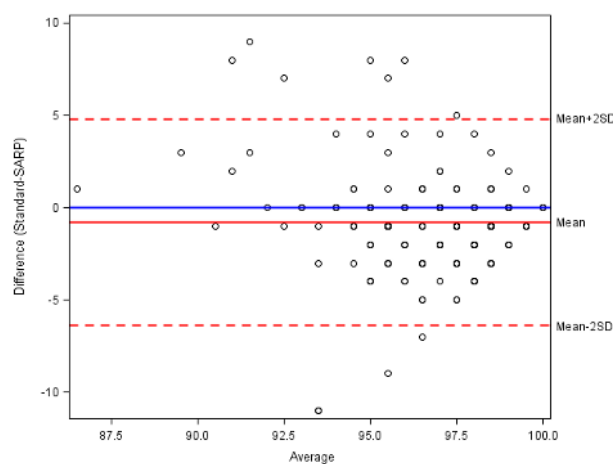
<sup>a</sup>ICC was obtained as the proportion of within-subject variance over the total variance. An intercept-only mixed-effects model was constructed with random effects for patient and for patient across the two methods to account for multiple observations per patient per method.

<sup>b</sup>SpO<sub>2</sub>: oxygen saturation.

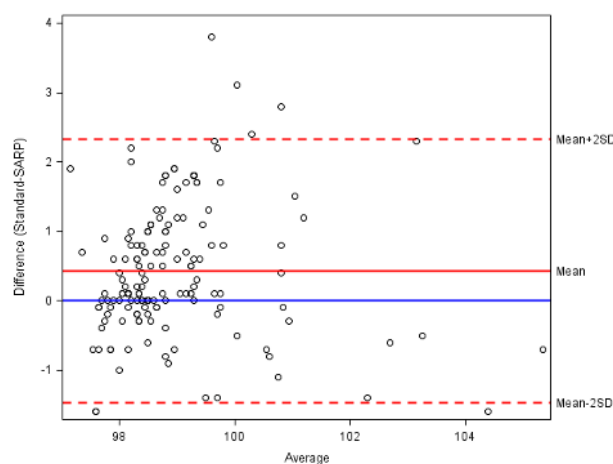
**Figure 1.** A Bland-Altman plot of heart rate agreement between the standard and remote monitoring methods. SARP: Sensing At-Risk Patients.



**Figure 2.** A Bland-Altman plot of oxygen saturation agreement between the standard and remote monitoring methods. SARP: Sensing At-Risk Patients.



**Figure 3.** A Bland-Altman plot of temperature agreement between the standard and remote monitoring methods. SARP: Sensing At-Risk Patients.



### The Predictive Model

Finally, a predictive model was developed combining all 3 vital signs assessments in order to analyze the success of triggered alerts using the stated thresholds (heart rate >100 bpm, oxygen saturation <92%, temperature >37.8 °C) (Table 5). Again, the remote monitoring heart rate assessment produced an odds ratio

of 248 compared to the standard in-hospital monitoring system, indicating the odds of measuring true tachycardia with the remote system. However, because there was substantial collinearity, only 4 models combining temperature, heart rate, and oxygen saturation converged, and additional combination did not significantly improve the predictability of any singular measure.

**Table 5.** A predictive model of alerts triggered.

Model and parameters <sup>a</sup>	Odds ratio (95% CI)	P value	AUC <sup>b</sup> (95% CI)
<b>Model 1</b>			0.97 (0.94-0.99)
Heart rate	248 (22-2896)	<.001	
SpO <sub>2</sub> <sup>c</sup>	— <sup>d</sup>	—	
Temperature	—	—	
<b>Model 2</b>			0.97 (0.94-0.99)
Heart rate	268 (24-2992)	<.001	
SpO <sub>2</sub>	6.1 (0.82-44.5)	.08	
Temperature	—	—	
<b>Model 3</b>			0.95 (0.91-0.98)
Heart rate	—	—	
SpO <sub>2</sub>	—	—	
Temperature	8.05 (1.16-55.9)	.04	
<b>Model 4</b>			0.95 (0.92-0.98)
Heart rate	—	—	
SpO <sub>2</sub>	2.2 (0.21-23.4)	.51	
Temperature	7.2 (1.0-51.4)	.047	

<sup>a</sup>All variables were included as binary predictors (ie, cutoff at the thresholds that would trigger an alert). The model with all 3 variables did not converge.

<sup>b</sup>AUC: area under the curve.

<sup>c</sup>SpO<sub>2</sub>: oxygen saturation.

<sup>d</sup>Not available. Model convergence limited by multicollinearity.

## Discussion

### Principal Results

This exploratory pilot study demonstrated the feasibility of a self-monitoring system in an at-risk population while accurately providing multiple indicators of clinical status. In particular, the heart rate data alone were highly repeatable compared to a standard in-hospital heart rate assessment, as demonstrated by an ICC value of 0.865 and the correlation shown in the Bland-Altman plot. When using a cutoff analysis (heart rate >100 bpm), this finding was further corroborated, with a sensitivity and specificity of 88% and 97%, respectively; using a predictive model, the odds ratio was 248. These findings support both the repeatability of the remote heart rate data compared to standard in-hospital monitoring and the accuracy at which it can capture true tachycardia in an at-risk population. In combination with the temperature data, heart rate can serve as both a surrogate and adjunctive marker of clinical change, whether that be an FNE or an alternative, clinically significant change like dehydration requiring prompt intravenous fluid administration.

As a population, less than 40% of patients with an FNE may demonstrate concurrent tachycardia [18]. Within this cohort specifically, only 12 of the 17 true FNEs were associated with a heart rate >100 bpm. However, tachycardia associated with the FNE represented a high-risk feature, indicating possible clinical decline. In fact, in a multicenter prospective study of

346 patients with 515 FNEs, tachycardia at presentation was one of the strongest predictors of mortality [18]. The association was higher than all other abnormalities in vital signs, including tachypnea and hypotension, as well as many other known risk factors such as previous invasive fungal infections, oliguria, or initial positive blood cultures. Thus, the excellent performance of the heart rate monitor compared to standard inpatient monitoring represents additional, highly relevant clinical data which providers may use to early intervention, improving health outcomes and decreasing overall health care utilization.

### Comparison With Prior Work

Few studies have examined self- or remote monitoring in an at-risk cancer population and even fewer have prospectively assessed the implementation of wearable devices [19]. These studies have solely focused on continuous temperature monitoring in patients at high risk of neutropenia episodes. For instance, Dambrosio et al [20] used a continuous temperature skin patch on patients in the inpatient stem cell transplant unit and successfully demonstrated the repeatability of temperature assessment. Vera-Aguilera et al [12] went a step further by evaluating a wearable, continuous temperature monitor (tPatch) in patients undergoing autologous stem cell transplant in the outpatient setting. Measured febrile episodes were compared to self-measured oral temperatures taken every 3 to 4 hours using a standardized thermometer; the authors were able to demonstrate that the incidence of fever using the tPatch was 58.8% compared to 29.4% in the standard monitoring group. The success of these studies highlights the feasibility of remote



temperature assessment. However, the unilateral assessment also leaves room for substantial improvement in optimizing patient care, especially given the predictive nature of other vital signs signifying potential clinical decline in an FNE. In comparison to these studies, by capturing a combination of temperature, heart rate, and oxygen saturation in a hospitalized, high-risk patient population, we were able to mirror a potential intervenable group, particularly in a postdischarge setting where the risk of readmission remains high. Furthermore, our novel approach provides additional variables beyond temperature monitoring, which can improve the likelihood of decreased health care utilization through early provider assessment and intervention prior to clinical decline.

### Limitations

With the spread of SARS-CoV-2 in 2019, and the resulting COVID-19 pandemic, there has been near-universal adoption of noncontact, infrared thermometers as an initial screening tool at the entrance of public spaces including hospitals, office buildings, retail stores, etc. These devices have largely been selected because of their availability, affordability, ease of use, and simultaneous noninvasive approach, which also prompted their inclusion in our remote monitoring system. Despite their many strengths including ease of use and patient familiarity, multiple studies have questioned their validity [21]. Admittedly, the digital infrared thermometer does lag in terms of repeatability when compared to the standard hospital monitor used in this analysis. Specifically, it has a relatively lower sensitivity in capturing FNEs, which does highlight some of the challenges of remote monitoring. Ideally, as technology improves, more reliable thermometers and pulse oximeters will limit these potential false negatives. Regardless, it is critical to emphasize that a remote monitoring system acts as a complement to traditional outpatient monitoring, which would typically consist of clinic visits with a singular assessment of vital signs upon presentation. While the additional data presents tremendous opportunity for improvement in clinical outcomes, the lack of a fever or hypoxia as captured by the remote system should not be interpreted as true absence of fever or hypoxia.

Although the remote temperature and oxygen assessment may miss some hypoxia or febrile episodes, it also has the potential to capture alternative markers of early clinical deterioration via incorporation of heart rate and oxygen saturation assessment. For instance, patients with cancer are more likely to be diagnosed with COVID-19 than the general population and more likely to have severe complications, such as intubation [22]. Beyond emphasizing the importance of vaccination in this

patient population, monitoring temperature, heart rate, and oxygen saturation, provides additional opportunities to capture early infection and/or clinical deterioration, such as progressive hypoxia, which may precede intubation. Furthermore, additional objective assessments will likely enrich the understanding of COVID-19 among patients with cancer.

### Future Directions

After demonstrating the feasibility of this exploratory pilot study among inpatients, the critical next step is its implementation in a high-risk patient population in the outpatient setting, such as those who have recently been discharged after CAR T-cell therapy, those receiving outpatient autologous stem cell transplant, or those with prolonged neutropenia (eg, after consolidation with high-dose cytarabine). For reference, up to 32% of CAR T-cell recipients experience prolonged cytopenia of unclear etiology beyond day 28 and remain at substantially high risk of infection and subsequent rehospitalization [23]. Thus, applying the remote monitoring system to this group of patients with self-monitoring every 4 to 6 hours would provide real-time clinical indicators to providers with the capability to send alerts for abnormal vitals, such as a temperature  $>38^{\circ}\text{C}$  or a heart rate  $>100$  bpm. In particular, because the sensitivity and specificity of the heart rate monitor is exceptional while the sensitivity of detecting hypoxia or fever lags, an alert set for tachycardia combined with either hypoxia or fever could specifically serve as a marker of clinical deterioration while limiting false alerts. The alert would then be sent to the designated provider who would have the flexibility to determine if the change in vital signs warrants a telephone call, in-person assessment, or neither. Such a protocol would further clarify whether tachycardia truly represents an FNE, whether the alerts are actionable, and most importantly, whether the alerts impact clinical outcomes.

### Conclusion

In summary, this exploratory study involving temperature, heart rate, and oxygen saturation assessments successfully provides real-time, clinically valuable feedback to providers. While the temperature and oxygen saturation lacked sensitivity when compared to a standard in-hospital system, the heart rate assessment provided highly accurate complementary data. As a whole, the system provided additional information that was applicable to a clinically vulnerable population. By transitioning its application to high-risk patients in the outpatient setting, our novel system can help prevent additional health care utilization through early provider intervention and potentially improve outcomes.

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### Conflicts of Interest

AN is a founder of InvistaHealth, Inc, which develops applications and analytics focused on at-risk, frail older populations.

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## Abbreviations

**ALL:** acute lymphocytic leukemia  
**AML:** acute myeloid leukemia  
**CAR:** chimeric antigen receptor  
**FNE:** febrile neutropenia episode  
**HIPAA:** Health Insurance Portability and Accountability Act  
**ICC:** intraclass correlation coefficient  
**SARP:** Sensing At-Risk Patients

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Original Paper

# Using Mobile Phone Apps to Deliver Rural General Practitioner Services: Critical Review Using the Walkthrough Method

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## Abstract

**Background:** The widespread use of mobile phones represents new frontiers for improving access to health care. This includes using mobile apps to deliver general practitioner (GP) services in rural areas. However, the wider adoption of apps for increasing access to rural GP services relies on understanding how they might intersect with the rural health system context.

**Objective:** This research aims to critically review mobile apps for delivering GP services in a rural health service context using the walkthrough method.

**Methods:** The sample comprised 3 GP service apps under the top 100 list in the medical category in the Apple App Store (also available via the Google Play Store) in Australia as of June 2020. The walkthrough method was applied to extract data and critique the *explicit factors*, such as the app interface elements, and *implicit factors*, such as the embedded cultural features related to use for people in rural settings. Data analysis was undertaken between 3 researchers over 6 months applying the walkthrough method and using critical reflection.

**Results:** There were 3 main themes: improving rural access, addressing rural health care needs, and providing quality of care. App-based GP services may improve rural GP service availability. However, this may be at a relatively superficial level that does not encompass the scope and intensity of the services needed in rural areas (including relevant chronic and emergency care) at a cost that rural patients can afford. The apps showed signs of limited tailoring to the cultural dimensions of rural health care as a barrier to rural use. Patients generally self-selected to use GP service apps with limited support, potentially leading to inappropriate uptake especially by disadvantaged groups with lower health literacy. Although the apps claimed to avail most GP services (70%-80% in some cases), it emerged after enrollment that emergency, complex, and serious conditions might be excluded, potentially imposing more complex caseloads on in-person rural GPs. Apps provided limited information about continuity and coordination of care and sharing information with rural GPs, potentially leading to fragmented and low-quality care. There was commonly no assurance of rural skills and experience of physicians staffing apps despite the wider scope of skills needed to be effective in rural general practice.

**Conclusions:** GP apps may increase the availability of GP services, but they may require clearer exclusions, appropriate use through decision-making tools, more rural-tailored interfaces, and capacity to align appointment times and costs with patients with complex needs to engage and be useful in a rural context. It is also important to consider how these app-based services could share information with local health care staff for safety and continuity of rural primary care. Finally, information about the physicians' rural training and experience is critical for quality.

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**KEYWORDS**

rural health; mHealth; general practice; cell phone; rural health services; mobile applications; primary health care; morbidity; mobile phone

## Introduction

### Background

Although health is one of the fundamental rights of every human being, poor access to health care in rural areas remains a major global issue impeding equity. At least half of the world's population lacks full coverage of essential health services such as primary care [1]. This situation worsens in countries with a more rural population distribution. Where rural populations exceed 70%, only 16% have universal access to services [2]. The World Health Organization has a range of global strategies to increase access to rural health care, including developing the rural health workforce [3] and improving health care affordability [4]. Increasingly, mobile (cellular) phones are being considered a new frontier for improving universal access to rural primary care services as part of mobile health (using mobile and wireless technologies) [5]. This includes delivering general practitioner (GP or family physician) services via mobile phone apps to give rural people access to timely primary care by skilled physicians regardless of where they live and where the physicians are distributed [5]. Governments may be attracted to this because this strategy has the potential to be cost-effective and to enable real-time responsiveness to rural needs. However, widespread adoption depends on evaluating whether GP service apps can achieve the same goals as in-person GP care and not widen rural disadvantage.

Much of the literature has focused on using mobile health in rural areas for selective functions, including enhancing referrals; improving access for target populations such as birthing women; and as an adjunct to other forms of care [6-9] supporting rural health workers [10-12], supporting self-management [13], and delivering health promotion interventions [14]. There is limited research on the use of apps for the delivery of holistic primary care by GPs, which typically involves an array of first point of contact screening, diagnostic, intervention, and referral services that most of the population needs [15]. This is an important area to understand if GP service apps are to be adopted as a potential alternative to in-person GP service models. GP service apps may play a role in rural communities that have no GPs or too few GPs for the level of demand. GP service apps may offer convenience to rural patients as well as lower costs compared with the time, travel, and consultation fees they may face for in-person GP visits, although this has not been appraised.

The context of rural health care provides an important backdrop for critiquing apps. A major international agenda is to protect the health of the rural poor by availing health care that is needed (at the depth of coverage and intensity required) and in such a way that nobody suffers financial hardship as a result of obtaining the services they need [16]. This is challenging as rural populations have relatively more acute and chronic health care needs in low-, middle-, [2] and high-income countries [17], which increase with remoteness from urban centers. Beyond regional centers, towns of <50,000 population have access to

fewer local health care providers (and other physicians), where rural GPs typically provide a broader range of both primary care and other specialist areas (approximately 10 additional hours in hospital atop of a typical primary care workload) [18,19]. They enable lifesaving procedural care for rural women and children and respond to medical emergencies [20,21], facing undifferentiated presentations that demand problem solving within limited resources [22]. In Australia, the achievement and maintenance of skilled GPs to service rural areas has been noted to require specific investment in rural-based training and ongoing professional support [21,23,24]. To this end, approximately 58% of Australia's rural GPs engage in educating the next generation of GPs [25]. Introducing apps that could substitute for skilled rural generalist physicians and address the breadth of community needs may be challenging.

Evidence points to the need for rural GP service models tailored to population needs, including respecting community characteristics, cultural aspects of care, and the need for self-determination [26-28] to cater to the higher proportion of older adults, poor people, and First Nations people in many rural settings [29]. Adaptability and careful design underpin the viability of these models as contexts become increasingly remote [27,30,31]. It is unknown how well apps may be delivered within these dimensions or effectively reach more remote communities than in-person services can achieve.

Ensuring that rural GP care is affordable is inherent to enabling access by the rural poor. This may vary widely by health care insurance schemes in different countries. In countries such as Australia, a national Medicare policy provides a universal health insurance system to rebate the cost of GP care at the discretion of the GP [32]. In >80% of GP consultations, GPs *bulk bill* patients, resulting in no out-of-pocket costs [32]; however, this is less common in rural areas, where GPs tend to set their fees higher than the government rebate [33,34]. The degree of cost that apps may impose against the flexibility and ceiling of any patient charges for in-person care per country may be important to affordability.

The rapid growth of apps is recognized as having the potential to challenge issues of access, quality, and safety for different patient groups [35]. For rural populations, there may be gaps in digital inclusion, including for low-income rural populations, aging cohorts, and those with limited education and employment [36,37]. Some web-based platforms may segment the population, primarily targeting relatively healthy people in employment [38]. Although apps may allow for more client-centered health care, this also needs to be evaluated considering the findings of research that note that patients perceive safe and high-quality health care as bound to their interaction with a trusted physician [39]. This may depend on how well apps can accommodate a relationship with the same physician and the health service over time.



## Objective

With this background in mind, our research aims to critically review mobile apps for delivering GP services in a rural health service context using the walkthrough method.

## Methods

### Context of Study

Australia was chosen as a case study for this research given its extensive focus on delivering rural GP care for 29% of the population living rurally across a wide geographic landscape [40]. It is also invested in rapid policy development in digital health, proposed as a modern means of delivering safe, high quality, and effective health services [41]. In 2017, 80% of Australians owned a smartphone, and digital health care uptake increased during the COVID-19 pandemic, potentially laying the groundwork for increased use of digital health care delivery [42].

### Walkthrough Method

We used the walkthrough method as described by Light et al [43]. This is based on the Actor–Network Theory which foregrounds experience as shaped by sociocultural and technical processes. It provides a lens through which one can understand how user interfaces and functions within technology mediate social processes within a system of networks. Networks can include humans, things, ideas, or concepts [44]. This allows for an in-depth analysis of the complexity of apps and their aims to uncover traces of their inner workings, intentions, positioning, and environment of expected use. The walkthrough method involves active engagement with an app via step-by-step progression through the interface using an environmental and technical scan via a structured template (Multimedia Appendix 1) [43].

Although the walkthrough method has been used to critically review communication, media, and cultural apps, few studies have applied it to appraise health care delivery—1 study evaluated an app for mental health self-monitoring and another focused on disease surveillance and tracking [45,46]. For this reason, we first established the boundaries of the project by writing and agreeing on a study protocol, which included the intention to explore *explicit factors*, such as the interface elements themselves, and *implicit factors*, such as the embedded cultural values framed by these elements, and how these may intersect with the rural health system.

Within the technical walkthrough, we also applied the framework of person-centered access to health care within systems by Levesque et al [47]. This framework specifically addresses the opportunity for consumers to identify health care needs and seek, reach, obtain, and use these services to achieve their goals. This ensured that the technical walkthrough collected structured data specific to health care provision to critique issues around approachability, quality, relevance, and satisfaction.

### Sampling Frame and Data Collection

We sampled the 3 most used GP service apps that offered consultations from the Apple App Store under the top 100 list in the medical category as of June 2020 in Australia to ensure

we critiqued apps with the highest levels of use. We sampled these apps as we wanted to understand a range of apps that people are likely to experience to access GP services. The chosen apps were independent services not affiliated with GP services that were based in a physical location. These apps were also available via the Google Play Store.

The researchers first downloaded each app (called apps 1, 2, and 3) and established a dummy profile. This was done by entering all the normal client information such as the name and payment information required by the apps to register as a client. This enabled the researchers to access all the app functions for a thorough analysis. None of the researchers had used apps to access GP services before commencing this research, and none were health care providers to minimize bias. In total, 2 researchers had iPhones and 1 had an Android device, allowing for a complete analysis that accounted for any difference between platforms. Over a 10-week period, the researchers used a preagreed walkthrough template (Multimedia Appendix 1) to independently explore and document reflections about the elements of the app and its background. This was done by each researcher exploring the app independently to promote critical analysis. They also read about each app on the related webpage and on the Google or Apple store as well as in any of its business reviews (material about the app available on the web). There was no interaction with patients on the web or with GPs as the purpose was to engage with the app interface. The environmental scan explored the context of expected use, including social, political, economic, and cultural contexts, and the technical scan explored mediator characteristics of actual use, with room for additional comments. Screenshots were also recorded to assist with data interpretation and discussion.

### Analysis

Each week, the researchers (BOS, DC, and IN) met and reflected on their independent data from field notes, screenshots, and emails received from the apps, with a researcher (IN) summarizing this discussion in written notes. From this discussion, several conceptual ideas arose, including the need to confirm or disconfirm theories or practicalities. This involved the researchers identifying and sharing relevant literature and revisiting the app to update new observations. Any emerging findings about an app were used to stimulate deeper exploration of the other apps. This was done until clear findings emerged that allowed for sufficient critique across the 3 apps with respect to the rural health system. The research team continually discussed arising material, critiquing the apps through sociological, patient, and system lenses and reading more widely about the rural health system to agree on the 3 cross-cutting themes that are presented.

Our research team included 3 researchers of mixed career stages skilled in clinical, public health, rural health services, and health sociology to aid reflexivity (testing biases and assumptions). One was employed in a rural First Nations community-controlled health service, another in a Rural Clinical School, and the third was employed as a city-based medical student. In total, 2 had experience working clinically in primary care (as physiotherapists). All were women.

This project did not require ethics as there was no data collection from humans or animals, and only publicly available data about a system of care, rather than patients, were used.

## Results

A total of 3 key themes were identified, which included how the apps related to improving rural access, addressing rural health care needs, and the provision of quality services.

### Improving Rural Access

The apps targeted rural access within a wider market offering of accessing GP services from anywhere ([Multimedia Appendix 2](#)). A business review (app 2) claimed that the service was appropriate for “patients in metro, regional, remote and foreign locations.” App 3 also claimed that they supplemented access for towns in a context where they had no GP “or if it does, they may be booked out for 3 or 4 weeks.” The apps were mostly founded by non-GP professionals (apps 1 and 3). App 1 worked as a stand-alone MedTech company (allowing for public trading and investors), and app 2 was an Australian Stock Exchange-listed company (which is ranked by market capitalization). This suggests that apps offer business opportunities for nonmedical entrepreneurs. Despite profit motivations, all the apps sought to position themselves as affordable as part of promoting access:

*...consultation costs are extremely competitive and lower than any private practice for a standard consultation... [App 3]*

User costs were mostly hidden in the app’s background information (except in app 3, where users could choose to read frequently asked questions [FAQs], including information about costs, before booking; [Multimedia Appendix 2](#)). Otherwise, costs had to be deducted at the point of booking based on displayed appointments, each of which noted the price the user would pay (apps 1-2; [Multimedia Appendix 2](#)). When trying to book an appointment, it became apparent that app-based services were billed at fixed time slots (10-15 minutes) using fully private billings to patients (Aus \$40-\$60 [US \$28.69-\$43.04]; apps 1-2) without reimbursement from Medicare (selective Medicare allowances for app 3 and timed appointments ranging from Aus \$35 [US \$25.10] to Aus \$105 [US \$75.31] by time category; [Multimedia Appendix 2](#)). It was necessary to enter payment details before booking an appointment. This mainly required users to have a credit or debit card (app 2 had some other options for payment for people without a credit card; [Multimedia Appendix 2](#)). Although the apps offered appointment options that were promoted as “instant” and “on demand,” it was not explicit as to whether this related to accessing a consultation with any particular physician and being able to see the same physicians over recurrent consultations or whether this may vary widely between different occasions of use.

Visual imagery was extensively used within app 1 and on all the apps’ websites to support engagement. Predominantly White women were depicted, with perfect skin and painted nails, presenting as mildly unwell (indicated by a box of tissues or a thermometer) sitting in clean houses with quality furnishings and clean and up-to-date technology devices. The images

emanated users having positive interactions with the GP provider on the web, smiling and waving at the screen implying a personable relationship that is at odds with the app’s ideal of real-time care of any GP available on the day. The images of physicians presented were also mostly White, elegantly groomed women or late middle-aged men in white laboratory coats with stethoscopes. However, when choosing an actual GP appointment in app 1, the image of the GPs with whom real appointments were made and the information about their country of training depicted providers of widely differing cultural backgrounds and overseas qualifications. In terms of approachability, the apps were differentiated by various opening hours and wider availability than in-person GP services (all offered GP care 7 days per week, one noted coverage 24/7, and app 1 allowed overseas clients; [Multimedia Appendix 2](#)).

The user’s technology requirements were relatively flexible ([Multimedia Appendix 2](#)) and, therefore, accommodating. However, there was an assumption that the user would have digital access and find the technology:

*...easy to use our service...all you need...just click on the button... [App 1]*

### Addressing Rural Health Care Needs

The apps used marketing to position their utility as responsive, high-quality, simple, comfortable, and affordable health care regardless of location:

*...patient-centred...convenient, quality healthcare...at a time and location that suits you...[enabling healthcare that is]...simple and affordable. [App 1]*

They also claimed that they could provide most GP services (on website promotions): “70% of GP presentations can be handled by telehealth (\*)” (app 1), which they claimed was based on American research, but this was not cited. Furthermore, it was claimed that “80% of normal GP services can be done online” (app 2), with no justification for this ([Multimedia Appendix 3](#)). The apps did not collect critical information about the patient’s rural context, such as their town name; access to local hospitals, pharmacies, or specialists; distances from referral centers; and transport options, despite these factors being strongly tied to the capacity to address rural health care needs.

The apps proceeded to claim that they delivered a wide service range: “we do everything” (app 1). However, their booking features ([Multimedia Appendix 3](#)) depicted more limited allowances, covering prescriptions, medical certificates, referrals, or other (seeing a GP for something more general). With reference to apps 2 and 3, the nature of the services available was only described under the *FAQs* and *learn more* sections that patients could choose to view or not before booking; however, these sections were not obvious to the user. There was also a conflicting narrative about the range of services that the apps offered between what was described on the app’s website and the app itself. The app 2 website denoted use for weight loss, alcohol, and drugs, although this utility was not mentioned in the *learn more* section of the app.

Using the app for *other* functions (app 3) suggested poorly defined boundaries. There was no warning of exclusions or

support to help patients discern the relevance of the service for addressing these needs, including any exclusions for a physical examination or for presentations such as pregnancy. Mostly, the apps provided refunds if users cancelled appointments—app 2 did so only if cancellations were given with 24 hours' notice, thereby excluding the app's purpose of accessing immediate care, and app 3 did so if the GP deemed the patient unsuitable (Multimedia Appendix 2).

It emerged that, despite their claimed utility, all apps excluded emergency services (only noted via the websites of apps 1-2; Multimedia Appendix 3):

*If you have a medical emergency please stop now and contact local emergency services.* [App 2]

Only app 3 included FAQs to define emergencies:

*...chest pain, head or spinal injuries, severe bleeding, loss of movement, breathing difficulties and reduced level of consciousness.* [App 3]

This definition provided clear boundaries but excluded a range of early warning symptoms such as headaches, sensory changes, or loss of balance that could be equally considered emergency situations in rural contexts.

Complex care was also excluded (Multimedia Appendix 3):

*Doctors reserve the right not to treat you if you are complex.* [App 1]

*This service is not suitable for serious medical conditions which should be handled by your GP.* [App 1]

Complex care was not defined, and there were no qualifiers as to what conditions might be "serious," including no material on the website's FAQs to guide decision-making. It became apparent for app 1 that this exclusion was related to the time involved in managing such cases rather than the limitations of the web-based model:

*Complex medical problems may not be suitable for Telehealth Consultation as they may require a longer time than 15 minutes.* [App 1]

Additional service exclusions were evident when attempting to book a consultation with an individual physician on apps 2 and 3. Further exclusions were noted for lengthy issues requiring physical examination or difficult negotiations:

*[We are] unable to process mental healthcare plans.* [Apps 2 and 3]

*Fit for Work Certificate, Centrelink Certificate...you will need to present to a GP in-person.* [App 3]

*...schedule 4 drugs that have the potential to cause harm should be sourced from your regular GP.* [App 1]

## Providing Quality Services

App 1 employed GPs who were generally registered but not qualified through the Australian General Practice training colleges—The Royal Australian College of General Practitioners or the Australian College of Rural and Remote Medicine (each requiring 3-4 years of vocational training and rural-specific

training to prepare physicians for working in rural settings). The apps provided information about the title of qualifications the physicians held and the country the qualifications were obtained in. Apps 2 and 3 used Australian-qualified GPs; however, for app 3, it was not possible to see the qualifications of the GPs until the user's payment details were entered (Multimedia Appendix 4).

For the GPs employed in app-based services, there was no information about rural skills or experience or about any cultural safety training that they may have done or not to ensure capability to provide quality rural GP care. For app 1, the GPs were subcontracted providers with their own Australian Business Number (Multimedia Appendix 4), and the app noted that the GPs' advice was not guaranteed:

*[We] do not represent, warrant or guarantee the quality of any medical advice provided by a doctor during a consultation.* [App 1]

Apps 2 and 3 did not disclose how the physicians were employed or make any disclaimers about the quality of their GPs' services (Multimedia Appendix 3), whereby it can be assumed that their advice to rural and remote patients is guaranteed. None of the apps mentioned clinical backup for the GPs providing the consultations should an urgent situation arise or the physician need to advise on something beyond their scope of experience. In app 2, there was a disclaimer about the capacity of the GPs to deliver the services users may want under some circumstances, although the nature of the "circumstances" underpinning this situation was not clear:

*Circumstances beyond our control may render it impossible to offer you an adequate service in which case you should seek the services of a local doctor.* [App 2]

The claims of safety of the app-based services were founded on the quality of the technology and guidelines around telehealth consultations rather than the quality of the medicine (Multimedia Appendix 4):

*...using the latest in web technology...our health practitioners comply with all relevant professional standards including the RACGP Standards for telehealth and the Australian Health Practitioner Regulation Agency (AHPRA) Guidelines for technology-based patient consultations.* [App 1]

No apps mentioned how health care would be followed up or coordinated between providers or by the same GP if the app was used again (Multimedia Appendix 4). Only app 2 made provisions for patients to see their own physician if their own physician registered with the app-based service as a potential revenue generator for the app supply chain and its service volume.

App 2 also had a strong platform to promote web-based Medicare-rebatable specialist referrals; however, these were not guaranteed to occur in coordination with a rural user's regular GP. The apps did not provide any information about teaching or professional support for the employed GPs. There was no training framework embedded for supporting workforce



development, although this is a legitimate part of quality within any primary care ecosystem.

App 1 provided an option for script renewal without needing to see a GP:

*...request a repeat prescription for a select range of medications they have used before by simply completing an online questionnaire... [App 1]*

Finally, all the apps only shared notes with the regular GP if the patients requested it ([Multimedia Appendix 4](#)).

## Discussion

### Improving Rural Access

Apps represent a major departure from traditional physician-led general practice businesses that have emerged from a professional philosophy within medicine of treating the ill to the best of one's ability under ethical standards (conscience, integrity, and confidentiality), relegating livelihood to a secondary issue [48]. Their strong profit motivations may counter any mission to improve rural access and deliver the range of services needed by rural patients, particularly if doing so could be costly.

Although the apps made claims of affordability, they did not give explicit and up-front information to users about the costs they might incur in before engaging with the app, which could lead to unintended use and costs, deterring rural users from accessing ongoing primary care. The service structure around set appointment times and fixed payments may have limited benefits for improving access to services of the intensity, range, and affordability needed by rural people with chronic and complex care, including older adults and First Nations people who are overrepresented in rural communities [49]. Furthermore, it may be a barrier for rural users who may have lower education, higher unemployment, and volatile earning capacity (occupations susceptible to policy, business, and environmental conditions) [50]. In-person GPs can exercise discretion over appointment length and patient costs, including giving patients to the national Medicare rebate system, which flexes to consultation length and complexity at the discretion of the individual GP [33]. On the other hand, apps may not adequately address universal access goals of health care that aligns with need but is also affordable in a rural economy [16].

The apps are positioned in a way that counters rural community-centered norms, values, and culture, where health care is provided by physicians and health workers who are trusted and known in the community. First Nations people rely on services that are community-centered and that account for local community beliefs and values [49]. Instead, the apps seek to connect to an individual, shutting out the community context. What is offered is an aspirational lifestyle that is potentially at odds with the lived reality of the multicultural and rural poor. The reality of illness in rural overcrowded housing is juxtaposed against the elite and airy environment of the mildly unwell White woman presented [51]. Physicians depicted with stethoscopes seek to validate the provider's skills as trustable, although the reality is that this claim cannot be tested by users through a web-based setting [52]. The different values portrayed

may create uncertainty among rural users as to whether the app can work for them as promised, possibly hindering use. The lack of rural-specific language, culture, or dress of patients and providers in visual imagery could also deter rural and First Nations users from engaging with apps given that all aspects of health care need tailoring to promote access by groups that do not have Western medical ideals [49,53].

The focus on providing a payment mode before the consultation may challenge the rural psyche around a collective economy where goods and services are shared for community well-being and sustainability [54]. This rests within an Australian medical culture where GPs can be seen with no out-of-pocket costs because of the social values of fair and equitable health care [32]. Apps also somewhat oppose the rural ideals of self-determination and patient-centered care by positioning the protection of assets outside of the community as temporally more important than responding ethically and with ongoing commitment to supporting unwell people in a challenging environment.

Although the apps were marketed as easy to use, it is possible that older adults and digitally isolated people in rural and remote areas could find the use of apps challenging [37].

### Addressing Rural Health Care Needs

The degree to which apps account for 70%-80% of in-person rural GP services may need to be tested as to how well they align with the wider scope of rural GPs [18]. This relates to the role that in-person rural GPs play in addressing most medical needs in rural places where specialists and allied health providers are in shortage [55,56]. The assumption that apps can support most rural patient needs underplays the role of contextual and holistic patient- and place-based knowledge that is necessary for physicians to deliver effective GP services in rural places [22,57]. By espousing such a wide reach, apps are setting unrealistic expectations about how much they can assist rural users. One key example is that they do not disclose that they cannot provide physical examinations; however, Australia's peak agency in web-based health, the Digital Health Agency, notes that telehealth is only useful "when a physical examination isn't necessary" [58].

There is a clear orientation to profit over addressing rural needs as the apps were positioned to enable rural users to book inappropriate appointments because the service limitations were inadequately disclosed. A major policy review related to services provided by GPs recommended the use of clinical decision support tools to help with "the provision of advice at the point of care (when decisions are being made by the medical professional) that is tailored to the clinical context of the specific patient" [59]. Clinical decision support tools could be applied to promote the appropriate use of apps where indicated for rural patients.

Chronic and complex conditions are more prevalent in rural communities and, by excluding these conditions, apps are likely to miss the bulk of rural population needs. Some chronic conditions may be amenable to web-based consultation, for example, mental illness; however, the default referral of all complex problems to in-person GPs suggests that apps reject

chronic illness to target a lucrative revenue base. Meanwhile, this may increase rural GP burnout and add to rural GP retention problems that already worsen with rurality [60]. This undermines the capacity of apps to address rural health care needs; rather, they have the potential to worsen rural GP burnout. Rural GPs seeing patients who have used app-based services may also need to spend more time chasing tests and referrals that patients may not easily recall. This may increase service duplication for patients and create inefficient and delayed care. The apps also failed to provide ongoing, coordinated care for rural people, which is inherent to supporting a high prevalence of chronic diseases in rural areas [61] and supporting aging and First Nations populations in rural communities [29].

With respect to delegating emergency care to local service providers, the apps assumed that rural users have access to such services locally. There was no attempt to screen for rural patients' health service amenities, distance, and costs, as well as their emergency risks, when establishing appointments. The reality for many rural underserved populations facing distance and cost barriers is that complex health issues can remain dormant only to surface as an acute medical emergency at any time [22,62]. If apps do not screen for these issues appropriately and rural patients have no local GP to back up an app service, this could lead to emergencies being handled via app-based GPs unfamiliar with the service context and inefficient at mobilizing the local resources needed for lifesaving, rapid patient stabilization and retrieval [22].

Although apps propose a wide market position in GP care for rural populations, the Consumer Rights Law and the National Guidelines for Advertising of Regulated Health Services (section 29 of the National Law) suggest that apps may be marketing beyond their utility and creating unreasonable expectations of treatment. First, the Australia Consumer Rights Law requires that products do all the things that they propose they will do before people purchase services [63]. Second, the National Law requires that regulated health services do not create unreasonable expectations of beneficial treatment or encourage indiscriminate or unnecessary use [64]. The apps seem to nudge into the territory of doing both, particularly in light of their interface with rural consumers.

### Providing Quality Services

The major thrust of Australian policy aims to train and retain skilled rural GPs that can work effectively across the scope of patient care required in rural areas [21,23]. However, despite proposing to provide health care anywhere, the apps appointed GPs without disclosing their rural skills and experience and, in some cases, noted that they could not guarantee their advice. This contrasts strongly with the normal guarantees of in-person GP services, including the commitment of rural GPs to take on wider liability for patients where the caseload is vastly more undifferentiated and there are fewer health care resources [22].

The lack of support and upskilling provided for GPs working in the app business is unusual given the propensity for GPs to face difficult cases in rural areas. Countering this, rural health care quality is supported within in-person GP service models through team-based decision-making and clear escalation policies. The oversight of any service backup is perhaps

managed by the app's feature of self-selecting simple caseloads, but rural patients with complex or urgent care needs have a high chance of using the app inappropriately because they are inadequately screened and informed of exclusions before use. In addition, the apps did not mention anything about health worker training despite medical workforce supervision being an inherent part of rural GP practice quality improvement [65]. Training may be poorly accommodated within app-based models if it uses profitable time and has no payment attached to the learner.

There is some potential for app-based GP services to integrate better with local GP services rather than operating as stand-alone businesses. This could be led by rural GPs if a prototype app were developed for them to apply within their local business to manage waiting lists and promote early intervention. The benefits of this would be that the model occurs within the boundaries of an ongoing physician-patient relationship and reinforces rural GP business sustainability. Recent policy changes allowing in-person GPs to gain reimbursements via Medicare for new telehealth item numbers, incorporating rebates for services they deliver by telephone, support this expansion [66].

Although there was 1 example of an app proposing to provide for script renewal without an appointment, even small changes or continuation of medications may cause acute exacerbations in older adults and complex patients, which is common in rural settings. The app model depends on self-declaring existing medications, which may also be difficult for patients to recall. The result of this model may be that rural patients who have acute exacerbations will place pressure on limited rural staff and infrastructure atop of an already busy workload. Higher-quality care could be achieved if app-based consultation information were shared with a regular GP, thereby valuing rural physicians who understand the comprehensive patient history contextualized to place.

### Conclusions

In conclusion, app-based GP services may improve rural GP service availability. However, this may be at a relatively superficial level that does not encompass the scope and intensity of the services needed in rural areas (including relevant chronic and emergency care) at a cost that rural patients can afford. Apps show signs of limited tailoring to the cultural dimensions of rural health care, which presents a key barrier to rural use. Patients generally self-select to use apps with limited support, potentially leading to inappropriate uptake especially by rural cohorts who may be disadvantaged. Although apps claim to avail most GP services (70%-80% in some cases), after enrolling in these services, it emerges that emergency, complex, and serious conditions may be excluded, potentially imposing more complex patient caseloads on in-person rural GPs. They also provide limited information about continuity and coordination of care and sharing information with rural GPs as a source of fragmented and low-quality care for rural patients. There is commonly no assurance of rural skills and experience of app-based medical staff despite the wider scope of skills needed to be effective in rural general practice. It is advisable for



app-based GP services to attend to these issues to better address rural access and health care needs.

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## Authors' Contributions

BOS conceived the study. IN, DC, and BOS collected and analyzed the data, and BOS wrote the first version of the manuscript. DC and IN contributed to editing. All authors agreed on the final manuscript for publication.

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## Conflicts of Interest

BOS was employed by a Rural Clinical School that aims to train the medical workforce in rural areas, but this relationship did not influence the collection or interpretation of the data.

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### Multimedia Appendix 1

Data collection template related to the walkthrough method.

[DOCX File, 16 KB - [formative\\_v6i1e30387\\_app1.docx](#) ]

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### Multimedia Appendix 2

A summary of the app business models and allowances.

[DOCX File, 19 KB - [formative\\_v6i1e30387\\_app2.docx](#) ]

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### Multimedia Appendix 3

A summary of the app appointment functions and utility.

[DOCX File, 18 KB - [formative\\_v6i1e30387\\_app3.docx](#) ]

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### Multimedia Appendix 4

A summary of the app quality, privacy, and troubleshooting.

[DOCX File, 17 KB - [formative\\_v6i1e30387\\_app4.docx](#) ]

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## Abbreviations

**FAQ:** frequently asked question

**GP:** general practitioner

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Original Paper

# Patient Preferences for Patient Portal–Based Telepsychiatry in a Safety Net Hospital Setting During COVID-19: Cross-sectional Study

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## Abstract

**Background:** Patient portals are a safe and secure way for patients to connect with providers for video-based telepsychiatry and help to overcome the financial and logistical barriers associated with face-to-face mental health care. Due to the COVID-19 pandemic, telepsychiatry has become increasingly important to obtaining mental health care. However, financial and technological barriers, termed the “digital divide,” prevent some patients from accessing the technology needed to use telepsychiatry services.

**Objective:** As an extension to a clinic’s outreach project during COVID-19 to improve patient engagement with video-based visits through the hospital’s patient portal among adult behavioral health patients at an urban safety net hospital, we aim to assess patient preference for patient portal–based video visits or telephone-only visits and to identify the demographic variables associated with their preference.

**Methods:** Patients in an outpatient psychiatry clinic were contacted by phone, and preference for telepsychiatry by phone or video through a patient portal, as well as device preference for video-based visits, were documented. Patient demographic characteristics were collected from the electronic medical record.

**Results:** A total of 128 patients were reached by phone. A total of 79 (61.7%) patients chose video-based visits, and 69.6% (n=55) of these patients preferred to access the patient portal through a smartphone. Older patients were significantly less likely to agree to video-based visits.

**Conclusions:** Among behavioral health patients at a safety net hospital, there was relatively low engagement with video-based visits through the hospital’s patient portal, particularly among older adults.

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**KEYWORDS**

patient portal; telemedicine; telepsychiatry; COVID-19; portal; mental health; psychiatry; engagement; behavior; video; hospital; urban; outreach

## Introduction

There has been a rapid shift in the delivery of outpatient medical and mental health care from in-person to virtual through

teleconferencing services/platforms since the World Health Organization declared the COVID-19 outbreak a global pandemic on March 11, 2020 [1]. Virtual mental health care and telepsychiatry encompasses care provided through various



electronic means, often involving live video and audio, but also including telephone-only visits [2]. Prior to COVID-19, telepsychiatry use by phone and video was highly region-dependent and was used more in rural and Health Profession Shortage Areas in which geographic isolation and provider shortages created difficulties in accessing face-to-face mental health care [2,3]. For example, between 2014 and 2016, only 0.1% of psychiatrists in Massachusetts performed telepsychiatry work, compared to 24.2% of psychiatrists doing so in North Dakota [2]. To support safe and accessible health care services, the Centers for Medicare and Medicaid Services expanded coverage for telemedicine and telepsychiatry services at the beginning of the COVID-19 pandemic by declaring that it would reimburse video and audio-only evaluation and management services at rates equivalent to in-person visits. As a result of these changes, by the end of March, most hospitals in the United States had begun offering virtual appointments for their patients [2]. A subsequent June 2020 national survey found that 85% of psychiatrists were seeing most of their patients through telepsychiatry [4].

In addition to helping limit viral spread, telepsychiatry carries other advantages for both the patient and provider. For patients, telepsychiatry enables access to mental health services from their own homes, which for some, decreases anxiety and stress associated with leaving a safe and private environment, and allays financial burdens associated with transportation and taking time off from work [2,5,6]. From a provider standpoint, clinical care can be enhanced through greater understanding of the patient's family and living situation [2]. Furthermore, studies have suggested that telepsychiatry assessments are as effective as in-person visits across various psychiatric diagnoses and patient populations [2,5]. Telepsychiatry can occur over the phone or by video, although video-based appointments have been described by clinicians as superior to phone-only visits for providing reassurance, building rapport, and gathering greater clinical information [7].

Although telepsychiatry provides many advantages in the current environment, successful use of these services requires a consistent level of technological access that may be prohibitive for some patients. A 2019 Pew Research Center report found that, although most Americans are able to access the internet through laptops, desktops, and tablets, lower educational attainment and lower annual income were associated with decreased access to these types of devices and to broadband internet access [8]. Currently, at least 21 million Americans lack consistent access to broadband internet, which results in a reliance on mobile devices to access internet services [9]. Although most Americans have smartphones, 17% of Americans are "smartphone-dependent," relying almost exclusively on smartphones for online access. The number of "smartphone-dependent" individuals has also approximately doubled since 2013 [8,10]. Increasingly, mobile devices are the primary method of internet access for vulnerable populations [8,10,11]. The impact of the "digital divide," defined as the inequality between those who have access to devices and the internet and those who do not, on health, education, and employment has been previously recognized [8,11,12]. However, the COVID-19 pandemic has made these inequities

more evident due to the greater demand and need for fast, reliable access to the internet [13]. More than ever before, the internet has become essential for allowing patients to interface with the mental health system. In many health care systems, this rapid expansion of telepsychiatry services during the COVID-19 pandemic did not allow for adequate evaluation of barriers to telepsychiatry use or preparation of a plan to manage these barriers [11]. An inability to adequately address these issues may result in further disparities and a widening of the "digital divide" [11].

One means by which telepsychiatry visits can occur is through online patient portals. Patient portals are secure locations on the internet from which patients can access personal health information, schedule appointments, communicate with their providers, and connect with providers for video-based appointments [14-16]. In behavioral health settings, patient portals have been shown to increase a sense of patient autonomy, improve patient activation, and decrease administrative inefficiencies [17,18]. A recent study in a large health system across multiple specialties has also demonstrated patient portal activation is associated with increased patient ability to complete telemedicine visits [19]. Furthermore, video-based appointments performed directly through electronic medical record (EMR)-based patient portals such as MyChart provide an additional layer of security compared to separate virtual platforms such as Doximity or Skype [15] and have the advantage of closer integration with the patient's medical record, which may help with documentation and billing [20]. Unfortunately, direct comparisons between different virtual platforms are limited. Notably, individuals who access the internet only through smartphones are significantly less likely to access patient portals than individuals with a wired connection [10].

Given the importance of patient portals for secure, expedient, and high-quality psychiatric care through video-based visits, it is important to evaluate patient portal access among behavioral health patients, as research on patient portal-based video visits in behavioral health settings has lagged behind similar research in primary care settings [18,21]. Early in the COVID-19 pandemic, our outpatient adult behavioral health clinic at an urban safety net hospital sought to assess patient preference for patient portal-based video visits or telephone-only visits since telepsychiatry had not been offered prior to the pandemic. Safety net hospital systems consist of hospitals and providers that deliver a substantial amount of their care to patients insured through Medicaid or who have no insurance. Historically, safety net hospitals have cared for vulnerable and underserved populations, often consisting of racial and ethnic minorities [22,23].

The aim of this study is to describe patient preference for telepsychiatry visits and evaluate for demographic characteristics associated with preference for video-based visits. Based on past research on patient portal use, we hypothesized that patients who have public insurance, are homeless, and are older will be less likely to choose video-based visits through the patient portal, due to diminished ability to access the required technology [10,14,20,24-27].

## Methods

### Study Design and Recruitment

Since telepsychiatry had not been offered prior to the pandemic, our outpatient adult behavioral health clinic at an urban safety net hospital conducted an 8-week outreach project to improve patient engagement with video visits through the hospital's patient portal. This clinic is based at an academic medical center and serves a demographically diverse patient population. The clinic treats a range of psychiatric disorders, including mood disorders, anxiety disorders, trauma-based disorders, psychotic disorders, and substance use disorders. Outpatient services, including medication management, individual therapy, and groups, are available on site at the clinic. There is also a subspecialty clinic for psychosis that administers long-acting injectable antipsychotics and closely monitors patients on clozapine. Prior to the COVID-19 pandemic, visits only took place in-person, and in 2019, there were 7405 unique patients seen in the clinic between January and December. At the time of the outreach efforts, the majority of clinic visits were virtual, although face-to-face visits were still available, for example, for the antipsychotic injection clinic.

Between June 15 and August 21, 2020, clinic staff contacted all patients by telephone, both new and established, who were scheduled for an upcoming appointment in the clinic. Using a previously defined script, staff asked patients about their preference for future telepsychiatry visits—video based through the patient portal or telephone only. If a patient expressed preference for a video visit, they were asked whether they would use a smartphone or computer. For telephone-only visits, if a patient reported availability of a smart device or computer and internet access, this was also recorded. Data on preference for face-to-face visits was not collected, as the goal was to collect information on preference for the type of telepsychiatry visits.

For this study we included patients  $\geq 18$  years of age who demonstrated plans to continue care in the clinic with upcoming appointments. We used the information collected by clinic staff and conducted a retrospective chart review of the EMR to collect demographic information including age, sex, race, ethnicity, insurance, and homeless status. Ethnicity data was divided into two categories based on the EMR's categorization, which divides ethnicity into "Yes-Hispanic or Latino" or "No-Not Hispanic or Latino." Homeless status was determined through review of clinical documentation as well as a search of the EMR for the words "homeless," "housing," "lives," and "stays."

A total of 315 patients were called by clinic staff. Seven patients were excluded from the sample because they were not  $\geq 18$  years of age ( $n=1$ ), were no longer receiving treatment in the clinic

or informed clinic staff they were cancelling their upcoming appointments ( $n=4$ ), or for whom a valid medical record number was not listed ( $n=2$ ). Among the 308 patients included in the sample, clinic staff were able to contact 128 (41.6 %) patients. This study was approved by the Institutional Review Board.

### Statistical Analysis

We first stratified patients by those who clinic staff were and were not able to contact, and compared demographic characteristics between groups. We then limited our sample to those who clinic staff were able to contact and compared the rates of those who chose video-based visits through the patient portal between patients with different demographic characteristics. We used bivariate analyses in the form of *t* tests to analyze continuous outcomes and Pearson chi-square or Fisher exact tests to analyze categorical outcomes. Crude odds ratios were calculated based on the bivariate analyses. In the event of zero cells, we added 0.5 to all cells to calculate the odds ratio. Analyses were performed with Stata, Version 16.1 (StataCorp).

## Results

Patients who were contacted by clinic staff did not differ significantly from patients who the staff were not able to contact ( $n=180$ ) with respect to age, sex, race, ethnicity, or homeless status (Table 1). However, there was a significant difference in insurance status between groups ( $P<.001$ ). The group of patients who the clinic staff were able to contact had a greater percentage of patients with no insurance compared to the group that the clinic staff were unable to contact ( $n=11$ , 8% vs  $n=0$ , 0%).

Among the 128 patients that clinic staff were able to contact, 79 (61.7%) preferred video-based visits through the patient portal and 49 (38.3 %) preferred phone-only visits (Table 2). Among those who chose video-based visits, 55 (69.6%) patients preferred to access the patient portal through a smartphone, 16 (20.3%) through a computer, 3 (3.8%) through a tablet, and 5 (6.3%) did not have a preference documented. Among the 49 patients who preferred phone-only visits, clinic staff notes for 8 patients indicated that 2 did not have internet access, and 6 did not have access to a smart device or computer. The percentage of patients who chose video-based visits through the patient portal significantly differed by patient age group (Table 2). Patients who were  $\geq 55$  years of age were at 91% and 84% decreased odds of choosing video-based visits through MyChart when compared to patients 18-34 years of age and 35-54 years of age, respectively. There were no significant differences in preference for video visit through the patient portal by gender, race, ethnicity, insurance status, or housing status.

**Table 1.** Demographics characteristics of adult outpatient psychiatry clinic patients who clinic staff were and were not able to contact by telephone between June 15 and August 21, 2020.

	Not able to contact (n=180)	Able to contact (n=128)	P value
Age (years), mean (SD)	45.0 (13.5)	42.2 (14.2)	.08
<b>Age groups (years), n (%)</b>			.33
18-34	54 (30)	44 (34)	
35-54	78 (43)	59 (46)	
≥55	48 (27)	25 (20)	
Male gender, n (%)	72 (40)	49 (38)	.76
<b>Race, n (%)</b>			.36
White	75 (42)	42 (33)	
Black/African American	64 (36)	48 (37)	
Asian	2 (1)	1 (1)	
Native American	0 (0)	2 (2)	
Other (including Hispanic/Latino)	8 (4)	8 (6)	
Declined	31 (17)	27 (21)	
<b>Ethnicity, n (%)</b>			.07
Not Hispanic/Latino	148 (82)	94 (73)	
Hispanic/Latino	31 (17)	30 (23)	
Declined	1 (1)	4 (3)	
<b>Insurance, n (%)</b>			<.001
Public (Medicare/Medicaid)	140 (78)	88 (69)	
Private	40 (22)	29 (23)	
Uninsured	0 (0)	11 (8)	
<b>Homeless, n (%)</b>			.67
Not homeless	146 (81)	105 (82)	
Homeless	23 (13)	18 (14)	
Unknown	11 (6)	5 (4)	

**Table 2.** Demographic characteristics of adult outpatient psychiatry clinic patients who chose telepsychiatry visits by telephone or video through a patient portal.

	Telephone (n=49)	Video (n=79)	Video over telephone visits, odds ratio (95% CI)	P value
Age (years), mean (SD)	49.5 (2.1)	37.7 (11.7)	N/A <sup>a</sup>	<.001
<b>Age groups (years), n (row %)</b>				<.001
18-34 (reference)	10 (23)	34 (77)	N/A	
35-54	20 (34)	39 (66)	0.57 (0.24-1.39)	
≥55	19 (76)	6 (24)	0.09 (0.03-0.30)	
<b>Gender, n (row %)</b>				.08
Male (reference)	14 (29)	35 (71)	N/A	
Female	35 (44)	44 (56)	1.47 (0.61-3.59)	
<b>Race, n (row %)</b>				.38
White (reference)	18 (43)	24 (57)	N/A	
Black/African American	19 (40)	29 (60)	1.44 (0.49-2.66)	
Asian	0 (0)	1 (100)	N/A	
Native American	2 (100)	0 (0)	N/A	
Other (including Hispanic/Latino)	2 (25)	6 (75)	2.22 (0.34-24.96)	
Declined	8 (30)	19 (70)	1.78 (0.64-4.98)	
<b>Ethnicity, n (row %)</b>				.94
Not Hispanic/Latino (reference)	37 (39)	57 (61)	N/A	
Hispanic/Latino	11 (37)	19 (63)	1.12 (0.48-2.62)	
Declined	1 (25)	3 (75)	1.94 (0.15-104.95)	
<b>Insurance, n (row %)</b>				.67
Public (Medicare/Medicaid; reference)	36 (41)	52 (59)	N/A	
Private	9 (31)	20 (69)	1.54 (0.63-3.76)	
Uninsured	4 (36)	7 (64)	1.21 (0.28-6.06)	
<b>Homeless, n (row %)</b>				.06
Not homeless (reference)	39 (37)	66 (63)	N/A	
Homeless	10 (56)	8 (44)	0.47 (0.17-1.30)	
Unknown	0 (0)	5 (100)	6.53 (0.35-121.36)	

<sup>a</sup>N/A: not applicable.

## Discussion

### Principal Results

Results of an outreach project to adult outpatient behavioral health patients at a large urban safety net hospital during the COVID-19 pandemic and subsequent chart review showed that 61.7% (n=79) of patients contacted preferred telepsychiatry visits by video through the hospital's patient portal to phone. We also found patients 55 years and older were 84% to 91% less likely to choose video-based visits through the hospital's patient portal compared with younger patients ages 18-34 years and 35-54 years, respectively. Finally, among patients who chose video-based visits through the patient portal, 69.6% (n=55) preferred to use a smartphone.

### Comparison With Prior Work

Our main finding that 61.7% (n=79) of patients preferred video-based visits through the hospital's patient portal to phone visits is lower than a similar survey during the COVID-19 pandemic of patients in a large hospital-based psychiatry clinic that found 82.8% of patients chose video-based visits through a patient portal [28]. The differences in preference for video-based visits over phone visits could be related to demographic differences between clinics that may reflect access to technology, clinic workflow, or other structural influences [29]. Notably, our sample included patients who primarily had public insurance (n=88, 69%) and had greater racial diversity (n=48, 37% Black, n=42, 33% White) compared to the prior study where patients primarily had private insurance (65.2%) and were largely White (77.5%) [28]. A recent survey of providers in a safety net hospital in a non-mental health setting

showed results consistent with our study [29]. These providers reported that most visits were conducted over the telephone due to patient preference, with technological problems and digital literacy being the most common barriers to video visits [29]. Given the importance of video-based visits through patient portals for delivering safe [29], high-quality psychiatric care, increased research with demographically diverse patient samples is needed to identify what barriers may be leading to decreased preference for this type of telepsychiatry visit.

The finding that older patients in behavioral health were 84% to 91% less likely than younger patients to choose video visits through the hospital's patient portal is consistent with the survey previously mentioned that was conducted during the COVID-19 pandemic with patients from a hospital-based psychiatry clinic [28]. Severe and colleagues [28] found patients 44 years and older were 1.2 times more likely than younger patients to choose telephone visits over video-based patient portal visits [28]. These findings are also similar to research done prior to the COVID-19 pandemic in the primary care setting that found older adults 65 years and older were less likely to use patient portal-based video visits than adults 18–44 years of age [30]. Previous research has identified that older adults are less likely to use patient portals due to issues with computer literacy, physical and cognitive limitations, and concerns regarding privacy [25,26,31]. Since video-based visits provide greater flexibility for patients with transportation barriers [5,7,30,32] and possible opportunities for increased caregiver or family involvement [2,33], additional research is needed to develop strategies to address barriers to older adult engagement in video-based patient portal visits.

Our finding that 69.6% (n=55) of people who chose video-based visits through a patient portal preferred to access them by smartphone is similar to another study conducted within another safety net health system, the Los Angeles County Department of Health Services, which found 70% of patients accessed the patient portal through a mobile device [24]. In contrast, other studies in health care systems with predominantly private payors have found patients most commonly access the patient portal through a desktop computer [24,27,34,35]. Differences in the type of device used to access patient portals may be due to income since patients with low incomes are more dependent on smartphones for online access, as broadband internet is an added expense [24,30,35]. Screen size is a key difference between mobile devices and desktop computers, as larger screen size is correlated with a greater sense of user control over the device and increased feelings of satisfaction when using the device, which may be due to greater ability to perceive affective stimuli on larger screens [36]. Therefore, it is important that the controls and designs of patient portal interfaces be optimized for all devices. This may help increase equitable access to video-based visits through patient portals for patients who use smartphones to access the platform.

### Limitations

Results from our study must be considered in light of its limitations. First, data regarding preference for other types of video visits was not collected as part of this initial outreach project, as the goal of this outreach was to improve engagement

with video visits through the hospital's patient portal. As a result, it was not possible to compare preference for video visits through a patient portal with video visits through another modality such as Doximity or Skype. Clinic staff were also unable to contact the majority of patients scheduled for appointments, which limits the generalizability of our findings across the clinic population. Nevertheless, demographic characteristics were extracted from the medical record, and the only difference found between patients who staff were and were not able to contact was in the number of patients without insurance. However, other clinical characteristics that may have impacted patient preference for video visits through the patient portal were not extracted from the medical record or collected by clinic staff, including prior duration of treatment, psychiatric diagnosis, employment status, income, and the availability of assistance from others. These characteristics will be important to examine in future research. This study also took place at a single site, which limits generalizability to clinics in other parts of the country. Furthermore, we were limited in our ability to determine why patients chose phone visits instead of video-based visits through the patient portal since the data collected did not consistently document whether patients were unable to use video-based visits since they could not access the technology or because they did not want to use this type of telepsychiatry visit. As a result, the exact number of individuals who are "smartphone dependent" could not be determined. Additionally, some of the variables we investigated, such as homeless status, had relatively few patients, which limited our statistical power to detect a difference. Lastly, due to the time-limited nature of the patient outreach, we were unable to examine any evolution of trends in patient portal-based video visits over the course of the pandemic.

### Conclusions

In summary, although the benefits of video-based visits through patient portals are well documented, there has been limited research on the use of this type of telepsychiatry visit in behavioral health, particularly in vulnerable populations in safety net health care systems. We found relatively low engagement in video-based visits through the hospital's patient portal, particularly among older adults, when compared to a health care system serving patients with mostly private insurance. We also found that most patients preferred to access patient portals through their smartphone. Compared to previous studies, this paper adds to the existing literature around technological equity by exploring patient-level engagement with patient portals in a safety net population. There is currently limited research on patient preference for telepsychiatry modality in this specific patient demographic, particularly in a behavioral health setting. Clinicians, hospital administrators, and researchers should keep in mind that some patients may be particularly hesitant to obtain care through this modality, even with the previously discussed benefits. Thus, there is a need for additional research to evaluate ways to increase patient engagement with video-based visits through patient portals in a behavioral health setting, especially as these types of visits may remain prominent modalities even as in-person appointments resume [37].



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## Conflicts of Interest

AY is currently receiving National Institutes of Health funding and is a consultant to Gavin House and Baycove Human Services (clinical services). HY is currently part of the Doximity Clinical Fellows Program. The remaining authors report no financial or other relationship relevant to the subject of this paper.

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## Abbreviations

**EMR:** electronic medical record

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Original Paper

# Design and Evaluation of a Just-in-Time Adaptive Intervention (JITAI) to Reduce Sedentary Behavior at Work: Experimental Study

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## Abstract

**Background:** Employees in sedentary occupations tend to spend prolonged hours physically inactive. Physical inactivity is a main factor in the increase in the risks of a wide range of chronic diseases, including obesity, diabetes, hypertension, and heart disease. This has drawn researchers' attention to investigate methods of increasing the level of activity of employees during working hours and in their daily lifestyle.

**Objective:** The objective of this paper is to investigate the effectiveness of using personalized messages that include user information, user goals, daily routine, and the surrounding environment to increase the level of activity among employees. In this study, we hypothesize that sending context-aware motivational messages to workers in sedentary occupations after sitting for 40 minutes can break sedentary behavior and increase daily active time compared to static reminder messages.

**Methods:** A 66-day between-group study using a mixed methods design approach was conducted with employees who are located in Qatar and spend most of their working day sedentary. The 58 participants used 2 different interventions: The control group (n=29, 50%) used a mobile app that only sends a static message after prolonged sitting (MotiFit Lite), and the intervention group (n=29, 50%) used a mobile app that sends context-aware personalized messages to promote physical activity (PA; MotiFit). Both apps log the received messages, the step count before and after the messages are sent, and the user response to the messages to obtain an idea of the impact of the messages. The study received approval from the Qatar Biomedical Research Institute's institutional review board (IRB application #2019-10-037).

**Results:** The questionnaires showed satisfaction of the designed apps' subjective quality and perceived impact. The quantitative analysis showed a high level of engagement in the intervention group compared to the control group ( $P < .001$ ). The results support the original hypothesis that using context-aware motivational messages can increase PA at work compared to static messages ( $P < .001$ ). However, the analysis showed no significant impact of the message type on the overall activity level during the day ( $P = .06$ ).

**Conclusions:** Context-aware motivational messages motivate employees to increase their PA in the workplace. However, future research will further develop the analysis to investigate the impact on increasing the overall activity level during the day.

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**KEYWORDS**

sedentary behavior; persuasive technology; behavior change; physical activity; adaptive intervention

## Introduction

An inactive lifestyle is a main controllable cause of metabolic syndrome (MetS), along with obesity and insulin resistance [1]. MetS is defined according to the International Diabetes Federation (IDF) as the group of risk factors that raise the likelihood of getting health complications, such as heart disease, diabetes, and stroke [2]. These risk factors can be in the form of traits, conditions, or habits. PA benefits health in many ways, including the prevention of obesity, hypertension, heart disease, stroke, type II diabetes mellitus, and hypercholesterolemia [3]. Moreover, some studies have proved that an active work style improves creativity, self-esteem, mental health, and stress tolerance, as well as work performance and productivity [4,5]. Studies have also shown that frequent rest breaks are successful in reducing self-reported discomfort in the upper limb muscles by up to 35%, while improving work productivity and speed [6].

Mobile health coaching approaches have many benefits over traditional face-to-face methods because they are more accessible, scalable, cost-effective, and time-location independent. They can also be personalized to meet the user's needs and preferences. This personalization makes mobile apps getting used by more people generally and makes mobile apps popular for motivating PAs particularly [7]. Moreover, mobile apps use phone sensors, such as accelerometers, gyroscopes, and the Global Positioning System (GPS). The use of an accelerometer embedded into mobiles for measuring PAs has been evaluated, and the results have shown accuracy and reliability in measuring and quantifying PAs in both laboratory and real-life settings [8].

According to the just-in-time support, following an intervention-determined scheme rather than a participant-determined scheme provides the right type of support at the right time [9]. Multiple components are used to construct the foundation to design these interventions: decision points, intervention options, tailoring variables, and decision rules. A decision point in just-in-time adaptive intervention (JITAI) is the time at which an intervention decision is made [10]. An intervention option is a set of possible actions that would be used at a given decision point for different types, methods, and amounts of support, delivered through a particular medium. Tailoring variables are information concerning an individual that is used to decide which intervention to offer and at what time. Tailoring variables in JITAI can be attained using ongoing assessment, passive assessment, or both. Finally, the decision rules in JITAI systematically link the intervention options and the tailoring variables to operationalize the adaption by specifying which intervention option to provide, for whom, and when [11].

Mobile apps in health care are equipped with supportive functionalities to make them more persuasive toward behavioral change. For example, some apps make use of the sensors integrated into smartphones and handle the interaction through a persuasive mobile app [12]. In a pilot study, researchers presented an activity logger mobile app (BEN'FIT) that aims to motivate PA by suggesting equipment-free exercises that can

be done in the home or work environment. In another study, a mobile app (SitCoach) was investigated for the effectiveness of using reminders after prolonged sitting time to reduce sedentary behavior at work [13]. Another study used gamification to design an app based on self-determination theory that records user steps, then converts them into points, and allows the users to compete with each other, hence motivating them to walk more [14].

Other studies have combined fitness tracking with context awareness to come up with persuasive suggestions to improve well-being. One mobile app, for example, detects active and inactive behaviors and uses time, location, weather, and personal information to achieve its motivational target [15]. Another aims to encourage users to walk more by using their location and weather information and then an outdoor detour map to recommend walks. The results of evaluation among 8 participants showed user satisfaction with the app, especially logging and visualization of PAs. However, some participants highlighted that sedentary behavior alerts are frequent. Additionally, the study revealed that the participants would follow the recommendations only when the suggestion is easy. Participants also suggested to use a mobile app for step count acquisition to avoid prolonged phone-on-table periods.

In this study, we investigate the effectiveness of using context-aware and personalized messages in breaking sedentary behavior. We propose a mobile app, MotiFit, that is designed to increase the level of PA among employees in sedentary occupations by encouraging them to walk more. The approach followed is to send personalized motivational messages to workers after prolonged sitting to remind them to walk. The proposed personalization takes advantage of user goals, location, weather information, and daily routine to employ context awareness in the generated motivational messages. The study evaluates the effectiveness of the designed messages to advocate positive behavior change and encourage workers to walk more, hence maintaining a healthier lifestyle. To prove the study hypothesis, we evaluated the MotiFit app for 66 days with a mixed methods design. We hypothesized that sending context-aware motivational messages to workers in sedentary occupations after prolonged sitting can break sedentary behavior and increase daily active time.

## Methods

### Overview of the Approach Followed

The study investigated the effectiveness of personalized, context-aware motivational messages in breaking the sedentary behavior of employees in sedentary occupations and increasing their daily activity level compared to static reminders. First, participants were given a prestudy online questionnaire for collecting their demographic information ([Multimedia Appendix 1](#)) and the International Physical Activity Questionnaire (IPAQ) to determine the level of PA before the study, hence distributing the participants with different PA levels equally into 2 groups [16]. Then, the participants were given the mobile app that automatically logs their step count. Participants in the control group received static reminders, while participants in the intervention group received context-aware motivational



messages, and when the participants received them, they were asked to rate the messages in terms of correctness and reliability.

After the duration of the study elapsed, the participants were given the user version of the Mobile Application Rating Scale (uMARS) questionnaire to measure the usability of the app [17]. All the participants were invited to a semistructured interview to obtain information about the context of use. The interview included some questions about the overall app experience in terms of usability, functions, and features. In addition, some questions were directed toward the challenges that the participants encountered and suggestions for enhancements.

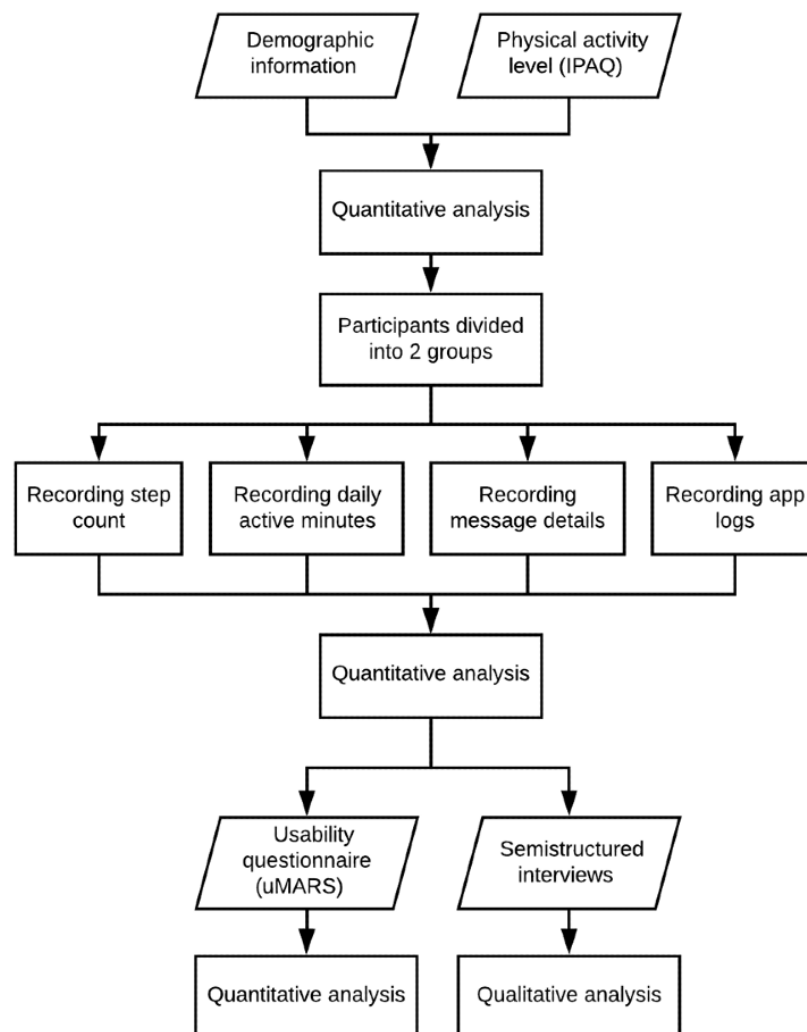
The study followed the between-group design, where the participant is only exposed to 1 condition so that they do not learn from different task conditions. Since the participants only need to complete tasks under 1 condition, the time it takes each participant to complete the study is much shorter than in a

within-group design. As a result, exhaustion and frustration can be effectively controlled [18].

In this study, the thematic analysis approach was followed to examine the participants' perspectives to generate unanticipated insights. This method involves an iterative and reflective process to simplify the text into codes that focus on the important characteristics of the data, then sort them into themes that bring meaning to the data [19]. Figure 1 summarizes the overall approach followed in the study.

We received approval from the Qatar Biomedical Research Institute's institutional review board for all users who participated in this study (IRB application #2019- 10-037). Participation was entirely voluntary, and participants were sent an approved informed consent form, which contained all the details about the study. All participants were assured of their data confidentiality and security and informed that they have the right to withdraw from the study without justifications or penalties.

**Figure 1.** Study procedure. IPAQ: International Physical Activity Questionnaire; uMARS: user version of the Mobile Application Rating Scale.



## Study Hypotheses

In this study, we explored the impact of context-aware motivational messages against static reminders on the PA level following a mixed methods research approach applied in a field study. A causal-comparative quantitative approach was followed to examine the effect of the independent variable on the dependent variable within a cause-effect relationship. The dependent variable was the inactivity intervals. The independent variables were the possible causes of the change in the dependent variable. The investigated causes, or what were known as the independent variable, were the context-aware motivational messages against static reminders.

Experimental studies should be based on a predefined hypothesis, not driven by data [18]. Hence, it is critical to identify the study hypotheses at an early stage as given next.

### *Hypothesis 1*

*Sending context-aware motivational messages to workers in sedentary occupations after sitting for 40 minutes can break sedentary behavior compared to static reminder messages.*

The static reminder message is a message that does not change its content, for example, "Hey, you've been sitting for long. How about you take a short walk?"

Sedentary behavior is defined as jobs that require sitting for most of the working time, including computer professions [20].

### *Hypothesis 2*

*Sending context-aware motivational messages to workers in sedentary occupations after sitting for 40 minutes can increase daily active time compared to static reminder messages.*

Active time increase is measured by the time the user spends moving during the day.

## Recruitment

In total, 58 participants, all sedentary workers in different sectors in Qatar, were recruited following the snowballing sampling

method. Participants were selected on the basis of the following inclusion criteria: having a predominantly sedentary job and working at least 6 hours a day, 5 days a week; age between 23 and 39 years; having the ability to walk, since the study was based on accelerometer data; owning an Android smartphone; and having a level of understanding of the English language, enough to understand the app and answer the questionnaires. The participants were divided into a control group and an intervention group. The intervention group consisted of 29 participants (50%: 21 [72%] within the age range of 23-30 years, 19 [66%] females). The control group consisted of 29 participants (50%: 21 [72%] within the age range of 23-30 years, 17 [59%] females).

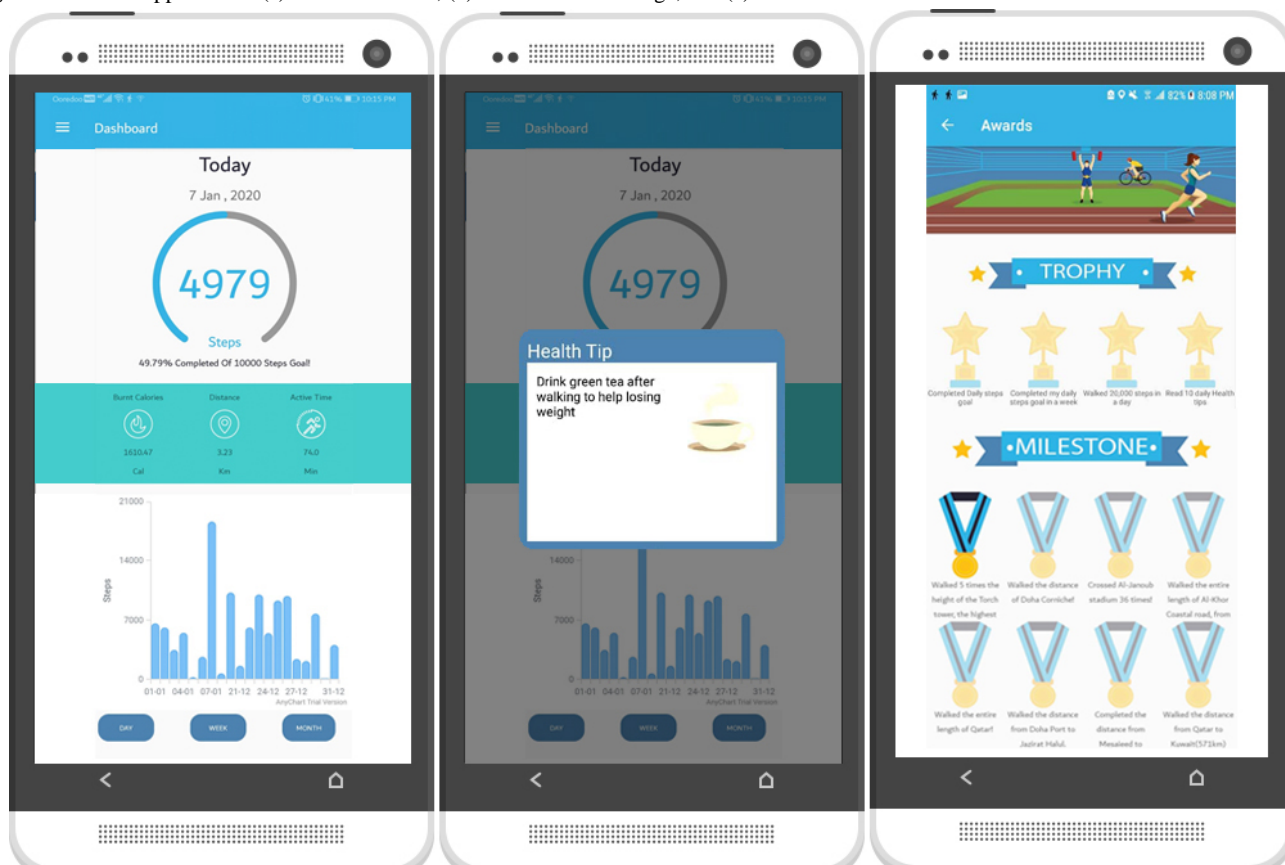
## Study Duration

The participants were asked to use the mobile app for 66 days in their daily routine. The duration choice was based on an empirical study that investigated the time required for a behavioral change to happen. It was conducted over the range of 18-254 days, and it found that on average, it takes 66 days for a repeated behavior to reach its maximum level of automaticity [21].

## App Design

The MotiFit app was designed to be easy to use in terms of the methods to input user information and output the processed data in a visual and textual format. The app is designed not to consume time such that data are automatically recorded and user interruption is minimal. The app does not require a lot of effort physically; for example, the given tasks are easy for various fitness levels. The messages are designed considering the social environment and culture, so they are familiar, and they do not go out of the norm culturally. All these elements are considered together to ensure that the target audience is able to effectively use the app toward achieving the behavioral change goal. Based on this reasoning, the app was created as a persuasive technology app that focuses on positive social, behavioral change. Figure 2 gives an overview of the app prototype.

Figure 2. MotiFit app screens: (a) main dashboard, (b) motivational message, and (c) achievements.



**Motivational Message Design**

To form new habits, we considered 2 key concepts: focusing on 1 habit at a time and connecting the new behavior to already existing activities [21]. Hence, MotiFit focuses only on the walking habit, and the motivational messages are designed to persuade walking through context awareness, considering the surrounding environment and the user’s routine. Experts recommended engaging the new behavior with daily activities, such as eating and sleeping [22]; hence, MotiFit checks for lunch breaks and the end of working hours during weekdays at the time of sending messages to suggest activities that can fit during the particular time frame.

**Rest Duration Choice**

A study concluded that microbreaks every 40 minutes help reduce discomfort in the shoulders, wrists, and backs of the participants, with no evidence of microbreak effect on productivity reduction at work [23]. For this study, the app was set to send motivational messages every 40 minutes, and the duration of the breaks was estimated as 1-3 minutes. This duration is equivalent to at least 67 steps to break sedentary behavior [24].

**Location**

The location information retrieved is used to find nearby locations of different destinations, such as restaurants, gyms, parks, or malls, depending on the situation when the message is sent. Some locations are chosen to be reached by walking, and for this, locations within 500 m are retrieved. Other locations are chosen to be reached by driving; for the lunch break, locations within 1.5 km are retrieved, while for after working hours, locations within 6 km are retrieved.

**Weather Information**

Weather information helps identify the nature of the activity that the user can do, whether indoors or outdoors. The weather information is fetched using the Open Weather Application Programming Interface (API), which returns 3 parameters: temperature, humidity level, and weather forecast. Based on these parameters, the classification of suitable and unsuitable weather for outdoor PAs is performed. Information shows the classification of weather information, as performed by Gupta and Sood [25]. Since the study was conducted in Qatar during the winter season, we adjusted the suitable temperature range, as shown in Table 1, to 13-35C.

Table 1. Classification of weather information.

Parameter	Suitable level	Unsuitable level
Temperature, C	13-35	>35
Humidity level, %	<90	>90
Forecast	Clear skies, sunny, cloudy	Windy, rainy, thunderstorm, hailstorm

**Time Information**

The decision point in JITAI is the time at which an intervention decision is made. In this study, we used prespecified time intervals based on the duration of inactivity [10]. The messages are designed to be triggered 30 minutes before lunch break if the user is inactive in order to allow the user to make lunch plans accordingly. The motivational messages that are triggered before the end of the working day are sent 1 hour before so that receivers get enough time to arrange after-work plans. The same thing applies to messages that are triggered before the end of the day such that users get enough time to finish their daily step goals, if possible.

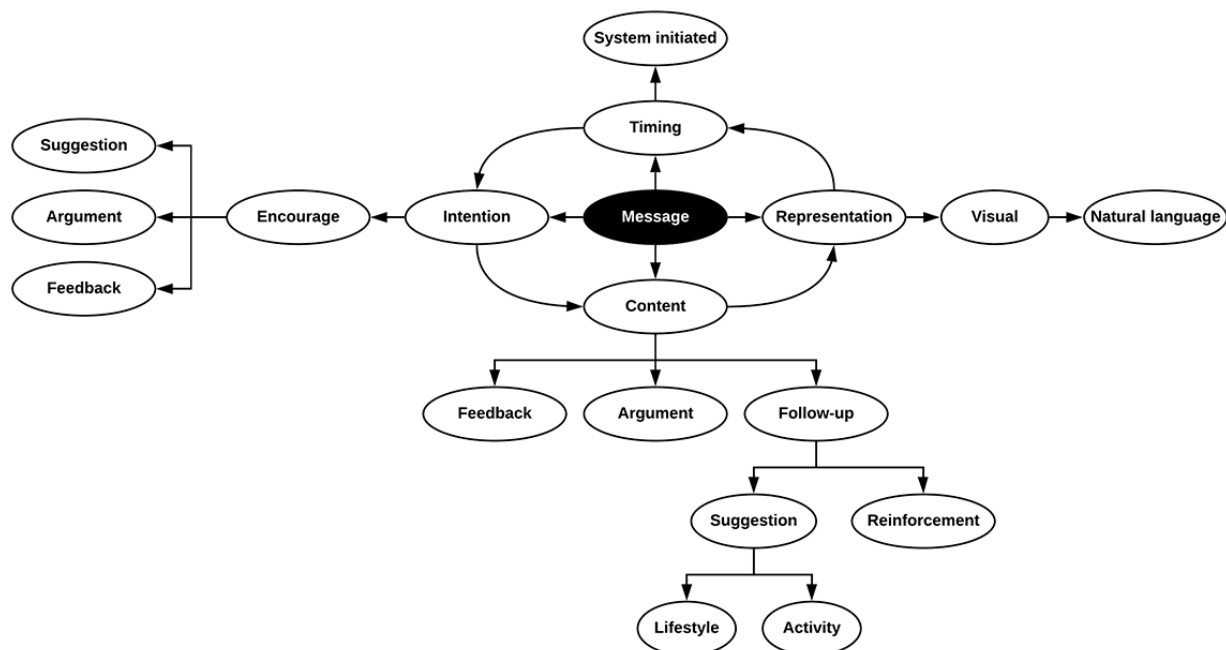
**Motivational Message Structure**

The motivational message model follows a modified version of Akker et al’s [26] model, as shown in Figure 3. The modified

model is a subset of the Akker model, which starts with a system-initiated trigger based on the time with an intention to encourage walking behavior through suggestions, arguments, and feedback. Then, the content of the message is identified, whether it is feedback, an argument, or a follow-up on progress. Finally, the content of the message is represented in an adaptive textual format and sent to the user as a mobile app notification.

The structure of the motivational message consists of 2 parts: a heading and a message body. The heading is a short, catchy phrase, and the body of the message has the actual content. The body of the message uses slot filling to adapt dynamic content based on the fetched data when the message is sent, as shown in Multimedia Appendix 2.

**Figure 3.** Modified model of motivational message generation.



**Motivational Message Algorithm**

The choice of the messages is made following a simple decision-making flowchart, as shown in Multimedia Appendix 3. A total of 260 unique motivational messages were generated based on the flowchart. Although the messages are divided into 15 categories, the messages within the same category consist of 2 main types: messages targeting self-efficacy and framed messages [27]. Messages targeting self-efficacy are those messages that tackle an individual’s belief in their capacity to perform some behavior. Message framing, however, can be gain-framed, focusing on the positive outcomes, or loss-framed, focusing on the costs and losses [28]. Our analysis further investigated the impact of the different types of messages.

**Results**

**Sample Characteristics**

The first set of study results were obtained for the control group, which used the lite version of the app that always sends the same static message (MotiFit Lite). The second set of results was obtained for the intervention group, which used the full version of the app that sends personalized motivational messages (MotiFit).

Table 2 describes the demographics of the sample. A total of 58 participants were included in the study. The participants were divided into a control group (n=29, 50%) and an intervention group (n=29, 50%). The participants of the 2 groups were mostly female (36/58, 62%), and they fell in the 23-30-year age group. Most of the participants were bachelor’s degree holders (33/58, 57%), and their current occupation was under the office work category (30/58, 52%). With regard to the fitness

level, the participants had different body mass index (BMI) levels. from underweight to obese.

The IPAQ classifies the participants' PA level into 3 categories: low, moderate, and high. The classification is based on the participants' weekly PAs based on their energy requirements defined in metabolic equivalents (METs). METs are multiples of the resting metabolic rate, and a MET minute (MET-min) is computed by multiplying the MET score of the activity by the minutes performed [29]:



where MET level=3.3 METs for walking, 4.0 METs for moderate-intensity PA, and 8.0 METs for vigorous-intensity PA.

According to the scoring guide of the IPAQ, a person is classified in the low-active group if they do less than 600 MET-min/week, in the moderate-active group if they do more than 600 MET-min/week and less than 3000 MET-min/week, or in the high-active group if they do more than 3000 MET-min/week [29]. The IPAQ classification was used mainly to distribute participants with different PA levels into control and intervention groups, as shown in Figure 4. This classification was used to eliminate bias from the recruitment process.

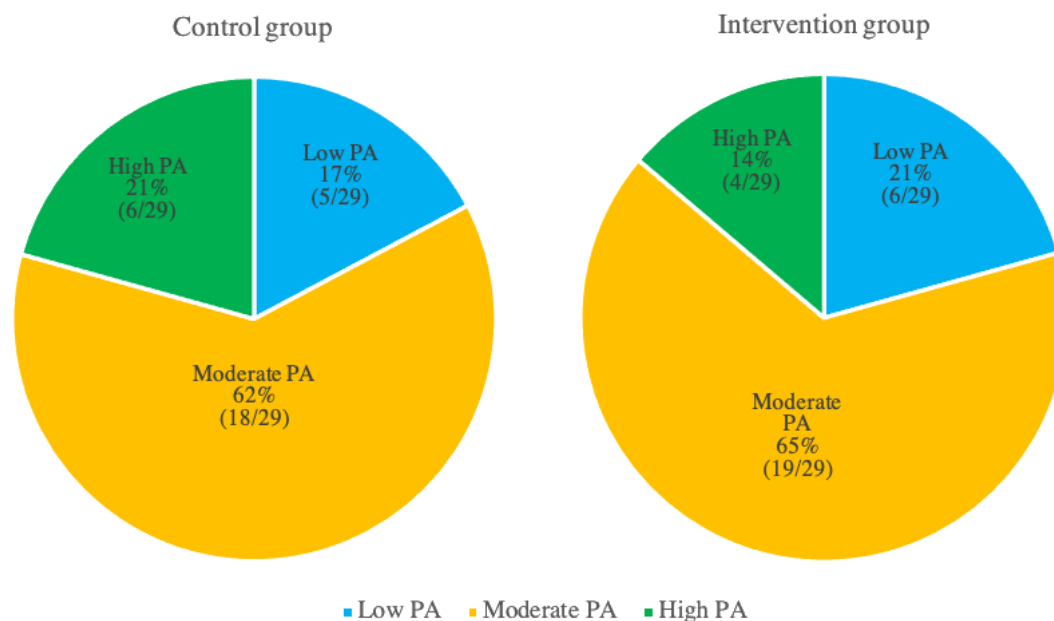
**Table 2.** Participants' demographic information (N=58).

Characteristics	Control group (n=29, 50%)	Intervention group (n=29, 50%)
<b>Gender, n (%)</b>		
Female	19 (66)	17 (59)
Male	10 (34)	12 (41)
<b>Age (years), n (%)</b>		
23-30	21 (72)	21 (72)
31-39	8 (28)	8 (28)
<b>BMI<sup>a</sup> assessment, n (%)</b>		
Underweight	1 (3)	0 (0)
Normal	12 (41)	17 (59)
Overweight	9 (31)	11 (38)
Obese	7 (24)	1 (3)
<b>Education, n (%)</b>		
High school/diploma	8 (28)	0 (0)
Bachelor's degree	14 (48)	19 (66)
Master's degree	6 (21)	8 (28)
Doctorate	1 (3)	2 (7)
<b>Work status, n (%)</b>		
Academics	8 (28)	6 (21)
Engineering	0 (0)	2 (7)
Health profession	1 (3)	1 (3)
IT	3 (10)	2 (7)
Office work	16 (55)	14 (48)
Sales and services	1 (3)	4 (14)

<sup>a</sup>BMI: body mass index.



**Figure 4.** Participants' distribution over PA categories. PA: physical activity.



### User Engagement

The study took place over 66 days. However, not all participants completed the full duration. The full duration defined here is the duration for which each participant was enrolled in the study, from the starting date to the ending date of using MotiFit. The number of days for which the reminder messages were sent was defined based on the logged data. In addition, the logs showed the number of days for which the app was running, but no messages were sent to the participant. This could be due to an increase in the participant's PA or a technical issue in the app.

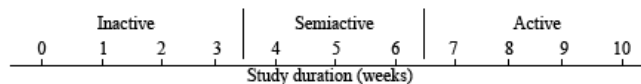
From the resulting data, we decided to follow the approach used by Al-Ansari et al [30] to classify the participants' engagement into 3 categories: inactive, semiactive, and active. The participants who used the app for 3 weeks or less were considered inactive, those who used the app for 4-6 weeks were considered semiactive, and those who used the app for 7 weeks or more were considered active, as shown in Figure 5. The distribution of participants over the engagement categories was

summarized for both control and intervention groups, as shown in Table 3.

We wanted to further investigate the relationship between user engagement and the gender within the intervention group. The results in Table 4 showed no statistically significant difference between genders, with a chi-square test result of  $\chi^2=1.5$  ( $P=.47$ ). We also investigated the relationship between user engagement and age within the intervention group. The results showed no statistically significant difference between the 2 age groups, with a chi-square test result of  $\chi^2=2.7$  ( $P=.26$ ).

We also used data obtained from Google Analytics to track the participants' engagement on a daily basis based on the app's screens. Considering a significance level of .05, the average time spent surfing the main dashboard was significantly higher in the intervention group, with a Mann-Whitney result of  $W=119$  ( $P<.001$ ). Since the main dashboard contains all the activity-level trackers, this can tell us that the intervention group participants were more interested in the activity-level details and comparison than the control group participants.

**Figure 5.** Participants' categorization based on their engagement in the study.



**Table 3.** Engagement levels of control and intervention groups (N=58).

Engagement level	Control group (n=29, 50%)	Intervention group (n=29, 50%)
Inactive, n (%)	11 (38)	1 (3)
Semiactive, n (%)	12 (41)	12 (41)
Active, n (%)	6 (21)	16 (55)

**Table 4.** Engagement levels in the intervention group between gender and age (n=29).

Characteristic	Inactive participants, n (%)	Semiactive participants, n (%)	Active participants, n (%)
<b>Gender</b>			
Male	1 (3)	5 (17)	6 (21)
Female	0 (0)	7 (24)	10 (35)
<b>Age (years)</b>			
23-30	0 (0)	9 (31)	12 (41)
31-39	1 (3)	3 (10)	4 (14)

### Logged Messages

The logged data header for the intervention group contained the following attributes shown in Figure 6.

For the control group, the same attributes were logged, except for the message type, category, and text, since the app always sends the same static message: “Hey, you’ve been sitting for long. How about you take a short walk?”

The message is marked with a flag that detects whether the message was dismissed from the notifications or whether it was

viewed for less than 2 seconds. The choice of 2 seconds was made by estimating the read time of the shortest message using a read-o-meter tool [31]. Hence, we considered any message that was not dismissed by the participant but viewed for less than 2 seconds as dismissed.

From the messages that were not dismissed, the difference in steps within 30 minutes of sending the messages was calculated and then, a new attribute was generated to determine whether the messages broke the sedentary behavior: if the difference in the step count  $\geq 67$  steps, the user has broken their sedentary behavior; otherwise, they have not.

**Figure 6.** Data header attributes for intervention group messages.

Date	Time	Current step count	Step goal	Step count after 30 mins	Message rating by user	Duration reading the message	Dismissed (Y/N)	Message text	Message category	Message type
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Table 5 shows the results after cleaning the data, which consist of 1125 records for the control group (MotiFit Lite) and 5228 records for the intervention group (MotiFit). The results were statistically significant, showing a chi-square test result of  $\chi^2=12.9$  ( $P=.001$ ), which indicates that the intervention group was using the app more actively compared to the control group.

To investigate the effectiveness in breaking inactivity, we combined the information in the message and the participant’s response to it in order to determine the impact of the message on breaking sedentary behavior. We recorded information about the type of message, an indication of whether the message was dismissed, and the difference in the step count before and after the message was received. Then, we performed the chi-square test to investigate the relationship between the message type and the breaking of inactivity, as shown in Table 5. The results were statistically significant ( $\chi^2= 410.1$ ,  $P<.001$ ). Hence, MotiFit has an impact on breaking inactivity.

**Table 5.** Messages’ (N=6353) impact on control and intervention groups.

Type of message	Messages that did not break inactivity (n=3348, 52.69%)	Messages that broke inactivity (n=3005, 47.31%)
Context-aware message, n (%)	2447 (73.09)	2781 (92.55)
Static message, n (%)	901 (26.91)	224 (7.45)

We wanted to further study the impact of different categories of the messages used in the intervention group. The categories are gain-framed messages, loss-framed messages, and messages targeting self-efficacy. Of the messages that were not dismissed by the intervention group (n=5228), 3058 (58.49%) were categorized as gain-framed, 1479 (28.29%) were categorized as loss-framed, and 691 (13.22%) were categorized as messages targeting self-efficacy. The results for each category with an impact of the personalized context-aware messages on breaking inactivity are presented in Table 6.

The chi-square test was performed to investigate the relationship between different categories of messages with regard to breaking inactivity in the intervention group. The results were not statistically significant ( $\chi^2=4.2$ ,  $P=.12$ ). Hence, there is no direct impact of the category of the message on breaking inactivity.

**Table 6.** Different message (N=5228) categories vs breaking inactivity in the intervention group.

Characteristic	Messages that did not break inactivity (n=2447, 46.81%)	Messages that broke inactivity (n=2781, 53.19%)
Gain-framed message, n (%)	1467 (60)	1591 (57.2)
Loss-framed message, n (%)	672 (27.5)	807 (29)
Messages targeting self-efficacy, n (%)	308 (13.8)	383 (13.8)

### Logged Active Minutes

This set consists of the active minutes per day, which includes all types of PAs done throughout the day. These data are automatically recorded through the app by the end of each day to determine the effectiveness of the app to increase daily active time. However, since not all participants completed the full duration of the study, we selected the 6 most engaged participants each from the control and intervention groups and tried to determine the maximum common period of using the app among these participants, which was found to be 39 days.

Next, we used the multivariate Mann-Kendall trend test to examine whether there was a monotonic trend (increasing or decreasing) of active time over the study period. The control group showed  $Z_{MK}=0.42$  ( $P=.67$ ), while the intervention group showed  $Z_{MK}=0.005$  ( $P=.99$ ). None of the 2 groups showed a significant monotonic trend in the daily active time. We also performed the Mann-Whitney  $U$  test to examine whether there was a difference in the daily active time between the intervention group and the control group [32]. The test showed that there was no significant difference ( $W=572$ ,  $P=.06$ ) in the daily active time between the 2 groups.

### Usability Results

The uMARS questionnaire was given to the participants to rate their experience with using the app in terms of the ease of use and the functionalities available. The questionnaire is divided into 3 sections: app quality, app subjective quality, and perceived impact. The rating is scored out of 5 based on the scoring criteria given by the questionnaire developers [17].

Generally, the uMARS questionnaire rates the usability of an app. Since both apps given to the control and intervention groups are almost the same, we did not expect significant differences in the scores. We performed the Mann-Whitney  $U$  test for the 3 sections (app quality, app subjective quality, and perceived impact) of the uMARS questionnaire. The analysis results did not show any significance for the questions in the app quality and app subjective quality sections. This was expected, given that the 2 apps are identical in terms of the user interface, user experience, and content.

Moreover, the results were significant for most of the questions in the perceived impact section. The overall perceived impact score of the control group was significantly higher than that of the intervention group ( $W=566$ ,  $P=.02$ ). The scores of the awareness question were significantly higher for the control group ( $W=435$ ,  $P<.001$ ). Similarly, for the attitude and help-seeking questions, the scores of the control group were significantly higher ( $W=556$ ,  $P=.02$  and  $W=588$ ,  $P=.006$ , respectively). However, for knowledge, intention to change, and behavior change, there was no significant difference

( $W=500$ ,  $P=.18$ ;  $W=535$ ,  $P=.06$ ; and  $W=517$ ,  $P=.10$ , respectively).

## Discussion

### Principal Findings

This study designed and evaluated a mobile health app for employees in sedentary occupations to promote walking and engage them in PA. The mobile app aims to remind and encourage employees to move after prolonged sitting. Integrating the findings from quantitative and qualitative analyses led to interferences, which described the impact of the intervention in a comprehensive way. Overall, the results emerged from the quantitative analysis were compatible with those from the qualitative analysis. We found that the app is engaging as most of the participants (16/29, 55%) were active throughout the study period. The quantitative analysis of Google Analytics data showed that participants were specifically interested in viewing the main dashboard, which contains all the activity-level trackers. Moreover, we found that the context-aware motivation messages sent by MotiFit encouraged users to take more breaks during their prolonged inactive time. However, the results did not show a significant difference in the daily active time. It can be argued that the number of records was small and that the duration was not enough to make an impact on the participants' lifestyles, especially since many of the participants did not complete the full duration of the study. Moreover, many external factors could affect the results in a real-life setting, especially since the study was conducted in a period that included several holidays, which could affect the participants' daily routine. The qualitative analysis of usability surveys showed no impact of MotiFit for knowledge, intention to change, and behavior change; however, the quantitative analysis revealed contrasting results with high engagement rates and more success rates to break sedentary behavior in the intervention group.

Considering the integrated findings from both analyses, we inferred that the mobile health design with JITAI is engaging and usable and can empower users to integrate PA in their daily routine. The results of this study can act as propositions that give researchers a solid starting point for future research on persuasion and behavioral change for health promotion.

### Limitations

The main limitations of the study were the small sample size, the participants' engagement to continue the study for the entire study period, and the type of the participant information collected.

A larger sample size could provide more insight into the effect of the intervention and increase the statistical test power. The timing of the study was unfortunate since the recruitment took

place in December, which is a high season for holidays, academic breaks, and annual leaves for employees. Hence, recruitment and user engagement were challenging.

Another limitation was the type of user information fetched in the study, which affected the personalization of the messages. The user information was limited to gender, age, step goal, and timing information according to the IRB committee agreement. Therefore, the personalization of the messages was limited to our knowledge of the participants. If the acquired information is more inclusive such that it contains health status, calendar information, and hobbies, then the app can generate a bigger variety of yet precise messages.

## Conclusion

This study investigated the potential of developing a mobile health intervention to encourage people to become more active during their working hours. The intervention was designed specifically for workers who spend most of their day at work sitting, yet it can be used by anyone. Previous studies have investigated behavioral change through personalized notification messages. However, this study additionally considered the participant's personal information, step goal, daily routine, and the surrounding environment. For this investigation, a mobile app called MotiFit was developed and evaluated to gain insights

into the effectiveness of personalized electronic health interventions to break inactivity.

The results proved that context-aware motivational messages can effectively break sedentary behavior compared to static reminders. However, the results showed no monotonic trend in the daily active time over the study period among the most engaged participants. In addition, the results did not show a statistical significance between the message category (gain-framed, loss-framed, targeting self-efficacy) and breaking sedentary behavior.

Several ways of improving the study results could be followed by obtaining more insights into the target population characteristics and increasing the amount of data acquired. Another approach is to increase the sample size and the duration of the study, to make the messages more personalized, and to enhance the mobile app interface. Future work can include integrating social aspects such that users can share their achievements on their social networks, compete with each other, and track other users' performance, which could increase user engagement and prolong the app usage period. In addition, the motivational messages if-else algorithm can further be enhanced to use artificial intelligence to provide more personalized and accurate messages.

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## Conflicts of Interest

None declared.

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### Multimedia Appendix 1

Participants demographic information questionnaire.

[PNG File, 178 KB - [formative\\_v61e34309\\_app1.png](#)]

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### Multimedia Appendix 2

Dynamic context attributes in motivational messages.

[DOCX File, 13 KB - [formative\\_v61e34309\\_app2.docx](#)]

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### Multimedia Appendix 3

Motivational messages decision-making flowchart.

[PNG File, 338 KB - [formative\\_v61e34309\\_app3.png](#)]

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## Abbreviations

**API:** Application Programming Interface  
**BMI:** body mass index  
**GPS:** Global Positioning System  
**IPAQ:** International Physical Activity Questionnaire  
**IRB:** institutional review board  
**JITAI:** just-in-time adaptive intervention  
**MET:** metabolic equivalent  
**MetS:** Metabolic Syndrome  
**PA:** physical activity  
**uMARS:** user version of the Mobile Application Rating Scale

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Original Paper

# Accessing Patient Electronic Health Record Portals Safely Using Social Credentials: Demonstration Pilot Study

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## Abstract

**Background:** Patient portals allow communication with clinicians, access to test results, appointments, etc, and generally requires another set of log-ins and passwords, which can become cumbersome, as patients often have records at multiple institutions. Social credentials (eg, Google and Facebook) are increasingly used as a federated identity to allow access and reduce the password burden. Single Federated Identity Log-in for Electronic health records (Single-FILE) is a real-world test of the feasibility and acceptability of federated social credentials for patients to access their electronic health records (EHRs) at multiple organizations with a single sign-on (SSO).

**Objective:** This study aims to deploy a federated identity system for health care in a real-world environment so patients can safely use a social identity to access their EHR data at multiple organizations. This will help identify barriers and inform guidance for the deployment of such systems.

**Methods:** Single-FILE allowed patients to pick a social identity (such as Google or Facebook) as a federated identity for multisite EHR patient portal access with an SSO. Binding the identity to the patient's EHR records was performed by confirming that the patient had a valid portal log-in and sending a one-time passcode to a telephone (SMS text message or voice) number retrieved from the EHR. This reduced the risk of stolen EHR portal credentials. For a real-world test, we recruited 8 patients and (or) their caregivers who had EHR data at 2 independent health care facilities, enrolled them into Single-FILE, and allowed them to use their social identity credentials to access their patient records. We used a short qualitative interview to assess their interest and use of a federated identity for SSO. Single-FILE was implemented as a web-based patient portal, although the concept can be readily implemented on a variety of mobile platforms.

**Results:** We interviewed the patients and their caregivers to assess their comfort levels with using a social identity for access. Patients noted that they appreciated only having to remember 1 log-in as part of Single-FILE and being able to sign up through Facebook.

**Conclusions:** Our results indicate that from a technical perspective, a social identity can be used as a federated identity that is bound to a patient's EHR data. The one-time passcode sent to the patient's EHR phone number provided assurance that the binding is valid. The patients indicated that they were comfortable with using their social credentials instead of having to remember

the log-in credentials for their EHR portal. Our experience will help inform the implementation of federated identity systems in health care in the United States.

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## KEYWORDS

patient portal access; single sign-on; federated identity; social credentials; social identity; patient portal; electronic health records; EHR; credentials; patient communication; communication; clinical support; feasibility; acceptability

## Introduction

### Background

Providers and patients operate within a complex and fragmented health care environment. Challenges in delivering and receiving care across distinct health care organizations (eg, primary care clinics, specialty clinics, hospitals, and psychiatric facilities) require the exchange of information and access to organizationally distinct information systems. Electronic health record (EHR) software is being increasingly adopted by hospitals and health care entities. The promotion of provider and patient involvement in the delivery of health care for quality and safety of care is of critical importance [1,2]. Furthermore, government incentive programs and regulations have influenced health care organizations to implement patient access [3]. With the increasing need for access to the EHR, user account credential management has become a growing problem. A Microsoft study found that an average user has 25 different accounts and uses 6.6 passwords shared across 3.9 sites [4]. The study also found that a user types an average of 8 passwords per day. Furthermore, a McAfee survey reported that the average consumer deals with 23 web-based accounts that require a password [5]. The same survey showed that each user had an average of 13 unique passwords, and 31% used only 2 to 3 passwords for their accounts so that they could easily remember them. Approximately 52% reported that writing down passwords (either on paper or digitally) is the most common way to remember them.

Forgotten passwords are problematic, as illustrated in a press report referencing a joint Mastercard and Oxford University study [6]. The study found that 25% of consumers had 1 password reset per day and that 33% of shopping carts for web-based purchases were abandoned at checkout because of password problems. In addition, another study reported that 78% of respondents required a password reset in their personal life in the past 90 days, and 57% required a work password reset in the past 90 days [7]. The same study found that over one-third of the respondents had >20 passwords for their personal life, and almost 20% had >10 work-related passwords.

Another factor that adds to the friction associated with access is that some sites require strong passwords (typically a minimum of 8 characters with numbers, upper or lower cases, and often a special character) and may also require periodic password changes, despite a recent National Institutes of Standards and Technology (NIST) recommendation against complexity and password expiry in favor of long passphrases [8]. The NIST recommends the use of multifactor authentication (MFA) in conjunction with a passphrase that does not expire unless there

is reason to believe that the password or passphrase has been compromised [8].

The number of EHR patient portals is rising in the United States largely because of the US Electronic Health Record Incentive Program and Meaningful Use [9] and patients' desires to make appointments on the web, communicate with their providers, request appointments and medication refills, and view test results [10-12]. For example, a 2019 study exploring hematology patients' desires for a patient portal found that a large proportion of patients (>75%) wanted the ability to contact their physicians and access laboratory tests, imaging results, appointments, personal data, current medication lists, medication history, and reports to other physicians [10]. A large proportion of patients (>75%) also wanted the ability to make appointments, set up appointment reminders, request medication refills, change their personal data, and access medication and disease information [10]. During the COVID-19 pandemic, patient portals have served as a way for patients to self-triage and self-schedule appointments based on their needed level of care [13] and access vaccines [14].

In the United States and in countries with similarly fragmented health systems, for an individual or their family, having their health care records spread out among multiple facilities causes fragmentation [15,16] and does not provide the health care provider or individual with comprehensive information in an EHR. Patients are often faced with having multiple log-in credentials for each facility where they had received health care services.

Although access to and aggregation of patient data from multiple sources is rapidly evolving, there are 3 general approaches [17]. There are directed exchanges where health provider organizations (HPOs) send and receive information to coordinate care, query-based exchanges where one HPO queries another for information on a specific patient, and consumer-mediated exchanges where patients can direct and control the aggregation and use of their information. Proprietary data exchanges, typically within an EHR vendor's technology ecosystem, allow data to be exchanged among HPOs who use the same EHR vendor. Examples are Epic's Care Everywhere *Happy Together* [18] and Cerner's *HealtheLife* [19]. These are patient portals that allow patients to see all their EHR data across different HPOs that use the same EHR vendor with a single log-in. However, if, for example, a patient had EHR data in an Epic system and another set of data in a Cerner system, the patient would have to use 2 different EHR patient portals, each with their own log-in credentials and password complexity requirements. This makes it cumbersome to easily obtain one's health information and requires remembering multiple

passwords. A federated credential would allow patients to get the source data with a single log-in.

Health information exchanges allow providers to share health information, although they may use different EHR systems, and other data-sharing initiatives such as CommonWell Health Alliance [20] have the potential to allow patients to self-enroll from a patient portal or personal health record (PHR) and access all of their EHR data across multiple HPOs regardless of the EHR system used. Again, this somewhat reduces the burden of additional credential management; however, it can be further reduced using a federated identity that the patient is comfortable with and uses frequently.

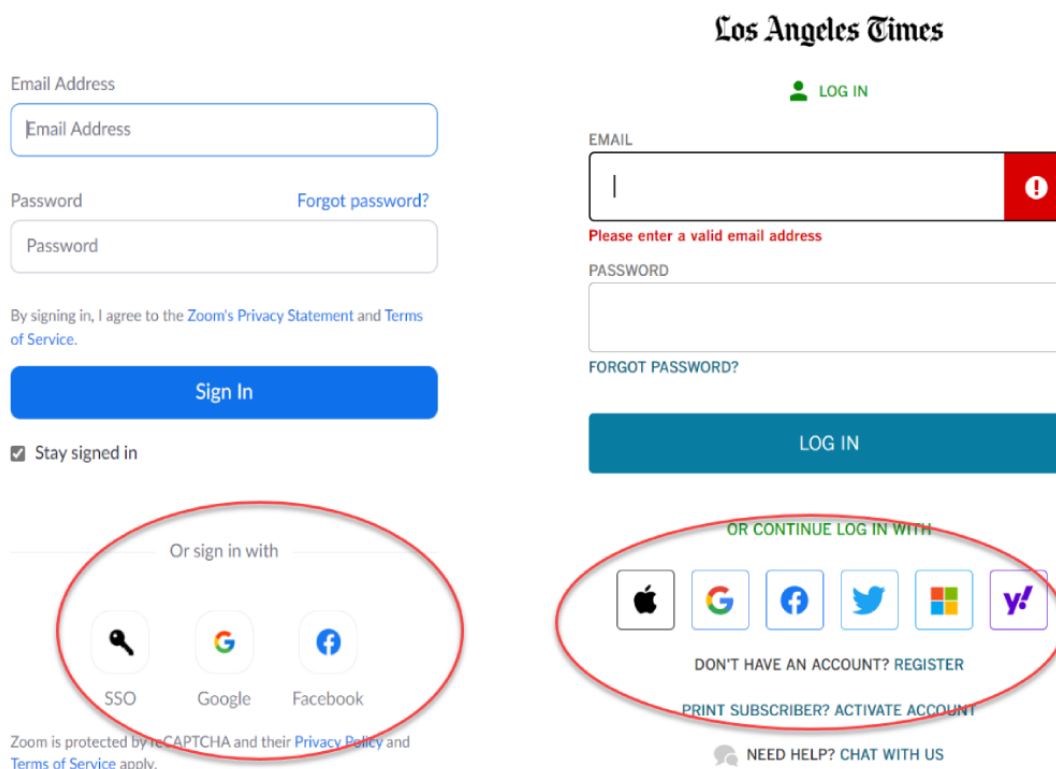
Substitutable Medical Applications, Reusable Technologies (SMART) on Fast Healthcare Interoperability Resource (FHIR) apps [21] allow patient-directed EHR data sharing. After successful authentication at each portal, SMART on FHIR apps access EHR data from each participating HPO and allow them to be downloaded or shared with a third party. Two examples are the Apple Health app [22], which is representative of a SMART on FHIR solution that allows patients to download EHR data to a mobile device, and the Sync for Science app [23], a pilot to demonstrate the ability to share a patient’s EHR data for the direct volunteer cohort of the National Institutes of Health–sponsored All of Us Research Program [24]. Again, although these solutions have the potential to reduce patients’ password burden, they may increase the burden if they require their own unique credentials, and patients may still have to contend with different log-in credentials for each EHR portal when first setting up the SMART on FHIR app unless they support federated log-in credentials. In an ideal scenario, the

same federated credentials could be used for the EHR portal and to access the SMART on FHIR app.

A common way to reduce the friction associated with passwords on mobile devices is the use of biometric attributes such as fingerprint or facial recognition for access. On the surface, these approaches make access simpler; however, an underlying problem is that log-in credentials are required at the initial configuration, and a software upgrade or device reset may erase the cached password and prompt the user to enter credentials that likely have been forgotten since, especially if it is one of many that are infrequently used.

A single sign-on (SSO) approach that relies on a secure federated identity and associated credentials can reduce the friction associated with EHR data access [8,25,26]. Such approaches are increasingly common in the non–health care arena, as illustrated in Figure 1, which shows the use of social credentials such as Facebook, Google, or Twitter to access a newspaper portal and videoconferencing. As these examples illustrate, SSO allows a user to use a single credential to have access to resources among different organizations. SSO used with a federated identity is predicated on having multiple distinct organizations that agree to a common set of practices, policies, and protocols to manage a single identity. This identity is trusted to access services and devices across participating organizations [27]. In a 2017 report, NIST noted that federated architectures have significant benefits, including enhanced user experience, cost reductions because of fewer authenticators needed, data minimization, and mission enablement, as organizations can focus on their mission as opposed to the business of identity management [8].

**Figure 1.** Two samples of single sign-on using a social credential. The Zoom login on the left allows a Google or Facebook credential, while subscribers to the Los Angeles Times (right) can use an Apple, Google, Facebook, Twitter, Microsoft, or Yahoo account for single sign-on.



As web-based SSOs are becoming a common technique that allows users to easily self-register and sign onto web-based resources using social media accounts, NIST and the Office of the National Coordinator for Health Technology (ONC) selected the Cedar-Sinai Medical Center (CSMC) to pilot the use of a federated identity to access EHR data across multiple independent HPOs for both patients and providers and assist with the development of a *lessons learned* document. The primary requirements for the pilot were as follows:

- Implement SSO for EHR access at  $\geq 2$  distinct health systems using a federated, verified identity based on effective identity-proofing processes
- Allow use of pseudonymous identities
- Use MFA
- Incorporate privacy-enhancing technology
- Collaborate with NIST and ONC representatives to develop a lessons learned document that can inform future deployments of federated identity solutions in health care in the United States

In addition to the strict software development efforts required to implement a federated identity management solution, other types of barriers include the following:

1. **Technology standards:** This covers interoperability among the infrastructure components of each federation partner and the choice of standards (such as OpenID Connect, OAuth 2, and security assertion markup language) and vendor-specific implementation of standards.
2. **Governance:** This requires acceptance of a trust framework whereby the members of a federation agree to their respective roles and responsibilities, determine what type of information can be exchanged, what safeguards are needed, and dispute resolution procedures.
3. **Legal:** There are state and federal laws specific to the exchange of health records, including the requirements for security and privacy controls. For this pilot, our software had to accommodate the use of proxies (often caregivers or family members) for patients, and we conducted several security and privacy reviews to minimize risks to patient identifiers.
4. **Organizational constraints:** These include organizational priorities, staffing, and budgets that affected the deployment of the pilot.

## Objective

The objective of this project is to demonstrate, in a real-world environment, that it is possible to overcome both software and nonsoftware barriers to the adoption of a federated identity for patient EHR access and to enroll actual patients to test the concept.

The use case selected for a real-world test of this pilot project was inpatient transitions from a US-based acute care hospital to a US-based inpatient rehabilitation facility. This has been a focus of attention [28] because of its inherent vulnerable population—individuals with high levels of care needed after discharge from a hospital—that are at risk for morbidity and mortality, resulting too often in readmissions. The lack of information access is complicated by the fact that many patients

and providers must access  $\geq 2$  distinct EHR systems for information retrieval and continuity of care.

Therefore, the primary aim of this study is to implement a Single Federated Identity Log-in for EHRs (Single-FILE) to facilitate access to EHR data on distinct systems at multiple health care institutions for patients via federated identities and SSO, with both EHR portals visible at the same time. Many EHR implementations rely primarily on passwords as a primary security control; however, these credentials may have been unknowingly stolen. Single-FILE incorporates 2 features to minimize this risk when patients access EHR data via Single-FILE. When a patient is on-boarded into Single-FILE, a one-time passcode (OTP) is sent to the phone number previously registered in the patient's EHR record to confirm the legitimacy of the username and password log-in.

In this paper, we describe the technological approach we used to develop and implement the Single-FILE web portal. We then present the methods and results of interviews with patients who signed up for and used the webportal and provided feedback. We conclude with lessons learned from this pilot, which have broad applicability beyond the current project.

## Methods

### Security and Privacy

One of the sponsors' primary requirements was that any architecture we arrived at had to be privacy-preserving, so our approach was to avoid storing any direct patient identifiers, demographics, or other EHR data in Single-FILE. Information security was also an important consideration, so the project team conducted multiple design workshops that were attended by an external information security consultant and the CSMC chief privacy officer. These were supplemented by design review workshops with the NIST and ONC staff. When the development was finished, automated security scans were performed on the Single-FILE components, and these were augmented by 2 independent, manual penetration tests, and vulnerabilities were corrected.

A supplement to the security scans and penetration tests was the requirement by NIST that we use a privacy risk assessment methodology (PRAM) [29] and that the results and remediation be reviewed and approved by our chief privacy officer. The PRAM is a holistic systematic review of a system that requires an analysis of the path that each data element takes in the system and an assessment to determine the possibility of the breach of the data element and the harm that could result from the breach. For data elements where the risk of breach and harm is great, mitigating controls must be implemented before the go-live. We worked with the CSMC chief privacy officer, who indicated that such a structured approach was relatively novel and that much of her focus (and of her peers' focus) is still on compliance with regulations rather than taking a holistic, structured analysis of a system to uncover potential privacy risks.

### Technological Approach

Although we provided a way for patients to self-register an account managed by Single-FILE, we also allowed the patient

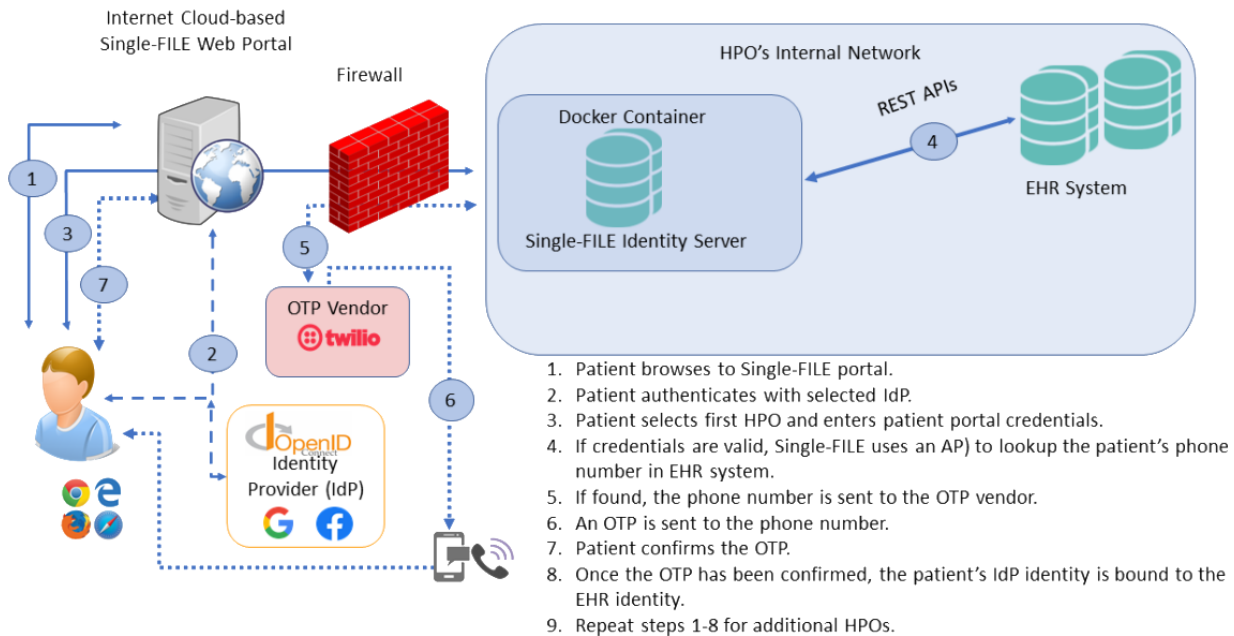


to select a social identity to use as a federated identity. In either case, we bound the identity to the corresponding EHR identity.

Binding a social identity requires that the social identity be legitimate, and, following the OAuth 2 protocol [30], the patient must successfully enter their social identity credentials. For this

project, Facebook and Google were selected as the social identity providers (IdPs). As illustrated in Figure 2, the patient accesses the Single-FILE webportal and, upon selecting an IdP, is redirected to the selected IdP's log-in screen. Upon a successful log-in, the IdP returns an authorization token as evidence that the social identity is valid.

**Figure 2.** Single Federated Identity Log-in for electronic health records architectural overview. API: application programming interface; HPO: Health care provider organization; IdP: identity provider; OTP: one-time passcode; REST: Representational State Transfer; Single-FILE: Single Federated Identity Log-in for electronic health records.



The next step is to bind the social identity to the patient's EHR record. Patients were prompted to enter their EHR portal credentials at the Single-FILE portal, and upon successful log-in to the EHR patient portal, the patient's phone number that was previously recorded in the EHR (typically when the patient was admitted and an EHR record created) was retrieved. As there is a risk that a malicious actor could have knowledge of the patient's social and EHR credentials, an OTP is sent to the phone number stored in the EHR (either voice or SMS text message, depending on the type of phone). Once the patient acknowledges the OTP, the social identity is bound to the EHR identity. Essentially, the phone is used as a *token* that the patient has control of and is used as an additional authentication factor.

The Single-FILE portal was installed on an Amazon Web Services instance, and the identity server was installed at each HPO as a Docker container [31], which is a way of packaging up software along with all the environmental dependencies (code, system tools, system libraries, and settings) so that everything is contained in a ready-to-execute software package. This ensures that the software will run despite the differences between the development and development settings. The Docker container (1) is deployed inside each HPO's network perimeter and provides the connection between the Single-FILE webportal and each respective HPO's EHR system, (2) preserves privacy by containing only the minimum necessary patient information to operate, and (3) provides a way to ensure that the Single-FILE software is not changed by a malicious actor.

Single-FILE was deployed and tested with patients who were discharged from CSMC and admitted to the California Rehabilitation Institute (Cal Rehab). Both CSMC and Cal Rehab use Epic for their EHR vendors; however, the concept can be readily extended to other EHR vendors.

### Participants and Setting

Our study involved patients who received care at an acute care hospital in Los Angeles, California (CSMC), who were discharged and immediately admitted to an inpatient rehabilitation hospital (Cal Rehab), also located in Los Angeles, California. The acute care hospital, CSMC, serves the Los Angeles community with 886 licensed beds, 2100 physicians in every clinical specialty, 2800 nurses, and thousands of other health care professionals, staff, and volunteers. The CSMC has approximately 90,000 emergency department visits, 50,000 admissions, and 17,000 inpatient and 13,000 outpatient surgeries per year. The health system is an academic medical center with trainees in medicine, nursing, pharmacy, public health, and clinical and basic science. Cal Rehab is a 138-bed inpatient physical medicine and rehabilitation hospital located in Los Angeles. It is a partnership between CSMC, University of California Los Angeles Health System, and Select Medical. Patients at Cal Rehab have intensive rehabilitation needs for conditions such as spinal cord injury, brain injury, orthopedic surgery, and stroke and work with physical medicine and rehabilitation physicians as well as physical and occupational, and speech-language pathologists.

## Real-world Evaluation of Federated Identity for EHR Access by Patients

### *Patient Recruitment and Interviews*

To identify potentially eligible patients to test Single-FILE, we identified patients recently admitted to the rehabilitation hospital (Cal Rehab) who consented to research. Patients are asked on admission to Cal Rehab if they would be interested in consenting to research, and a list is generated daily of patients who have consented to research. This list and a list of patients recently admitted to the facility were obtained by one of the investigators (PR) who oversaw research initiatives at the rehabilitation hospital. Before approaching patients, we conducted a short chart review to examine whether they previously had an inpatient stay at the acute care hospital (CSMC) preceding their stay at Cal Rehab and whether they had not yet been discharged from Cal Rehab, as some rehabilitation stays are short. Initially, we aimed to enroll patients with existing patient portals; however, as the patient population of inpatient rehabilitation hospitals skews toward older adults, and this population is less likely to have a patient portal [32], we expanded our eligibility criteria to patients who stayed at both locations but did not require that the patient had a patient portal. A qualitative researcher (MSK) approached patients and caregivers (if the patient was unable to communicate) at Cal Rehab and discussed the study objectives and procedures. If patients and caregivers (or both) consented to participate, we worked with patients and caregivers to set up a patient portal log-in at CSMC and Cal Rehab (if needed) and registered them in the Single-FILE portal. We subsequently conducted a short 15- to 20-minute in-person interview using a semistructured interview guide, which included a short demographic questionnaire. Topics in the guide included a short description of the patients' condition and experiences in the acute and postdischarge settings, experiences transitioning from one facility to another, previous use of a patient portal, preferred functionality in patient portals, and use of the internet to access health information. The demographic questionnaire included questions about gender, race, ethnicity, education level, marital status, health status, level of interest in using the internet to manage health care (high, some, none, do not know or need more information) and health literacy (question: "How confident are you in filling out medical forms on your own?" answers: "Not at all, a little bit, somewhat, quite a bit, extremely"). We also called patients 30 days after their enrollment in the study to explore their use of Single-FILE.

### *Qualitative Analysis*

Framework analysis and open coding were used to analyze qualitative data. This methodology includes the transcription of the data, thorough reading of each transcript, coding of the data using open coding development of an analytical framework, applying the analytical framework or codebook, charting the data using a framework matrix, and interpreting the data.

## Results

### **Implementation Barriers**

As part of the implementation of Single-FILE for a real-world pilot, there was a need for cooperation and coordination with

our implementation partner, Cal Rehab. These are documented in a *lessons learned* document published by the ONC and fall into 4 broad categories.

### *Technology Standards*

This specific pilot was limited to 2 sites using independent Epic implementations. We encountered delays because the application programming interfaces (APIs) used by Single-FILE were dependent on features of a version of Epic that was not implemented in earlier versions. At the start of the project, we anticipated that Cal Rehab would upgrade to the current version of Epic; however, they made a business decision to skip to the next upgrade, delaying the project by over 12 months.

In addition, in our case, both CSMC and Cal Rehab used Epic as the EHR vendor. If Cal Rehab was using another vendor, the web service calls would have to be modified. While this pilot was underway, integration based on FHIR advanced rapidly, and as discussed later, the use of FHIR calls for patient identity verification, and binding eliminates EHR vendor-specific software and provides a standards-based API.

### *Governance*

For any federated identity to be acceptable, the participating parties must be able to trust that other parties adhere to the same security and privacy standards. A trust framework document spells out the responsibilities of each party. Our work revealed that for our (CSMC) environment, the idea of a trust framework was novel to our health system leaders, and our chief privacy officer indicated that this was likely true for other health systems.

### *Legal*

EHR access by proxies was a requirement for patients who were unable to access their EHR data on their own. Although this was not a major challenge to implement, we also had to ensure that we were compliant with several federal and state regulations to help ensure the privacy and confidentiality of patient information. The security scans, penetration tests, and PRAM review provided a high level of assurance that we would meet state and federal privacy and confidentiality standards.

### *Operations*

The expertise and authority needed to make decisions are compartmentalized within organizations and vary among organizations, and the implementation staff are not necessarily aware of or able to influence policy decisions. In addition, implementation targets and timelines were heavily affected by organization priorities. As mentioned earlier, the Single-FILE platform architecture relied on specific Epic web service calls; however, Cal Rehab was 1 version behind and did not support the needed web service calls. Cal Rehab made the decision to skip the upgrade and wait until the next version, delaying implementation by approximately 1 year.

Other delays were encountered as security and interface configurations were controlled by different, siloed teams within the same organization; thus, there were delays in making configuration changes and troubleshooting sessions to identify problems. An additional complication was the outsourcing of

parts of the EHR infrastructure, which further impeded troubleshooting and tuning the final configuration.

### SSO Acceptability

A total of 8 patients and their caregivers were interviewed at Cal Rehab. Most patients did not have an existing portal log-in for at least one site. Sign-up for the patient portal or portals and Single-FILE took approximately 60 to 90 minutes. This included the time needed to explain the project and get signed consent. The demographic characteristics of the patients are presented in Table 1. The patients enrolled were predominantly White (7/8, 88%) and non-Hispanic (5/8, 62%). Half of the patients or their caregivers reported that the patient had *fair* health. Most patients and their caregivers reported *high* or *some* level of interest in using the internet to manage their health. Health literacy levels were distributed throughout the spectrum, with 25% (2/8) of patients and their caregivers noting low levels of health literacy, 38% (3/8) reporting some levels of health literacy, and 25% (2/8) reporting *quite a bit* or *extremely* high levels of health literacy.

Approximately three-fourths of the patients and caregivers reported already using the Epic patient portal (MyChart). The most common uses of the patient portal included being able to track or change upcoming appointments, reviewing laboratory or test results, or contacting the clinician directly. A patient noted that he used the portal to look at the visit notes and explained the following:

*Oh, I like being able to just pop on and schedule an appointment, and check appointments, change them. See any of my tests that have been run for me, or*

*referrals, and really all of it. I don't want paper, and I don't want to make a phone call, if I can save it.*  
[Patient 1]

Another patient noted that he liked to have access to his medical information quickly:

*I knew from my doctor's office that they had a portal that I could sign up with that I could add, all my doctors would be added to it. All my appointments would be added to it. All my MRIs, CAT scans, lab work, the reports would all go on to that so I could look at it before my doctor even called me. And I like to have information as quick as possible.* [Patient 2]

Of those who did not regularly use the patient portal before signing up for Single-FILE, barriers included not feeling comfortable navigating the internet or using technology overall. One patient who did not use the patient portal noted the following:

*I hardly use the internet. I really don't.* [Patient 3]

This patient relied on her caregiver, a sibling, to access the patient's portal.

Patients noted that they appreciated only having to remember 1 log-in as part of Single-FILE and being able to sign up through Facebook. However, we did not see the use of Single-FILE by patients after they signed up. We attempted to reach patients and their caregivers via phone calls 30 days post sign-up but were not able to interview individuals, as this time coincided with the beginning of the COVID-19 pandemic, and the individuals reached did not want to participate in interviews at that time.

**Table 1.** Patient demographics and characteristics (N=8).

Characteristics	Values
Age (years), mean (SD)	65 (16.3)
<b>Gender, n (%)</b>	
Male	5 (62)
Female	3 (38)
<b>Race, n (%)</b>	
White	7 (88)
Black	1 (12)
Other	0 (0)
<b>Ethnicity, n (%)</b>	
Hispanic	1 (12)
Non-Hispanic	5 (62)
Other	2 (25)
<b>Education, n (%)</b>	
Less than high school, high school, or General Educational Development	0 (0)
Some college	4 (50)
College	3 (38)
Graduate school	1 (12)
<b>Marital status, n (%)</b>	
Single	2 (25)
Married	4 (50)
Widowed	1 (12)
Divorced	1 (12)
Domestic partnership or cohabiting with partner	0 (0)
<b>Self-reported health, n (%)</b>	
Excellent	0 (0)
Very good	2 (25)
Good	2 (25)
Fair	4 (50)
Poor	0 (0)
<b>Internet health literacy (what is your level of interest in using the internet to manage your health?), n (%)</b>	
High	3 (38)
Some	4 (50)
None	1 (12)
Do not know or need more information	0 (0)
<b>Health literacy (how confident are you in filling out medical forms on your own?), n (%)</b>	
Not at all	2 (25)
A little bit	0 (0)
Somewhat	3 (38)
Quite a bit	1 (12)
Extremely	1 (12)

## Discussion

### Principal Findings

The implementation of Single-FILE demonstrated that it is possible to safely bind a social identity to an EHR identity. The use of the OTP sent to the patient's EHR phone number provides a high degree of confidence that the binding is valid. However, we did not see use by patients of the Single-FILE portal after sign-up. We hypothesize that patients typically use the patient portal when they receive an email or text from the site that an appointment is upcoming or laboratory results are available, which then takes them directly to an EHR portal or app on a mobile device and not to Single-FILE. In other words, the use of the patient portal is typically reactive rather than proactive, which limited the use of Single-FILE as we implemented it via a webportal. However, regardless of how the patients access their EHR records (via a webportal or a mobile app), log-in credentials are still required at some point, and we demonstrated that those log-in credentials could be safely associated with a federated identity such as one used for social media.

As health information technology has evolved, the value of access to HPO-specific patient portals [33,34] via a browser is being superseded by access via mobile devices that make it easier for patients to access their EHR data. As previously discussed, there are vendor-specific patient portal solutions that aggregate all of a patient's EHR data onto an app; thus, this has the same functionality as SSO if the patient stays within that vendor's ecosystem. In addition, there are some cross-vendor solutions that allow aggregation of EHR data across different vendors, as well as PHR systems that aggregate data from HPOs and other data sources such as pharmacies and fitness trackers. However, these solutions may not readily allow the use of federated credentials for access. The patients we interviewed for this study showed that they appreciated the convenience of using their social credentials to access their EHR data and that remembering EHR portal credentials was a hindrance to access. As previously discussed, biometric authentication may ease the friction associated with access; however, ultimately, log-in credentials are needed, either at the initial configuration for biometric access, when a password reset has been performed, or if an app or mobile device has been upgraded.

When the Single-FILE was being developed, SMART on FHIR was an emerging technology and not widely supported by EHR

vendors; therefore, we developed a web-based proof of concept based on the APIs provided by Epic. At the time, we realized that expanding the concept to other EHR vendors would require additional software development as each EHR vendor would have different APIs. SMART on FHIR technology is now stable, and we have successfully replicated the binding of a social identity to an EHR identity by using the patient's log-in to an EHR portal and FHIR calls to retrieve the patient's phone number for an OTP challenge or response. The use of SMART on FHIR has the advantages of being vendor agnostic and more robust with respect to EHR software upgrades.

Furthermore, with the adoption of the Interoperability and Patient Access Final Rule (CMS-9115-F) and efforts by the ONC, FHIR has been identified as the basis for secure data exchange via APIs. These standards will foster the development of applications that aggregate health data from a variety of sources in addition to the traditional EHR. If these applications provide support or federated identities, they will enhance the ability of patients to get a holistic, longitudinal view of their EHR data without requiring yet another set of credentials for access.

### Conclusions

In this pilot project, we demonstrated that patients could use an identity they are comfortable with (ie, social identity and associated credentials) as a federated identity to safely ease the friction associated with access to EHR data as they are more likely to access social media more frequently than an EHR or even a PHR portal. Another important feature we built into our pilot software was the ability to use MFA, which provides an additional layer of protection in case one's log-in credentials are stolen or compromised. Although our solution involved the use of a webportal, the same approach can be used for an app on any mobile device.

This pilot illustrated the need for all participants in a federated identity management system to have high-level organizational support to ensure timely implementation and ensure compatibility with EHR software upgrades. Most of the barriers we encountered can be rendered moot if the support for a federated identity is incorporated into the EHR software and if the EHR vendors adhere to open standards. This is being driven by the ONC's effort to have EHR vendors incorporate support for FHIR in their software, and it has the added advantage of removing vendor-specific dependencies.

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### Conflicts of Interest

None declared.



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## Abbreviations

**API:** application programming interface

**CSMC:** Cedar-Sinai Medical Center

**EHR:** electronic health record

**FHIR:** fast healthcare interoperability resource

**HPO:** health provider organization

**IdP:** identity provider

**MFA:** multifactor authentication

**NIST:** National Institutes of Standards and Technology

**ONC:** Office of the National Coordinator for Health Technology

**OTP:** one-time passcode

**PHR:** personal health record

**PRAM:** privacy risk assessment methodology

**Single-FILE:** Single Federated Identity Log-in for electronic health records

**SMART:** Substitutable Medical Applications, Reusable Technologies

**SSO:** single sign-on

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Original Paper

# Effects of Acceptance and Commitment Therapy (ACT) on Mental Health and Resiliency of Migrant Live-in Caregivers in Canada: Pilot Randomized Wait List Controlled Trial

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## Abstract

**Background:** Temporary migrant live-in caregivers constitute a vulnerable stream of temporary foreign workers in Canada. This is because the majority are racialized women from the Global South, the gendered nature of caregiving work has historically been undervalued, and their working and living spheres are intertwined which makes application of labor laws and surveillance almost impossible. Their invisible position in the fabric of Canadian society along with their precarious employment and immigration status place their mental health at jeopardy. There is a paucity of research about psychological support for this population.

**Objective:** Our pilot study Women Empowerment—Caregiver Acceptance and Resilience E-Learning (WE2CARE) aimed to assess the efficacy of a 6-week online delivery of a psychological intervention based on acceptance and commitment therapy (ACT) in reducing psychological distress and promoting resiliency among live-in care givers in the Greater Toronto Area.

**Methods:** A pilot randomized wait list controlled design was used. Participants were recruited by two community peer champions working with community health organizations serving migrant live-in caregivers. A total of 36 participants were recruited and randomly assigned to the intervention and wait list control groups; 7 dropped out of the study due to competing life priorities. Standardized self-reported surveys were administered online pre-, post-, and 6-week postintervention to assess mental distress (DASS-21), psychological flexibility (AAQ-2), mindfulness (CAMS-R), and Multi-System Model of Resilience (MSMR-I). Independent and dependent *t* tests were used to compare study outcomes at pre, post, and 6-week follow-up across and within both arms of the study. Linear mixed effects models were created for each outcome of interest from baseline to postintervention among intervention and control participants. Self-reported impact of the WE2CARE intervention was examined using independent *t* tests across the study arms.

**Results:** Average age of participants was 38 years. Many were born in the Philippines (23/29, 79%). The data on the impact of the psychological intervention showed a lower level of depression, anxiety, and stress among the intervention group compared with the control. However, the differences were not significant due to small sample size and COVID-19 crisis (6.94 vs 9.50,  $P=.54$ ; 6.94 vs 10.83,  $P=.20$ ; 7.76 vs 10.33,  $P=.44$ , respectively). There was a significant improvement in mindful qualities and external resilience, particularly in life satisfaction and accessible support among the intervention group (37.18 vs 32.92,  $t_{22}=2.35$ ,  $P=.03$ ; 20.29 vs 16.5,  $t_{21}=2.98$ ,  $P=.007$ ; 8.47 vs 6.75,  $t_{14}=2.41$ ,  $P=.03$ ; 7.59 vs 5.33,  $t_{16}=.008$ , respectively).

**Conclusions:** WE2CARE is among the first studies exploring the efficacy of online delivery of ACT in addressing mental health challenges among live-in caregivers. While there are increased web-based ACT interventions, few use group videoconferencing to promote peer connection and mutual support. WE2CARE showed promising results in reducing psychological distress and

promoting mindfulness and resiliency. The intervention highly motivated participants to engage collectively in building social support networks.

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## KEYWORDS

migrant live-in caregiver; women; mental health; acceptance and commitment therapy; depression; anxiety; stress; psychological inflexibility; resilience; social identity

## Introduction

The Caregiver Program, previously known as the Live-in Caregiver Program, is a stream of the Canadian Temporary Foreign Workers Program, which engages workers in home caregiving [1,2]. Workers who enter the country under this program constitute an underrepresented and vulnerable stream of temporary foreign workers in Canada since more than 90% of workers are women of color from the Global South; their employment falls in the purview of feminized work that historically and globally has been devalued, dehumanized, and underpaid; and the location of their services situated in the private sphere derails the application of labor laws, government surveillance, and unionization [3-5].

Under the Live-in Caregiver Program, migrant caregivers were restricted to work and live only for the employers stated on their work permits while providing care to their employers' children, seniors, or disabled family members. Despite Caregiver Program reforms in November 2014 which provided caregivers with the option of living outside of their employers' homes, most caregivers continued to live with their employer due to low wages, inability to afford independent housing, and precarious work permits [6].

Most caregivers are racialized women from lower- or middle-income countries, with the majority coming from the Philippines and a growing number from Haiti, Africa, Latin America, and Asia [1,3,7]. They are often the sole provider of income for their families back home, and their need to send regular remittances forces them to accept a submissive and discriminatory position, relinquish their basic human rights, and submit to precarious employment, financial exploitation (low wages, long working hours without compensation), emotional and physical abuse, and having little to no access to social or health care services despite paying into these programs [3,8,9]. Furthermore, the possibility of applying for permanent residency for not only themselves but also their immediate family members after completing 24 months of service often acts as an impetus for caregivers' acceptance of their dire living and working conditions in Canada. Considering that family separation is one of the requirements for caregivers' work permits in Canada under both the Live-in Caregiver Program and Caregiver Program, securing permanent residency for caregivers symbolizes the hope for family reunification. It is noteworthy that the process of gaining permanent residency for this group can take from 4 to 10 years. While Caregiver Program reforms in November 2014 have included a commitment to reduce processing times for permanent residency of caregivers

[10,11], the processing time until 2016 remained at a minimum average of 6 years.

Most studies with temporary migrant workers explored their vulnerability in the areas of occupational injury and hazard, sexual and reproductive health, and chronic and infectious diseases like HIV/AIDS [12-20]. These vulnerabilities have been reported to be associated to temporary migrant workers' working and living conditions such as discrimination, precarious work permit and immigration status, stigma, limited social support, and fear of job loss [12,14,17-20].

Although live-in caregivers face a multitude of challenges in the host countries, there is limited research related to the impact of these challenges on their mental health. The few studies that have explored this issue found a high level of psychological distress, feeling of alienation and loneliness, and limited social support [9,21]. Multiple barriers to accessing mental health services were also reported including long working hours, fear of job loss and deportation, and limited knowledge about available mental health resources. Considering these barriers, offering online psychosocial support programs can be an effective strategy in reducing temporary migrant live-in caregivers' psychological distress and promoting their mental well-being.

Acceptance and commitment therapy (ACT) is a cognitive behavioral approach that promotes psychological flexibility. Psychological flexibility is the aptitude of adjusting to any situational demand which in turn allows for living a meaningful life. ACT targets psychological flexibility through advancing 6 core skills: acceptance (experiences of both pleasant and unpleasant thoughts, emotions, and feelings instead of trying to avoid or control them), defusion (stepping back and observing thoughts as thoughts), contact with the present moment (consciously engaging in any moment and being mindful of thoughts, feelings, and actions), self-as-context (awareness and self-perspective), values (being clear about what matters), and committed action (taking actions that are guided by one's values) [22,23]. All these processes can be viewed as efforts directed at relinquishing antecedent stimulus control that exist due to verbal conditioning. In other words, ACT does not focus on reducing clinical symptoms but rather aims at altering their behavioral impact. This is done through deconstructing the individual experience in the context of personal values and acceptance of both negative and positive components of experience. Acceptance and mindfulness are core processes of psychological flexibility [24,25].

A significant body of literature has provided support for the efficacy of ACT in promoting well-being and reducing



psychological distress among both clinical and nonclinical populations [26-29]. Furthermore, the internet-based delivery of ACT has been reported to be promising in managing anxiety, depression, chronic pain, and distress related to trauma and promoting mental wellness and psychological flexibility [30-32].

Engaging migrant live-in caregivers in learning ACT skills can support their mental health by decreasing distress through strategies like mindfulness, defusion from negative thoughts, and increasing committed action consistent with the value of self-care (eg, engaging in culturally syntonetic activities like singing or praying and building social support networks). Given that live-in caregivers work long hours and have extremely limited free time and restricted social support, a web-based approach is the best-suited medium for the delivery of self-help psychological treatment in this population. Earlier studies with this population reported a preference for online health resources among this population due to their precarious work permit and fear of repatriation—being sick or seeking medical care may put their livelihood in jeopardy [9,21]. This approach offers flexible access while promoting virtual social connection. To our knowledge there is a paucity of research about the effectiveness and suitability of an internet-delivered psychological intervention based on ACT for this population.

Our pilot study, Women Empowerment—Caregiver Acceptance and Resilience E-Learning (WE2CARE), aimed to address this gap by exploring the efficacy of a 6-week online psychological intervention based on ACT for temporary migrant live-in caregivers.

## Methods

### Theoretical Framework

Our study was guided by the population health promotion framework, which is grounded in the principles of social justice and equity [33-35]. This framework acknowledges that health disparities are the outcomes of myriad social determinants including access to physical, psychological, social, and financial security. In this study, we recognized that the life circumstances of live-in caregivers are shaped by systemic issues in both Canada and their countries of origin. As upstream strategies (policy reform and resource redistribution) will take years to implement and achieve, it was critical to implement midstream

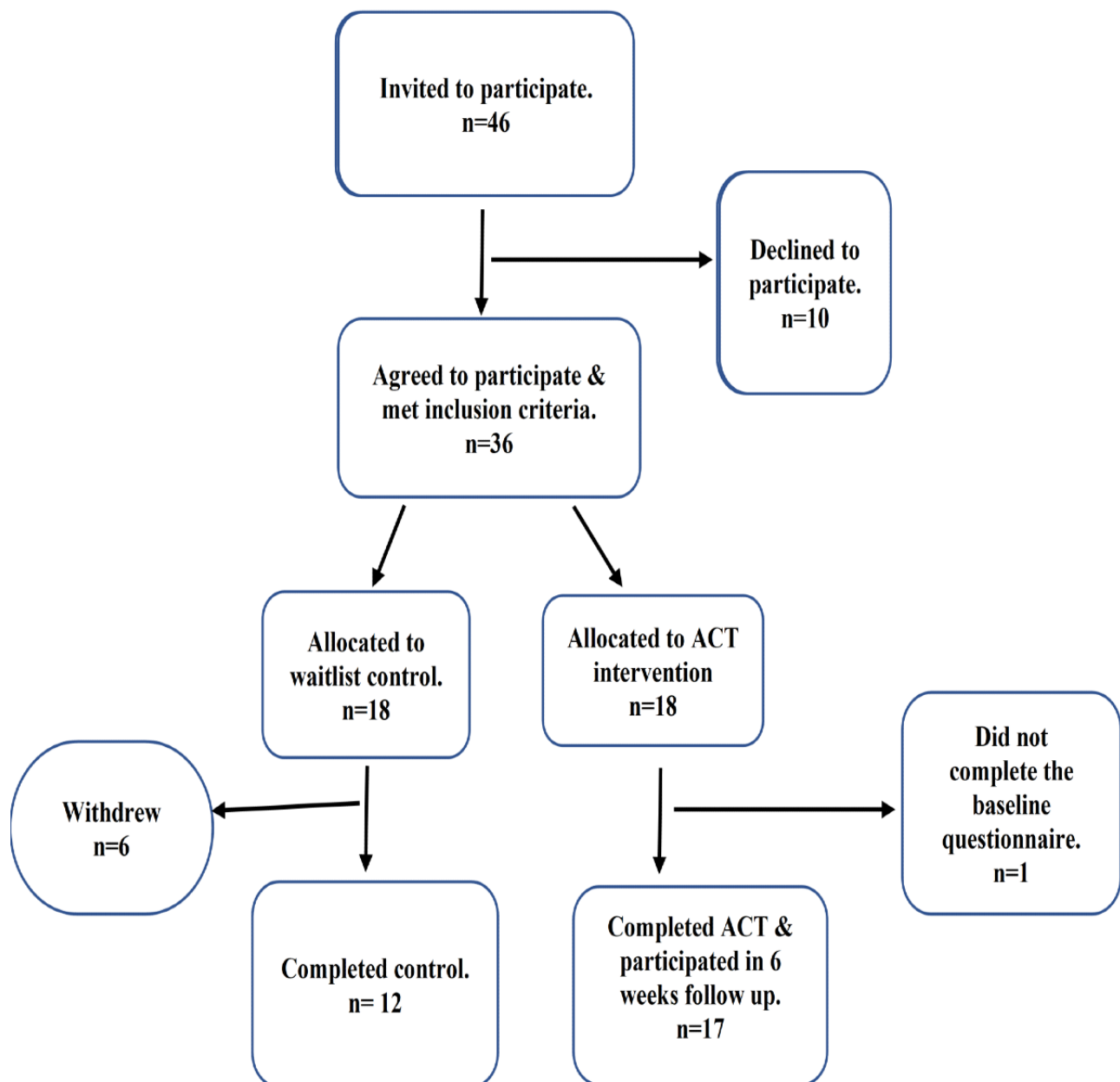
(supportive environment, community engagement) and downstream (individual coping, self-care) strategies to address the urgent mental health needs of live-in caregivers. To address the latter, we applied culturally safe and adult learning principles.

### Design

A pilot community-based mixed methods study was used to examine the feasibility and efficacy of WE2CARE in reducing psychological distress (depression, anxiety, and stress) and promoting committed actions of self-care and identify perceived barriers and facilitators to using WE2CARE. In this paper, we report only on the findings from the quantitative component of the study, which consisted of a randomized controlled wait list design and explored the feasibility and efficacy of the intervention.

### Participants and Recruitment Strategies

The study protocol received ethical approval from the research ethics review boards at the affiliated universities. Those included Ryerson University (REB 2019-036) and University of Toronto (RIS37623). A total of 36 participants were recruited by 2 community champions (trusted members of live-in caregivers' community) and snowball technique. Eligible participants met the study inclusion criteria: (1) self-identified as female aged 18 years or older, (2) residing in the Greater Toronto Area, (3) working on a temporary work permit as a live-in caregiver, (4) able to speak and read English, (5) had internet access, and (6) able to take part in the 6-week intervention. They were randomly divided into the intervention arm and wait list control arm using a random number generator. Of 18 participants in the intervention group, 1 did not complete the baseline questionnaire, while 6 of 18 participants in the control group withdrew from the study due to other competing life priorities. The total number of participants who completed the pilot study was 29, with 17 in the intervention group and 12 in the wait list control group. The intervention group was further divided into 2 cohorts, 9 and 8 participants each, to enhance participation. After those in the intervention group received the 6-week online intervention, it was offered to the control group to respect the ethical principle of beneficence (Figure 1). All participants were compensated for their participation in the study and the cost of internet use.

**Figure 1.** Flowchart of WE2CARE study participants.

### WE2CARE Intervention

The WE2CARE intervention consisted of 6 e-learning modules that explained the ACT processes. Each week, participants were invited to complete an online self-directed, interactive experiential session on ACT strategies (approximately 1 hour to complete) and attend a 1.5-hour online live videoconference. The videoconference was designed to support participants in applying ACT strategies in their everyday life and consisted of a group discussion, peer sharing, and question and answers. The videoconference was facilitated by 2 of our research team members with extensive knowledge and experience in ACT. Prior to each videoconferencing, which took place on mutually agreed weekdays in the evening, participants were given a week to complete their assigned weekly module. Details of the study protocol have been reported elsewhere [36].

### Data Collection and Measures

Data were captured through self-report instruments administered online at pre-, post-, and 6-week postintervention. The preintervention survey included sociodemographic and health-related questions that were identified as important in previous research with temporary migrant workers [14,16]. The standardized scales administered at pre-, post-, and 6-week follow-up included: (1) Depression, Anxiety and Stress Scale (DASS-21)—a set of 3 self-report scales (21 items) designed to measure the emotional states of depression (DASS-D), anxiety (DASS-A) and stress (DASS-S); Cronbach alpha values of 0.81, 0.89 and 0.78 for the subscales of depressive, anxiety and stress respectively; (2) Acceptance and Action Questionnaire-2 (AAQ-2)—a 7-item scale designed to measure the impact of ACT core process conceptualized as psychological flexibility; (3) Cognitive and Affective Mindfulness Scale (CAMS-R)—a 12-item measure designed to capture a broad conceptualization

of mindfulness not specific to any particular type of meditation training; and the (4) Multi-System Model of Resilience (MSMR-I), consisting of 3 subscales: internal resilience (MSMR-IR), coping pursuits (MSMR-CP), and external resilience (MSMR-ER). Each subscale contains 9 self-reported items and indicates where the barriers to one's resilience lie. These scales have shown good psychometric properties including internal consistency, test-retest reliability, and validity. For instance, the depressive, anxiety, and stress subscales in DASS have been found to have excellent Cronbach alpha values of .81, .89, and .78, respectively. AAQ-2 was reported to have good internal consistency ( $\alpha=.88$ ) and good test retest reliability over 3 and 12 months at .81 and .79, respectively. CAMS-R was reported to have good Cronbach alpha (.67) and good convergent validity that is supported by its negative relationship to the DASS-21 is negatively correlated to DASS (-.28). MSMR-I also showed excellent internal consistency with Cronbach alpha of .90 and high test-retest reliability .84 [37-43].

### Data Analyses

Descriptive statistics were used to summarize participants' sociodemographic and self-reported health characteristics. Fisher exact tests were used to compare participant characteristics by study arm allocation. Both independent and dependent *t* tests were used to compare study outcomes pre, post, and 6-week follow-up across and within both arms of the study. Linear mixed effects models were created for each outcome of interest from baseline to postintervention among intervention and control participants. Self-reported impact of the WE2CARE intervention was examined using independent *t* tests across the study arms. Data were entered and analyzed using the SPSS Statistics (version 27, IBM Corp). A threshold of .05 was used to determine the level of significance for all *P* values.

## Results

### Sociodemographic and Self-reported Health Characteristics

Average age of participants was 38 years. Many participants were born in the Philippines (23/29, 79%) and have lived in Canada for more than 24 months (17/29, 59%). Most participants were married (12/29, 41%) and had children (18/29, 62%), but none of their children were in Canada. Most had college or university degree (19/29, 66%) and rated their English literacy as being good (19/29, 66%). Nearly 90% (26/29) of participants

were temporary workers with a valid visa and work permit; 83% (24/29) worked as live-in caregivers, 79% (23/29) worked full-time, and 62% (18/29) worked 35 to 44 hours per week. Among those who reported their income, 59% (13/22) earned less than CAD \$24,999 (US \$19,441) after taxes. Although most (23/29, 79%) participants did not share their sleeping area or bedroom with others, for those who did share, they shared their sleeping area with, on average, 2 other people. Lack of privacy was a common concern raised by participant who were concerned about their accommodation.

A total of 7% (2/29) of participants rated their health at the time of entry to Canada as poor or fair compared with other people their age. However, this proportion was considerably increased (8/29, 28%) after arrival to Canada. Regarding satisfaction with life, 10% (3/29) were dissatisfied or very dissatisfied and 24% (7/29) were neither satisfied nor dissatisfied. The mean self-rated level of stress was more than 50 on a scale of 0 to 100 (0 being no stress and 100 being extremely stressful). About a fifth (6/29, 21%) of the participants rated their mental health as fair or poor compared with other people of their own age. More than half (15/29, 52%) of the participants were dissatisfied with their quality of sleep and reported having difficulty falling sleep, staying asleep, or getting sufficient hours of sleep. Overall, participants were relatively healthy before and after coming to Canada although they felt their overall physical and mental health were gradually deteriorating. Only a few people had been diagnosed with high blood pressure, cancer, intestinal/stomach problems, or depression since arriving in Canada.

More than 50% (17/29) of participants had been tested for HIV (a required medical test for entry to Canada), and of those, 41% (7/29) stated that their test was done sometime from 2018 to 2019. Interestingly, the rate of screening for sexually transmitted infections appeared to be quite low among this population. Most (20/29, 69%) participants stated that they have never been tested for human papillomavirus, a common cause of cervical cancer, or any other sexually transmitted infection (21/29, 72%).

Participants were asked about their use of health care services since coming to Canada. A total of 28% (8/29) did not use health care services while the rest did. A wide variety of reasons were given; the most common reason (8/21, 38%) was annual checkup followed by job requirement for flu vaccination (3/21, 14%).

There were no differences between the intervention and control groups on demographic variables and self-reported health characteristics as can be seen in [Table 1](#).

**Table 1.** Sociodemographic and clinical characteristics of study participants.

	Overall (n=29)	Intervention (n=17)	Control (n=12)	P value <sup>a</sup>
<b>Demographic characteristics</b>				
Age (years), mean (SD)	38.38 (6.62)	38.41 (7.11)	38.33 (6.18)	.98
<b>Country of birth, n (%)</b>				
Philippines	23 (79)	13 (77)	10 (83)	— <sup>b</sup>
Other	6 (21)	4 (24)	2 (17)	—
<b>Time lived in Canada, n (%)</b>				
Less than 12 months	3 (10)	2 (12)	1 (8)	—
12 months or more	26 (90)	15 (88)	11 (92)	—
<b>Immigration status, n (%)</b>				
Refugee applicant	1 (3)	0 (0)	1 (8)	—
No status	2 (7)	1 (6)	1 (8)	—
Temporary foreign worker with a valid visa and work permit	26 (90)	16 (94)	10 (83)	—
<b>Marital status, n (%)</b>				
Divorced	2 (7)	2 (12)	0 (0)	—
Married	12 (41)	6 (35)	6 (50)	—
Separated	1 (3)	1 (6)	0 (0)	—
Single (never married)	11 (38)	7 (41)	4 (33)	—
Widowed	3 (10)	1 (6)	2 (17)	—
<b>Has children, n (%)</b>				
Yes	18 (62)	9 (53)	9 (75)	.27
<b>Has children in Canada, n (%)</b>				
No	18 (100)	9 (100)	9 (100)	>.99
<b>English literacy, n (%)</b>				
Poor	1 (3)	1 (6)	0 (0)	—
Fair	5 (17)	1 (6)	4 (33)	—
Good	19 (66)	11 (65)	8 (67)	—
Very good/excellent	4 (14)	4 (24)	0 (0)	—
<b>Education, n (%)</b>				
Less than high school (grade 8 or less)	1 (3)	0 (0)	1 (8)	—
High school (grade 12) or equivalent	7 (24)	3 (18)	4 (33)	—
College (eg, diploma) or university (eg, BA, BSc)	19 (66)	12 (71)	7 (58)	—
Some or completed postgraduation (eg, Master's, PhD)	2 (7)	2 (12)	0 (0)	—
<b>Employment status, n (%)</b>				
Full-time (minimum of 35 hours/week)	23 (79)	14 (82)	9 (75)	—
Part-time	2 (7)	1 (6)	1 (8)	—
Unemployed	3 (10)	1 (6)	2 (17)	—
Other	1 (3)	1 (6)	0 (0)	—
<b>Work hours per week, n (%)</b>				
0	3 (10)	1 (6)	2 (17)	—
Less than 24	1 (3)	0 (0)	1 (8)	—
25-34	1 (3)	1 (6)	0 (0)	—

	Overall (n=29)	Intervention (n=17)	Control (n=12)	P value <sup>a</sup>
35-44	18 (62)	12 (71)	6 (50)	—
45+	6 (21)	3 (17)	3 (25)	—
<b>Current occupation, n (%)</b>				.69
Live-in caregiver	24 (83)	15 (88)	9 (75)	—
Personal support worker	2 (7)	1 (6)	1 (8)	—
Not employed	3 (10)	1 (6)	2 (17)	—
<b>Income after taxes (CAD \$), n (%)</b>				.89
Less than \$24,999	13 (45)	7 (41)	6 (50)	—
\$25,000-\$39,999	9 (31)	6 (35)	3 (25)	—
Prefer not to answer	7 (24)	4 (24)	3 (25)	—
<b>Health assessment</b>				
<b>Self-rated general health when arrived in Canada, n (%)</b>				.30
Poor	0 (0)	0 (0)	0 (0)	—
Fair	2 (7)	0 (0)	2 (17)	—
Good	11 (38)	7 (41)	4 (33)	—
Very good/excellent	16 (55)	10 (59)	6 (50)	—
<b>Self-rated general health since arrival in Canada, n (%)</b>				.94
Poor	2 (7)	1 (6)	1 (8)	—
Fair	6 (21)	3 (18)	3 (25)	—
Good	11 (38)	7 (41)	4 (33)	—
Very good/excellent	10 (35)	6 (35)	4 (33)	—
<b>Life satisfaction since arrival in Canada, n (%)</b>				.95
Very dissatisfied	1 (3)	1 (6)	0 (0)	—
Dissatisfied	2 (7)	1 (6)	1 (8)	—
Neither satisfied nor dissatisfied	7 (24)	5 (29)	2 (17)	—
Satisfied	17 (59)	9 (53)	8 (67)	—
Very satisfied	2 (7)	1 (6)	1 (8)	—
Self-rated level of stress since arrival in Canada (0=not at all stressful, 100=extremely stressful), mean (SD)	57.31 (27.47)	53.41 (28.16)	62.83 (26.66)	.37
<b>Self-rated general mental health, n (%)</b>				.50
Poor	2 (7)	1 (6)	1 (8)	—
Fair	4 (14)	1 (6)	3 (25)	—
Good	16 (55)	11 (38)	5 (42)	—
Very good/excellent	7 (24)	4 (24)	3 (25)	—
<b>Quality of sleep, n (%)</b>				.71
Satisfied	14 (48)	9 (53)	5 (42)	—
Dissatisfied	15 (52)	8 (47)	7 (58)	—
<b>Diagnosed health conditions since arrival in Canada, n (%)</b>				.43
High blood pressure	2 (7)	0 (0)	2 (17)	—
Cancer	1 (3)	1 (6)	0 (0)	—
Intestinal problems (ulcer, Crohn disease, irritable bowel syndrome)	1 (3)	1 (6)	0 (0)	—
Depression or other mood disorders (anxiety)	1 (3)	0 (0)	1 (8)	—
STIs <sup>c</sup>	1 (3)	1 (6)	0 (0)	—



	Overall (n=29)	Intervention (n=17)	Control (n=12)	P value <sup>a</sup>
Others	1 (3)	0 (0)	1 (8)	—
<b>Last tested for HPV<sup>d</sup>, n (%)</b>				.33
Before 2013	1 (3)	1 (6)	0 (0)	—
2018-2019	4 (14)	3 (18)	1 (8)	—
Never	20 (69)	11 (12)	9 (75)	—
Not sure	2 (7)	0 (0)	2 (17)	—
Prefer not to answer	2 (7)	2 (12)	0 (0)	—
<b>Last tested for STI, n (%)</b>				—
2018-2019	3 (10)	3 (18)	0 (0)	.33
Never	21 (72)	11 (65)	10 (83)	—
Not sure	3 (10)	1 (6)	2 (17)	—
Prefer not to answer	2 (7)	2 (12)	0 (0)	.38
Last tested for HIV				—
Prefer not to answer	3 (10)	2 (12)	1 (8)	—

<sup>a</sup>Fisher exact test was used to compare count data. *T*-test was used to compare means.

<sup>b</sup>—: not applicable

<sup>c</sup>STI: sexually transmitted infection.

<sup>d</sup>HPV: human papillomavirus.

### Study Outcome Measures: DASS, AAQ-2, CAMS-R, and MSMR-I

Tables 2 and 3 demonstrate the mean score differences within the intervention group before, after and at 6-week follow-up for all the outcome measures. Table 4 shows the mean score differences between the intervention and control groups for all the outcome measures. Tables 5 and 6 show the linear mixed effects regression analyses using the pre- and postassessment on the main outcomes across both groups.

The mean scores for DASS-D, DASS-A, and DASS-S decreased steadily among the intervention arm post and 6-week follow-up: 40% drop in depression level, 23% drop in anxiety level, and 52% drop in stress level (Figure 2). However, these changes were not significant except for the stress level after 6-week follow-up (10.59 vs 5.06,  $t_{16}=2.6$ ,  $P=.02$ ). Furthermore, overall resiliency (MSMR) and external resiliency (MSMR-ER), particularly in the sphere of access to needed support (ie, MSMR accessible support), significantly increased compared to baseline (62.53 vs 65.35,  $t_{16}=-3.33$ ,  $P=.004$ ; 19.65 vs 21.35,  $t_{16}=-2.71$ ,  $P=.02$ ; 6.71 vs 7.88,  $t_{16}=-2.85$ ,  $P=.01$ , respectively).

**Table 2.** Paired sample *t* test among intervention participants at pre/baseline (T1) and postintervention (T2).

Variable	Baseline (n=17), mean (SD)	Postintervention (n=17), mean (SD)	<i>t</i> score	<i>df</i>	<i>P</i> value
DASS-D <sup>a</sup>	6.47 (10.67)	6.94 (9.83)	-0.26	16	.80
DASS-A <sup>b</sup>	8.71 (9.25)	6.94 (5.57)	0.71	16	.49
DASS-S <sup>c</sup>	10.59 (9.92)	7.76 (6.32)	1.02	16	.32
AAQ-2 <sup>d</sup>	18.65 (8.68)	17.94 (8.42)	0.34	16	.74
CAMS <sup>e</sup>	37.24 (4.45)	37.18 (4.46)	0.07	16	.95
MSMR <sup>f</sup>	62.53 (5.40)	62.71 (7.02)	-0.11	16	.91
MSMR_IR <sup>g</sup>	20.71 (3.06)	20.00 (3.39)	0.8	16	.44
MSMR_CP <sup>h</sup>	22.18 (2.53)	22.41 (2.55)	-0.30	16	.77
MSMR_ER <sup>i</sup>	19.65 (2.37)	20.29 (3.02)	-1.11	16	.28
MSMR_HealthWellness	5.82 (1.81)	6.18 (1.98)	-0.88	16	.39
MSMR_HealthReserve	7.94 (1.30)	7.24 (2.25)	1.76	16	.10
MSMR_PsychRegulation	6.94 (1.95)	6.59 (1.73)	0.82	16	.42
MSMR_LifeSatisfaction	8.24 (0.97)	8.47 (0.94)	-0.78	16	.45
MSMR_GrowthCapacity	8.59 (0.80)	8.06 (1.43)	1.77	16	.10
MSMR_SelfEsteem	5.35 (2.40)	5.88 (1.90)	-0.80	16	.43
MSMR_SocialSecurity	6.47 (1.62)	6.65 (1.77)	-0.43	16	.68
MSMR_SocialFunction	6.47 (1.42)	6.06 (1.25)	1	16	.33
MSMR_AccSupport	6.71 (1.96)	7.59 (1.28)	-1.74	16	.10

<sup>a</sup>DASS-D: Depression, Anxiety and Stress Scale–depression.

<sup>b</sup>DASS-A: Depression, Anxiety and Stress Scale–anxiety.

<sup>c</sup>DASS-S: Depression, Anxiety and Stress Scale–stress.

<sup>d</sup>AAQ-2: Acceptance and Action Questionnaire–2.

<sup>e</sup>CAMS: Cognitive and Affective Mindfulness Scale.

<sup>f</sup>MSMR: Multi-System Model of Resilience.

<sup>g</sup>MSMR\_IR: Multi-System Model of Resilience–internal resilience.

<sup>h</sup>MSMR\_CP: Multi-System Model of Resilience–coping pursuits.

<sup>i</sup>MSMR\_ER: Multi-System Model of Resilience–external resilience.

**Table 3.** Paired sample *t* test among intervention participants at baseline and 6 weeks postintervention.

Variable	Baseline (n=17), mean (SD)	6 weeks postintervention (n=17), mean (SD)	<i>t</i> score	<i>df</i>	<i>P</i> value
DASS-D <sup>a</sup>	6.47 (10.67)	3.88 (6.65)	1.14	16	.27
DASS-A <sup>b</sup>	8.71 (9.25)	6.71 (7.17)	0.80	16	.43
DASS-S <sup>c</sup>	10.59 (9.92)	5.06 (4.25)	2.60	16	.02
AAQ-2 <sup>d</sup>	18.65 (8.68)	16.24 (7.05)	1.13	16	.28
CAMS <sup>e</sup>	37.24 (4.45)	36.76 (4.42)	0.49	16	.63
MSMR <sup>f</sup>	62.53 (5.40)	65.35 (5.93)	-3.33	16	.004
MSMR_IR <sup>g</sup>	20.71 (3.06)	20.88 (2.52)	-0.33	16	.75
MSMR_CP <sup>h</sup>	22.18 (2.53)	23.12 (2.37)	-1.59	16	.13
MSMR_ER <sup>i</sup>	19.65 (2.37)	21.35 (3.06)	-2.71	16	.02
MSMR_HealthWellness	5.82 (1.81)	5.94 (1.48)	-0.36	16	.73
MSMR_HealthReserve	7.94 (1.30)	8.00 (1.27)	-0.22	16	.83
MSMR_PsychRegulation	6.94 (1.95)	6.94 (1.39)	0	16	>.99
MSMR_LifeSatisfaction	8.24 (0.97)	8.59 (0.87)	-1.69	16	.11
MSMR_GrowthCapacity	8.59 (0.80)	8.23 (0.97)	1.46	16	.16
MSMR_SelfEsteem	5.35 (2.40)	6.29 (1.96)	-1.96	16	.07
MSMR_SocialSecurity	6.47 (1.62)	6.82 (1.51)	-1.24	16	.23
MSMR_SocialFunction	6.47 (1.42)	6.65 (1.58)	-0.34	16	.74
MSMR_AccSupport	6.71 (1.96)	7.88 (1.50)	-2.85	16	.01

<sup>a</sup>DASS-D: Depression, Anxiety and Stress Scale–depression.

<sup>b</sup>DASS-A: Depression, Anxiety and Stress Scale–anxiety.

<sup>c</sup>DASS-S: Depression, Anxiety and Stress Scale–stress.

<sup>d</sup>AAQ-2: Acceptance and Action Questionnaire–2.

<sup>e</sup>CAMS: Cognitive and Affective Mindfulness Scale.

<sup>f</sup>MSMR: Multi-System Model of Resilience.

<sup>g</sup>MSMR\_IR: Multi-System Model of Resilience–internal resilience.

<sup>h</sup>MSMR\_CP: Multi-System Model of Resilience–coping pursuits.

<sup>i</sup>MSMR\_ER: Multi-System Model of Resilience–external resilience.

**Table 4.** Independent sample *t* test between study arms postintervention.

Variable	Intervention (n=17), mean (SD)	Control (n=12), mean (SD)	<i>t</i> score	<i>df</i>	<i>P</i> value
DASS-D <sup>a</sup>	6.94 (9.83)	9.50 (12.33)	-0.60	20.27	.56
DASS-A <sup>b</sup>	6.94 (5.57)	10.83 (8.96)	-1.33	16.96	.20
DASS-S <sup>c</sup>	7.76 (6.32)	10.33 (9.94)	-0.79	17.21	.44
AAQ-2 <sup>d</sup>	17.94 (8.42)	18.00 (12.60)	-0.01	17.82	.99
CAMS <sup>e</sup>	37.18 (4.46)	32.92 (5.04)	2.35	21.94	.03
MSMR <sup>f</sup>	62.71 (7.02)	55.67 (12.31)	1.79	16.06	.09
MSMR_IR <sup>g</sup>	20.00 (3.39)	19.42 (4.21)	0.40	20.44	.70
MSMR_CP <sup>h</sup>	22.41 (2.55)	19.75 (5.75)	1.50	14.08	.16
MSMR_ER <sup>i</sup>	20.29 (3.02)	16.50 (3.61)	2.98	21.02	.007
MSMR_Health wellness	6.18 (1.98)	5.25 (2.09)	1.20	22.94	.24
MSMR_Health reserve	7.24 (2.25)	7.33 (1.37)	-0.15	26.56	.89
MSMR_Psychological regulation	6.59 (1.73)	6.83 (1.80)	-0.37	23.26	.72
MSMR_Life satisfaction	8.47 (0.94)	6.75 (2.34)	2.41	13.55	.03
MSMR_Growth capacity	8.06 (1.43)	6.83 (2.44)	1.56	16.34	.14
MSMR_Self esteem	5.88 (1.90)	6.17 (2.52)	-0.33	19.47	.74
MSMR_Social security	6.65 (1.77)	5.75 (2.01)	1.25	21.84	.23
MSMR_Social function	6.06 (1.25)	5.42 (1.78)	1.15	19.76	.26
MSMR_Accessible support	7.59 (1.28)	5.33 (2.35)	3.03	15.61	.008

<sup>a</sup>DASS-D: Depression, Anxiety and Stress Scale–depression.

<sup>b</sup>DASS-A: Depression, Anxiety and Stress Scale–anxiety.

<sup>c</sup>DASS-S: Depression, Anxiety and Stress Scale–stress.

<sup>d</sup>AAQ-2: Acceptance and Action Questionnaire–2.

<sup>e</sup>CAMS: Cognitive and Affective Mindfulness Scale.

<sup>f</sup>MSMR: Multi-System Model of Resilience.

<sup>g</sup>MSMR\_IR: Multi-System Model of Resilience–internal resilience.

<sup>h</sup>MSMR\_CP: Multi-System Model of Resilience–coping pursuits.

<sup>i</sup>MSMR\_ER: Multi-System Model of Resilience–external resilience.

**Table 5.** Linear mixed effects models: effects of WE2CARE on outcomes among intervention participants.

Parameter	Coefficient (95% CI)	Standard error	t score	P value	Random effect (SD)
Intercept	7.88 (3.10 to 12.66)	2.42	3.26	.005	7.59
DASS_D <sup>a</sup>	-0.59 (-5.05 to 3.87)	2.21	-0.27	.79	6.46
Intercept	8.71 (5.08 to 12.33)	1.85	4.70	<.001	2.35
DASS_A <sup>b</sup>	-1.76 (-6.78 to 3.25)	2.49	-0.71	.49	7.26
Intercept	10.59 (6.64 to 14.53)	2.02	5.25	<.001	1.91
DASS_S <sup>c</sup>	-2.82 (-8.37 to 2.72)	2.78	-1.02	.32	8.09
Intercept	18.65 (14.56 to 22.74)	2.07	8.99	<.001	6.04
AAQ-2 <sup>d</sup>	-0.71 (-4.89 to 3.47)	2.08	-0.34	.74	6.05
Intercept	37.24 (35.09 to 39.38)	1.08	34.45	<.001	3.67
CAMS <sup>e</sup>	-0.06 (-1.81 to 1.69)	0.87	-0.07	.95	2.53
Intercept	62.53 (59.54 to 65.52)	1.52	41.16	<.001	4.23
MSMR <sup>f</sup>	0.18 (-3.01 to 3.37)	1.58	0.11	.91	4.62
Intercept	20.71 (19.17 to 22.24)	0.78	26.44	<.001	1.95
MSMR_IR <sup>g</sup>	-0.71 (-2.48 to 1.07)	0.88	-0.80	.44	2.57
Intercept	22.18 (20.97 to 23.38)	0.62	35.99	<.001	1.05
MSMR_CP <sup>h</sup>	0.24 (-1.36 to 1.83)	0.79	0.30	.77	2.31
Intercept	19.65 (18.34 to 20.95)	0.66	29.87	<.001	2.12
MSMR_ER <sup>i</sup>	0.65 (-0.52 to 1.82)	0.58	1.11	.28	1.69
Intercept	5.82 (4.91 to 6.73)	0.28	30.53	<.001	0.77
MSMR_HealthWellness	0.35 (-0.46 to 1.16)	0.30	-1.77	.10	0.87
Intercept	7.94 (7.06 to 8.82)	0.52	10.21	<.001	0.99
MSMR_HealthReserve	-0.71 (-1.51 to 0.10)	0.66	0.80	.43	1.92
Intercept	6.94 (6.06 to 7.83)	0.41	15.72	<.001	1.19
MSMR_PsychRegulation	-0.35 (-1.22 to 0.51)	0.41	0.43	.68	1.21
Intercept	8.24 (7.78 to 8.69)	0.28	30.53	<.001	0.77
MSMR_LifeSatisfaction	0.24 (-0.38 to 0.85)	0.30	-1.77	.10	0.87
Intercept	8.59 (8.03 to 9.14)	0.28	30.53	<.001	0.77
MSMR_GrowthCapacity	-0.53 (-1.13 to 0.07)	0.30	-1.77	.10	0.87
Intercept	5.35 (4.33 to 6.38)	0.52	10.21	<.001	0.99
MSMR_SelfEsteem	0.53 (-0.80 to 1.86)	0.66	0.80	.43	1.92
Intercept	6.47 (5.66 to 7.28)	0.41	15.72	<.001	1.19
MSMR_SocialSecurity	0.18 (-0.66 to 1.01)	0.41	0.43	.68	1.21
Intercept	6.47 (5.84 to 7.11)	0.32	19.96	<.001	0.59
MSMR_SocialFunction	-0.41 (-1.24 to 0.42)	0.41	-1.00	.33	1.2
Intercept	6.71 (5.92 to 7.49)	0.40	16.71	<.001	0.75
MSMR_AccSupport	0.88 (-0.14 to 1.90)	0.51	1.74	.10	1.48

<sup>a</sup>DASS-D: Depression, Anxiety and Stress Scale–depression.

<sup>b</sup>DASS-A: Depression, Anxiety and Stress Scale–anxiety.

<sup>c</sup>DASS-S: Depression, Anxiety and Stress Scale–stress.

<sup>d</sup>AAQ-2: Acceptance and Action Questionnaire–2.

<sup>e</sup>CAMS: Cognitive and Affective Mindfulness Scale.



<sup>f</sup>MSMR: Multi-System Model of Resilience.

<sup>g</sup>MSMR\_IR: Multi-System Model of Resilience–internal resilience.

<sup>h</sup>MSMR\_CP: Multi-System Model of Resilience–coping pursuits.

<sup>i</sup>MSMR\_ER: Multi-System Model of Resilience–external resilience.

Looking across the 2 arms of the study, even though the mean scores for DASS-D, DASS-A, and DASS-S decreased more among the intervention group than the control, these changes were not significant. Furthermore, there were no significant differences in overall MSMR-I scores between intervention and control participants. However, there were significant increases postintervention in mindful qualities (CAMS-R) and external resilience (MSMR-ER), particularly in life satisfaction and accessible support among the intervention group (37.18 vs 32.92,  $t_{22}=2.35$ ,  $P=.03$ ; 20.29 vs 16.5,  $t_{21}=2.98$ ,  $P=.007$ ; 8.47 vs 6.75,  $t_{14}=2.41$ ,  $P=.03$ ; 7.59 vs 5.33,  $t_{16}=.008$ , respectively).

For the linear mixed effects models (Tables 5-6), the following outcomes saw a greater amount of improvement among intervention participants than controls. Compared with control group, those in the intervention group experienced a decrease in anxiety (–1.76 vs –0.50) and stress level (–2.82 vs –1.5) and an improvement in mindful qualities (–0.06 vs –2.75) and external resilience, particularly with respect to accessible support (0.88 vs 0.42), life satisfaction (0.24 vs –0.17), social security (0.18 vs –0.33), and self-esteem (0.53 vs 0.5).

**Table 6.** Linear mixed effects models: effects of WE2CARE on outcomes among control participants.

Parameter	Coefficient (95% CI)	Standard error	t score	P value	Random effect (SD)
Intercept	12.00 (5.03 to 18.97)	3.49	3.44	.006	10.16
DASS-D <sup>a</sup>	-2.50 (-7.93 to 2.93)	2.66	-0.94	.37	6.53
Intercept	11.33 (6.06 to 16.60)	2.65	4.28	.001	7.13
DASS-A <sup>b</sup>	-0.50 (-5.31 to 4.31)	2.36	-0.21	.84	5.79
Intercept	11.83 (5.49 to 18.18)	3.17	3.73	.003	9.23
DASS-S <sup>c</sup>	-1.50 (-6.47 to 3.47)	2.44	-0.62	.55	5.97
Intercept	24.25 (16.47 to 32.03)	3.85	6.29	.001	12.48
AAQ-2 <sup>d</sup>	-6.25 (-10.20 to -2.30)	1.94	-3.22	.008	4.75
Intercept	35.67 (32.86 to 38.47)	1.39	25.57	<.001	4.29
CAMS <sup>e</sup>	-2.75 (-4.59 to -0.91)	0.91	-3.04	.01	2.22
Intercept	52.92 (44.70 to 61.13)	4.07	13.00	<.001	13.08
MSMR <sup>f</sup>	2.75 (-1.64 to 7.14)	2.15	1.28	.23	5.28
Intercept	17.25 (14.36 to 20.14)	1.45	11.90	<.001	4.10
MSMR_IR <sup>g</sup>	2.17 (-0.25 to 4.58)	1.19	1.83	.09	2.91
Intercept	19.25 (15.63 to 22.87)	1.79	10.78	<.001	5.90
MSMR_CP <sup>h</sup>	0.50 (-1.06 to 2.06)	0.76	0.65	.53	1.87
Intercept	16.42 (14.04 to 18.80)	1.18	13.87	<.001	3.69
MSMR_ER <sup>i</sup>	0.08 (-1.41 to 1.58)	0.73	0.11	.91	1.80
Intercept	4.58 (3.37 to 5.79)	0.62	7.40	<.001	0.45
MSMR_HealthWellness	0.67 (-1.04 to 2.37)	0.86	0.78	.45	2.10
Intercept	6.50 (5.24 to 7.76)	0.64	10.18	<.001	1.60
MSMR_HealthReserve	0.83 (-0.44 to 2.11)	0.63	1.33	.21	1.53
Intercept	6.17 (5.00 to 7.34)	0.59	10.37	<.001	1.26
MSMR_PsychRegulation	0.67 (-0.69 to 2.02)	0.67	1.00	.34	1.63
Intercept	6.92 (5.57 to 8.27)	0.67	10.29	<.001	2.08
MSMR_LifeSatisfaction	-0.17 (-1.03 to 0.70)	0.42	-0.39	.70	1.04
Intercept	6.67 (5.29 to 8.04)	0.69	9.71	<.001	2.03
MSMR_GrowthCapacity	0.17 (-0.86 to 1.20)	0.51	0.33	.75	1.24
Intercept	5.67 (4.06 to 7.27)	0.79	7.14	<.001	2.59
MSMR_SelfEsteem	0.50 (-0.27 to 1.27)	0.38	1.32	.21	0.93
Intercept	5.42 (3.96 to 6.88)	0.74	7.36	<.001	1.91
MSMR_SocialSecurity	-0.33 (-1.07 to 1.74)	0.69	0.48	.64	1.69
Intercept	6.08 (5.04 to 7.12)	0.52	11.66	<.001	1.46
MSMR_SocialFunction	-0.67 (-1.55 to 0.21)	0.43	-1.54	.15	1.06
Intercept	4.92 (3.62 to 6.21)	0.66	7.50	<.001	1.55
MSMR_AccSupport	0.42 (-0.97 to 1.80)	0.68	0.61	.55	1.66

<sup>a</sup>DASS-D: Depression, Anxiety and Stress Scale–depression.

<sup>b</sup>DASS-A: Depression, Anxiety and Stress Scale–anxiety.

<sup>c</sup>DASS-S: Depression, Anxiety and Stress Scale–stress.

<sup>d</sup>AAQ-2: Acceptance and Action Questionnaire–2.

<sup>e</sup>CAMS: Cognitive and Affective Mindfulness Scale.

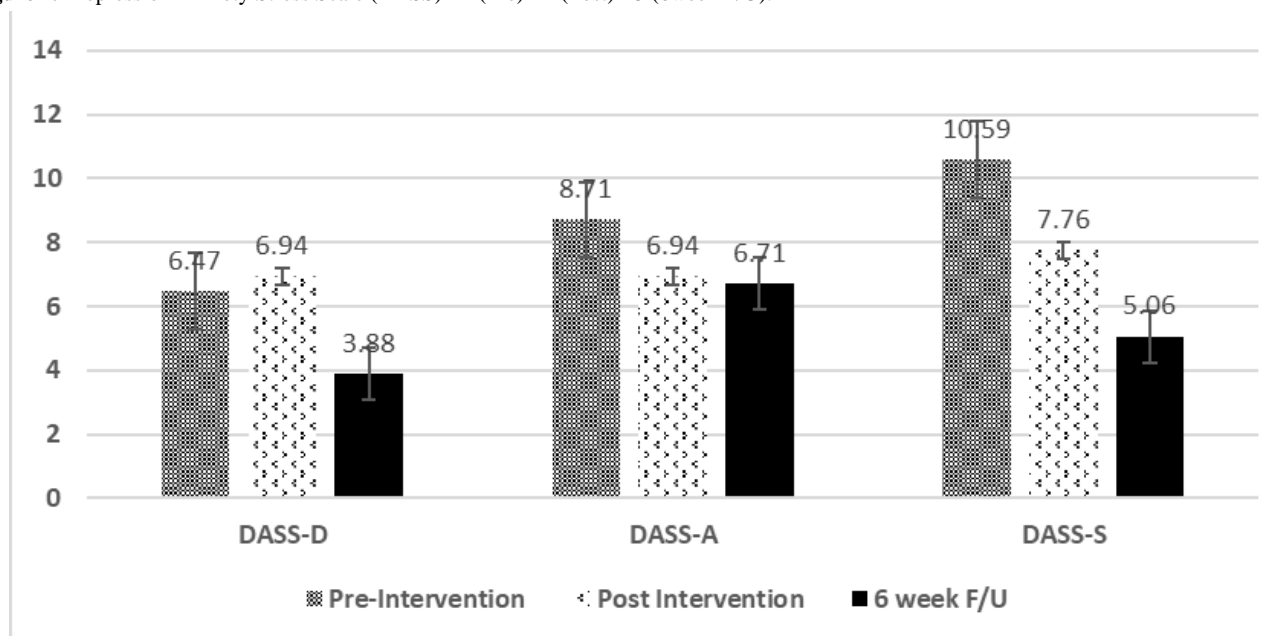
<sup>f</sup>MSMR: Multi-System Model of Resilience.

<sup>g</sup>MSMR\_IR: Multi-System Model of Resilience–internal resilience.

<sup>h</sup>MSMR\_CP: Multi-System Model of Resilience–coping pursuits.

<sup>i</sup>MSMR\_ER: Multi-System Model of Resilience–external resilience.

**Figure 2.** Depression Anxiety Stress Scale (DASS) T1 (Pre) T2 (Post) T3 (6week F/U).



### Self-Reported WE2CARE Impact

Table 7 displays the participants' self-reported satisfaction with WE2CARE intervention. Significant differences in the evaluation of the WE2CARE program were observed between the intervention and the control group. Overall, those in the intervention group gained more knowledge, confidence (self-efficacy), and behavioral activation than those in the

control group. Those in the intervention group reported gaining more knowledge about stigma, having a clear idea about their values and being able to take committed actions that are in line with those values, and being aware of and able to access health and social services in their community. Moreover, they reported improvement in accessing health information, practicing self-care, receiving peer support, and engaging in community activities.

**Table 7.** Evaluation of WE2CARE postintervention by study arm allocation.

Participant Feedback	ACT <sup>a</sup> (n=17)	Control (n=12)
1. I have gained more knowledge about stigma.	4.47 (0.62)	2.83 (1.11)
2. I am clearer about my values (or what matters to me).	4.88 (0.33)	4.00 (0.60)
3. I am more able to act based on my values (or what matters to me).	4.82 (0.39)	4.00 (0.60)
4. I am more aware of health services in my community.	4.71 (0.47)	3.92 (1.00)
5. I am more aware about of social services in my community.	4.65 (0.61)	3.75 (1.22)
6. I am more able to access services to support my health.	4.76 (0.44)	3.58 (0.90)
7. I am more able to access information to support my health.	4.82 (0.39)	3.67 (0.98)
8. I am more able to keep my prescribed treatments.	4.29 (1.10)	3.75 (0.75)
9. I am more able to practice self-care to support my health.	4.82 (0.39)	4.00 (0.74)
10. I have gained more peer support.	4.76 (0.44)	3.83 (0.94)
11. I am more able to provide peer support.	4.47 (0.62)	3.83 (0.94)
12. I have gained in more community activities that support my health and well-being.	4.59 (0.71)	3.83 (0.83)
Total	56.06 (3.25)	45.00 (8.02)

<sup>a</sup>ACT: acceptance and commitment therapy.

## Discussion

### Principal Findings

Our pilot study is among the first to use an online ACT intervention to address psychological distress among temporary migrant live-in caregivers. Our findings suggest that this intervention highly motivated participants to engage collectively in building social support networks and to some extent improved their mental health and resiliency.

The study participant sociodemographic characteristics and their living and working conditions were comparable to earlier studies [3,8,9,17,21]. Most reported working long hours and earning close to or below the Canadian low-income after-tax cutoff point. They were also concerned about the lack of privacy and inability to have control over their living/working conditions. About two-thirds reported being stressed and a fifth rated their mental health as fair/poor since arrival to Canada. The result of this study supports the healthy immigrant effect (ie, migrant workers arrive healthy as indicated during predeparture medical screening); however, their health status declines during their stay in Canada [21,44-46]. Although the participants in our study reported being healthy at the time of entry to Canada, a requirement for receiving a temporary work permit in Canada, they expressed a gradual decline in their physical and mental health. It is also interesting that despite having access to Ontario Health Insurance Plan, none of the participants had been tested for human papillomavirus, a known risk factor for cervical cancer. This highlights that the health of temporary female migrant workers particularly in the area of cervical cancer screening is ignored in our Canadian health care system and corroborates earlier findings about cancer screening disparities among vulnerable immigrant women [47-51].

This pilot waitlist-controlled trial found preliminary support for psychosocial improvements for the treatment group in comparison with the control group. A steady reduction in the levels of depression, anxiety, and stress were noted among the intervention group compared with control group even though these changes, except for stress level, were not statistically significant. The pattern of reduction is consistent with earlier studies exploring the impact of ACT on psychological distress among clinical and nonclinical population [27-29,52,53]. The inability to show significance may either be due to the small sample size or to the fact that our pilot study coincided with the COVID-19 crisis, which caused more psychosocial distress for our participants who were anxious about their own health and their loved ones back home. They may also have experienced COVID-19-related racism, which could have resulted in poorer mental health. Furthermore, during 2019, the Caregiver Program was further revised, and new conditions and programs were introduced. The two pilot programs that the Canadian government introduced in 2014 to replace Live-in Caregiver Program, the Caring for Children and Caring for People With High Medical Needs pilots, were replaced with two new pilots, the Home Child Care Provider and Home Support Worker pilots. Minimum language requirements and education credentials that restricted direct eligibility for permanent residency stayed unchanged. These changes caused further confusion, anger, and

stress for temporary migrant caregivers as they had to again be reshuffled in the list of those waiting for their permanent residency. These conditions may have negatively impacted the mental health of participants. However, despite these conditions, the treatment group's mental health still showed improvement postintervention and at 6-week follow-up.

Our pilot data also showed a significant worsening of mindfulness in the control group compared with the intervention group. This indicates that our intervention promoted participant uptake and use of mindfulness strategies. Considering this study took place during COVID-19, which increased mental distress, our data show that our intervention group may have benefited from the use of mindfulness exercises and teaching provided in our weekly modules compared with the control group, which had no access to this intervention. Empirical evidence suggests that mindfulness is associated with attention to and continuous engagement with both positive and negative experiences rather than avoidance of internal negative experiences [54,55]. Acceptance of one's life experiences is a core ACT process that allows people to accept negative thoughts and feelings without being characterized by them, which in turn promotes their self-esteem and resiliency.

It is reported that ACT promotes psychological flexibility using experiential and attentional exercises (mindfulness), clarifications of values, and committed actions directed by values [22]. Our study found an increase in psychological flexibility among the control compared with the intervention group. This is because the participants' mean score was higher in the control group compared with the intervention group prior to start of the intervention (23.75 vs 18.65) and dropped postintervention (18 vs 17.94). In other words, there was a bigger drop in mean scores in the control group because they were less flexible at the start of the study. This may be due to selection bias, as we used nonprobability sampling strategies to recruit our sample, as well as our small sample size. Future study with a larger sample size is needed to examine the impact of ACT on psychological flexibility through online delivery.

Furthermore, we found a significant increase in external resiliency among participants in the intervention group compared with the control group specifically across the dimensions of life satisfaction and accessible support. Our weekly videoconferencing provided an opportunity for our participants to connect with their peers and engage collectively in building social support networks. The weekly videoconferencing provided a vehicle to facilitate the building of a virtual community of mutual support that continued beyond the project. Some of the participants continued connecting through social media like WhatsApp.

The results from the evaluation survey component where participants were asked to comment on the utility of the intervention further support the positive influence WE2CARE had on participants. Compared with the control group, those in the intervention group self-reported an increase in knowledge about stigma, gained more peer support, and participated in more community activities that supported their health and well-being. This demonstrates how ACT equipped participants with the ability to expand their social network that supports

their health. These findings suggest that participants made improvements in their resiliency and coping after receiving WE2CARE.

Our study offers numerous implications for practice: (1) evidence-informed online interventions enhance participation access and implementation feasibility, (2) web-based interventions can be effective in promoting mental health, (3) the combined use of individual self-directed e-learning and group videoconferencing allows peer connection and reduce social isolation, and (4) online group videoconferencing offers opportunities for marginalized groups, like temporary foreign workers, to get connected and engage in social action to challenge existing exploitative policies and practices to achieve equity.

### Limitations

There are some limitations to this study that should be considered when reviewing the results. First, the small sample size limits our ability to generalize findings to the larger community of migrant live-in caregivers. However, the goal of this study is not to generalize to the larger community of migrant live-in caregivers but rather to explore the feasibility of an internet-based psychological intervention in promoting caregiver mental well-being. Furthermore, due to the nature of a pilot study, having a small sample size is acceptable considering the paucity of information surrounding not only the use of ACT in reducing psychological distress but also internet delivery of the intervention for migrant live-in caregivers. Second, the study relied on self-report measurements that are prone to biases in this type of assessment (eg, social desirability, environmental

biases like fatigue or privacy). A combination of self-report measures with physiological measures may deliver further insight. However, the unique living and working conditions of our target population (eg, long working hours, limited free time, fear of deportation due to health issues) in addition to COVID-19 public health restrictions made the use of self-report measures a viable option. Third, considering Caregiver Program reforms in November 2014, some migrant caregivers may be living outside their employers' home. Except for 2 participants in our study, the rest lived with their employers. Hence, it would be important for future studies to explore the efficacy of ACT in reducing psychological distress among those migrant caregivers who live outside their place of employment.

### Conclusion

WE2CARE is among the first studies to explore the effectiveness of ACT in addressing mental health challenges among temporary migrant live-in caregivers. Our pilot data provided preliminary results on the efficacy of ACT in reducing mental health distress and promoting self-care. The results help to inform the development of culturally safe web-based interactive programs to increase access to individual psychological support among socially isolated and marginalized groups, promote the establishment of peer social networks and supportive environments, and promote collective engagement toward advancing social change. A large-scale study is warranted to confirm the preliminary results obtained in this study. There is a great potential for adapting WE2CARE for use with other temporary foreign workers like seasonal migrant farm workers across Ontario, other Canadian provinces, and internationally.

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### Authors' Contributions

MM (research coordinator) and AA (research assistant) helped with downloading, following up with the participants for missing data, and cleaning up the dataset based on specifications provided by MV (the nominated principal investigator). MV processed and analyzed the data and drafted the article. JPW and KPF (coprincipal investigators) reviewed the article critically for intellectual content. All the authors gave final approval of the version to be published and agreed to serve as guarantors of the work.

### Conflicts of Interest

None declared.

**Editorial notice:** This randomized study was not registered as it is pilot study. The editor granted an exception from ICMJE rules mandating prospective registration of randomized trials, because the risk of bias appears low and the study was considered formative, guiding the development of the online delivery of the intervention. However, readers are advised to carefully assess the validity of any potential explicit or implicit claims related to primary outcomes or effectiveness.

Multimedia Appendix 1

Consort-EHEALTH V1.6.

[\[PDF File \(Adobe PDF File\), 99 KB - formative\\_v6i1e32136\\_fig.pdf\]](#)

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## Abbreviations

**AAQ-2:** Acceptance and Action Questionnaire–2

**ACT:** Acceptance and Commitment Therapy

**CAMS-R:** Cognitive and Affective Mindfulness Scale

**DASS-21:** Depression, Anxiety and Stress Scale

**DASS-A:** Depression, Anxiety and Stress Scale–anxiety

**DASS-D:** Depression, Anxiety and Stress Scale–depression

**DASS-S:** Depression, Anxiety and Stress Scale–stress

**MSMR-CP:** Multi-System Model of Resilience–coping pursuits

**MSMR-ER:** Multi-System Model of Resilience–external resilience

**MSMR-I:** Multi-System Model of Resilience

**MSMR-IR:** Multi-System Model of Resilience–internal resilience

**WE2CARE:** Women Empowerment—Caregiver Acceptance and Resilience E-Learning

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Original Paper

# Feasibility, Acceptability, and Design of a Mobile Ecological Momentary Assessment for High-Risk Men Who Have Sex With Men in Hanoi, Vietnam: Qualitative Study

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## Abstract

**Background:** Men who have sex with men (MSM) are at a disproportionate risk for HIV infection and common mental disorders worldwide. In the context of HIV, common mental disorders are important and are frequent drivers of suboptimal prevention and treatment outcomes. Mobile ecological momentary assessments (EMAs), or the repeated sampling of people's behaviors and psychological states in their daily lives using mobile phones, can clarify the triggers and HIV-related sequelae of depressive-anxious symptoms and contribute toward the design of ecological momentary interventions (EMIs) that cater to the contextually varying needs of individuals to optimize prevention and treatment outcomes.

**Objective:** This study aims to characterize the feasibility and acceptability of mobile EMA among high-risk MSM in Hanoi, Vietnam. It aims to evaluate the perceived relevance, usability, and concerns of this group with regard to the content and delivery of mobile EMA and the potential of leveraging such platforms in the future to deliver EMIs.

**Methods:** Between January and April 2018, a total of 46 participants were recruited. The participants completed 6 to 8 mobile EMA surveys daily for 7 days. Surveys occurred once upon waking, 4 to 6 times throughout the day, and once before sleeping. All surveys queried participants' perceived safety, social interactions, psychological state, and mental health symptoms. The morning survey further queried on sleep and medication use within the past 24 hours, whereas the night survey queried on sexual activity and substance use and allowed participants to share an audio recording of a stressful experience they had that day. At the end of the week, participants were interviewed about their experiences with using the app.

**Results:** Participants completed an average of 21.7 (SD 12.7) prompts over the 7-day period. Excluding nonresponders, the average compliance rate was 61.8% (SD 26.6%). A thematic analysis of qualitative interviews suggested an overall positive reception of the app and 5 recurring themes, which were centered on the relevance of psychological and behavioral items to daily experiences (eg, mental health symptoms and audio recording), benefits of using the app (eg, increased self-understanding), worries and concerns (eg, privacy), usability (eg, confusion about the interface), and recommendations for future design (eg, integrating more open-ended questions).



**Conclusions:** Mobile EMA is feasible and acceptable among young MSM in Vietnam; however, more research is needed to adapt EMA protocols to this context and enhance compliance. Most participants eagerly provided information about their mental health status and daily activities. As several participants looked toward the app for further mental health and psychosocial support, EMIs have the potential to reduce HIV and mental health comorbidity among MSM.

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## KEYWORDS

men who have sex with men; HIV; mental disorder; ecological momentary assessment; mobile phone; mHealth; sexual minorities; pilot projects

## Introduction

### Background

Approximately one-third of people living with HIV worldwide meet the criteria for a common mental disorder (CMD), such as depression and anxiety [1-4]. Among men who have sex with men (MSM) specifically, the prevalence of CMDs may be magnified, with an estimated 35% reporting a history of suicidal ideation worldwide [5], 43% living with HIV reporting depression [6], and at least one-third in the United States meeting criteria for past-year alcohol use disorder [7]. The pronounced stigma, vulnerability to intimate partner violence, discrimination, and criminalization of same-sex sexual activities that this group confronts worldwide may have multiplicative effects on the development and maintenance of CMDs [8-10]. In the context of HIV, CMDs are the important and frequent drivers of suboptimal prevention and treatment outcomes. Depression has been found to be associated with a reduced likelihood of initiating antiretroviral therapy (ART) [11], lower ART adherence [12-14], increased mortality risk [15], and accelerated HIV progression [16]. Although anxiety disorders, including posttraumatic stress disorder (PTSD), have been less frequently investigated in the context of HIV, growing evidence suggests that they can reduce the likelihood of achieving at least 80% adherence [17,18]. Anxiety may also increase sexual transmission risk behaviors, suicidal ideation, and cognitive impairments [2]. Among those HIV-, CMDs are linked to hazardous drinking [19], inconsistent condom use [20-22], and lower pre-exposure prophylaxis (PrEP) adherence [23], all of which increase the risk of HIV transmission.

Smartphones and other information and communication technologies have become increasingly attractive options for optimizing prevention and treatment strategies. Given their accessibility, affordability, and availability, these digital technologies promise to widen access to health care generally and specifically among vulnerable groups by lowering costs and the traditional barriers (eg, stigma and access) hindering participation. Mobile health (mHealth), or the delivery of interventions and other health services via digital technologies, can take the form of SMS text messages, multimedia messages, mobile apps, and social media campaigns, among other options. mHealth interventions have shown promising results in improving medication adherence [24,25], health care engagement [24,26,27], and other health-promoting behaviors such as engagement in physical activity [28-30] in diverse populations. Furthermore, mHealth may be an acceptable and feasible approach for delivering care, including mental health

care, to MSM both in high-income countries and low- and middle-income countries (LMICs), including Malaysia, China, India, Thailand, and Vietnam [31-40]. This is because MSM are often early adopters of technology and may already use such platforms to access health information and search for sexual partners [34,41]. A recent survey of young MSM between the ages of 18 and 24 years found that approximately 70% were willing to participate in a web-based or mobile HIV prevention program, whereas only 1% would attend in-person programs exclusively [33]. As the access to and use of digital technologies do not appear to differ by mental health burden or HIV risk [42,43], mHealth may be a particularly attractive option for engaging underrepresented groups in settings where services are scarce.

Given the heterogeneity of risk among MSM [44-46], mHealth may further enable the tailoring of mental health and psychosocial interventions to the members' individually varying needs. However, one of the key limitations of the literature on mental health and HIV acquisition risks and treatment is its reliance on cross-sectional data, whereupon participants are tasked to recall symptoms or behaviors unfolding weeks or months prior. Recall can bias individuals to particular events, for instance, by increasing the salience of negative memories when depressed [47], modifying the memory of past judgments when providing new information [48], and skewing estimates of symptom severity based on its peak or most recent occurrences [49]. Similarly, although these data allow for estimations of an event frequency (eg, an experience of heightened depressive symptoms or a sexual encounter), they provide little information about the contextual factors leading up to, during, or after the event, that is, on the triggers and HIV-related sequelae of depressive-anxious symptom experience.

Mobile ecological momentary assessments (mEMAs), or the repeated sampling of individuals in real time during the flow of their everyday lives using mobile phones, can reduce the impact of these biases and provide the high-resolution data necessary to model these relationships longitudinally *within* an individual. Comparisons of ecological momentary assessment (EMA) to retrospective approaches using calendars or audio and computer-assisted self-interviews have suggested that the retrospective approaches may contribute to the underestimation of sexual and substance use behaviors by as much as 50% and lead to distortions in specific details, including partner characteristics [50,51]. Comparing EMA reports of patients' experience of side effects associated with antidepressant use with their reports to their general practitioner, 1 study found



that although 43% of the patients reported experiencing dizziness in the moment, <20% of them reported this to their general practitioner [52]. By clearly delineating the relationships between mental health and HIV risk-taking behaviors, mEMA approaches may thus contribute to a scientific understanding of what drives differentials in temporary and long-term treatment compliance, outcome, and cessation. This can inform the design of ecological momentary interventions (EMIs) that cater to the dynamically changing risks of individuals across time and context.

## Objective

Although many mHealth studies have been implemented in LMICs [53], to our knowledge, only 1 mEMA study has been conducted in an LMIC. Specifically, Soong et al [54] evaluated the feasibility and acceptability of monitoring tobacco use in urban India and found lower compliance (46%) than is typical in substance use research conducted in high-income countries (65%-92%). This suggests the need to evaluate how EMA protocols can be adapted to low-resource settings and particularly vulnerable populations to maximize their feasibility, acceptability, and usability for future intervention design. Although there is a lack of consensus on how such protocols should be culturally adapted, qualitative methods can be particularly beneficial in understanding the target population's needs and contexts of use. Integration of the target population's input into the design process can increase the perceived ownership of the technology and optimize the relevancy, uptake, and eventual utility of the platform. Thus, this study sought to determine the feasibility and acceptability of an mEMA app focused on the behavioral and psychosocial linkages between mental health and HIV-related behaviors among high-risk MSM in Hanoi, Vietnam. In Vietnam, MSM continue to experience significant HIV and mental health burdens amidst decline among other key populations [55-58]. The findings from this study can optimize the design of future mEMA protocols and lay the foundation for EMIs tailored to this population.

## Methods

### Study Design

This study recruited participants from an existing pool of MSM (n=198) who had previously participated in a study examining the association between HIV and PTSD in Hanoi, Vietnam [59]. All participants in the original sample were recruited from sexual health clinics and community-based organizations in Hanoi, were between the ages of 18 and 29, had reported having engaged in anal intercourse with a same-sex partner within the past 6 months, and had a smartphone.

From the existing pool of participants who had agreed to be recontacted (190/198, 96%), a subsample was derived based on the HIV serostatus and probable PTSD diagnosis of individuals, which was indicated by their scores on the Modified Posttraumatic Stress Scale [60]. The criteria for PTSD are dependent on the presence of a criterion A trauma (death, the possibility of death, or serious bodily harm, or actual or threatened sexual violence) alongside at least one intrusive symptom, three avoidance or numbing symptoms, and two hyperarousal symptoms that have been present for at least one

month, as indicated on the Modified Posttraumatic Stress Scale. A total of 4 PTSD-HIV strata (PTSD+/HIV+, PTSD+/HIV-, PTSD-/HIV+, and PTSD-/HIV-) were created, and a list of individuals belonging to each group was randomly generated. Individuals were recontacted in that order.

Upon enrollment, participants completed assessments of their mental health and sexual and drug use history. The study staff then instructed the participants on how to install a secure web app enabling real-time data collection, KoBoToolbox [61], on their smartphones. Briefly, the participants were first added to the KoBo system and then sent a link to download the web app onto their phone, where it could then be accessed. The web app was powered by Enketo and specifically designed for low-resource settings. Other countries where KoBo has previously been implemented include Vietnam, Indonesia, Ghana, and Malawi [62,63]. This platform was selected as it was free and open source, adaptative in a range of challenging contexts with varying Wi-Fi availability, and had accessible features that could be further expanded and customized depending on user feedback during the exit interview. Data collected through KoBo were stored on a secure server hosted by Amazon Web Services, which provided network and infrastructure security and monitored host and end point security. Only the study staff had access to the data. Screenshots of the app are provided in [Figure 1](#).

After KoBo was installed, the participants were asked to complete a sample survey. The study staff were available to answer any questions or concerns. During the next 7 days, the participants were prompted to complete 6 to 8 surveys daily: 1 survey every morning upon waking (morning survey), 4 to 6 surveys at random time points throughout the day (midday survey), and 1 survey before sleeping (night survey). Most prompts occurred during midday. This decision was motivated by our scientific interest in understanding the dynamic interactions between PTSD and HIV-related risk-taking behaviors. Specifically, one of the features of PTSD is emotional lability or intense, unpredictable, and frequent shifts in emotional experience [64]. Emotional lability can hinder social relationships and functioning and contribute toward risk-taking behaviors. Repeated sampling of emotions, symptom experiences, and social experiences throughout the day would enable us to characterize emotional lability and the trajectory of symptoms and affective experiences leading up to a risk-taking episode. Through this study, we thus aim to test the acceptability and feasibility of such a granular measure of daily experience among a high-risk population.

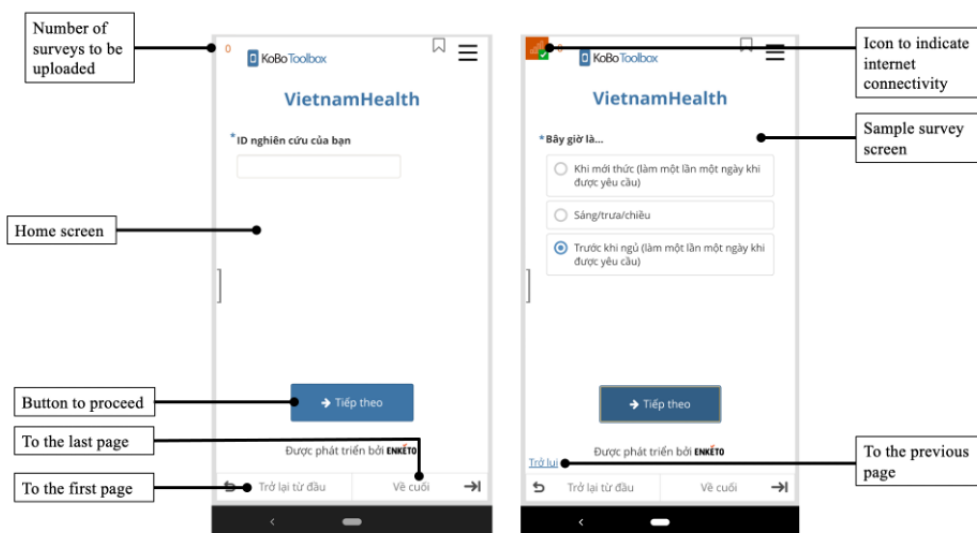
Prompts were structured around participant-provided schedules and delivered randomly in 1- to 3-hour windows; the windows were approximately 30 minutes apart (eg, 7:30 AM to 9 AM and 9:30 AM to noon). With each prompt, participants received an SMS text message, reminding them to complete their survey on KoBo within the next 30 minutes. If the participants were unable to respond within that time frame, they were instructed to wait until the next prompt. Each morning and night survey could be completed in approximately 3 to 7 minutes, whereas midday surveys were completed in approximately 3 to 5 minutes. Prompts were uploaded automatically upon completion

if internet access was available; otherwise, they were stored locally on the participants' smartphones.

At the exit session, participants were interviewed about their experiences using the app, including their motivations for participating, perceived benefits or drawbacks of using the app, any worries or concerns they experienced, and their recommendations for future research. Interviews were semistructured and conducted in Vietnamese by trained research staff. Questions were open ended and intended to elicit feedback

on the content, appearance, and functionality of the app. Participants were compensated  $\$150,000$  (US \$6.45) for completing the exit interview, which averaged 20.4 (SD 17.1) minutes. For each EMA survey they completed, the participants were additionally compensated  $\$7000$  (US \$0.30). The maximum amount individuals could be compensated for participation in the EMA component of the study was  $\$350,000$  (US \$15.05).

**Figure 1.** Screenshots of the mobile ecological logical momentary app that was powered by Enketo and piloted among young men who have sex with men (N=46) in Hanoi, Vietnam.



## Ethical Considerations

The study was approved by the institutional review boards of Emory University (approval number: IRB00097736) and Hanoi Medical University (approval number: IRB00088463). All participants were provided detailed information about the study procedures and expectations, risks, and benefits before their providing of written consent. The participants were told that they could choose to discontinue the mobile surveys at any point.

## Measures

In all surveys (morning, midday, and night), participants answered a standard set of questions. At each survey, the participants reported their current location, including perceived safety, and number of social interactions since the last prompt. For their most recent interaction, participants were asked to identify their relationship to that individual (eg, friend or sibling) and rate the ease of the interaction, the quality of the interaction, and their perception of what the other person had thought of them on a 7-point Likert scale. In addition, participants were asked to rate the degree to which they felt safe on a 6-point

Likert scale and report whether they had experienced a range of PTSD and somatic symptoms (*yes* or *no*) within the past hour. Emotional states were assessed by asking the participants to rate the intensity of their emotions using the Positive and Negative Affect Schedule [65]. In only the morning survey, the participants were asked about their sleep (eg, times and quality) and ART or PrEP use within the past 24 hours.

For the night survey, sexual and drug use behaviors and desires within the past 24 hours were additionally assessed. For each reported sexual activity, the participants answered questions about the sexual act (eg, anal and oral), the sex of the partner, the nature of their relationship (eg, stable and casual), condom use, and drug use during sex. Finally, in the night survey, the participants were asked to recollect, in an audio recording, an event within the past 24 hours that made them tired, anxious, or stressed about the future. They were instructed to freely associate, in detail, the potential causes, consequences, or scenarios associated with this event, including their feelings about what has occurred or could have occurred. Table 1 shows how these different modules were distributed across the morning, midday, and night surveys.

**Table 1.** Modules in the morning, midday, and night surveys administered to young men who have sex with men (N=46) in Hanoi, Vietnam, between January and April 2019.

Variables	Morning prompt	Midday prompt	End-of-day prompt
Time	✓	✓	✓
Location	✓	✓	✓
Whether someone else is present and their identity	✓	✓	✓
In their most recent interaction, the quality of interaction	✓	✓	✓
In their most recent interaction, the ease of interaction	✓	✓	✓
In their most recent interaction, perception of what the person thought of them	✓	✓	✓
Perception of the level of safety at the time of the survey	✓	✓	
Time they went to sleep and woke up	✓		
Self-rated quality of sleep and current tiredness level	✓		
Experience of different emotions (eg, anger) and somatic symptoms (eg, dizziness) within the past hour	✓	✓	
Experience of difficulty in concentrating or regulating emotions or behaviors within the past 24 hours	✓	✓	
Use of PrEP <sup>a</sup> or ART <sup>b</sup> within the past 24 hours	✓	✓	
Level of stress at the moment and cause		✓	
Experience of different PTSD <sup>c</sup> symptoms since the last prompt		✓	
Desire for different substances since the last prompt		✓	
Use of any substances since the last prompt		✓	
Experience of different emotions (eg, anger) and somatic symptoms (eg, dizziness) at the moment			✓
Experience of different PTSD symptoms within the past hour			✓
Desire for different substances at the moment			✓
Sexual activity within the past 24 hours			✓
Substance use within the past 24 hours			✓
Exposure to drugs or other substances			✓
Stressful experience within the last 24 hours (audio recorded)			✓

<sup>a</sup>PrEP: pre-exposure prophylaxis.

<sup>b</sup>ART: antiretroviral therapy.

<sup>c</sup>PTSD: posttraumatic stress disorder.

Measures of PTSD and somatic symptoms, as well as Positive and Negative Affect Schedule, had previously been culturally adapted using the 5-step translation process by van Ommeren et al [66]: (1) translation, (2) review by mental health professionals, (3) focus group discussions, (4) back translation, and (5) pilot of the measures among MSM in Hanoi, Vietnam. This 5-step approach has been used in several LMICs to maximize conceptual, semantic, technical, and content equivalence of measures in a new population or context [67]. Other items on the surveys were forward (English to Vietnamese) and backward (Vietnamese to English) translated by 3 bilingual translators.

### Qualitative Data Analysis

Interviews from the exit session were transcribed verbatim and anonymized by 2 research assistants and then imported into MaxQDA (VERBI), a qualitative data analysis software. Using content analysis [68], 2 authors (KT and LXL), who were

bilingual, then independently reviewed the transcripts and generated a preliminary codebook before meeting to refine primary and secondary code definitions. The codebook contained both inductive and deductive codes. Coding was guided by the Unified Theory of Acceptance and Use of Technology model, which posits that adoption of technology is dependent on (1) performance expectancy or perceived benefit of using the technology; (2) perceived effort or ease of use; (3) social influences, including norms around the social acceptability of the technology; and (4) facilitating conditions or availability of technological, cultural, or organizational resources supporting technology use [69]. Of particular interest to coding was feedback on existing study design and questions, including the perceived relevance of each in the daily lives of the participants, and recommendations for future research design. Once the codebook was established, 2 analysts coded each transcript. The two met regularly to refine the codebook,

discuss emergent themes, and resolve any disagreements about coding. After all transcripts were coded, the authors (KT and LXL) reviewed the excerpts to identify salient themes and select quotations that illustrated the major themes and subthemes.

## Results

### Participant Characteristics

Of the 198 participants in the original sample, 50 (25.3% of the original sample; 50/73, 69% of those invited) returned to complete this study between January and April 2019. The four groups differed in their participation rate: 95% (19/20) of those in the PTSD-/HIV- group who were invited to participate did, 67% (8/12) among the PTSD+/HIV- group, 54% (6/11) among the PTSD-/HIV+ group, and 57% (17/30) among the PTSD+/HIV+ group. Among those who did not participate, 40% (9/23) had moved and were no longer in Hanoi, 30% (7/23) could not be reached, and the remaining 30% (7/23) refused. Among those who agreed to participate, later, 4 participants (n=3, 75% PTSD+/HIV+ and n=1, 25% PTSD+/HIV-) withdrew

from the study after the initial interview because of personal reasons (eg, too busy with work), leaving a final analytical sample size of 46.

The sociodemographic characteristics of the participants are summarized in [Table 2](#). On average, the participants were aged 23.5 (SD 2.5) years. Approximately two-thirds had some university education. Most of the participants (35/46, 76%) earned >US \$35 million or more (>US \$1509) annually, which was considered the minimum needed to survive in Hanoi, where the average annual salary was approximately US \$53 million (US \$2337) to US \$7,600,000 (US \$3351) [70], which approximately 59% (27/46) of our participants either met or exceeded. In the sample, 41% (19/46) had neither PTSD nor HIV, 13% (6/46) were HIV+ and without PTSD, 15% (7/46) were HIV- and with PTSD, and 30% (14/46) had both HIV and PTSD. Among those with PTSD, the mean score on the PTSD Symptom Scale was 30.3 (SD 11.0), whereas, among those without PTSD, the mean was 12.4 (SD 7.9).

**Table 2.** Sociodemographic characteristics of men who have sex with men who participated in the mobile ecological momentary assessment study (N=46).

Variables	Values
<b>Sex, n (%)</b>	
Male	46 (100)
<b>Age (years), n (%)</b>	
18-22	14 (30)
22-26	27 (59)
26-29	5 (11)
<b>Migrant, n (%)</b>	
Yes	26 (57)
No	20 (44)
<b>Education, n (%)</b>	
Some high school	5 (3)
High school graduate	49 (25)
Some university	74 (38)
Graduated university	69 (35)
<b>Annual salary (US \$), n (%)</b>	
0-35 million (0-1542)	11 (24)
35-55 million (1542-2424)	8 (17)
55-75 million (2424-3305)	14 (30)
75-100 million (3305-4407)	8 (17)
≥100 million (4407)	5 (11)
<b>PSS<sup>a</sup> score, mean (SD)</b>	
Total	20.6 (12.9)
PTSD <sup>b</sup> -/HIV-	12.6 (8.6)
PTSD+/HIV-	34.0 (13.0)
PTSD-/HIV+	11.7 (5.8)
PTSD+/HIV+	28.4 (9.8)

<sup>a</sup>PSS: Posttraumatic Stress Scale.

<sup>b</sup>PTSD: posttraumatic stress disorder.

## Compliance

Participants completed an average of 6.9 (SD 1.1) days of EMA activity reporting. During this time, they each received approximately 38.3 (SD 7.8) prompts and completed an average of 21.7 (SD 12.7) prompts. The average response rate was 56.5% (SD 30.9%) but ranged from 0% to 97.4%. Excluding individuals who did not complete any surveys (4/46, 9%), the average compliance rate was 61.8% (SD 26.6%). Among these individuals, the response rates were 64.5% (SD 33.1%) on the

first day, 67.8% (SD 31%) on the second day, 66.9% (SD 31.6%) on the third day, 71.6% (SD 32.7%) on the fourth day, 64.7% (SD 35.6%) on the fifth day, 61.8% (SD 33.8%) on the sixth day, and 37% (SD 41.9%) on the seventh day. Demographics, group membership (based on HIV and probable PTSD diagnosis), and the number of prompts the participants received were not significantly associated with the response rate. Table 3 depicts representative quotes of each qualitative theme identified across groups of varying levels of compliance (75%-100%, 50%-75%, and <50%).



**Table 3.** Representative quotes from men who have sex with men participants with differing levels of ecological momentary assessment compliance.

Themes	High compliance (response rate >75%)	Medium compliance (response rate ≥50% and ≤75%)	Low compliance (response rate <50%)
Relevance	<ul style="list-style-type: none"> <li>“[The relevant items] were about emotions, about mental health. [They] allowed me to understand what I have gone through, the mental state I had, and how they were affected by the stress I was experiencing in my life. [They] allowed me to better understand myself, my emotions as they really were.” [22 years, PTSD<sup>a</sup>/HIV+]</li> </ul>	<ul style="list-style-type: none"> <li>“I think the questions that were most relevant had to do with whether I was around someone at that time and whether I was satisfied with that interaction. Generally, it allowed me reassess the person.” [20 years, PTSD-/HIV-]</li> </ul>	<ul style="list-style-type: none"> <li>“[The most relevant question] was whether I had used my medicine, the question before I went to sleep. It’s relevant because, one, every day I must take medicine. Two, it’s also quite beneficial because if there are days where I forget, forget to take my medicine—although that’s very unlikely to happen—but I think if I were to use the app over a longer period, it could also help remind me on the days I would have otherwise forgotten.” [24 years, PTSD+/HIV+]</li> </ul>
Benefits	<ul style="list-style-type: none"> <li>“There are benefits. For example, I can track when I go to sleep, when I rest, when I wake, and what I do every day. I can assess whether it’s appropriate, appropriate for my work situation.” [23 years, PTSD-/HIV-]</li> </ul>	<ul style="list-style-type: none"> <li>“When you are answering the questions, it’s as though you are interrogating yourself about your own emotions at a particular moment...In general, I felt that I became more honest, more honest with myself. I asked myself what emotions I had, and I answered [that question]. I felt it allowed me to listen to myself more.” [21 years, PTSD-/HIV-]</li> <li>“I don’t know if there were any. I just felt the same.” [20 years, PTSD-/HIV-]</li> </ul>	<ul style="list-style-type: none"> <li>“Sometimes when I am doing the surveys, I realized that there were certain experiences I had that I hadn’t noticed before. For example, in the past hour, I might have lost my calm or felt anxious...Whenever I receive a prompt, I’d do the survey and I’d remember and think, yes, I did encounter that.” [23 years, PTSD+/HIV-]</li> <li>“To be honest, I don’t think there are any benefits because [the surveys] just remind me [of what happened]. It’s like writing a diary at the end of the day; there’s nothing new.” [24 years, PTSD+/HIV+]</li> </ul>
Worries and concerns	<ul style="list-style-type: none"> <li>“No, because really it’s just like a test or survey. There’s no reason for worry or hesitation. It’s like, like, you’re monitoring your own health.” [25 years, PTSD+/HIV+]</li> <li>“Sometimes the number of assessments were bothersome, but aside from when I am working, it wasn’t really a problem. Meaning, when the surveys were during school hours, when I was commuting, or when I had some tasks where I need to concentrate, they were a little bothersome. But I felt that since I agreed to participate in this research, [fulfilling the surveys] was my responsibility, so I wanted to do everything to fulfill that responsibility. So, I felt a little self-pressure.” [26 years, PTSD-/HIV-]</li> </ul>	<ul style="list-style-type: none"> <li>“Sometimes I’d be doing something on the street and my phone would go off and tell me to complete a survey. It was a little inconvenient.” [20 years, PTSD-/HIV-]</li> </ul>	<ul style="list-style-type: none"> <li>“Usually there are no problems, but if in the course of the day, you ask me to do too many surveys, I will get lazy and won’t want to do any more...For example, after I finish [a survey], sometimes just an hour or two later I’d receive another prompt. Basically, it felt like I just completed a prompt and since that time, nothing has changed. So, I won’t do the other survey.” [24 years, PTSD+/HIV+]</li> </ul>
Usability	<ul style="list-style-type: none"> <li>“I had difficulty uploading the audio file on the app. But then I called [a research staff] and she showed me how to...then it was fine.” [28 years, PTSD-/HIV-]</li> <li>“I am okay with doing the surveys [for however long]...They are easy. Whenever I receive a prompt, I always do the survey right away. Because of [the nature of] my work, I’m always free.” [25 years, PTSD-/HIV-]</li> </ul>	<ul style="list-style-type: none"> <li>“I liked the file recording more than the surveys because it’s like you are speaking to someone, speaking directly to someone else. For example, when I want to share something with a friend, I’ll also [send audio files]. Every time I’m down, I’m more likely to audio record than message. The audio file is like that, like chatting with someone.” [20 years, PTSD+/HIV-]</li> </ul>	<ul style="list-style-type: none"> <li>“Normally, the surveys are pretty easy to complete, but the problem is that I am busy. If I am not busy, then I can complete them easily. But on days where I work, often I won’t get up until 10AM. I know I should complete the morning survey, but unfortunately, that might also be when I have a customer and I might not finish until 2-3PM. Then suddenly I’d receive the second survey and I won’t know what order I should reply in.” [29 years, PTSD+/HIV-]</li> </ul>

Themes	High compliance (response rate >75%)	Medium compliance (response rate ≥50% and ≤75%)	Low compliance (response rate <50%)
Recommendation	<ul style="list-style-type: none"> <li>• “[It would be more reasonable] if there were prompts every 3-4 hours, for example, one survey in the morning, one survey at night, and possibly two surveys in between. [As is, it] is too much.” [27 years, PTSD-/HIV-]</li> </ul>	<ul style="list-style-type: none"> <li>• “I just want all the emotion questions to be combined into one, a ‘how do you assess your emotional state right now?’ question. [This is] because sometimes I don’t experience any emotion strongly...and it’s hard to answer.” [20 years, PTSD+/HIV]</li> </ul>	<ul style="list-style-type: none"> <li>• “I think you can shorten the questions because many of them are very similar. They can just be combined.” [24 years, PTSD+/HIV+]</li> </ul>

<sup>a</sup>PTSD: posttraumatic stress disorder.

## Qualitative Results

### Relevance

Overall, participants considered questions about their social interactions (eg, perception of the person), mood, levels of stress, and health, including their experience of PTSD symptoms and medication use, most relevant to their daily experiences. Participants favored these items as they thought these items provided a dedicated space for daily reflections and made several participants feel as though someone cared for them. For these reasons, the audio recording was often singled out as the most meaningful survey component as it allowed participants to elaborate, in their own words, what had transpired that day:

*[After the recording], I felt a lot more comfortable, as though there was nothing more I wanted to share. Whenever I can share everything I want, I will feel lighter. [My mind] still feels heavy, of course, but my mental state will feel better than if I were to just dwell on it and keep it inside. [20 years, PTSD+/HIV-]*

In some cases, the audio recording was seen as even therapeutic as it allowed participants to share distressing thoughts or feelings that they otherwise would have concealed. One of the participants contrasted the freedom he exercised in sharing details of his life in the app with the caution he felt when disclosing to friends:

*[I] feel reluctant to be open, to share with others. You see a lot of surveys because I shared everything I had, because in my heart, I think that, first, you’re a stranger, and second, you won’t affect my life. So, I can say all those things comfortably, and even more. But when I must talk about these issues to my friends or co-workers, it becomes very difficult, very different. You can be very close to a colleague and think of them as a close friend, but when they’re not able to keep your secret, then a second person [might know]...In their mind, they might think they’re just sharing with a close friend of theirs, but that close friend might share with another close friend, then another close friend, then a rumor circulates. So, I have this cautiousness towards those whom I interact with. [25 years, PTSD+/HIV+]*

Questions that were considered less relevant to participants’ everyday experiences were generally centered on alcohol or drug use. Although a few participants reported drug use in the past 6 months, most felt that their use was not frequent enough for either drug use or drug craving to be repeatedly sampled:

*I’m not someone addicted to those drugs so most of the time I won’t be affected by them. It’s only sometimes when I feel like using them, and when I do, it’s only for fun. So, I think those questions are irrelevant to my life. [24 years, PTSD+/HIV+]*

Others thought that despite their infrequent use of substances, the questions were still relevant as they were still exposed to drug-related activities in their everyday lives. Several participants felt that they should be able to document those events as those exposures can make them feel uncomfortable or increase their desire to use.

As many questions focused on PTSD and negative affect, some participants felt that the prompts were more appropriate for someone in greater psychological distress than them. For this reason, some suggested the addition of more positive questions (eg, highlighting coping strategies or health-promoting behaviors). Furthermore, as multiple questions measured the same construct (eg, symptoms of distress), items were sometimes seen as repetitive and requiring a more careful read by participants. Some participants believed that the emotion measures, for instance, required them to parse their affect too finely. Instead of having items such as *hopeless* or *happy*, several participants favored using a Likert scale ranging from *negative* to *positive*:

*Questions like “happy” or “proud” are probably okay because people can separate between the two, because those emotions are different. But the questions that are more negative, [you should] reduce those because if someone is already thinking negatively and they keep reading those questions, it’ll also drag their mood down more. [28 years, PTSD+/HIV+]*

### Benefits of Using the App

Nearly half of those who used the app said that they believed it increased their self-understanding. In particular, many believed that using the app enabled them to better understand their emotions and the individuals or situations that elicited those feelings. In doing so, some participants believed that the app made them more truthful about their emotions and what specifically they had accomplished that day:

*When I do the surveys, I realize that sometimes I have symptoms that I didn’t notice before; like, an hour ago I might have felt calm, I might have felt anxious, or I might have felt something else...Before I wouldn’t notice these things. Since I started doing the*

surveys...I [started thinking] to myself that, yes, I do have these symptoms, symptoms I didn't notice before. [23 years, PTSD-/HIV+]

With this increased self-understanding, a few participants believed that an additional benefit of using the app was that it enabled them to better monitor and regulate their emotions over time, that is, to identify what they could control and what they might need to change. For some, this form of self-understanding formed the basis of their desire for greater self-care:

*I know how to control my emotions more because if every 2-3 hours I have to answer the survey, then automatically, I have to think about whether I was happy, sad, stressed, or whatever else in the past hour. When I answer those questions (for myself), then I have to reassess how the situations were affecting my mood. So, I can control those factors better. [25 years, PTSD+/HIV+]*

Those who reported no new self-understanding or benefit often found the questions too reflective of their everyday life and therefore could not offer new insights:

*It's because normally I am someone who understands themselves well already, so your app has the effect of helping me determine what I'm feeling at an exact moment. After that, I can adjust it myself so that [my mood] slowly goes back to being normal. But to say that I understand more about myself, I don't think I did. [25 years, PTSD+/HIV+]*

### Worries and Concerns

Participants reported a few worries or concerns associated with using the app as they perceived the survey as similar to other questionnaires they had completed before and because of the detailed briefing they received before starting the study:

*Actually, [the surveys are] like a test, or an assessment. They don't cause any problems or concerns. That's because it's...it's like you're just monitoring your health, doesn't really concern much else. [25 years, PTSD+/HIV+]*

*I mean, I already found out all the information before I agreed. For instance, if this were PrEP, even if you gave me a lot of money, I still wouldn't. The truth is I only do the things that are good for me. I'm not going to be a test mouse. Psychological questions are fine because it doesn't really affect me in any way, but PrEP, that affects my health. [26 years, PTSD-/HIV-]*

Others expressed privacy concerns related to the accessibility of their surveys. In particular, some participants worried that others might see their screen while they were answering sensitive questions about their sexual behavior or medication use, although only one of the participants experienced a situation in which someone had seen his responses:

*On one of the days [I participated], my nephew was being naughty and took my phone from me. It was also right when I had been filling out a survey. He read some of the questions and asked what I was*

*doing, why there were questions related to marijuana, drug use, all that. I had to sit him down and explain to him that I was participating in this study at Hanoi Medical University, that it wasn't anything serious...In this situation, I knew how to resolve it, but for others, it might create a misunderstanding. [24 years, PTSD+/HIV+]*

### Usability

Participants found completing the initial EMA survey with a research staff helpful. Most participants did not experience any difficulties in navigating the EMA form. Participants struggled the most when uploading an audio file. Depending on the model of their phone, some were not able to record and upload directly onto KoBo but had to use a third-party platform to save the files. Others were also initially confused about the kinds of files they could upload and submitted photos instead.

When asked whether they would use the app outside of the study, most participants said that they would but that their use would depend on how busy they were. Some emphasized that their use of the app was largely motivated by their current interest in mental well-being:

*It depends on the time-point. At this time-point, I'm very concerned about my mental health, and whenever I finish a survey, I always re-ask myself the questions. While I am still confronting these [mental health] problems, I will answer the prompts because they help me identify what works for me. In the future, when I no longer have these problems, I will think that [completing the questions] isn't important, that it is fine to respond, fine not to respond. I won't care anymore. [25 years, PTSD+/HIV+]*

When asked what features would encourage their long-term use of the app, a few said that they would feel more encouraged to use the app over a longer period if they could see daily or weekly trends in their responses or were given personalized recommendations to improve their health or general well-being (eg, sleep tips and coping strategies). Most participants emphasized that their continued use depended less on new features than on changes to the existing study design, including the number and scheduling of the prompts:

*When I am available, I will do it. When I am not, then I won't do it because it'll be too much. But if I'm free, then what else am I doing but playing [Candycrush]? [23 years, PTSD-/HIV-]*

Others thought that their willingness to answer the prompts was variable throughout the day, depending on their mood:

*When I am tired, I'll be truthful and say that I don't want to do [anything]...There are times when I don't want to do anything, let alone a survey taking 5-10 minutes, ticking off questions after questions. And, as I've said, it eventually gets boring when you have the same [set of questions] every day. I also think that [reception to] the survey will depend quite a bit on the psychological state, the mood, of the person taking it. [25 years, PTSD+/HIV+]*



## Recommendations

When asked to provide recommendations to increase future compliance and better tailor content to their everyday experiences, 5 main themes emerged. First, there was an emphasis on supplementing the initial training with detailed reminders on how to use the app, as the participants reported initial confusion when completing the first few surveys on their own and having to contact the study staff for assistance. Second, the wording of the daily prompts and study questions should be made as personable as possible. Although the current phrasing was deemed easily comprehensible, it was also seen as too clinical. Where possible, the participants thought the text should be more MSM friendly, prompting people to share (☒) their everyday experiences (☒) rather than strictly completing a survey. Having interactive features was also found to be critical in increasing engagement.

Third, although open-ended questions took more time to answer, they were considered more experientially relevant than the Likert scale responses. Integrating optional open-ended questions throughout the day was favored over having only the audio recording before sleep. The option to type rather than narrate the responses was considered very important, as some participants thought that the audio recording was inconvenient when others were nearby. Although generally preferring open-ended questions, participants also felt that all survey items, including the audio recording, should be optional. Reflecting on his experiences, one of the participants shared his belief that many Vietnamese people needed to be eased into doing the audio recording as it did not come naturally:

*It's because people feel embarrassed. Why? The audio recording is like a diary, except you write in a diary; here you have to record, retell. It's [related to] personality type, like, you might feel embarrassed because you're more introverted. It makes you feel autistic (☒). Personally, I feel too embarrassed to say aloud my inner thoughts. Writing is okay, but I fear sitting alone and talking aloud like that because when I do I feel as though I'm being autistic (☒). Singing is okay, but talking aloud like that is similar to splitting yourself in half [to sit there, look at yourself, and judge yourself]. [26 years, PTSD+/HIV+]*

Fourth, most participants found the number of assessments acceptable but took issue with their scheduling. Although participants were told that they did not have to answer the surveys when busy, many reported feeling obliged to do so and actively monitoring their phones for prompts. Participants recommended sampling only once or twice during prime hours and potentially lengthening the time frame they had to respond. This was seen as particularly useful when participants' schedules deviated from those they provided at enrollment, which often happened because of the types of work young MSM were engaged in. Finally, participants recommended reducing the number of questions to prevent future participants from answering the prompts haphazardly (cho nó qua). This could be done by combining similar questions, occasionally changing

the order of questions to make the surveys more interesting, and introducing new questions. Having access to aggregate data, particularly those that compared participants with the group average, was seen as potentially motivating, alongside receiving custom health information:

*[The app] keeps asking these questions, everyday these same questions. I think it needs to be a little different, so there's enthusiasm to answer. [28 years, PTSD-/HIV-]*

## Discussion

### Principal Findings


This study found that mEMA is a feasible and acceptable way of monitoring dynamic interactions between mental distress and HIV risk among young MSM in Vietnam. Overall, participants found the questions pertinent to their everyday experiences of psychosocial stress and were willing to use the app in the future. Participants identified items related to PTSD symptoms, emotions, and social interactions as most relevant to their everyday experiences. Most preferred having open-ended questions to elaborate on their stressful encounters, as they found doing so therapeutic or personally informative. Some expressed concerns about data privacy. Although the number and length of EMA surveys were considered potential hindrances to long-term participation, the impersonality of the app and the scheduling of the prompts rather than their frequency were identified as primary barriers to participation. Participants recommended that the language be made more MSM friendly and that future iterations of the app include personalized end-of-the-week reports to encourage long-term use.

Given that our sample was highly exposed to trauma, identification of barriers to feasibility and acceptability was important. Our compliance rate was noticeably lower than those reported previously in similar studies with MSM [71-73]. Although our assessment period was relatively shorter (1 week vs 4 weeks), we sampled participants more frequently and included more questions because of our interest in acquiring a thorough understanding of how PTSD interacts with HIV risk. This may have reduced the compliance rate. In addition, young MSM may introduce unique challenges. A recent meta-analysis of EMA studies found that age was the most significant predictor of compliance rate [74]. In particular, although the response generally declined over time, this decline was steeper among younger participants compared with that in older participants. Smiley [75] reported a response rate (57.3%) similar to ours among young gay and bisexual men (aged 21-25 years, which they attributed to the participants' work schedules. In the context of Vietnam, these issues may be further exacerbated, as several participants had highly variable work schedules. For instance, one of the participants did not answer any of the EMA prompts as shortly after enrolling in the study, he was assigned to a mining post in rural Northern Vietnam for the study duration and had limited access to his phone. Cases such as these lowered our overall response rate but may accurately reflect the challenges typical in implementing EMA protocols in LMIC contexts.

Incentivization structures can motivate compliance. Doherty et al [76] highlighted the use of extrinsic and intrinsic incentives to motivate participants' EMA engagement. Extrinsic motivation includes monetary remuneration per survey, compliance monitoring and feedback, and emphasis on participants' contributions to science during enrollment. In particular, providing feedback to participants during an EMA study, whether through reminder messages or weekly reports, has been found to increase their perception that someone cared and thereby motivate compliance; however, this may also contribute to reactivity [77]. In addition, although financial incentives are useful, they can also contribute to selection bias [76]. This was a concern that our participants also voiced, as some thought that the length of the survey, alongside financial incentivization, might encourage participants to answer haphazardly (cho nó qua). Coupling extrinsic incentives with features that cultivate intrinsic motivation may reduce these unwanted effects. These features enhance or support participants' inner desire to engage with the app, independent of momentary awards. For instance, Hsieh et al [78] found that participants who had access to visualizations of their data had a 23% higher compliance rate than those who did not. Similarly, the attitudes of research staff during enrollment and participants' ability to access their own response rate have been shown to motivate participation [79]. In our study, interest in mental health was a particularly strong motivator. Participants also perceived having an MSM-friendly language as highly important. A recent meta-analysis of mHealth interventions for young sexual and gender minorities suggests that these linguistic issues are often not well attended to; across studies, the most common concerns centered on language, specifically on prompts that were seen as too text-heavy, patronizing, or superficially targeted toward LGBTIQ+ (lesbian, gay, bisexual, transgender, intersex, and queer) people [80]. Among our study participants, an intrinsic motivation evidenced throughout multiple interviews was the desire to better understand and regulate their mental and emotional states.

Our concern that mental health stigma may lead participants to underreport experiences of mental health and psychosocial distress was largely unfounded [81-83]. For some participants, mental health stigma may have even enhanced the perceived attractiveness of the app, as it provided them an outlet to share details they otherwise could not. These findings underscore the value of testing assumptions regarding acceptability *in the wild*. Most of our participants readily looked to the app for mental health and psychosocial support information, which is encouraging for digital mental health interventions. However, this inadvertent reliance on the app for mental health and psychosocial support contributed toward a second set of concerns about reactivity or when the frequency, intensity, or quality of a target measure change as a result of monitoring [84]. Specifically, several participants reported that they intentionally used the app to track and regulate their emotional states; some reported becoming more aware of everyday triggers. Whether this altered the experience of mental distress or the relationship between mental distress and HIV risk behaviors is unclear. Variable effects have been documented in the literature. Although some studies report an improvement in mood or change in risk-taking behavior among participants using EMA [85,86], others have found no significant reactivity effect

[84,87,88]. Given the scope of this study, we were not able to determine whether the frequency, intensity, and correlations between measures varied significantly over time.

Responses to the survey further highlighted some of the cultural specificities that might contribute to differences in the perceived acceptability of an app in different populations. Notably, our sample strongly preferred open-ended questions about their life but disliked the option to self-record as they found the behavior—when done alone—to be indicative of  (roughly means “autism”), which is highly stigmatizing within the country. As mHealth and telehealth approaches are becoming more widely adopted worldwide [89], the question of how to culturally adapt and enhance the acceptability of these applications has become imperative. However, caution must be exercised in interpreting differences as necessarily cultural in nature. The feedback we received on the assessment of emotional states is illustrative: studies of emotion worldwide have demonstrated cross-cultural differences in emotional granularity or the degree to which individuals differentiate emotional states and identify them with precision and specificity [90]. Anthropological investigations of emotional experience worldwide have further demonstrated how conceptualizations and management of emotions differ worldwide (eg, are localized to the heart or seen as inseparable from thought) [91,92]. These differences point to the need not only to investigate the cultural appropriateness of EMA measurement approaches during the app design and evaluation process but also to evaluate alongside this the degree to which experiences of the app reflect differences based on mental health status. Specifically, emotional granularity has been shown to be reduced in a number of mental health conditions, including PTSD [93]. It is possible that those with higher PTSD symptom severity may experience greater difficulty in recognizing, differentiating, and labeling the different emotions they experience. Building in the means to tease apart the potential causes of difference is critical to tailor EMA protocols appropriately to local contexts and populations.

### Study Strengths and Limitations

This study is innovative in several ways. To our knowledge, this is the first study to examine the feasibility and acceptability of using mobile technology to model the dynamic relationships between mental distress and HIV risk in a low-resource setting, and it is the second EMA implemented in an LMIC [54]. The study demonstrates the potential of leveraging such technologies not only to complement existing prevention and intervention strategies but also to advance EMIs that cater to the dynamically changing risk of individuals across time and context. Furthermore, compared with similar feasibility and acceptable studies, the sample size for this study was larger than those that have been conducted among high-risk populations such as MSM, people living with HIV, and people with psychiatric disorders [71,73,94], allowing for a more granular analysis of how adherence to, tolerance of, and experience with EMA protocols differ in this population. Recruitment of individuals with both PTSD and HIV proved particularly challenging not only because many refused to participate but also because many either had physically relocated or been unreachable at follow-up. Of the



4 individuals who withdrew from the study, 3 (75%) were also from this group. Although it is not possible to discern the reasons that motivated this decision, future research should investigate how psychiatric comorbidities of HIV may affect the receptiveness of MSM to varying demands of mEMA research and explicitly assess the reasons for dropout across those different study designs.

The primary limitations of this study include the generalizability of the findings and potential reactivity. First, although the sample size was larger than comparable studies, participants were recruited from community-based organizations and clinics and, thus, present a subpopulation in Hanoi that accesses sexual health services and are engaged in care. Participants were additionally drawn from a previous study among those who had agreed to be recontacted; therefore, these individuals may be more inclined to volunteer in research. Compared with the national average, our sample was also more highly educated and had a higher income [95,96]. Concomitantly, all our participants owned a smartphone and, therefore, may represent a subpopulation that is more comfortable using mobile apps than their counterparts. This is unlikely to be representative of older Vietnamese MSM in urban settings and those in the country more generally among whom HIV risk and mental health burden may be both more stigmatized and pronounced [83,97,98]. Thus, the generalizability of these findings to other MSM should be taken with caution. Second, although participants noted that they had become more aware of their

emotions and were using self-reports to monitor and regulate aversive triggers, it is inconclusive whether using the app actually changed the frequency with which they engaged in risk-taking behaviors or experienced particular PTSD symptoms or emotions. Previous EMA research has found minimal reactivity to EMA [84,99]; however, given the stigma associated with both HIV and mental health issues within Vietnam, sharing otherwise concealed details of their lives to the app may have heightened therapeutic effects.

## Conclusions

Our study illustrates the feasibility and acceptability of mEMA studies among high-risk Vietnamese MSM. Participants were receptive to and invested in future studies and interventions. The findings of this study can inform the design of future EMA studies to optimize relevance, usability, and acceptability. Achievement of the Joint United Nations Program on HIV/AIDS [100] 95-95-95 targets by 2025 requires the integration of such novel technologies with existing prevention and intervention efforts. Given their ubiquity, mEMA studies hold tremendous promise for furthering our understanding of the proximal mechanisms potentiating HIV risk, including the contextual and psychological conditions under which they occur, which are conditions difficult to recall later on. Such information is essential for the design and delivery of EMIs that can efficiently and effectively provide resources to when, where, and whom they are most needed.

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## Conflicts of Interest

None declared.

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## Abbreviations

- ART:** antiretroviral therapy  
**CMD:** common mental disorder  
**EMA:** ecological momentary assessment  
**EMI:** ecological momentary intervention  
**LGBTIQ+:** lesbian, gay, bisexual, transgender, intersex, and queer  
**LMIC:** low- and middle-income country  
**mEMA:** mobile ecological momentary assessment  
**mHealth:** mobile health  
**MSM:** men who have sex with men  
**PrEP:** pre-exposure prophylaxis  
**PTSD:** posttraumatic stress disorder

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Original Paper

# Development of a Quality Assurance Score for the Nigeria AIDS Indicator and Impact Survey (NAIIS) Database: Validation Study

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## Abstract

**Background:** In 2018, Nigeria implemented the world's largest HIV survey, the Nigeria AIDS Indicator and Impact Survey (NAIIS), with the overarching goal of obtaining more reliable metrics regarding the national scope of HIV epidemic control in Nigeria.

**Objective:** This study aimed to (1) describe the processes involved in the development of a new database evaluation tool (Database Quality Assurance Score [dQAS]) and (2) assess the application of the dQAS in the evaluation and validation of the NAIIS database.

**Methods:** The dQAS tool was created using an online, electronic Delphi (e-Delphi) methodology with the assistance of expert review panelists. Thematic categories were developed to form superordinate categories that grouped themes together. Subordinate categories were then created that decomposed themes for more specificity. A validation score using dQAS was employed to assess the technical performance of the NAIIS database.

**Results:** The finalized dQAS tool was composed of 34 items, with a total score of 81. The tool had 2 sections: validation item section, which contains 5 subsections, and quality assessment score section, with a score of "1" for "Yes" to indicate that the performance measure item was present and "0" for "No" to indicate that the measure was absent. There were also additional scaling scores ranging from "0" to a maximum of "4" depending on the measure. The NAIIS database achieved 78 out of the maximum total score of 81, yielding an overall technical performance score of 96.3%, which placed it in the highest category denoted as "Exceptional."

**Conclusions:** This study showed the feasibility of remote internet-based collaboration for the development of dQAS—a tool to assess the validity of a locally created database infrastructure for a resource-limited setting. Using dQAS, the NAIIS database was found to be valid, reliable, and a valuable source of data for future population-based, HIV-related studies.

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**KEYWORDS**

database quality assurance; Delphi method; quality assurance tool; Nigeria AIDS Indicator and Impact Survey

## Introduction

HIV continues to be a global major public health threat, with about 38 million people living with the disease as of 2018 [1]. Nigeria, Africa's most populous country, with an estimated population of 203 million is home to 1.9 million individuals living with HIV/AIDS, making it the nation with the fourth highest number of individuals living with HIV/AIDS [1,2]. In addition, Nigeria ranks among the top 6 nations in the world that bear the triple threat of high HIV infection, low treatment coverage, and slow decline in new HIV infections [3]. Against this background, it becomes necessary to have high-quality, reliable, accurate, and timely public health information for improving, evaluating, and monitoring HIV-related health care services and programs [4,5]. However, resource-limited settings like Nigeria are continuously challenged by low-quality data that are often incomplete, unreliable, and inaccurate, which blunt their versatility for decision-making [4,5]. Data quality audits play a significant role in assessing if data meet the quality mandated to support their proposed use [6].

In 2017, Nigeria launched the Nigerian AIDS Indicator and Impact survey (NAIIS) with the overarching goal of obtaining reliable population-based metrics regarding the scope of the HIV situation in Nigeria. The NAIIS is a multistakeholder endeavor to reliably estimate the scope and burden of HIV in Nigeria to enable policy makers and stakeholders to address gaps in access to care, linkage to care and retention, treatment coverage, and viral RNA suppression. The NAIIS project gathered comprehensive information on sociobehavioral attributes, linkage to care, levels of HIV viral load suppression (VLS), hepatitis B and hepatitis C coinfection, and other

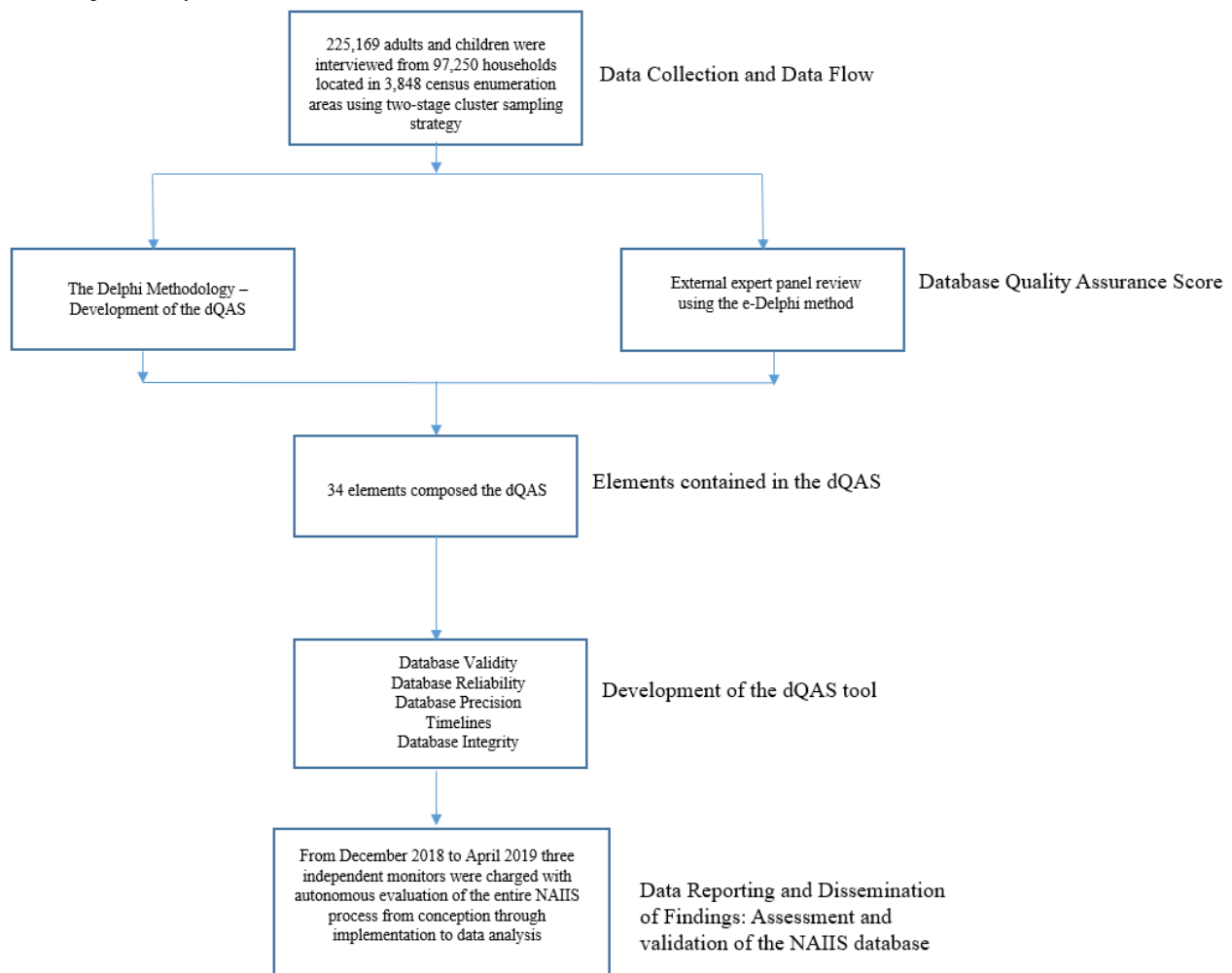
important data. The NAIIS is the largest population-based HIV survey ever undertaken to date. The NAIIS is also the first population-based study to include VLS, pediatric HIV prevalence, and antiretroviral therapy coverage as outcome assessments. The survey and estimates of biomarkers will provide critical data to assess the Joint United Nations Programme on HIV/AIDS (UNAIDS) 95/95/95 treatment targets at a national level.

The richness and complexity of the NAIIS project were reflected by the vast resources infused as well as the array of stakeholders involved in its planning, implementation, and monitoring. It was a joint endeavor of the Government of Nigeria (GON); Federal Ministry of Health; National Agency for the Control of AIDS (NACA); the US Government President's Emergency Plan for AIDS Relief (PEPFAR) program in Nigeria; the US Centers for Disease Control and Prevention (CDC) in Nigeria and Atlanta; implementing partners from the University of Maryland, Baltimore (UMB); and data management partners, ICF Macro, as well as the Institute for Health Metrics and Evaluation (IHME). ICF Macro worked in partnership with UMB in the implementation of the survey to support data management. In this paper, we describe primarily the processes involved in the development of a new database evaluation tool called the Database Quality Assurance Score (dQAS) and secondarily the use of the dQAS to evaluate and validate the NAIIS database emanating from the multistakeholder project.

## Methods

The flow of the steps and processes followed in this project are shown in [Figure 1](#).

**Figure 1.** Flowchart showing the steps and processes. dQAS: Database Quality Assurance Score; e-Delphi: electronic Delphi; NAIS: Nigeria AIDS Indicator and Impact Survey.



## Data Collection and Data Flow

From July 2018 to December 2018, 225,169 adults and children were interviewed from 97,250 households located in 3848 census enumeration areas in this 2-stage cluster sampling cross-sectional study. Over 6000 field staff worked for 22 consecutive weeks to conduct interviews, collect blood samples, and perform rapid immunologic tests. Questionnaire and field laboratory data (eg, rapid test results) were collected on mobile tablet devices using the Census and Survey Processing System (CSPRO; a data capture software developed by the US Census Bureau). Within the household, questionnaire and laboratory data were transmitted between tablets via Bluetooth connections. Team leads transmitted all survey data collected in CSPRO via FTPS over a 4G or 3G telecommunications provider at least once a day. We used https via a 4G or 3G telecommunications provider for transmission of data to the central server by the field, laboratory, and logistics teams. Survey data as well as field laboratory data were synchronized daily to the main server. In addition to the server transfer, daily backups were made to secure portable USB drives that were stored in a different location. Paper tools were used to monitor daily data collection activities. There were 18 data entry persons that worked over the course of 150 days entering data from the field, yielding a total of 2700 data entry personnel days. On average, 1380

individual interview records were entered per day from the 18 data entry personnel, resulting in a total of 207,000 individual record entries over the course of the survey. An activity information management system was used to centrally manage all the data collected. These included specimen results and location data captured in a laboratory data management system, interview data captured in CSPRO, SureMDM data, procurement and inventory management data, and personnel data.

## Database Quality Assurance Score

### *The Delphi Methodology—Development of the dQAS*

Initially, we created an internal review panel comprised of 6 members and 1 facilitator based on their expertise in the following areas: (1) database management, (2) data science, and (3) epidemiology. These internal reviewers were charged with an initial assessment of metrics abstracted from the literature and the World Health Organization (WHO) guidelines for database quality evaluation [7]. The reviewers assessed domain coverage and candidate metrics by analyzing illustrative metrics items from the WHO guidelines and the published literature and identifying poorly informative database quality metrics, which were discarded or altered. Our team of experts then examined the potential candidate metrics pool with the purpose of creating the dQAS.



First, each reviewer assessed database evaluation domain coverage based on the following criteria: (1) relevance to practical application, (2) measurable within the developing country context, (3) clarity, and (4) conciseness. Each criterion was applied using a 7-point Likert-type rating scale (1=Poor to 7=Excellent). After rating each candidate metric on the 4 criteria, the ratings for each metric were averaged. Subsequently, each reviewer ranked the pool of itemized metrics. Top-ranked items were then shared and discussed in a plenary session. Consensus was attained when 2 reviewers independently selected the metric. An additional reviewer was consulted for a final decision on highly scored items (eg, more than 20 points) that were not selected by the initial reviewers. Following this preselection process, we were left with a manageable list of metrics of less than 100 items. By using this systematic approach, our team was able to exclude redundant items that did not have sufficient face validity for use in the development of a database assessment instrument. All selected items were entered in an item library with documentation of their definition and domain coverage.

### ***External Expert Panel Review Using the Electronic Delphi Method***

To enhance the validity of our internal panel review, we submitted the list of preselected metrics items to a sample of 8 database development and evaluation experts as well as community stakeholders outside the research team to gather diverse input and establish consensus regarding candidate metrics. They were asked to apply the same set of rating criteria used by the research team but to a manageable list of preselected items, with the goal of verifying the relevance of the metrics in measuring key aspects of database quality assessment. For this purpose, we used a technology-enhanced Delphi method using online data collection [8]. The Delphi method is a well-established technique of gathering opinions from a diverse group of experts and is particularly useful for forecasting and decision-making on practice-related issues [8]. This technique produces reliable expert panel consensus through iterative rounds of questions while encouraging open feedback and maintaining anonymity and confidentiality. Also, the Delphi technique is preferable to the nominal group technique or focus groups when the purpose is to generate more stable estimates that are comparable to statistitized groups [9,10].

The Delphi technique consisted of iterative sequential rounds of questions with experts, which was implemented online. The online modality (electronic Delphi [e-Delphi]) was preferred because it permitted an efficient and relatively quicker assessment of expert panel consensus [11]. During the first round of questions, all preselected metrics were presented to each expert in an anonymous online survey created and distributed via email with Qualtrics software [12]. In a second round of questions, the group results were presented online using a secure link that assured anonymity and confidentiality

of responses. In this round, panelists had the opportunity to reconsider their answers based on the aggregated data. Ratings were then analyzed quantitatively using the median as a cut-off point, and items rated higher than or equal to the group median were included for subsequent phases of the study [13,14]. Results were presented in a subsequent round, highlighting areas of agreement and disagreement, and opportunities for open-ended comments were offered. The final result was a set of database quality assurance metrics based on a robust expert-driven review process incorporating multifaceted perspectives.

### **Elements Contained in the dQAS**

The dQAS contained the elements that are listed in [Multimedia Appendix 1](#).

### **Development of the dQAS Tool**

A thematic framework was created and adapted for this study using the United States Agency for International Development (USAID) data quality assessments checklist derived from the USAID's Automated Directives System Chapter 597 Operations Performance Policy [15,16]. Thematic categories were developed to form superordinate categories that grouped themes together. Additionally, subordinate categories were created that decomposed themes for more specificity. This culminated in the development of the dQAS Tool ([Multimedia Appendix 2](#)).

### **Data Reporting and Dissemination of Findings: Assessment and Validation of the NAIIS Database**

From December 2018 to April 2019, 3 independent monitors were charged with autonomous evaluation of the entire NAIIS process from conception through implementation to data analysis. One of the tasks of the project monitors was to utilize the dQAS tool built for the NAIIS project to validate the database.

## **Results**

### **The dQAS Tool**

The dQAS tool is a qualitative key database performance measure consisting of 34 items with a total score of 81. The dQAS tool has 2 sections: validation item section and quality assessment score section. The validation item section is further categorized into 5 subsections ([Table 1](#)). These include (1) database validity (20 items), (2) database reliability (5 items), (3) database precision (4 items), (4) timeliness (1 item), and (5) database integrity (5 items). The quality assessment score section was assigned a score of "1" for "Yes" (performance measure item present) and "0" for "No" (measure absent). There were also additional scaling scores ranging from "0" to a maximum of "4" depending on the measure ([Multimedia Appendix 1](#) and [Multimedia Appendix 2](#)).

**Table 1.** Outcomes of implementing the Database Quality Assurance Score (dQAS) tool on the Nigeria AIDS Indicator and Impact Survey (NAIS) database.

Superordinate and subordinate categories (number of elements)	Quality assessment score
<b>Data validity (subtotal=37)</b>	
Data-entry-sample ratio (DESR)	2
Data entry/management personnel training	1
Data entry/management personnel certification	1
Data entry/management personnel troubleshooting session	1
Frequency of troubleshooting sessions	3
Presence of a data management supervisor	1
Presence of a data management deputy supervisor	1
Qualification of data managers	3
Qualification of the data manager supervisor	3
Data entry personnel/manager's database knowledge assessment	3
Type of database	1
Database selection justification	1
Architecture of database corresponding with the working conceptual framework	1
Database degree of complexity	1
Concordance of prevalence estimates	5
Weighting algorithm consideration	1
Justification of the weighting process	3
Appropriateness of the weighting algorithm	3
Files backup and transfer systems	1
Database dictionary creation	1
<b>Database reliability (subtotal=5)</b>	
Presence of data audit system	1
Presence of in-built checks mechanism	1
Presence of alert or inactivation system	1
Presence of additional audit systems	1
Employment of a double key data entry validation process	1
<b>Database precision (subtotal=9)</b>	
Variable missing ratio (VMR)	4
Observation missing ratio (OMR)	4
Duplicate ratio	1
<b>Timeliness (subtotal=8)</b>	
Quality assessment of the database dictionary	8
<b>Database integrity (subtotal=19)</b>	
Presence of a data and safety monitoring board (DSMB)	1
Description of DSMB membership and expertise of members	3
Database security and risk management procedures	12
Presence of external independent monitors	1
Database Transparency Index (DTI)	2

## Qualitative Findings of the Survey Evaluation

The NAIIS Evaluation Instrument score results are shown in [Table 1](#).

The dQAS tool results from the NAIIS are summarized in [Table 2](#). The maximum score for each validation item section was

**Table 2.** Database Quality Assurance Score (dQAS) categories, elements, and scores.

Validation item (superordinate categories)	Subordinate categories (number of elements)	Quality assessment score (subtotal=81)		Database assessment score (subtotal=78)
		Minimum	Maximum	
Data validity	20	0	38	37
Database reliability	5	0	5	5
Database precision	4	0	9	9
Timeliness	1	0	8	8
Database integrity	5	0	21	19

There were 2 areas in which the NAIIS database scored less than the maximum score. The first was the data-entry-sample ratio (DESR), which captured the number of data management persons per 1000 samples per day and was calculated as the proportion of personnel per daily data waves: the larger the proportion, the greater the personnel adequacy and the lower the expected error rate. The maximum score on this metric was 3 points. However, the NAIIS database achieved a score of 2 because its DESR was 13/1000 samples. The NAIIS database also scored suboptimally on the Database Transparency Index (DTI), which measured the extent to which independent accessors had access to the database. The NAIIS database scored 2 out of a maximum of 4 points on this index. [Multimedia Appendix 3](#) provides the details of the NAIIS database system evaluation findings.

The overall dQAS was categorized as Exceptional ( $\geq 95\%$ ; score of 77 out of 81), Outstanding (90%-94%; score of 73-76 out of 81), Excellent (85%-89%; score of 69-72 out of 81), Very Good (80%-84%; score of 65-69 out of 81), Good (75%-79%; score of 61-64 out of 81), Fair (65%-74%; score of 61-64 out of 81), or Poor ( $\leq 64\%$ ; score of  $\leq 60$  out of 81).

## Discussion

We evaluated and validated the NAIIS database derived from the world's largest population-based HIV survey conducted in Nigeria. We achieved this by using the e-Delphi method to develop the dQAS tool. We then applied the derived dQAS tool to assess the quality of the NAIIS database, which attained an overall exceptional score of 96.3% (score of 71 out of 81). Hence, we found the database to be valid for future scientific and scholarly work that would advance the field.

In our study, we utilized an e-Delphi method that was implemented via the internet, which enabled obtaining input from panelists who were living in different parts of the world. Compared with the traditional format, the e-Delphi method minimized prolonged delays in arriving at consensus and decreased nonparticipation by expert panel members associated

with the traditional Delphi technique, which typically employs surface or airmail systems to ensure anonymity [8,17,18]. Additionally, the e-Delphi method was flexible, convenient, and cost-effective and allowed for more robust collaboration between local and international researchers in our study [17-20].

assessed as 38 for database validity, 5 for the database reliability, 9 for timeliness, and 21 for database integrity ([Table 2](#)). The maximum total score was 81, out of which the NAIIS database achieved 78, or 96.3%, which placed it in the highest category denoted as "Exceptional."

An added quality assurance interface in our study that enhanced the rigor of the assessment was the layering of the e-Delphi into an internal and an external expert review panel. The internal expert review panelists performed the preselection of metrics for the creation of the dQAS. In addition, they eased the subsequent work by the external expert review panelists who were not directly involved in the study and whose main role was to authenticate candidate metrics. This 2-stage expert consensus-driven process facilitated by the internet-dependent e-Delphi method ensured reliability and validity of the metrics for developing dQAS, in addition to assuring that our study was conducted more effectively and efficiently [8,11,18,20].

There are multiple strengths in this study. A merit of the methodology is that it showed the feasibility of remote internet-based collaboration for the development of a tool to assess the validity of a database infrastructure. We specifically illustrated a feasible North-South partnership to establish the validity of a database that was locally created in a low-middle-income country. This broader approach enhances the robustness of the process. As with any study, there were certain limitations. We believe that more access should have been offered to the database evaluators, including running some of the analyses themselves. However, database managers were concerned about the likelihood of breaching the confidentiality agreement signed with the GON. Consequently, the DTI was assigned a very low score of 2 out of a maximum of 4. Despite this deficit, the overall technical performance of the database on the dQAS instrument was exceptional (71 out of 81, 96.3%). In conclusion, the NAIIS database is valid and reliable and has been proven to be a useful data source for future research projects. Further, the dQAS represents a unique database assessment asset that could be utilized by other countries, with modifications as needed.

## Conflicts of Interest

None declared.

### Multimedia Appendix 1

Database Quality Assurance Score (dQAS).

[[DOCX File , 18 KB - formative\\_v6i1e25752\\_app1.docx](#) ]

### Multimedia Appendix 2

Database Quality Assurance Score (dQAS) tool.

[[DOCX File , 17 KB - formative\\_v6i1e25752\\_app2.docx](#) ]

### Multimedia Appendix 3

Database management system: Database Quality Assurance Score (dQAS).

[[DOCX File , 24 KB - formative\\_v6i1e25752\\_app3.docx](#) ]

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## Abbreviations

**CDC:** Centers for Disease Control and Prevention  
**CSPRO:** Census and Survey Processing System,  
**DESR:** data-entry-sample ratio  
**dQAS:** Database Quality Assurance Score  
**DTI:** Database Transparency Index  
**e-Delphi:** electronic Delphi  
**FMOH:** Federal Ministry of Health  
**GON:** Government of Nigeria  
**IHME:** Institute for Health Metrics and Evaluation  
**LDMS:** laboratory data management system  
**NACA:** National Agency for the Control of AIDS  
**NAIIS:** Nigeria AIDS Indicator and Impact Survey  
**PEPFAR:** President's Emergency Plan for AIDS Relief  
**UMB:** University of Maryland, Baltimore  
**UNAIDS:** Joint United Nations Programme on HIV/AIDS  
**USAID:** United States Agency for International Development  
**VLS:** viral load suppression  
**WHO:** World Health Organization

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Original Paper

# Digital Health Skillsets and Digital Preparedness: Comparison of Veterans Health Administration Users and Other Veterans Nationally

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## Abstract

**Background:** As health care systems shift to greater use of telemedicine and digital tools, an individual's digital health literacy has become an important skillset. The Veterans Health Administration (VA) has invested resources in providing digital health care; however, to date, no study has compared the digital health skills and preparedness of veterans receiving care in the VA to veterans receiving care outside the VA.

**Objective:** The goal of the research was to describe digital health skills and preparedness among veterans who receive care within and outside the VA health care system and examine whether receiving care in the VA is associated with digital preparedness (reporting more than 2 digital health skills) after accounting for demographic and social risk factors.

**Methods:** We used cross-sectional data from the 2016-2018 National Health Interview Survey to identify veterans (aged over 18 years) who obtain health care either within or outside the VA health care system. We used multivariable logistic regression models to examine the association of sociodemographic (age, sex, race, ethnicity), social risk factors (economic instability, disadvantaged neighborhood, low educational attainment, and social isolation), and health care delivery location (VA and non-VA) with digital preparedness.

**Results:** Those who received health care within the VA health care system (n=3188) were younger (age 18-49 years: 33.3% [95% CI 30.7-36.0] vs 24.2% [95% CI 21.9-26.5],  $P<.01$ ), were more often female (34.7% [95% CI 32.0-37.3] vs 6.6% [95% CI 5.5-7.6],  $P<.01$ ) and identified as Black (13.1% [95% CI 11.2-15.0] vs 10.2% [95% CI 8.7-11.8],  $P<.01$ ), and reported greater economic instability (8.3% [95% CI 6.9-9.8] vs 5.5% [95% CI 4.6-6.5],  $P<.01$ ) and social isolation (42.6% [95% CI 40.3-44.9] vs 35.4% [95% CI 33.4-37.5],  $P<.01$ ) compared to veterans who received care outside the VA (n=3393). Veterans who obtained care within the VA reported more digital health skills than those who obtained care outside the VA, endorsing greater rates of looking up health information on the internet (51.8% [95% CI 49.2-54.4] vs 45.0% [95% CI 42.6-47.3],  $P<.01$ ), filling a prescription using the internet (16.2% [95% CI 14.5-18.0] vs 11.3% [95% CI 9.6-13.0],  $P<.01$ ), scheduling a health care appointment on the internet (14.1% [95% CI 12.4-15.8] vs 11.6% [95% CI 10.1-13.1],  $P=.02$ ), and communicating with a health care provider by email (18.0% [95% CI 16.1-19.8] vs 13.3% [95% CI 11.6-14.9],  $P<.01$ ). Following adjustment for sociodemographic and social risk factors, receiving health care from the VA was the only characteristic associated with higher odds (adjusted odds ratio [aOR] 1.36, 95% CI 1.12-1.65) of being digitally prepared.

**Conclusions:** Despite these demographic disadvantages to digital uptake, veterans who receive care in the VA reported more digital health skills and appear more digitally prepared than veterans who do not receive care within the VA, suggesting a positive, system-level influence on this cohort.

**KEYWORDS**

digital health literacy; Veterans Health Administration; health care; telemedicine; veterans; digital tools; social risk factors; digital uptake

## Introduction

In recent years, and further expedited by the COVID-19 pandemic, health systems have shifted greater amounts of health care from in-person to digital-based care. The gathering of online information, use of mobile apps, and virtual-based patient-provider interactions require greater digital knowledge and skills from health care consumers. These abilities, termed digital health literacy, refer to the “set of skills and knowledge that are essential for productive interactions with technology-based health tools” [1]. An individual’s digital health skillset remains important as recent studies have shown that individuals’ self-perceived skills to use online information may affect their health and quality of their health care and that a lack of such skills may lead to adverse clinical outcomes [1-3]. Prior work shows that multiple individual-level factors, including age, race/ethnicity, and social risk factors such as income, education, and marital status, influence one’s overall digital health literacy [2,4-6]. While digital health literacy frequently describes the individual skills or experiences a consumer may have, the degree to which an individual may be able to meaningfully engage digitally based (eg, digitally prepared) health care is lacking. Digital preparedness can be thought of as having sufficient digital skills and experiences using digital tools to support digital-based care.

The health care system in which a person receives care may impact an individual’s digital health skillset and, thus, their digital preparedness in important ways. For instance, the Veterans Health Administration (VA), which cares for more than 9 million individuals and is the largest integrated health care system in the United States, has used technology-based interventions to improve patient access and outcomes. Because many veterans who receive care from the VA reside in rural locations, telemedicine and other asynchronous digital modalities are commonly used to provide health care within the VA [7]. Even prior to the pandemic, the VA was seen as a leader in the implementation and use of digital health interventions [8]. While prior work has found that most veterans have basic digital access (ie, own a digital device) and digital literacy (ie, ability to use the internet) to engage in digital-based care [9,10], to our knowledge, no study has compared the digital health skillset and preparedness of consumers of different health systems, as well as individual-level factors such as age, sex, race, ethnicity, and social factors (eg, economic instability, education attainment, and social isolation). Due to the VA’s history and focus on the use of digital care, we hypothesize that individuals who obtain their health care from the VA may have a greater digital health skillset and higher rates of digital preparedness (ie, reporting more than 2 digital health skills) than those who receive care outside the VA health care system.

To examine this, we used the National Health Interview Survey (NHIS) to first describe the digital health skillset and examine

sociodemographic and social risk factors associated with digital preparedness among veterans who receive care from the VA in comparison with veterans who receive care outside the VA health care system. Then, we determined whether receiving care in the VA is associated with digital preparedness independent of these demographic and social risk factors.

## Methods

### Data Source

We used cross-sectional data from the 2016-2018 NHIS, a nationally representative sample of noninstitutionalized individuals residing within the United States, conducted annually by the National Center for Health Statistics at the Centers for Disease Control and Prevention [11]. The NHIS uses computer-assisted personal interviewing to annually administer the survey and collect health-related information from respondents. During the assessed years, the unconditional final adult response rate ranged from 53.0% to 54.3%. This study used publicly available data and was exempt from institutional review board review.

### Analytic Sample

After limiting the sample to respondents aged over 18 years and excluding individuals with missing data (<3%), our analytic samples included 3188 veterans who obtain care in the VA (which included VA, TRICARE [health insurance for active-duty military], and CHAMP-VA [Civilian Health and Medical Program of the Department of Veterans Affairs]) and 3393 veterans who received care outside the VA. To create these cohorts, we first used the question, “Have you ever served on active duty in the US Armed Forces, military reserves, or National Guard?” to identify veterans from nonveterans. Next, we used the question, “What kind of health insurance or health care coverage do you have?” and identified those who are receiving health care within the VA by those who answered, “military health care (TRICARE, VA, CHAMP-VA)” and those who received health care outside the VA by those who answered any type of insurance (ie, private, Medicare, Medicaid, Medigap) other than “military health care.”

Because this identification method may lack specificity, we also performed a sensitivity analysis on a secondary cohort from a 2018 subpopulation who were given the question “Have you ever enrolled in or used VA health care?” We then performed the same analysis among individuals who responded “yes” to this question.

### Covariates and Social Risk Factors

In our analysis of digital preparedness, we included age, sex, race, ethnicity, and 4 social risk factors (economic instability, disadvantaged neighborhood, low educational attainment, and social isolation) known to impact an individual’s digital health skillset [2,4-6]. The NHIS questionnaires were assessed for

questions that addressed any of the 4 social risk factors ([Multimedia Appendix 1](#)). Respondents were considered to have a social risk factor if they answered positively (eg, yes) to any question pertaining to any of the 4 social risk factors.

### Digital Health Skills and Digital Preparedness

We used the digital health questions available in the NHIS questionnaires. To assess an individual's digital health skillset, we used the following question, "During the past 12 months, have you ever used computers for any of the following...?" with the following 4 subquestions: "...to look up health information on the internet," "...to fill a prescription using the internet," "...to schedule an appointment with a health care provider on the internet," and "...to communicate with a health care provider by email." We then summed the total number of digital health skills questions in which an individual stated they had performed that particular task in the prior 12 months to present a digital health skills count. Based on clinical experience, we then defined digital preparedness as having 2 or more of any of the aforementioned digital health skills, chosen to create a reasonable dichotomization between those who may have only completed one of these tasks and those who potentially partake in several different aspects of digital-based health care, thus being labeled as digitally prepared.

### Statistical Analysis

First, we calculated descriptive statistics for veterans who obtained care within the VA and veterans who obtained care outside the VA and included estimated proportions and their 95% confidence intervals. Next, we calculated the estimated prevalence of digital preparedness based on age, sex, race, ethnicity, and social risk among the 2 cohorts. Finally, we used logistic regression to estimate unadjusted and multivariable model odds ratios and 95% confidence intervals for each characteristic, with adjusted analysis controlling for all previously described covariates. We performed this analysis on the primary cohort and on the secondary, 2018 cohort for the sensitivity analysis. All descriptive and regression estimates

accounted for the complex sampling design, and sampling weights were used to produce estimates representative of the US population. Given the unknown and complex pathways between the social risk factors, we assessed for multicollinearity between all variables before final modeling using variance inflation factor (threshold: >10) and tolerance values (threshold: <0.1) and found no evidence of collinearity. Statistical analyses were performed using SAS statistical software (version 9.4, SAS Institute Inc).

## Results

### Individual Characteristics

The analytic samples consisted of 3188 veterans who received care within the VA, and 3393 veterans who received care outside the VA. Those who received health care within the VA health care system were younger (age 18-49 years: 33.3% [95% CI 30.7-36.0] vs 24.2% [95% CI 21.9-26.5],  $P<.01$ ), were more often female (34.7% [95% CI 32.0-37.3] vs 6.6% [95% CI 5.5-7.6],  $P<.01$ ) and identified as Black (13.1% [95% CI 11.2-15.0] vs 10.2% [95% CI 8.7-11.8],  $P<.01$ ), and reported greater economic instability (8.3% [95% CI 6.9-9.8] vs 5.5% [95% CI 4.6-6.5],  $P<.01$ ) and social isolation (42.6% [95% CI 40.3-44.9] vs 35.4% [95% CI 33.4-37.5],  $P<.01$ ) compared to veterans who received care outside the VA ([Table 1](#)).

Veterans who obtained care within the VA reported more digital health skills than those who obtained care outside the VA, endorsing greater rates of looking up health information on the internet (51.8% [95% CI 49.2-54.4] vs 45.0% [95% CI 42.6-47.3],  $P<.01$ ), filling a prescription using the internet (16.2% [95% CI 14.5-18.0] vs 11.3% [95% CI 9.6-13.0],  $P<.01$ ), scheduling a health care appointment on the internet (14.1% [95% CI 12.4-15.8] vs 11.6% [95% CI 10.1-13.1],  $P=.02$ ), and communicating with a health care provider by email (18.0% [95% CI 16.1-19.8] vs 13.3% [95% CI 11.6-14.9],  $P<.01$ ; [Table 1](#)).

**Table 1.** Sociodemographics and digital health skills among veteran respondents to the National Health Interview Survey 2016-2018.

	Veterans who receive care within the VA <sup>a</sup> (n=3188), % (95% CI)	Veterans who receive care outside VA (n=3393), % (95% CI)	P value
<b>Age (years)</b>	— <sup>b</sup>	—	<.01
18-49	33.3 (30.7-36.0)	24.2 (21.9-26.5)	—
50-64	24.3 (22.3-26.2)	22.8 (20.7-25.0)	—
65-74	25.1 (23.2-26.9)	26.7 (24.7-28.6)	—
≥75	17.2 (15.5-18.8)	26.1 (24.3-27.9)	—
<b>Sex</b>	—	—	<.01
Male	65.2 (62.6-67.9)	93.3 (92.3-94.4)	—
Female	34.7 (32.0-37.3)	6.6 (5.5-7.6)	—
<b>Race and ethnicity</b>	—	—	<.01
White	78.9 (76.7-81.2)	85.0 (83.0-86.9)	—
Black	13.1 (11.2-15.0)	10.2 (8.7-11.8)	—
Other	7.8 (6.3-9.3)	4.7 (3.5-5.8)	—
Hispanic	9.1 (7.4-10.8)	7.1 (5.4-8.7)	.08
<b>Social risk factors</b>	—	—	—
Economic instability	8.3 (6.9-9.8)	5.5 (4.6-6.5)	<.01
Disadvantaged neighborhood	17.7 (15.8-19.5)	16.5 (14.7-18.4)	.38
Low educational attainment	71.3 (69.1-73.4)	69.0 (66.7-71.3)	.12
Social isolation	42.6 (40.3-44.9)	35.4 (33.4-37.5)	<.01
<b>Digital health skills<sup>c</sup></b>	—	—	—
Look up health information on the internet	51.8 (49.2-54.4)	45.0 (42.6-47.3)	<.01
Fill a prescription using the internet	16.2 (14.5-18.0)	11.3 (9.6-13.0)	<.01
Schedule a health care appointment on the internet	14.1 (12.4-15.8)	11.6 (10.1-13.1)	.02
Communicate with a health care provider by email	18.0 (16.1-19.8)	13.3 (11.6-14.9)	<.01
<b>Digital skills count<sup>d</sup></b>	—	—	<.01
0	43.1 (40.6-45.7)	49.9 (47.5-52.3)	—
1	31.5 (29.2-33.9)	30.6 (28.6-32.6)	—
2	11.7 (10.1-13.2)	10.5 (9.0-11.9)	—
3	9.0 (7.6-10.4)	5.8 (4.8-6.9)	—
4	4.5 (3.5-5.5)	3.0 (2.1-3.8)	—

<sup>a</sup>VA: Veterans Health Administration.

<sup>b</sup>Not applicable.

<sup>c</sup>Used a computer in the past 12 months for any of the following.

<sup>d</sup>Calculated by summing the total number of “yes” responses to the digital literacy questions.

### Prevalence of Digital Preparedness

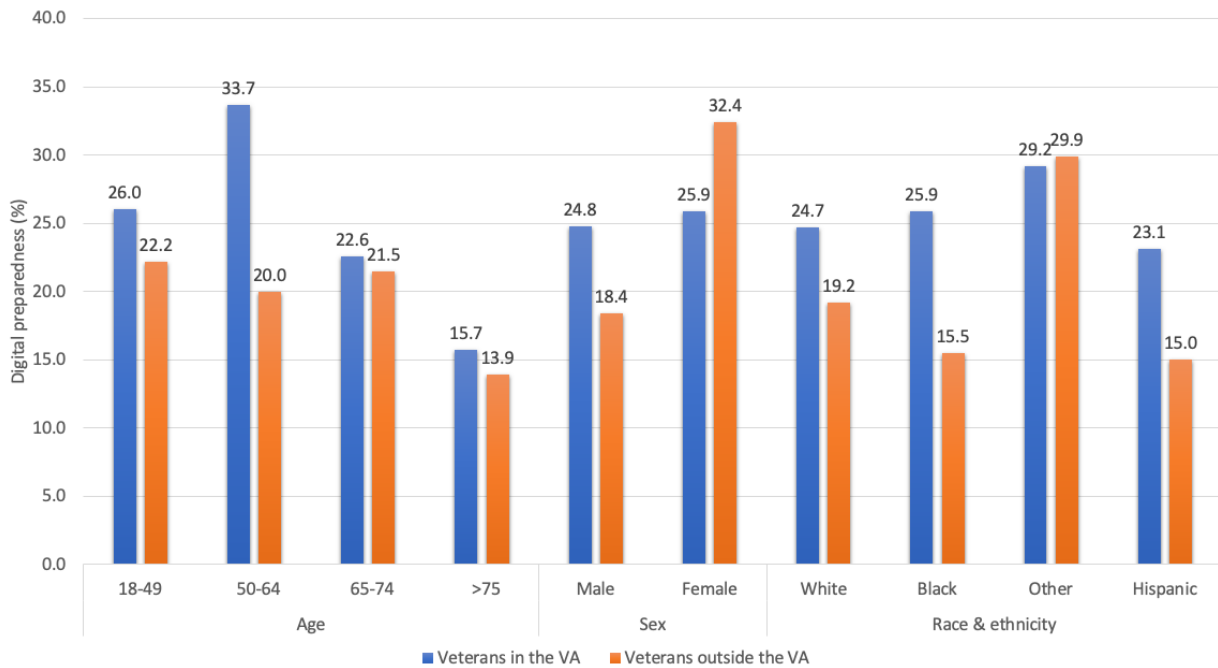
On average, veterans who received care in the VA were more digitally prepared (answering “yes” to more than 2 digital skills questions; mean 25.2%) than veterans who received care outside the VA (mean 20.8%). This difference was most pronounced

among those who were middle aged (age 50-64 years; 33.7% vs 20%), males (24.8% vs 18.4%) and those who identified as Black (25.9% vs 15.5%). Among women, those who received care outside the VA reported more digital health skills than those who received care within the VA (32.4% vs 25.9%; [Figure 1](#)).

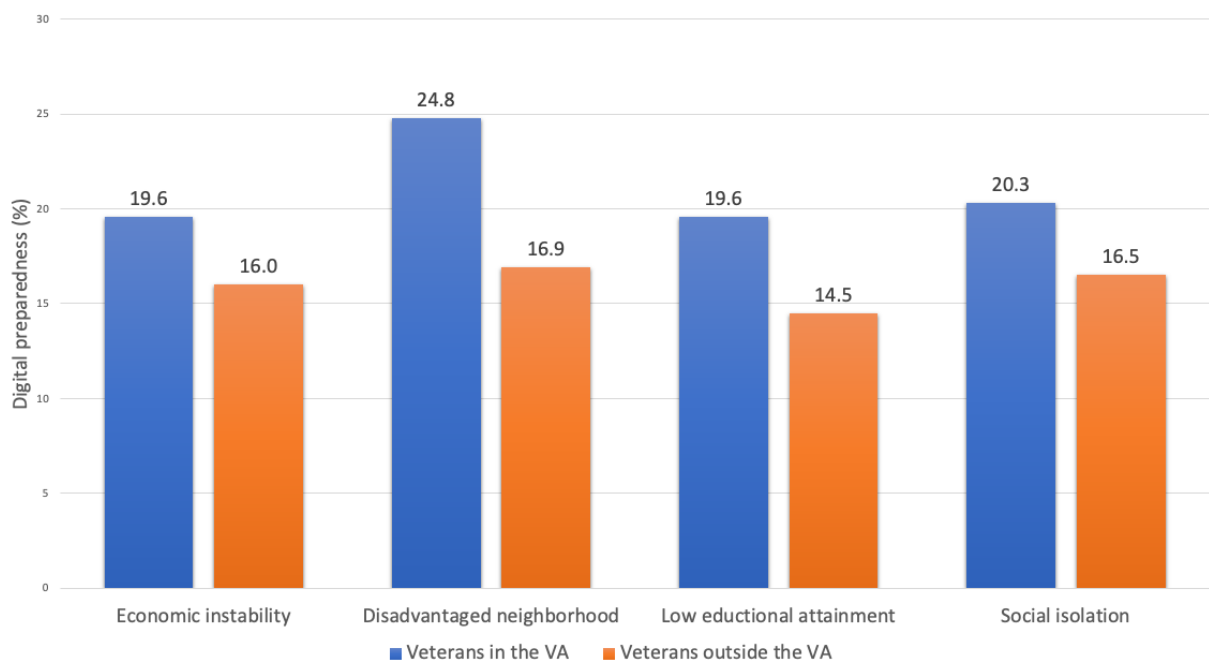
Veterans who received care within the VA and who also reported economic instability (19.6%, 95% CI 13.4-25.8) and low educational attainment (19.6%, 95% CI 17.2-22.0) had the lowest prevalence of digital preparedness. Among veterans who received care outside the VA, social risk factors appeared to

have a larger impact on the prevalence of digital preparedness (mean 15.5%) compared to those who received care within the VA (mean 21.2%), with individuals who reported low educational attainment (14.5%, 95% CI 12.6-16.5) having the lowest preparedness levels (Figure 2).

**Figure 1.** Prevalence of digital preparedness based on sociodemographics among veterans cared for within and outside the Veterans Health Administration. Digital preparedness is defined as having >2 “yes” responses to the four digital health skills questions. VA: Veterans Health Administration.



**Figure 2.** Prevalence of digital preparedness based on social factors among veterans cared for within and outside the Veterans Health Administration. VA: Veterans Health Administration.





## Associations of Digital Preparedness

In unadjusted analysis, older age (over 75 years), low educational attainment, and social isolation were associated with significantly lower odds of being digitally prepared, while being female, identifying as a racial minority other than Black (eg, Asian, American Indian, Alaska Native, Native Hawaiian, or Pacific Islander), and receiving care at the VA were associated with higher odds of digital preparedness. In

multivariable models, age over 75 years (adjusted odds ratio [aOR] 0.59, 95% CI 0.45-0.76), low educational attainment (aOR 0.40, 95% CI 0.34-0.48), and social isolation (aOR 0.78, 95% CI 0.66-0.92) remained significant negative predictors of digital preparedness. Receiving health care services from the VA was the only characteristic associated with higher odds (aOR 1.36, 95% CI 1.12-1.65) of being digitally prepared (Table 2).

**Table 2.** Sociodemographic, social risk factors, and health care systems association with digital preparedness<sup>a</sup>.

	Odds ratio of being digitally prepared <sup>b,c</sup> (95% CI)	
	Unadjusted	Adjusted <sup>d</sup>
<b>Age (years)</b>		
18-49	Reference	Reference
50-64	1.12 (0.89-1.41)	1.16 (0.92-1.46)
65-74	0.88 (0.70-1.11)	0.91 (0.72-1.16)
≥75	0.53 (0.41-0.69)	0.59 (0.45-0.76)
<b>Sex</b>		
Male	Reference	Reference
Female	1.42 (1.19-1.70)	1.15 (0.95-1.40)
<b>Race and ethnicity</b>		
White	Reference	Reference
Black	0.95 (0.74-1.24)	0.87 (0.66-1.14)
Other <sup>e</sup>	1.52 (1.09-2.12)	1.40 (0.97-2.01)
Hispanic <sup>f</sup>	0.83 (0.55-1.26) <sup>e</sup>	0.72 (0.48-1.07)
<b>Social risk factors</b>		
Economic instability	0.76 (0.56-1.05)	0.87 (0.62-1.22)
Disadvantaged neighborhood	0.90 (0.72-1.12)	1.01 (0.80-1.26)
Low educational attainment	0.39 (0.33-0.46)	0.40 (0.34-0.48)
Social isolation	0.70 (0.60-0.82)	0.78 (0.66-0.92)
<b>Health care access</b>		
Non-VA <sup>g</sup> health care	Reference	Reference
VA health care	1.40 (1.19-1.67)	1.36 (1.12-1.65)

<sup>a</sup>Missingness ranged from 1.2% to 3.1%.

<sup>b</sup>Digitally prepared is defined as having 2 or more “yes” responses to digital literacy questions.

<sup>c</sup>Reference is 0-1 “yes” responses to digital skills questions.

<sup>d</sup>Controlled for age, sex, race, ethnicity, and social risk factors.

<sup>e</sup>Other includes: Asian, American Indian, Alaska Native, Native Hawaiian, and Pacific Islander.

<sup>f</sup>Non-Hispanic is reference.

<sup>g</sup>VA: Veterans Health Administration.

In the sensitivity analysis among those who answered “yes” to “Have you ever enrolled in or used VA health care?” we found similar results. In adjusted analysis, receiving health care from the VA (aOR 1.33, 95% CI 1.04-1.69) was associated with digital preparedness (Multimedia Appendix 2).

## Discussion

### Principal Findings

In this national survey assessment of US veterans, we found that despite demographic and social disadvantages to digital uptake, veterans who received care in the VA reported more digital health skills and were more likely to be digitally prepared

(defined as having more than 2 digital literacy skills) compared to veterans who did not receive care within the VA. While previous work has highlighted individual-level factors that can affect digital skills, to our knowledge, this is the first study to assess how the health care system in which an individual receives care may influence an individual's preparedness to use digital-based care. There are several potential explanations for these findings.

First, we found that veterans' digital skillsets may be low regardless of where they obtained care (within or outside the VA health care system). These levels are similar to other national data which show that approximately one-fifth of all Americans may not have proper digital literacy skills [12]. We note that digital health skills may be low due to the sociodemographics associated with the veterans cared for by the VA, as it selectively cares for individuals who are older, less educated, more rural, and with lower socioeconomic status [13]—all factors known to be associated with lower digital health literacy [4,14,15]. Despite these demographic disadvantages to digital uptake, veterans who receive care in the VA appear to have more digital health skills and be more digitally prepared than veterans who do not receive care within the VA, suggesting a positive, system-level influence on these individuals. We highlight potential age and gender differences between our survey respondents, who appear to be younger than the general veteran population (median age 57.5 [SD 15.2] years) and disproportionately female (median 11.5% among VA users and 8.8% among non-VA users) when compared to known VA demographics [16,17].

We hypothesize that the differences in digital skillsets and preparedness may be a product of the VA's historical use of telemedicine and digital-based tools. Beginning in 1994, the VA began a progressive uptake and use of telemedicine, with early phases characterized by local innovations and pilot studies centered around telehealth delivery [18]. A second phase of the VA's dissemination and use of telehealth modalities began in 2004 and centered around systems approaches that supported early adoption of telemedicine and created national clinical, technological, and business foundations for the VA's developing telemedicine platforms [18]. The growth in telemedicine use over the subsequent two decades led the VA to report that in 2016, 12% of all veterans had received some of their care through telemedicine modalities [19], while fewer than 1% of Medicaid and rural Medicare beneficiaries used telehealth services during the same time period [20,21]. In recent years, other large, integrated health care systems such as Kaiser Permanente have placed a large emphasis on the use of telemedicine to provide access to care for its constituents, although it is unclear how such efforts have impacted their constituents' digital health skills [22].

In addition to its early use of telemedicine, the VA was an early adopter in using on-demand tools, mobile apps, and other forms of digital outreach to connect with the individuals it serves [23]. For example, in 2010, the VA was the first health care system to institute the Blue Button program, an online health portal that allows users direct access to their health data [24]. Additionally, in 2016, the VA was one of the first health care systems to perform mass distribution of video-enabled tablets

to at-risk populations as a means of improving access to care [25]. We note that the impact of telemedicine and these programs may be amplified by veterans' rural demographics (approximately 25% reside in rural areas) [26], and thus encouraging and potentially requiring greater use of these digital resources than the general public.

The nature of the digital health skills questions used in this assessment may also offer further insight into the degree of digital connectedness among these cohorts. While previous work around digital health primarily focuses on basic digital access parameters such as owning a computer or smartphone, access to broadband internet, and use of email [9,27,28], the questions used in this survey represent higher order or more active engagement of digital health services than simply having access to a digital device or internet. This component of our assessment is particularly interesting given that prior research has found that digital connectedness is more often associated with younger age, higher education, and better health status [29]. Our findings highlight that while veterans have access to digital tools (eg, on average 80% use the internet or own a private computer) [9], only 1 in 6 veterans who received care within the VA (and only 1 in 8 who received care outside the VA) use these skills to meaningfully engage the health care system (eg, fill a prescription, schedule a health care appointment, or communicate with a health care provider through a computer or the internet). These findings suggest that simply relying on questions that assess access technology or internet use to estimate digital literacy may overestimate the actual degree of digital health literacy among this group [30].

Improving digital skills and literacy will be an important topic for health care systems to address as use of digital-based technologies expands in the coming years. It is well known that to improve use of digital tools, health care must go beyond access alone and improve individuals' digital and health knowledge, numeracy, navigability, communication, and decision-making skills [31]. Several strategies have been used to improve digital literacy, including collaborative learning (ie, interacting with others to improve an individual's digital skillset), which was found to improve participants' computer and web knowledge, digital self-efficacy, and overall literacy skills [4], whereas studies that provided tailored educational interventions significantly improved not just digital literacy skills but health outcomes such as blood pressure [32,33] and medication adherence [34,35]. Our findings along with a review of the literature [4] show that interventions targeted at older, more vulnerable populations may be highly impactful and needed as more care migrates to such modalities.

## Limitations

Our study has notable limitations. First, the categorization method used to classify respondents based on where they receive their health care could misclassify some individuals, as some veterans may have military health insurance but could be obtaining care outside the VA. We note that our findings did not change when we performed a sensitivity analysis on respondents who directly stated they had VA-based health care. Second, our definition of being digitally prepared may be overly strict and potentially overpenalizes our characterization of who

is digitally prepared. Third, this study did not include other potential risk factors that may have direct or confounding effects on digital preparedness, such as secondary barriers to digital access—cognitive, psychosocial, or functional barriers (eg, visual impairment)—that may impede optimal uptake and use of digital resources. Fourth, our outcomes of interest (digital health skills and digital health preparedness) are based on self-report, which could be biased or incorrect, as prior work has shown that individuals can both over- and underestimate their digital skillset [2], although such misclassification would likely be similar for those who receive care within the VA and those who receive care outside the VA. Fifth, the use of the term computer in the survey question could be misleading and may underestimate the use of cellphones or other smart devices to accomplish the queried task. Finally, this survey was conducted in the years prior to the COVID-19 pandemic, after which health care systems rapidly adopted telemedicine and other digital care

modalities, and thus our findings may not be representative of current digital health skillsets or preparedness levels.

## Conclusions

Veterans who obtain services within the VA report greater digital health skills and appear more prepared to engage with health providers through digital means compared to veterans who receive their care outside the VA health care system, despite a higher prevalence of risk factors known to negatively impact digital literacy. These findings suggest that while individual-level barriers to digital care exist, there may be system-level factors or influences that moderate such barriers among at-risk populations such as those served by the VA. As digital-based care becomes more prominent, future work should focus on what system-based interventions or programs are improving individuals' digital skillsets and ability to engage through digital mechanisms.

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## Acknowledgments

CW had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

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## Conflicts of Interest

None declared.

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### Multimedia Appendix 1

Domains and specific questions of social risk.

[\[DOCX File, 13 KB - formative\\_v6i1e32764\\_app1.docx\]](#)

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### Multimedia Appendix 2

Sensitivity analysis among 2018 respondents who stated they have enrolled in or used VA-based health care.

[\[DOCX File, 15 KB - formative\\_v6i1e32764\\_app2.docx\]](#)

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## Abbreviations

**aOR:** adjusted odds ratio

**CHAMP-VA:** Civilian Health and Medical Program of the Department of Veterans Affairs

**NHIS:** National Health Interview Survey

**VA:** Veterans Health Administration

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Original Paper

# Perceptions of Digital Technology Experiences and Development Among Family Caregivers and Technology Researchers: Qualitative Study

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## Abstract

**Background:** Caregiving is highly stressful and is associated with poor mental and physical health. Various technologies, including mobile and eHealth apps, have been developed to address caregiver needs. However, there is still a paucity of research examining the technology perceptions of informal caregivers, especially from the perspectives of sex, gender, and diversity.

**Objective:** To address the research gap and inform the development of future caregiving technologies, this study aims to examine how family caregivers perceive using technology to assist with their caregiving routines; identify the sex, gender, and diversity factors that shape these perceptions; and understand how these perceptions and needs are reflected within the current technology development process.

**Methods:** Semistructured interviews were conducted with 16 informal caregivers of individuals with a range of chronic medical conditions and 8 technology researchers involved in caregiving technology projects.

**Results:** Three main themes with subthemes were developed. The first main theme is that *caregivers see a need for technology in their lives*, and it comprises the following 3 subthemes: *caregiving is a challenging endeavor*, *technology is multifaceted*, and *caregiver preferences facilitate technology use*. The second main theme is that *relationships play a vital role in mediating technology uptake*, and it comprises the following 2 subthemes: *the caregiver-care recipient dynamic shapes technology perceptions* and *caregivers rely on external sources for technology information*. Finally, the third main theme is that *barriers are present in the use and adoption of technology*, and it comprises the following 2 subthemes: *technology may not be compatible with personal values and abilities* and *technology that is not tailored toward caregivers lacks adoption*.

**Conclusions:** The findings highlight the multifaceted role that technology can play in aiding caregiving while drawing attention to the perceived drawbacks of these technologies among caregivers. The inclusion of technology researchers in this study provides a more holistic understanding of technologies in caregiving from their initial development to their eventual uptake by caregivers.

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**KEYWORDS**

caregiving; digital technologies; sex; gender; diversity

## Introduction

Globally, an increasing number of individuals are providing unpaid assistance and support to family members or acquaintances with physical, psychological, or developmental needs [1]. Approximately 17% of Americans have provided care to adults who are ill, disabled, or aged [2]. In Canada, approximately 25% of Canadians aged 15 years and above provide help or care to a family or friend with a chronic health problem [3], whereas in the United Kingdom, approximately 10% of the population are family caregivers [4]. As families and households are getting smaller because of lower birth and marriage rates, there are fewer family caregivers to meet the increasing care demands of the growing older population [5]. This creates challenges in maintaining a work-caregiving balance, assisting with daily living activities, and managing services for the care recipient [2,6]. As such, caregiving remains a stressful experience and exerts a considerable burden on family caregivers [7-10]. As a multidimensional response to the stressors associated with the caregiving experience, caregiving burden can have devastating and long-term effects on family caregivers [11,12].

Researchers have developed a range of technological interventions to assist in reducing the caregiving burden and overcoming the challenges faced by family caregivers [13,14]. These domains where technology can be leveraged include but are not limited to caregiver platforms, caregiver support, care coordination, telehealth or diagnostics and digital care delivery, alternative therapeutics, transitions of care, housing and operations, and end-of-life planning [15,16]. Although technologies can reduce objective burden, some of the physical responsibilities of caring, and the subjective burden by providing carers access to support negotiation for emotional effort entailed in providing care [17], significant challenges and barriers still exist with respect to the use and adoption of technologies [18-21]. For example, technologies aimed at the caregivers of people living with dementia have been perceived as too complex and can create ethical issues such as reduced privacy, data security, and informed consent [18-21]. In addition, systemic shortcomings, such as a lack of awareness and accessibility and insufficient integration with existing health care services, have limited the rate of technology adoption among caregivers [22]. Given these gaps between technology development and adoption, understanding technology perceptions among family caregivers is becoming increasingly important for identifying specific barriers and facilitators that can then be addressed during the technology development process for promoting the technology uptake.

Recently, researchers began to gather technology perceptions from family caregivers [23-26]. These pioneering works have highlighted a variety of feature preferences relating to technology, with all of them reporting a limited use of technologies because of barriers such as a lack of familiarity, awareness, and availability [23-26]. Although these studies set the groundwork by pioneering the examination of family caregivers' perceptions of technology in general, there has been limited exploration of (1) how sex, gender, and diversity characteristics shape these perceptions or (2) how the

perceptions are considered during the technology development process. The sex and gender gap in general technologies has been extensively studied [27,28]; however, the lack of research on technology perception among informal caregivers still exists despite considerable sex and gender differences with respect to well-being as well as psychosocial and overall health [29-32].

A recent systematic search of the literature on caregiving technology identified only a few studies that have assessed informal caregiver needs with respect to technology from the perspectives of sex and gender [23,33-35]. In all of these studies, there were more female caregivers, ranging from 51% [35] to 73.3% [34]. Sex and gender differences were observed in terms of the perceived usefulness of technology [33], willingness to pay for technology [35], and overall attitudes toward technologies [23,34] designed to assist with caregiving. The systematic search found that the included studies highlighted important differences in the preferences and reception of technology among male and female caregivers but had methodological limitations, including small sample sizes [33,34] and a lack of qualitative studies. Moreover, with the rapid pace of technology development, including an increasing availability through web-based and mainstream shopping, reduced cost of off-the-shelf technologies, and shifting caregiver demographics, these results may no longer reflect the latest trends and opinions toward technology. As such, an up-to-date, in-depth exploration of how sex and gender influence the perceptions of caregiving technology among family caregivers and how these perceptions are incorporated in the technology development process is timely.

This qualitative study aims to address these gaps by examining how family caregivers perceive the use of technology in assisting with their caregiving routines; identifying any sex, gender, and diversity factors that shape these perceptions; and how these perceptions and needs are reflected in the current technology development process. We took a qualitative descriptive approach to allow for a detailed description and understanding of the *who*, *what*, and *where* of technology perceptions, as it relates to caregiving and technology development [36]. By drawing on the general tenets of naturalistic inquiry, which involves the shift from tangible variables to focus on the social constructions of research participants, this study also aims to explore these technology perceptions as a product of characteristics and behaviors that are socially and culturally contingent [36,37].

## Methods

### Participants

Our study sample comprised 16 adults providing care for an adult or older adult family member and 8 technology researchers. Tables 1 and 2 describe the characteristics of the family caregivers and technology researchers, respectively. These individuals were recruited using purposive sampling from the communities in Ontario, Canada, through various organizations, such as the March of Dimes Canada, Disabled Women's Network Canada, Aging Gracefully across Environments using Technology to Support Wellness, Engagement and Long Life, University of Toronto, University Health Network, and Health Quality Ontario (collectively

referred to as *recruitment partners*). The staff of these organizations distributed study emails and flyers to potential participants. In addition, members of the research team (CX and GEKR) delivered presentations about the study to potential participants at meetings organized by our recruitment partners. Interested participants contacted the research coordinator (GEKR) by phone or email, where they received more information about the study.

Participants were eligible if they were aged  $\geq 18$  years, able to communicate in English, and unaffected by neurocognitive or physical conditions that might have impeded interviewing. In addition, to be included, family caregivers needed to be taking care of an adult member in their household for the past 12 months for an average of 3 hours or more per week. The inclusion criterion for technology researchers was that they had been involved in projects that developed technologies for assisting with caregiving for the past 12 months.

**Table 1.** The characteristics of family caregivers within this study (N=16).

Characteristics of family caregivers	Values, n (%)
<b>Age (years)</b>	
≤55	9 (56)
>55	7 (44)
<b>Assigned sex</b>	
Male	6 (37)
Female	10 (63)
<b>Gender</b>	
Cisgender man	6 (38)
Cisgender woman	9 (56)
Gender queer or gender nonconforming	1 (6)
<b>Highest level of education</b>	
Some postsecondary education or below	4 (25)
Trade certificate, bachelor's degree, or university certificate below bachelor's degree	8 (50)
Advanced degree	4 (25)
<b>Ethnicity</b>	
European origin	11 (69)
Other (Asian, Canadian descent, or Caribbean)	5 (31)
<b>Marital status</b>	
Never married	5 (31)
Married or common law	5 (31)
Divorced, separated, or widowed	6 (38)
<b>Employment status</b>	
Full-time or part-time employment	6 (38)
Unemployed, retired, or on disability support	8 (50)
Not reported	2 (12)
<b>Finances at the end of the month</b>	
Just enough to make ends meet	6 (38)
Some or more money left over	7 (44)
Not reported	3 (18)
<b>Length of care provision (years)</b>	
1-2	5 (31)
3-5	4 (25)
≥6	7 (44)
<b>Care recipient condition<sup>a</sup></b>	
Musculoskeletal	7 (44)
Dementia	5 (31)
Cardiopulmonary	8 (50)
Psychological	7 (44)
Neurological	4 (25)
Hepatic, renal, or digestive	5 (31)
Other	10 (63)
<b>Number of care recipient conditions</b>	

Characteristics of family caregivers	Values, n (%)
≤3	10 (63)
≥4	6 (38)

<sup>a</sup>Overlap due to multiple reported conditions per care recipient.

**Table 2.** The characteristics of technology researchers within the study (N=8).

Characteristics of technology researchers	Values, n (%)
<b>Age (years)</b>	
≤35	5 (63)
>36	3 (37)
<b>Assigned sex</b>	
Male	3 (37)
Female	5 (63)
<b>Gender</b>	
Cisgender man	3 (37)
Cisgender woman	5 (63)
<b>Highest level of education</b>	
Some postsecondary education	1 (13)
Bachelor's degree or university certificate below bachelor's degree	4 (50)
Advanced degree	3 (37)
<b>Ethnicity</b>	
Chinese	3 (37)
European origin	2 (25)
Other (Iranian, Arab, or Canadian descent)	3 (37)
<b>Occupation</b>	
Professor	1 (13)
Research staff	3 (37)
Student	2 (25)
Other	2 (25)
<b>Work location</b>	
Research lab	6 (75)
Other	2 (25)

## Procedure

Ethics approval was obtained from the University of Toronto, and all participants provided verbal and/or written informed consent for participation and the use of their information.

Semistructured interviews were conducted in person or over the phone with (1) family caregivers to explore their technology perceptions and (2) technology researchers to examine how they incorporate caregivers' perceptions within the technology development process. Before conducting the interviews, GEKR had no contact with the participants except for scheduling the time and place of their meeting (if applicable). Interviews were conducted in a private room at the University of Toronto, ranged between 45 and 120 minutes, and were recorded using an encrypted digital recorder. Before commencing the interviews,

GEKR explained the purpose of the study and the detailed procedure of the interview to the participants. Open-ended questions were first asked to initiate discussion, and probing questions followed to further enrich the conversation. Upon the conclusion of the interview, GEKR collected a demographics questionnaire from the participant. Remuneration was offered in the form of a Can \$40 (US \$30) gift card delivered via mail, in person, or via email. Field notes were taken by GEKR during and after each interview, which were used as a starting point during our analyses and discussion.

During each caregiver interview, participants were asked about their knowledge of technology related to caregiving; experiences with technology; and how they perceived the influences of sex, gender, and diversity on their technology use. For the interviews, technology was communicated to participants as digital



technologies, such as, but not limited to, mobile apps, medications, and smart home technologies. Nonetheless, participants were given the opportunity to explore other technologies that they were aware of or have used within their caregiving context. During each technology researcher interview, participants were asked about their current research; knowledge of sex, gender, and diversity considerations in caregiving technology; and the extent to which these considerations were incorporated in the technology development process. Full versions of the interview guides for caregivers and technology researchers are provided as [Multimedia Appendices 1 and 2](#).

Verbatim transcriptions were outsourced to a data transcription service (NVivo Transcription; QSR International). Each transcript was reviewed by 2 members of the research team (CX and GEKR) to ensure accuracy. To ensure confidentiality, all participants were assigned an alphanumeric code, and any identifying information was removed from the data corpus during the review of the transcripts.

### Data Analysis

All data from the transcripts were coded and analyzed using the framework method [38], which is a form of thematic analysis designed to identify the patterns across a data corpus and describe participants' experiences and perspectives [39,40]. In addition, thematic analysis has the potential to yield complex and nuanced analyses [39,40]. The framework method comprises the following 7 stages: transcription (CX and GEKR), familiarization with the interview (CX and GEKR), coding (CX and GEKR), the development of a working analytical framework (CX and GEKR), the charting of data into the framework matrix (CX, GEKR, and AS), and data interpretation (CX and AS) [41]. By providing clear steps for following and producing a visually straightforward presentation of patterns and themes, the framework method is helpful for projects with multiple groups of participants, as in our study [41].

NVivo was used to code and manage the coded data. Transcribed interviews were coded independently by CX and GEKR, who noted all caregivers' perceptions and experiences relating to technology from the caregiver interviews. During the preliminary coding of the initial interviews, the authors uncovered additional significant influences on technology perceptions in addition to sex and gender. Furthermore, with the advancement of sex and gender understandings, a paradigm shift was observed in the interpretation of sex and gender within a more comprehensive framework that prioritizes diversity [42]. As such, the authors examined sex and gender in conjunction with other diversity factors that may shape technology perceptions, including, but not limited to, age, socioeconomic status, personal relationships, ethnicity, and culture.

Given the aim of examining how caregivers' perceptions of technology are integrated within the technology development process, the authors discussed their coding processes and created an analytical framework based on the collated codes gathered from the transcripts of both technology researchers and caregivers. This allowed the charting of the data onto the developed framework. During the final data interpretation stage, the authors moved beyond collated codes by sorting them into

categories and refining these categories into themes. Regular discussions between the authors were held during each step of the data analysis, facilitating further exploration of participants' responses, discussion of deviant cases, and agreement on recurring themes.

## Results

### Overview

Tables 1 and 2 describe the characteristics of the family caregivers and technology researchers included in this study, respectively. Among family caregivers, approximately 63% (10/16) were females and 56% (9/16) self-identified as cisgender women. The majority of caregivers were of European origin and were aged  $\leq 55$  years. Family caregivers within our sample have a diverse range of education levels, length of care provision, marital status, and employment status. Care recipients have a wide range of medical condition types, including, but not limited to, musculoskeletal, cardiopulmonary, and neurological conditions. Among the technology researchers, approximately 63% (5/8) were females and self-identified as cisgender women. Most technology researchers work in a research lab and were aged  $\leq 35$  years. Technology researchers within our sample have a diverse range of education levels, ethnicities, and occupations.

Three main themes with subthemes were developed to capture the benefits and challenges of using and adopting technologies for caregiving. The first main theme is that *caregivers see a need for technology in their lives*, and it comprises 3 subthemes: *caregiving is a challenging endeavor*, *technology is multifaceted*, and *caregiver preferences facilitate technology use*. The second main theme is that *relationships play a vital role in mediating technology uptake*, and it comprises 2 subthemes: *the caregiver-care recipient dynamic shapes technology perceptions* and *caregivers rely on external sources for technology information*. Finally, the third main theme is that *barriers are present in the use and adoption of technology*, and it comprises 2 subthemes: *technology may not be compatible with personal values and abilities* and *technology not tailored toward caregivers lacks adoption*. Finally, the influences of sex, gender, and diversity will be discussed with respect to all 3 main themes.

### Theme 1: Caregivers See a Need for Technology in Their Lives

#### *Caregiving is a Challenging Endeavor*

Caregivers describe several difficulties in fulfilling their caregiving duties. Specifically, the need to provide care to their care recipient challenges their ability to meet the needs of both themselves and the care recipients. Caregivers report making significant adjustments to their daily routines to provide care. For example, one caregiver notes that he is no longer able to exercise and his life essentially revolves around caring for his mother as well as his own job (CG03). By putting the care recipient's needs above their own, caregivers face difficulties in striking a balance and often find themselves neglecting their own health despite recognizing the importance of looking after their own well-being. As one caregiver expresses:

*Everyone tells me, "Oh you need to look after yourself; if you look after yourself, you can look after her." Yes, it's all well said and done. [Caregiver 06]*

As a result of these changes entailed while providing care, caregivers were both physically and emotionally burdened by the entire caregiving experience. Faced with the stress of having to take on a lot within a very short time, caregivers experience a drop in their quality of life. The health care system further exacerbates the caregivers' physical burden and is called a *rugged* system that requires a lot of effort to receive assistance. Caregivers highlight a lack of clarity in the information provided and lengthy wait times for services such as home care support.

In addition to the physical difficulties that are experienced, caregiving also puts an emotional drain on caregivers, as CG02 shares:

*I worry about her because she cannot. It's hard for her to defend herself because of the language issue...the memory issue, because she has no power and no credibility. So she's highly vulnerable, so I feel stuck with that and I also feel, I don't know, scared for what's going to come. [Caregiver 02]*

As CG02 takes on the caregiving role, she is confronted with the uncertainties associated with the ever-changing condition of her care recipient. She expresses the fear of what the future holds, a sentiment shared among several caregivers in the study. For others, the emotional drain takes the form of guilt toward the care recipient. In particular, caregivers develop the perception that they are not doing enough and that there is much more that they could do to help their care recipient.

### **Technology Is Multifaceted**

Technology plays a multifaceted role in mediating caregiving challenges. Caregivers describe a wide range of tasks for which they perceive technology to be the most useful. Specifically, caregivers value the convenience of using technology to connect and communicate with loved ones on demand and remotely when the caregivers are away. In a similar vein, caregivers use technologies to obtain up-to-date information and resources, as CG18 shared:

*See for me...Googling stuff is my way of finding out information about my father. So, I'll go on like WebMD, I'll go on the Mayo Clinic, like things like Diabetes Canada, Health Canada [Caregiver 18]*

By using the internet, caregivers are able to save time and effort in obtaining information and redirect this time and effort toward taking care of their care recipients. This not only increases their caregiving efficiency but also opens opportunities for caregivers to engage in self-care activities. From browsing social media to using meditation apps, caregivers see technology as a tool to allow them to relax and unwind amid their hectic schedules, which can also be managed using technology. As CG04 notes:

*As part of Google Calendar, which I use almost conclusively, you can set up a variety of calendars there: your personal, your work. But yeah, there is one for [my care recipient] in there. I mean, she does not see it because she doesn't have a computer really. She tells me about an appointment or whatnot, I go right in then and just type that sucker and make sure to follow up. [Caregiver 04]*

With these internet-based calendars, caregivers can better plan their day and avoid running the risk of missing appointments or scheduling conflicting commitments. Given the need to balance both personal and care recipient needs, these time management tools allow caregivers to appropriately apportion the time between themselves and the care recipient. With regard to care provision, technology has been used to support regular chores and provide a sense of security to caregivers. By enabling caregivers to keep track of care recipients' health status and whereabouts on a regular basis, the use of technologies, such as wearable devices and home monitoring cameras, has been mentioned by the majority of caregivers as a means of alleviating caregiving burden and providing them with a piece of mind.

### **Caregiver Preferences Facilitate Technology Use**

Although technology has its rightful place in helping with caregiving, not all technologies are created equally. Caregivers report looking for specific features and characteristics of the technologies that they are willing to use on a regular basis (Textbox 1). Technologies that do not encapsulate these characteristics are not as well-received. In line with the dominant expectations of technology acceptance and adoption between genders [43,44], a greater proportion of males (within our sample) express a greater appreciation of and a desire to acquire the latest technologies. As one caregiver notes:

*I am like an early adopter of technology. Like I always try to be first among people to get technology. I mean when I got my phone like it was just on the market for like three months before I like I went for it.... [Caregiver 18]*

In contrast, female caregivers in our sample tend to gravitate toward technologies that resemble the items that they previously used. As one female caregiver expresses:

*I think however we can use make technology, design a technology in a familiar way even if there's all kinds of fabulous things going on, you know, a little microchip, put in a huge box just to make them feel like they are using something that they remember using in the past. [Caregiver 01]*

Female caregivers are uncomfortable in acquiring new technologies that are unfamiliar to them, citing reasons such as an inability to unlock the technology's full potential. In addition, older caregivers (aged >55 years) expressed a desire to have technologies that are packaged in a way that is familiar to them.

**Textbox 1.** The technology preferences of family caregivers, technology descriptions, and quotes.

#### Accessibility

- Technology with features that meet specific needs
- Accessibility considerations include hearing, visual, or mobility impairments; communication disorders; and learning disabilities
- Products should include features that speak to these key areas, such as screen readers, speech recognition, adaptive keyboards, and simplified language and instructions.
  - “I think if there was like the ability to have...that personal one on one aspect in terms of the development of the products, it might be beneficial, just because...each person’s spinal cord injury, in my experiences, has been very, very different from the others. So if there was like a customized element to it, it would probably make it more attractive to me to want to even invest the money, even if it was costly.” [CG15]

#### Bang for the buck

- Caregivers consider cost effectiveness, affordability, and value for money while making decisions about purchasing technology.
- Devices should be long lasting, with a widespread availability of parts and software updates for older models.
  - “I know they got to make money to cover the development of the app.... But still, it’s got to be a reasonable fee. Charging a hundred dollars a year, two hundred dollars a year, is going to make it impossible for some people in certain categories and you’re going to end up with one sector of the population able to use it and another sector unable because they can’t afford it.” [CG12]

#### Blast from the past

- Caregivers feel more comfortable using products that look and operate in a way that is familiar to them or resemble something from their background.
  - “It has to be in language because you’re dealing with people who are aging and have some problems with cognition or ability to adapt and to incorporate new technology into their life.... They have to be using something that looks or feels like something from their past.” [CG01]

#### Eco-friendly

- Caregivers cited a preference toward technology that minimizes environmental impact, including products that are recyclable or otherwise reduce carbon footprints.
  - “I think if something was eco-friendly it would make a huge difference. I think people would be more inclined to actually get it because they don’t want to...increase their carbon footprint so that that would be important to me at least.” [CG15]

#### Latest and greatest

- Caregivers would like to be aware of the latest technology and be at the forefront of products that can assist with caregiving.
- A consideration for technology adoption includes the availability of consistent upgrades to the software and hardware.
  - “...What I’d look for in technology, something where software is constantly being upgraded. Like [my] phone upgrades itself sometimes three times a day every, it’s like a new phone. It is literally like a brand new phone once a day.... So I constantly get the technology. It comes through immediately. And that’s what I would look for: upgrading.” [CG03]

#### Multifunctionality

- Due to their busy lifestyles and multiple responsibilities, caregivers have a strong preference for products that can assist with various caregiving tasks simultaneously.
  - “If I was to get the tech, if there was an application my mother could figure out or if there was a caregiver where I could split the screen. Talk to the caregiver on one half of the screen and then the other half still be able to keep a line open for business and whatever I have to do.” [CG03]

#### Readily available training

- Caregivers would feel highly supported with the availability of clear resources that assist with the operation and use of the technology.
- This includes information on how support can be accessed, minimal wait times, and 24-hour availability.
  - “Make all kinds of support readily available. If you have an issue at 3:00 p.m., at 3:00 am. Let make there be like a technical support staff that you can talk to. You know, live chat, email, texting.... So there’s always someone readily available to address your needs.” [CG18]

#### Seamless operation

- To better integrate technology into their lives, caregivers prefer products that require minimal user input and interaction.
- “It is like really...non-invasive, easy for her to...use in the sense. It seemed almost like seamless for her, like seamless technology.” [CG06]

## Theme 2: Relationships Play a Vital Role in Mediating Technology Uptake

### Caregiver-Care Recipient Dynamic Shapes Technology Perceptions

Caregivers report frequently taking the opinions of the care recipient into account when faced with technology decisions. The way technology fits within the caregiver-care recipient space determines how it is being perceived and how likely it is to be adopted within the caregiving context. Caregivers are eager to convey the importance of including the care recipient within the discussion on technology use and uptake. Perceptions toward these devices have been reported by caregivers as being established through a 2-way conversation between themselves and the care recipient. One caregiver taking care of her mother describes the process of acquiring technology to help with caregiving, saying:

*I know with families you have different ability levels as it relates to technology, so I'm thinking if I was sharing this responsibility with my mom and we both wanted to input on something, it would probably [have] to be something fairly simplistic. [Caregiver 08]*

In the caregivers' experience, they consider not only their own level of technology competency but also that of their care recipients, which, on occasion, takes precedence over their own. This has led to instances where opportunities to enhance caregiving using technology are missed, as one caregiver taking care of her mother notes:

*As my mother deteriorated and she was in another city, about like 45 minutes away, I really looked into some technology to sort of bridge that gap because you know – it...could hopefully help me in helping her. Unfortunately, she's very anti-technology because she was born in that time when you [didn't] rely on machines, you [relied] on human beings, so it's been a bit of a struggle to sort of help with the assistance of technology. [Caregiver 04]*

### Caregivers Rely on External Sources for Technology Information

When it comes to identifying resources such as technology to assist with caregiving, caregivers report a disconnect between reality and the support that ought to be available. One caregiver taking care of her mother sums up her experience in obtaining support from the health care system:

*The health, the community, everything else, you know, all of these supports that were “supposed to be there,” you know, none of them are there. So, you know, all – the whole burden – is come up to me. And so, once they look at it, that I'm there, they're basically probably, you know, going to say “Oh she's doing it.*

*So, we really don't need to provide that service now.” [Caregiver 06]*

The process of navigating the health care system is perceived as a burdensome process that lasts for a long time for the caregivers. There are many obstacles in the process of obtaining help, which is mainly caused by a lack of communication between different health care entities. Owing to a lack of support from the public health infrastructure, caregivers turn to their peers for technology information. They highlight the importance of using their social networks and connections as an avenue to gain awareness of technology and support them within their roles. A case in point is CG07, a caregiver who turns to her son, a former computer engineer, for technology-related information:

*We also, well, you know, we have a son who is an electrician. He is actually an industrial electrician. Now, I would ask him to because he was a computer engineer before. Before he did that. So once, you know, he is a computer [person]. [Caregiver 07]*

By approaching these alternative information sources, caregivers are introduced to various technologies through word of mouth and experiences of peers who are in similar caregiving situations. Given similar backgrounds and high levels of rapport, caregivers see these sources as credible and well intentioned, which represents a stark contrast to their expressions of disappointment and doubts with government support and assistance.

## Theme 3: Barriers are Present in the Use and Adoption of Technology

### Technology Is Not Compatible With Personal Values and Abilities

Although caregivers recognize the benefits that technology can bring to their lives, they continue to face a wide range of challenges related to its use, which in turn limits its adoption. Most caregivers do not have extensive knowledge of the types of technology, skills to fully take advantage of its potential, and the ability to troubleshoot any technical issues. When asked to describe his perceptions of the barriers to technology adoption, one caregiver noted:

*The average person does not have the idea that it exists, but if they have any ideas, they have no way of contact. There's no one to contact to see if that could happen. You know, to see if it's even possible to ask if it's out there. I mean there's a lot of things that are out there. People aren't aware of because they don't know [whom] to call. [Caregiver 07]*

As much as technology has evolved and proliferated over the last few years, there remains an information gap between technology development and its intended users. Caregivers do not have the time and energy to actively seek out available technology, especially when there is a lack of a centralized information source or resource for such information. As



previously mentioned, much of their technology awareness is attributed to their interaction with peers, friends, and family. Therefore, for a technology to be adopted by caregivers, its introduction ought to involve the caregivers' social and support networks, such as their physicians, nurses, other allied health professionals, and support organizations. Alternatively, greater emphasis can be placed on the development and promotion of centralized information centers for technology where caregivers can seek out information on available technologies. However, difficulties with technology go beyond the acquisition process. As one caregiver describes her experience with technology:

*When a person is under stress, as we know, they're not able to function as if they didn't have any stress. So, you couple...the illness and then add to it a stress level which leads to a panic mode. And you're unable to do a lot of very simple operations. You get frustrated, annoyed, upset, all of the above, and nothing works very well. [Caregiver 09]*

The worries and exhaustion of caring tasks, the stress of being the caregiver, and the management of the care recipient's illness come together and interfere with the ability of caregivers to operate technology, which has been described as complicated, unintuitive, and difficult to navigate. This creates even more stress and frustration as caregivers struggle to make sense of their devices. As such, a vicious circle is created, which, as CG09 notes, makes caregivers feel angry and annoyed at the technology. In addition, caregivers are also concerned about the security and privacy of their data while using certain technologies. They are reluctant to share information about themselves and their care recipients without knowing who will have access and how their data will be used.

Given these challenges in gaining awareness and using technology, many caregivers return to previously established caregiving routines that do not involve technology, as they are not only familiar with these tasks but also able to preserve a level of in-person interaction, which has been gradually eroded with the introduction of technology. As one caregiver describes:

*You reach out to try to find help. And in real life there really isn't a whole lot of support out there. So yes, you have to turn to technology...which is such an anonymous support and doesn't at the end of the day give you any kind of "Oh good job", no pats on the back. [Caregiver 05]*

From the caregivers' perspectives, technology is limited in providing feedback and validation of their actions. In contrast to the traditional forms of caregiving support, such as peer groups, caregivers perceive that they are unlikely to experience the same level of interpersonal connections through technology use. As such, caregivers will only accept these technologies in situations where they have no other choice, such as in rural areas or when they are at a distance from their care recipient.

### **Technology Is Not Appropriately Tailored Toward End Users**

Caregivers note that the current technology has not been designed with their needs in mind. As one caregiver looking after her mother expresses:

*If they have used someone with the lived experience, they would have designed all of this technology there. People who don't have the lived experience or loved one[s] with the lived experience – so they're doing this in a vacuum [Caregiver 01]*

In addition to lacking a basic understanding of the caregiving experience and perspective, caregivers also perceive technology development to be an isolated process that does not consider the diverse needs and preferences across the caregiving population. In particular, caregivers are concerned about the lack of accommodation in language and cognitive abilities, which can vary widely across individuals. As one caregiver looking after her mother comments:

*It has to be in [their] language because you're dealing with people who are aging and have some problems with cognition or ability to adapt and to incorporate new technology into their life. [Caregiver 01]*

These sentiments are in stark contrast with the perspectives of technology researchers, who highlight the importance of involving caregivers during the technology development process. As such, the conflicting remarks represent a gap between the perceptions of technology researchers during their development process and the reality caregivers are facing.

### **Technology Researchers' Perspectives**

For technology researchers, building rapport and establishing a relationship with caregivers have been highlighted as important steps in the technology development process. Technology researchers recognize the need to involve caregivers during the development process through consultations and workshops. As a technology researcher working in the field of caregiving technologies for the past 5 years describes:

*I involve the people I'm building the technology for in the design and development the whole ways through, like ideation, prototyping, feedback on early prototypes and then efficacy. It's not just building in a vacuum. [Technology Developer 05]*

By involving caregivers in the development process, technology researchers have been able to build a level of empathy with these end users. Not only are technology researchers able to gain a firsthand understanding of the needs and feedback of caregivers, but they also expressed a greater motivation to make a positive impact on their lives by building technologies that fully address their needs and preferences. Furthermore, technology researchers report various efforts they have begun making to take a variety of relevant demographic and sociocultural factors of caregivers into consideration within their own work as appropriate. These factors span physical characteristics, such as ability and body type; socioeconomic indicators, such as education and rurality; and cultural factors, such as family background and language. For example, one technology researcher working on an app that monitors caregiver posture comments:

*That should do. Definitely I think weight is one thing that would affect it. Because generally to people who are thinner would be easier to bend so they just go*



*and bend whenever they wanted. But the people who are a bit more heavy, and have some more weight generally tend to bend less because the posture loads are bigger. [Technology Developer 01]*

By recognizing the diverse range of factors that influence technology use and perceptions, technology researchers have taken a first step in ensuring that the needs of caregivers are being better addressed through technology. Nonetheless, despite acknowledging and incorporating the diverse characteristics among caregivers within their work, most technology researchers within our sample continue to hold assumptions about caregivers' technology needs and preferences. Technology researchers' perspectives tend toward generalizations, grouping caregivers into stereotypical buckets that may not reflect the broad spectrum of needs across diverse populations. For example, when asked about sex and gender influences on technology and caregivers, a technology researcher commented:

*When I'm trying to imagine a community of caregivers, I would think that it's much easier to promote a device across the female population as they probably tend to share more among each other. And if they come up with a good device, [they're] probably gonna tell other people, or if they need support, they are going to ask. Which is like not as good among the male population. And they're probably not going to be that much sharing and then, at the same time, not that much caring about their fellow male care providers. [Technology Developer 07]*

Beyond the conceptual misunderstandings, technology researchers also face challenges in incorporating diversity within their current work, which has been attributed to budgetary constraints. When asked to describe his research process, one technology researcher commented:

*Yeah, funding is always a problem. Yes, I mean I think that's true of everyone right. Like even bigger corporations that have a lot more flexibility in terms of that, they still have a budget to run and they still have a quarter leg and everything else, so you know if money was infinite, then things are pretty much infinitely possible. [Technology Developer 05]*

Owing to a lack of funding and time constraints, technology researchers are often limited in their ability to recruit diverse participants in their development process. In addition, the sheer range of diversity factors, including, but not limited to, age, socioeconomic status, education level, and geographical location, requires the collection of a large number of data points and variables as well as expertise in conducting a sex- and gender-based analysis, both of which add complexity to the already challenging endeavor of technology development.

## Discussion

### Principal Findings

In this first-of-its-kind study to our knowledge that included both family caregivers and technology researchers, we analyzed interviews to gain a deeper understanding of technology

perceptions among caregivers as well as whether these preferences are being incorporated within the technology development process. Through our analysis, it is apparent that caregivers perceive technology as a double-edged sword. Caregivers see technology as a valuable addition to their caregiving routines by opening a range of opportunities for them to enhance their care provision and reduce their caregiving burden. However, caregivers remain wary of the limitations and complications technology use may bring; it is associated with privacy concerns with personal health information; a lack of personalized feedback; and above all, an added frustration when things go wrong. With respect to sex, gender, and diversity, it is recognized that although sex and gender differences are explicit in technology preferences among caregivers, characteristics such as physical and cognitive abilities as well as caregiver-care recipient relationships have an influence on other aspects of technology perceptions, including barriers and uptake.

We demonstrated how caregivers' needs for technology ranged across caregiving contexts. In line with previous literature [7-10], caregivers described caregiving experience as stressful and filled with numerous challenges. Faced with these significant physical, psychological, emotional, and financial burdens, caregivers have sought support from various sources, including health care and governmental organizations. For some caregivers, these groups have facilitated access to resources, including technology to assist with their caregiving tasks. However, for many other caregivers, navigating these organizations proved to be a challenge. Hence, they turn to alternative sources of informal support, which include the use of technology. As such, the findings reveal a need for technology among caregivers driven by not only caregiving burden [45] but also the lack of well-advertised and accessible support within the health care system. This presents a pressing need for the current health care systems to implement changes to improve their reach and, most importantly, streamline their processes for caregivers looking to access support, a move that can be facilitated by using technology.

Similar to a previous study on technology adoption conducted with older adults [46], caregivers have identified a wide range of features and characteristics that they are looking for while considering technology. These factors include not only the physical function and design but also the acquisition process and the after-sales support. Given the diverse range of factors to consider, these preferences highlight the multifaceted nature of caregivers' technology adoption. Further adding complexity is the caregivers' sociocultural backgrounds, which play a significant role in informing their perspectives toward technology. Unlike younger caregivers, we found that older caregivers in our sample tended to express a desire for technologies designed and operated in a way that is familiar to them. A similar observation was also found with gender, with female caregivers in our sample preferring familiar technology. These findings are congruent with previous conceptual work on technology adoption across the general population, which have highlighted age and gender as important factors that shape technology acceptance [47-49].

In addition, our study uncovered the influence of caregivers' external environment in determining technology awareness and uptake. Caregiving is rarely done in isolation, and caregivers recognize the need to consider the views and opinions of their care recipient while considering technology. Such a collaborative spirit has also been reflected in the caregivers' interactions with their informal networks, particularly interactions with peers, family, and friends. Technology has become an integral part of caregivers' conversations with these individuals. As such, these social networks influence caregivers' attitudes toward technology. Specifically, caregivers with a tech-savvy family and friends often described technology in a more favorable tone. In contrast, some caregivers with little or no exposure to technology in their social circles paint a bleaker picture of potential technologies to assist them in their care routines. Given the prevalence of obtaining technology-related information through word of mouth among caregivers, it may be worthwhile to explore alternative methods of technology dissemination, such as social media and caregiving support groups. Information about technology could also be made available by health and social care and nongovernmental organizations providing care and support to people living with various conditions that family caregivers support. For example, the Alzheimer's Society in the Durham Region of Ontario has a selection of currently available technologies that clients can test. These clients can also ask questions to an informed staff member.

Our study also highlighted the existing barriers caregivers faced while acquiring technologies to help with caregiving. Given that most of the caregivers in our study were older adults, it is expected that their views would be congruent with findings from recent work on technology adoption among the general older adult population [50-52]. Specifically, these barriers are characterized by concerns regarding technology literacy, user-friendliness, accessibility, and privacy. Caregivers in this study tend to associate technology adoption with a lack of ability to understand or operate them. As a result, it creates a source of frustration during their interactions with technology, which is further exacerbated by the unintuitive and hard-to-navigate interfaces of both hardware and software. As these older caregivers may not be introduced to technologies until later in their professional careers, they may have a lower level of technology literacy that impedes their ability to adapt or welcome new technologies within their lives. Hence, they may have felt more discomfort by changing their routines and embracing foreign technology, especially if its use requires a substantial learning curve. In addition, the physical and cognitive changes associated with the aging process have limited the accessibility of many technologies. Caregivers often find that technologies are not designed to take account of their physical and cognitive abilities, especially in the area of visual and audio enhancements, which have been suggested to be inadequate or poorly designed for common uses [50]. Finally, caregivers are hesitant to surrender their personal data to connected technologies. Such a mistrust in the data handling processes can be a significant obstacle in the development and introduction of technologies driven by big data analyses.

Given the diverse spectrum of technology needs and preferences among caregivers (Textbox 1), technology researchers need to take steps to better understand and address these when developing solutions aimed at caregivers. Although the researchers report that they recognize the importance of involving and connecting with caregivers to solicit their perspectives during the technology development process, in practice this seems not to be done in any systematic way. The technology researchers in this study have reported several internal and external obstacles that limit their ability to understand caregiver perspectives. For some researchers, the assumptions and stereotypes they make about caregivers and their roles occlude the perceived importance of approaching individuals with actual lived experiences. By holding on to personal opinions without corroborating research evidence, technology researchers have overlooked the importance of understanding the diverse needs within these groups. Being interrelated, sex and gender are not binary constructs but rather on a continuum, which necessitates greater attention and intricacy in disentangling the influence of both concepts in technology perceptions. As social identities, these interrelated concepts also intersect with other social identities, including, but not limited to, race, culture, and age, to create unique personas and perceptions toward technology across the caregiving population. Although they appreciate the value added by caregivers to the product, these researchers struggle to engage the caregivers of diverse backgrounds during the development process. Factors such as funding, time, data availability, and expertise have all been cited as obstacles in the process of incorporating diversity within technology development.

To help overcome these challenges, alternative design approaches, such as user-centered, participatory, and experience design, have been proposed [53]. These approaches provide models for the involvement of end users throughout the development process and, in many instances, place the focus on the user rather than the product [53,54]. However, as general approaches are applied across a wide range of product developments, they may not help in navigating the nuances of technology within the caregiving context and provide guidance on the incorporation of sex, gender, and diversity considerations, which are areas where more training and expertise are needed. As such, future technology projects can consider the assembly of multidisciplinary research teams that integrate members with experience working with caregivers and studying their perspectives from a diversity perspective.

### Strengths and Limitations

To our knowledge, this is a pioneering work in the field of technology perceptions across family caregivers using qualitative research methods. By including the caregivers of persons with various conditions and needs, we have captured and drawn attention to the diverse technology experiences and perspectives across caregiving contexts. With one of the largest samples for such a qualitative study, the findings highlight the multifaceted role technology can play in aiding caregiving while highlighting the drawbacks of these technologies perceived by caregivers. Furthermore, by including technology researchers in the study, we gathered a more holistic understanding of technology in caregiving from its initial development to eventual

uptake by caregivers. In particular, the findings reveal the diversity of caregivers' technology needs and perspectives that will need to be addressed during the technology development process.

Limitations of the study include the rather small sample sizes of technology researchers, which is limited in part due to our criteria for a focus on technologies relevant to caregiving. Future research can be conducted with a greater number of technology researchers to better capture the technology development process across a wider range of technology fields. Although our work includes both caregivers and technology researchers, the 2 main players within the field of caregiving and technology, we recognize that there are other stakeholders such as care recipients, health care providers, and policy makers. As such, future work should consider the perspectives of these stakeholders and explore the interactions between them. This is very relevant for exploring issues related to access to technology, including financial barriers, that caregivers, with their special needs to support their caregiving routines, face. Finally, it is recognized that the findings may not be

generalizable to the entire caregiving population. Hence, it is important for technology researchers to engage their target audiences to learn more about their specific needs and view these results as a guide to the range of worthwhile factors to consider during the development process.

## Conclusions

Family caregivers are turning toward technology to receive assistance in managing the demands of providing care at home. Technology has been helpful in a wide range of caregiving apps; however, there remain several barriers and unmet needs related to its use and uptake. As such, caregivers need support through the course of technology adoption. To provide this support, technology researchers ought to move beyond the current practices of technology development to gather greater knowledge and awareness of caregivers' diverse needs and preferences. Future work should focus on developing tools and resources for technology researchers to support a greater engagement with diverse caregivers such that their input can be used to develop products that better address their needs.

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## Authors' Contributions

CX and AC came up with the study concept and design. CX, GEKR, and AD contributed to the acquisition of data and provided administrative, technical, and material support. CX, GEKR, AC, and AD analyzed the data. CX drafted the manuscript. CX, AD, GEKR, AM, JIC, AA, EN, and AC reviewed and revised the manuscript for important intellectual content. All authors read and approved the final manuscript.

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## Conflicts of Interest

None declared.

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### Multimedia Appendix 1

Semistructured interview guide for informal caregivers.

[\[DOCX File, 19 KB - formative\\_v6i1e19967\\_app1.docx\]](#)

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### Multimedia Appendix 2

Semistructured interview guide for technology.

[\[DOCX File, 17 KB - formative\\_v6i1e19967\\_app2.docx\]](#)

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Original Paper

# Governing Data and Artificial Intelligence for Health Care: Developing an International Understanding

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## Abstract

**Background:** Although advanced analytical techniques falling under the umbrella heading of artificial intelligence (AI) may improve health care, the use of AI in health raises safety and ethical concerns. There are currently no internationally recognized governance mechanisms (policies, ethical standards, evaluation, and regulation) for developing and using AI technologies in health care. A lack of international consensus creates technical and social barriers to the use of health AI while potentially hampering market competition.

**Objective:** The aim of this study is to review current health data and AI governance mechanisms being developed or used by Global Digital Health Partnership (GDHP) member countries that commissioned this research, identify commonalities and gaps in approaches, identify examples of best practices, and understand the rationale for policies.

**Methods:** Data were collected through a scoping review of academic literature and a thematic analysis of policy documents published by selected GDHP member countries. The findings from this data collection and the literature were used to inform semistructured interviews with key senior policy makers from GDHP member countries exploring their countries' experience of AI-driven technologies in health care and associated governance and inform a focus group with professionals working in international health and technology to discuss the themes and proposed policy recommendations. Policy recommendations were developed based on the aggregated research findings.

**Results:** As this is an empirical research paper, we primarily focused on reporting the results of the interviews and the focus group. Semistructured interviews (n=10) and a focus group (n=6) revealed 4 core areas for international collaborations: leadership and oversight, a whole systems approach covering the entire AI pipeline from data collection to model deployment and use, standards and regulatory processes, and engagement with stakeholders and the public. There was a broad range of maturity in health AI activity among the participants, with varying data infrastructure, application of standards across the AI life cycle, and strategic approaches to both development and deployment. A demand for further consistency at the international level and policies was identified to support a robust innovation pipeline. In total, 13 policy recommendations were developed to support GDHP member countries in overcoming core AI governance barriers and establishing common ground for international collaboration.

**Conclusions:** AI-driven technology research and development for health care outpaces the creation of supporting AI governance globally. International collaboration and coordination on AI governance for health care is needed to ensure coherent solutions and allow countries to support and benefit from each other's work. International bodies and initiatives have a leading role to play in the international conversation, including the production of tools and sharing of practical approaches to the use of AI-driven technologies for health care.

**KEYWORDS**

digital health; artificial intelligence; health policy

## Introduction

### Background

The use of advanced analytics in health care may potentially unlock considerable benefits for patients, clinicians, and health and care services. Research shows that analytical techniques falling under the umbrella heading of artificial intelligence (AI) can recognize pathology in medical images [1-4], identify new medicines [5], and predict hospital readmissions [6]. However, the use of AI in health raises safety and ethical concerns that still need to be addressed by appropriate governance mechanisms (policies, ethical standards, evaluation, and regulation) [7]. Safety issues can arise following real-world implementation of AI systems into frontline health care because of their unpredictable performance in diverse settings, unknown human-computer interactions, lack of clarity around accountability and liability, and lack of education or preparedness among the health care workforce [8-10]. Ethical issues regarding AI systems go beyond issues of privacy. Ethical issues can be epistemic, normative, or related to traceability and affect individuals, relationships, groups, society, institutions, and the health care sector [11,12]. Ethical and safety concerns must be *proactively* taken into account for AI in health care to be helpful rather than harmful. Ultimately, one could argue that the responsibility for effective governance of AI technologies—and data, being the main *ingredient* for AI—across the health system and related sectors lies with governments. By doing so, governments help ensure that individuals, society, and health systems capitalize on the benefits of AI technologies while proactively preventing harm or misuse at all levels (the dual advantage of ethical AI) [13].

AI is often embedded in other digital technologies, products, or services (referred to in this paper as *AI-driven technologies*) when implemented in a health care system, for example, triaging chatbots such as *Babylon* or *Ada* [14]. These AI-driven technologies rely on large volumes of data for the purposes of training, testing, and validation. These data are collected, stored, and processed in a complex development pipeline [15]. Not all tasks in each stage of the development pipeline will be completed by the same organization or within the same national borders. Data increasingly flow across national borders, interacting with various technical infrastructures, actors, and data and technology standards [16]. Although some international data-sharing agreements exist, including biobanks and international consortia for medical imaging databases, most data used in developing AI technologies fall outside such agreements [9]. Different countries have different data protection laws [17], different understandings of socially acceptable uses of data, different values, and different ethical standards [18]. Unless monitored carefully, this patchwork of protections potentially enables companies to *ethics shop* or *ethics dump*, that is, to choose the most convenient and least restrictive location to conduct a specific task in the algorithm development

pipeline [19]. For health care, where poorly designed algorithms may cause physical or psychological harm to patients, it is essential that these inconsistencies are addressed and, thus, the risks of ethics shopping and dumping are mitigated; otherwise, countries with weaker data or ethics protections (typically lower-income countries) could become *training and development* grounds for AI-driven technologies that are then deployed *for real* in countries with stricter protections (typically higher-income countries). This pattern has been previously seen in the development of medical and biomedical products in the past and is not only exploitative but also highly unethical and likely to result in significant breaches of human rights.

A degree of international variation in governance approaches to AI for health care is understandable because of national variation. Government investment in AI for health care is partly motivated by the desire to be a world leader in the field, and different governments interpret the implications for the regulatory environment differently [20]. For example, the United States believes that regulation stifles innovation and seeks minimal governance [21]. The United Kingdom believes more firmly in the power of proportionate regulation to facilitate innovation by providing structure and clarity and relies on firmer approaches to governance to maintain public trust in emerging technologies [22]. In addition, different governments have different underpinning social values. In the United Kingdom, for example, values related to individuals, such as empowerment and autonomy, are central, whereas, in China, collective values such as harmony and the collective good are more prominent [23]. Explicit recognition of these differences is important as AI-driven technologies are *sociotechnical systems* and thus often have values embedded in their design. If international variations in social values are not recognized upfront, this could result in harm to individuals and to health care systems if an AI-driven technology with mismatched values were to be exported from country A and deployed in country B. For example, although it might be socially acceptable in country A to use AI-driven technology to highlight how *you* compare health-wise to other people in your social network, this might be considered socially unacceptable—to the point of damaging public trust in the use of AI—in country B. As important as it is to acknowledge differences such as these that arise from a specific cause, it is also important to note that other differences are likely because of the sheer pace of development and lack of time to collaborate and coordinate across the complexities of international variation. Hence, the range of international governance approaches to AI limits this technology's ability to deliver the full range of promised benefits.

A lack of international standardization of governance of AI for health care could create technical barriers to the adoption and realization of benefits from the perspective of interoperability and overarching accuracy. Without standardization of hardware, software, training data sets, and requirements for local adaptation, there is no guarantee that a model trained and

designed in one country or setting will achieve the same level of accuracy (specificity and sensitivity) in another [9]. Furthermore, without standardization of medical device regulations, there is no guarantee that accuracy issues will be identified before deploying AI-driven technology. For example, in China, IBM Watson for Oncology was deployed, having been trained on data from a US hospital, leading to inaccurate and potentially unsafe clinical advice to patients in other contexts [24,25]. These ethical considerations and the ever-widening gap between expectation and reality do little to bolster AI-driven technology investment. This is important as the gap between expectation and reality is considered responsible for the AI winter of the 1970s and 1980s [26].

A lack of policy cooperation can also hamper market competition. Health care systems worldwide will derive optimal benefits from investments in analytics, including AI, if there is an open and competitive ecosystem of innovators building on previous initiatives. The lack of unified standards and the diverse regulatory requirements force companies to develop different AI and other emerging technologies for different markets. Lack of uniformity in these areas makes it harder for start-ups and small businesses to compete with the incumbents [27], which may lead to their acquisition by larger companies. Unless addressed, AI-driven technologies will likely fail because of provider monopolies and vendor lock-in, as has happened with other technology transformation programs [28].

The consequences of a disconnect in AI governance at the international level are serious. This is true of AI governance in general but especially true in the context of health care for 2 reasons. First, health care is a safety-critical area where poorly designed AI-driven tools can cause serious physical or psychological harm to health care practitioners and patients; therefore, all nations should aim for the same high standard of safety, efficacy, and ethics for health AI products, tools, and systems. Second, as the COVID-19 pandemic has demonstrated, globalization has made the health of local populations dependent on the overall health of the global population. In other words, as is often quoted by those rightly calling for international vaccine equity, “we’re not safe, until we’re all safe.” Consequently, calls from academia, policy makers, and industries for greater international policy cooperation are unsurprising. International coordination would help reduce gaps in guidance and regulation, make quality and safety standards visible and clear, and create an accessible common reference for developers and users [29]. As Feijóo et al [20] highlighted, international cooperation has improved welfare and avoided undesirable outcomes in other technology areas. Therefore, it is essential to forestall any ethical, cultural, economic, and political repercussions from increased AI use in health care.

The need for international cooperation in AI governance has led to international initiatives. For example, 2 United Nations agencies—the World Health Organization (WHO) and the International Telecommunication Union (ITU)—established a Focus Group on Artificial Intelligence for Health (FG-AI4H) in July 2018. This group, which is developing a benchmarking process for health AI models and a standardized evaluation framework, could be the hub for further international coordination, debate and consensus on common policies and

standards, and knowledge sharing. Other international initiatives, such as the Global Partnership on AI (GPAI), founded in June 2020, are starting to understand and bridge the gap between AI research and implementation, including developing worked examples of AI use in areas such as the COVID-19 response that should inform public policy development.

Achieving broader international agreement on policies governing AI for health care is a complex undertaking. More work is needed to determine commonalities and differences between governance approaches to AI for health care, identify effective approaches, and share knowledge between countries. Building this evidence base will help policy makers, academia, and industry understand the context, expectations, and drivers of health AI development and implementation.

Importantly, there is no explicit agreement on which governance mechanisms, even once agreed worldwide, will ensure that emerging AI-driven technologies that act autonomously and continually learn and adapt are safe [30,31]. Designing governance for new technology is fraught with uncertainty, and any governance mechanisms will need regular review [32]. Therefore, developing internationally agreed policies will require greater flexibility than previously seen in other international policy contexts. All countries involved will need to work closely together, be open about the policies they are developing, and—when dissent arises—focus on building consensus.

## Objective

The barriers to achieving internationally accepted governance for AI in health care are significant. However, it is an important and exciting problem for policy makers. The opportunities and potential negative consequences are great, and the international community cannot afford to wait. For this reason, we set out to understand the current health AI governance mechanisms that the governments represented in the Global Digital Health Partnership (GDHP; a collaboration of 30 countries and territories and the WHO, with 31 members in total, which was formed to support the effective implementation of digital health) who commissioned this work are developing. We seek to identify commonalities and gaps in approaches, common challenges, and examples of best practices. The expected outcome is a set of policy recommendations serving as the foundation for internationally agreed AI governance mechanisms.

## Methods

### Overview

This research was commissioned by the GDHP, a collection of governments and territories, government agencies, and the WHO, which was formed in 2018 to support the effective implementation of digital health services. The Strategy and Policy team at the National Health Service (NHS) AI Laboratory in England, which is embedded inside the health service’s technology policy arm, *NHSX*, led the research with guidance from a researcher at the Oxford Internet Institute.

When designing a research program, the choice of methods depends on the nature of the research problem [33]. Typically, research focused on central government actions is answered



with methods associated with policy analysis [34], particularly concerning effectiveness, efficiency, ethics, short- and long-term evaluation, and making recommendations [35]. Such methods derived from sociology, anthropology, economics, and organizational management include agent-based modeling, surveys, controlled comparisons, ethnography (eg, participant observation), and discourse analysis [36,37]. Although such applied policy research can provide rich insights, these are methods that are primarily designed to understand the impact of a policy decision that has already been made. Identifying how to implement AI in health care systems safely, effectively, and proethically requires *prospective* policy research that aims to determine what the policy should be [38]. Similarly, health service research, influenced by evidence-based medicine, relies heavily on methodologies using inferential statistics and randomized controlled trials [39]. However, the simplistic assumptions of these methods are criticized for not capturing the complex realities of the health care environment [39].

Instead, what is needed are methods aligned with the complexity theory, which are capable of dealing with individuals within social structures while acknowledging that feedback from individuals can have significant, unpredictable impacts on structuration processes [40], such as the implementation of AI-driven technologies in health care. What is needed is a theory-led [41] recursive approach that does not separate technology and context but analyzes technologies in use to build theory (as opposed to testing). Therefore, we used a mixed methods approach comprising 4 different stages:

1. A rapid scoping review of the academic literature and a systematic review of policy following the method by Gough and Tripney [42,43].
2. A thematic analysis of policy documents published by selected GDHP member countries; the findings from this analysis and the literature review were then used to inform and contextualize the semistructured interviews and the focus group.
3. Semistructured interviews with relevant policy makers from the included GDHP member countries, exploring selected individual GDHP member countries' experience of developing and using AI-driven technologies in health care. The transcripts were analyzed using inductive coding.
4. A focus group with professionals working in international health and technology to discuss the themes and proposed policy recommendations from activities 1 to 3.

Both the interviews and the focus group were used, with the former providing a deep understanding of approaches taken by individual GDHP members and the latter providing the opportunity for representatives from member states to compare and contrast their approaches to data and AI governance for health care. This provided invaluable insight into the different priorities, principles, and values underpinning the different approaches of the different member states.

### Phase 1: Literature Review and Policy Analysis

Neither the literature review nor the policy analysis was designed to produce final outputs in and of itself. Instead, they were conducted in a pragmatic fashion, constrained by time to 2 days of searching and 3 days of reading by 2 separate

researchers each (either LM and JM or AM and KK) to identify the key underresearched policy areas to be discussed in the interviews and later the focus group. The literature review was, therefore, a *scoping* review rather than a systematic review, intended to provide an overview of the nature and extent of existing research rather than a complete overview of the literature in this domain [43]. The limitations of this approach are noted in the *Conclusions* section. Systematic reviews of other areas of data and AI in health care policy do already exist [18,44].

For the scoping review, papers were identified using the search terms (1) *AI and policy* and (2) *AI and regulation* to search Scopus, PubMed, and Google Scholar. Papers that were published before 2015, not in English, case studies of specific algorithms or AI-driven technologies, evaluations of specific algorithms or AI-driven technologies, and AI methodology papers were excluded. Papers published between 2015 and 2020, written in English, focusing on the governance (ethics, policy, and regulation) of AI and data for health care from any of the countries in the GDHP were included. In total, the abstracts of 260 papers were reviewed, and of these 260 papers, 32 (12.3%) were included in the review.

The final 32 papers were read by 2 researchers who analyzed them using an interpretive approach. As such, the codes used to analyze the papers were not selected in advance but rather derived from key concepts in the literature [45].

For the policy analysis, relevant governance documents (ethics, policies, or regulation) from the following countries were searched: Australia, Canada, India, Japan, the Republic of Korea, Singapore, the United Kingdom, and the United States. These countries were a convenience sample, representing countries that had confirmed their participation in the semistructured interview and been nominated by the GDHP as one of the more active members in this space. The documents were identified through (1) a Google search using *[country] health AI, [country] health AI policy, [country] health AI regulation, and [country] covid artificial intelligence*; and (2) exploration of available documents from a country's main health institutions, including health ministries, digital health agencies, medical device regulators, and other medical standard bodies.

As with the literature, documents were read by 2 researchers and analyzed using an interpretive approach to extract the key concepts.

Using the constant comparative method, the concepts extracted from both the literature and policy documents were combined into 6 key themes (codes) used to inform the development of the interview guide and, eventually, analyze the interviews themselves. [Multimedia Appendices 1 and 2](#) contain the themes and interview guide.

### Phase 2: Interviews and Focus Group

A total of 16 GDHP member countries were approached for interviews, of which 10 (63%) were available. The final list of interviewees represented a convenience sample based on responses to a previous NHSX survey on AI use by GDHP member countries [46] while seeking equitable distribution across the globe. Interviews were conducted by 2 researchers,



1 principal and 1 supporting, with translation services provided upon request (used by Uruguay and the Republic of Korea). The following countries participated in the interviews: Australia, Canada, Hong Kong, Italy, the Kingdom of Saudi Arabia, the Netherlands, the Republic of Korea, Singapore, Uruguay, and Wales (see [Multimedia Appendix 1](#) for the discussion guide). The interviews were recorded and transcribed by an independent contractor.

The interview transcripts were analyzed using the 6 key *codes* identified from the literature review and policy analysis. A total of 2 researchers analyzed each interview independently and compared their coding. Where opinions on how to theme a particular statement or quote differed between the 2 researchers, a discussion was had until an agreement could be reached. The final codes and themes for each interview—once an agreement was reached—were written up in a joint spreadsheet. All researchers then collectively reviewed the analysis of all the interviews and condensed the codes into 4 higher-level themes: leadership and oversight, an ecosystem approach, standards and regulatory processes, and engagement with stakeholders and the public. These themes were then used to guide the focus group discussions (more details on each are provided in the *Discussion* section).

A total of 10 participants with expertise in international health and technology organizations were invited to join the focus group. Some GDHP member countries unable to participate in the interviews were invited to attend the focus group to ensure representation from the GDHP membership. A total of 6 participants attended the focus group (with GDHP representation from Estonia, India, and Canada). The participants were split into 2 discussion groups, each facilitated by 2 researchers. The 4 themes mentioned earlier were used to guide the discussion. The participants were presented with statements describing each theme and the logic behind it, and they were then given question prompts around the theme to guide the discussion. As the focus group was conducted remotely, these prompts and statements were shown on the screen using Google Slides. The participants could then either respond verbally or use the web-based whiteboard *Jamboard* and write up their points using its post-it functionality. Where participants did not use these post-its themselves, the researchers noted their points for them. Using post-its enabled connections to be made in near real time, and the participants could give feedback if, for example, 1 of the researchers suggested that 2 separate points might be causally related.

In this way, the focus group was more idea-testing than idea-generating. The group dynamic was particularly important as it allowed for differences of opinion to be discussed openly and used in a generative fashion rather than being seen as an *issue that must be overcome*. It also, as mentioned earlier, allowed the researchers to develop an understanding of the *why* behind key differences in approaches.

Once the focus group had concluded, all research team members conducted a joint synthesis session. The key points under each theme from both groups were discussed and condensed into key summaries from which recommendations were extracted. These are discussed in the following section, which, for the purpose

of focusing on empirical results from *primary research*, primarily focuses on the results from the interviews and focus group.

## Results and Discussion

### Overview

As outlined previously, the focus group and the semistructured interview findings revealed 4 core areas in which international collaboration would be beneficial: leadership and oversight, an ecosystem approach, standards and regulatory processes, and engagement with stakeholders and the public. Notably—as the interview guide indicates—we were anticipating the COVID-19 pandemic to have an impact on the development of AI and data policies in GDHP member states. However, this topic came up relatively infrequently, given the extent to which the pandemic has (necessarily) pulled focus over the past 2 years. Consequently, the following discussion does not make significant reference to the impact of the COVID-19 pandemic, although the potential impact in terms of prioritization for policy makers is noted in the *Conclusions* section. The white paper's complete list of policy recommendations is shown in [Multimedia Appendix 3](#) [47].

Policy recommendations or frameworks for using AI-driven technologies in health care need to cover the entire AI life cycle. The development of AI-driven technologies is an iterative process involving scoping, designing and building, and then deploying the AI-driven technology with continuous monitoring followed by improvement as required (as per the AI lifecycle diagram produced by the Information Commissioner's Office [48]) The interviewees and focus group participants agreed on the need for an international body responsible for working with national representatives to build capability and ensure the implementation of recommended policies for each phase of the AI life cycle.

### Business and Use Case Development

Developers of AI-driven technologies (the supply) are usually not integrated into national health care systems and, even with demand signaling, may not know the areas of greatest need (the demand). Therefore, national governments and international consortia are responsible for clearly outlining the needs of the global, national, and local health care systems that could derive maximum benefits from AI-driven technologies. The participants in this study emphasized that the success of AI-driven technologies hinges on demonstrating their value, effectiveness, and safety in a clinical setting and across the broader health system. The interviewees advocated setting a vision for using AI-driven technologies in the health system at a national rather than state or provincial level, with opportunities for local interpretation and implementation. They stressed that high-level strategic vision should reflect areas within a country's health system where AI-driven technologies could most benefit the population's health. Similarly, Wirtz et al [31] noted that the best way to prevent market failure and harm to society when governing AI is to steer the market toward the greatest need to maximize efficiency. The participants in this study argued that such stewardship would bring a clear focus to the energies and funding for AI-driven technologies in a health system and help

overcome barriers currently experienced by developers in translating AI research into practice.

However, the participants emphasized the importance of setting a strategic direction at the right level of abstraction [49]. International agreement on the strategic direction is indicated in some instances, such as during the COVID-19 pandemic; however, in other times, national- or local-level needs should be identified. Furthermore, even when the strategic direction is set nationally, the participants advocated for flexibility in the national vision to allow for regional interpretation and adaptation for accuracy and context-specific implementation.

One issue that arose in this study that could affect the support and resourcing of health AI development was the current lack of understanding regarding what AI is and its relevance to health care. Misconceptions included AI being autonomous (instead of existing as a decision-support system), its applicability only to medical imaging, and confusion regarding its data requirements. Misconceptions may derive from confusing and hyperbolic depictions of AI in the media [50]. Suggestions for overcoming these difficulties included shifting the focus from theoretical and exploratory conversations on AI for health care to tangible examples of AI-driven technologies already used in health systems. Use cases of AI-driven technology in health systems are most powerful when they satisfy otherwise unmet needs, improve user experience, and improve health outcomes. For example, the potential for AI uses in medical imaging to support the diagnosis of COVID-19 and assess its impact on people's lungs illustrates the power of a needs-based approach with an actual use case. Several countries reported improved funding, access to and aggregation of health data, and political and public will for large-scale deployment of AI-driven technologies during the COVID-19 pandemic. This saw countries, including the United States, the United Kingdom, and Japan, set up national COVID-19 chest imaging databases specifically for AI development.

### Design Phase

As AI-driven technologies for health care can pose significant risks to patient safety, *hard* governance mechanisms, such as internationally accepted standards and regulations, are needed. The aspects of the AI life cycle that warrant more stringent control prompted lively discussions among the participants in this study. They agreed that new regulations should be limited and that new regulations should only be introduced if current medical device regulations are not fit for the purpose because of the unique features of AI-driven technologies.

A development stage approach to policy development should ensure that each component in developing AI-driven technologies within the AI life cycle receives equal consideration. For example, the start of the AI life cycle requires internationally agreed standards for access to aggregated data sets by researchers and developers. Standards could encompass secure trusted research environments and privacy-preserving techniques such as differential privacy [51]. Creating international standards for accreditation and access to research environments would improve cross-border access to health data without compromising data security. Ensuring health data are secure and deidentified creates possibilities for linkage with

other data sets within the international community, for example, data sets on air quality, to provide insights into wider determinants of health. The other end of the pipeline requires policies for validation and evaluation services (including access to expertise), the provision of synthetic data sets, and the creation of test beds in various sites. These policies would advance research beyond the initial stages and help build health care providers' trust in the accuracy of AI-driven technologies regardless of their origins. It would alleviate blind spots in AI governance. Taking inspiration from Crawford and Calo [52], AI governance requires a social systems approach, as each stage involves complex sociotechnical relationships that need careful consideration.

A key topic considered by the participants in this study was not *what* policies, standards, and regulations were required but *how* they should be developed. The participants stressed the need for transparency regarding the evidence and rationale for the approval of AI-driven technology or other emerging technology. Decisions in the approval process should be made public and disseminated to various stakeholders (including patients, the broader public, health care professionals, academics, industry representatives, and local government actors). The participants strongly favored active stakeholder involvement in the development of governance mechanisms. According to Kemper and Kolkman [53], meaningful transparency, which aids external critique and is not merely *ethics washing*, is crucial for maintaining stakeholders' trust. Moreover, Aitken et al [54] demonstrated that genuine stakeholder involvement ensures that the opinions of patients and the public form part of the solution instead of creating an additional problem.

However, several participants reported struggling to achieve successful engagement activities. The engagement methods mentioned included formal consultations, research with specific groups, and direct product feedback. The participants felt that the heterogeneity of the population limited meaningful public engagement. The most vocal groups and the most digitally literate groups might monopolize consultations. Canada (a country that prioritizes public engagement) noted the following:

*It's a fairly small portion of the population that can meaningfully contribute to a conversation like that so, frankly, a lot of that engagement ends up being sort of the loudest voices or even the folks that are sort of regularly around the table.*

Conversely, other GDHP countries expressed indifference or did not prioritize public engagement. This may reflect diverse cultural contexts.

### Training and Test Data Procurement

Training effective AI algorithms requires data of sufficient quality, adequate in size, and representative of the intended population. To aggregate data available nationally (or regionally if more appropriate), countries must first ensure appropriate legislative and policy frameworks for sharing and linking data across often disparate systems. An appropriately secure environment for data storage is required alongside agreed processes for data extraction from this environment and for analysis within it. There was broad awareness of needing to

meet these data infrastructure requirements across the countries in this research, with varying levels of maturity found.

Hong Kong's Data Collaboration Laboratory, operated by the Hospital Authority, provides an excellent example of an initiative that achieves access to high-quality data. Data collection began in the 1990s when Hong Kong first established infrastructure to create comprehensive (covering a large section of its population) and deep (covering patient history over decades) repositories of clinical information. The Health Authority Data Collaboration Laboratory (HADCL) provides the policies and infrastructure that enable access to the data for AI model training and development. The HADCL anonymizes and stores a large subset of the Hospital Authority data, including demographic, diagnostic, test, radiological, and other categories of clinical data. These data are stored at a physical location and are only accessible on-site. The on-site infrastructure includes a large data computational platform (with sufficient levels of compute) for state-of-the-art data storage, processing, access, governance, security, and operations. Researchers apply to access the data and computational power, and data-sharing agreements ensure that the HADCL has the rights of use if the AI models developed are clinically useful. Having HADCL rights of use ensures that a path to procurement and impact exists for the models. Previous models, such as an AI model scanning hip x-rays for fractures, are under consideration for wider clinical deployment.

Given the sensitive nature of health data [55], patients and the public are unlikely to trust AI-driven technologies without guaranteed data protection from end-to-end development pipelines. Safeguarding health data requires security and commercial protections to ensure that the fair value of data assets is realized. Safeguards are an essential aspect of public-private data partnerships, particularly those with large multinational companies. As citizens' health data move across borders, coherent international plans for the protection and value return of data assets are crucial. These protections will help maintain national, public, and health care professional support for AI-driven technologies in health care. Other industries recognize the importance of trust in the security, provenance, and accuracy of a product. Many industries use transparent, standardized documents, called *declarations of conformity*, to describe the lineage of a product along with the safety and performance testing it has undergone [56]. Declarations of conformity do not yet exist for AI in health care products.

## Building

Participants from across the GDHP were frustrated by barriers to translating research into practice (ie, deploying AI models from a laboratory in clinical settings). The difficulties faced included lack of funding, lack of skills, and poorly defined processes and regulations. The few suggestions on overcoming these barriers focused on greater alignment between supply and demand for AI-driven technologies through oversight of the entire AI life cycle.

The English National COVID-19 Chest Imaging Database (NCCID) set up by NHSX illustrates an effective supply and demand connection. The NCCID is a centralized database containing x-ray, computed tomography, and magnetic

resonance imaging images from patients in hospitals in the United Kingdom (COVID-19 positive and negative). The project's aim was 3-fold: (1) to provide training data to researchers, start-ups, and commercial companies to develop AI models capable of recognizing COVID-19; (2) to test the models against another section of the database reserved exclusively for validation; and (3) to select and deploy the best-performing models in clinical settings to assist frontline clinicians' response to the COVID-19 pandemic. The NCCID data are provided for free to developers to facilitate the deployment of AI models into practice. To ensure that this commercial arrangement benefits the NHS and the public, developers using the NCCID must provide their AI models for free to the NHS for its use during the pandemic. This approach should enable the market (the supply) to meet the pressing needs of the UK health system and its patients (the demand) while benefiting both parties (ie, the NHS and developers).

The NCCID is also an example of concurrent data policy and AI policy development. AI-driven technologies require access to data; therefore, streamlining policies from these 2 domains is essential to drive AI development and effective governance. However, many participants in this study raised concerns about the disconnect among the policy domains of data, AI, and less-complex digital health products (such as apps) apparent in their respective countries. The participants considered the disconnect among different but highly interrelated policy domains at the national and international levels as problematic. They proposed an ecosystem approach to policy development to ensure all policies relating to the entire AI life cycle were consistent and joined up.

The participants in this study were keen to build in-house technology workforces. However, they currently rely heavily on collaboration with private industry partners to deliver on the promises of AI-driven technologies, including progressing early-stage research into deployed products in clinical practice. Embedding technical skills within a health system was thought to offer 2 advantages. First, it would drive further innovation. Second, it would facilitate better integration of clinical expertise into digital health design, digital teams, and deployment processes.

In addition, international leadership could help alleviate government nervousness about public-private partnerships by supporting mechanisms for external scrutiny of private industry partners, standardizing terms for sharing and accessing patient data, and securing fair commercial terms between public and private partners. Ultimately, international policy collaboration was considered as a means of protecting the interests of public health systems faced with increasing involvement from private technology companies. Just as policy developments should consider all stages of the AI life cycle, so too must policy makers consider all potential actors.

## Testing and Validation

Larson et al [57] suggested that the existing European medical device law was deficient in 6 respects: (1) conflation of the diagnostic task with the diagnostic algorithm, (2) superficial treatment of the diagnostic task definition, (3) no mechanism to directly compare similar algorithms, (4) insufficient



characterization of safety and performance elements, (5) lack of resources to assess performance at each installed site, and (6) inherent conflicts of interest. The interviews and the focus group in this study focused on points 3, 4, and 5. Regarding algorithms, the need for more flexible, appropriate, and adaptable mechanisms for proving the efficacy of AI-driven technologies in health care, other than randomized clinical trials, was flagged. Testing and validation should include mandating open reporting of results and algorithmic code for error checking and assessing clinical benefits and cost savings over the status quo rather than effectiveness alone. The participants felt that showing the value of AI-driven technologies in health care alongside conventional methods was key to garnering further support for their development and use. However, lack of skills, capabilities, and knowledge within local regulator workforces was considered a significant barrier to remediating current and future gaps in medical device regulation.

There was a lack of consensus in this study on the confines of AI regulation and where responsibility for governance lay as a result of overlaps in data use and health care products. National governments' burdens could be reduced if the skill gap was filled or made superfluous through policy development at an international level. For example, national governments could assume responsibility for local adaptation of international frameworks. This would allow for counterchecks of products certified for use in comparator countries. Cohesion across international regulatory frameworks was considered a primary benefit of international policy collaboration. It could help redress the imbalance of regulatory experience and skills between nations and support low-resource or less digitally mature health systems in confidently and safely adopting AI technologies. Importantly, counterchecking standards must not be based on the lowest common denominator [27].

The United States and Japan have already embarked on updating their regulatory mechanisms to deal with the unique aspects of AI-driven technologies. Both countries are considering workflow changes for adaptive AI models. Unlike locked algorithms, adaptive algorithms can continuously learn and change their performance even after market rollout (eg, improving overall performance or adapting to new use conditions). AI-driven technologies can transform health care delivery as deployed models perform better over time and receive new information. However, existing regulation approaches are not optimal for regulating adaptive AI, as most performance changes require re-evaluating the entire AI model.

The US and Japanese approaches to workflow modification allow AI developers to articulate prospective future changes to an algorithm through a *predetermined change control plan*. A predetermined change control plan would include information about the types of intended modifications (eg, changes to the model's performance, input data, and intended use) and their implementation. The regulator would evaluate the predetermined change control plan as part of the standard premarket evaluation of the AI-driven technology. Subsequent changes to the AI model postmarket deployment could be evaluated against the approved change control plan; hence, implementing preapproved modifications would be straightforward. The US Food and Drug Administration's discussion paper on regulatory framework

modification labels this strategy part of a Total Product Life Cycle regulatory approach. It is specifically designed for AI-driven technologies. The Total Product Life Cycle approach also evaluates the manufacturers of AI-driven technologies to ensure that they have established quality systems and abide by good machine learning practices governing data acquisition, model training, tuning, testing, and model transparency. The international community would do well to evaluate this approach's effectiveness and test it on a larger scale.

## Deployment

Collaboration and multidisciplinary working by policy makers, technologists, health care professionals, and academics are needed to ensure appropriate expertise throughout the AI life cycle, especially during deployment of the technology into practice. Supporting research and implementation collaborations at a local level (eg, within a specific hospital or city) would create local showcase projects of AI research translated into practice. The design and execution of AI-driven technology trials require multidisciplinary approaches to assess clinical efficacy, comparative benefit and cost-effectiveness, and impact on clinical pathways and practice. Guidance on good trial design and reporting is now available with the AI-specific extensions to the CONSORT (Consolidated Standards of Reporting Trials)–AI and SPIRIT (Standard Protocol Items: Recommendations for Interventional Trials)–AI guidelines [58].

The lack of international coordination for the governance of AI in health care may limit its adoption because of issues of trust. There is consensus that trust is a core condition for successful innovation in digital health, including AI [59]. Clinicians are unlikely to trust the evidence of AI efficacy if they cannot scrutinize it and verify its origins. Clinicians will demand that AI for health care meet established standards of evidence and safety from familiar regulatory bodies.

Half of the GDHP member countries in this study highlighted apprehension among their clinical communities regarding AI-driven technologies in health care. The main reasons for clinicians' apprehension were concerns about data quality and privacy, a poor understanding of AI, fear of redundancy if technology replaces health care professionals, and anticipated extra work if AI-driven technologies disrupt existing workflows. Therefore, GDHP members recommended that international collaborations develop a comprehensive AI syllabus for clinicians. An AI syllabus should include a definition of AI, its use in digital health technologies, current examples of AI-driven technologies in health care (including clinical and operational pathways), and why AI-driven technologies are used (including benefits to end users and health systems compared with conventional methods). They noted that an international review should consider ways to incorporate this education into medical training rather than relegating it to a continuing professional development topic.

## Monitoring

The oversight of and strategic vision for AI-driven technologies in health systems varied considerably among the GDHP member countries in this study. All countries reported having an organization or body responsible for digital health and, therefore,

AI integration into digital health technologies. However, the organization of these bodies and their roles or responsibilities was inconsistent. The remits of these organizations variously included facilitating research, overseeing procurement, setting strategy, regulation, deployment of technologies, and a combination of these aspects. The use of statutory powers by countries varied from an advisory capacity to influencing legislation and standards. The variation in oversight mechanisms reflected significant differences in the stage of AI technological development; some countries in the early stages of developing AI-driven technologies in health did not share the imperative for strict oversight.

Improving national oversight procedures will support improved collective intelligence at an international level. Establishing such reporting and knowledge-sharing mechanisms would mean countries could access safety information about AI technologies that they are considering or have started using, bringing earlier identification of potential harms or risks.

## Conclusions

AI-driven technology research and development for health care outstrips available AI governance globally. International collaboration and coordination could facilitate comprehensive and coherent AI governance and enable countries to support and benefit from each other's work. The discussed policy recommendations aim to reduce the major governance barriers to implementing safe, effective, and ethical AI-driven technologies across the AI life cycle. Testing and adopting these recommendations by GDHP member countries would help develop common ground and a core set of policy recommendations for endorsement by the GDHP and other international bodies.

Organizations and initiatives such as the FG-AI4H of the WHO/ITU, the GDHP, and the GPAI could lead international conversations and produce practical tools for implementing AI-driven technologies for health care, including across borders, and indeed have started to do so, as indicated by the recent publication of the guidance document *Ethics and Governance of Artificial Intelligence for Health* from the WHO [60]. However, there is still a long way to go, and there are many other opportunities to define accepted practices for evaluating the efficacy and safety of health AI (something that has been pursued by the G7 during the United Kingdom's 2021 presidency), invest in and share educational materials (for the public and health care professionals), and create international benchmarking standards for AI models in set contexts (currently under consideration by the FG-AI4H of the WHO/ITU).

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Convening these discussions and working groups at a practice level (ie, with people developing AI-driven technologies and those leading implementation in clinical pathways) is beneficial in bridging cultural and political divides. It focuses the conversation on shared technical challenges and successes of health AI and helps create a common ground and shared purpose, which is fundamental to international coherence. It is, of course, important to recognize that convening these types of discussions and encouraging GDHP member states to direct resources toward data and AI policy will be difficult in the wake of the COVID-19 pandemic, which will, undoubtedly, have left all with other pressing priorities.

It is also important to acknowledge the limitations of this particular research, as no research is without flaws. Specifically, although the literature review was used to inform the interview guides and contextualize the discussions and analysis, the pragmatic approach taken means that there were undoubtedly gaps in the authors' knowledge at the time of designing the interviews and analyzing the results. Scoping reviews also typically lack rigor and do not involve a quality assessment. Therefore, there is a risk that the included papers were based purely on their *existence* rather than their quality, and this could have resulted in a skew in the topic selection for the interviews and focus group [43]. In addition, the convenience sampling method used to identify interview participants was sufficient for starting a conversation about this important topic but does mean that a relatively narrow range of opinions was gathered from GDHP member states, and there could be elements of bias in the findings as a result. These limitations and challenges in the wake of the pandemic mean that this paper and research should be viewed as an initial investigation—the starting point for further research rather than the conclusion.

The next steps will include conducting a more critical analysis of the emerging policies related to data and AI in health care from England and international comparators, analyzing how these policies compare to the *ideal* set out in the literature, and hosting further discussions with policy makers and subject matter experts as to how any gaps between reality and the ideal might be closed. Hopefully, through these conversations, the more strategic implications for global public health of investing in data and AI policy will become clear, providing a justification to GDHP members—and nonmember states—wishing to invest time and resources in these areas *even* in the wake of the COVID-19 pandemic.



## Authors' Contributions

KK conceptualized and supervised the project and was responsible for securing project resources, data curation, and project administration. KK and LM designed the project methodology. KK, JM, LM, and AM contributed to the delivery and formal analysis of the original research. JM, LM, and KK wrote the first draft; all authors reviewed and edited subsequent drafts. LM and KK edited the final draft. JM is the corresponding author. KK is the guarantor. All authors have seen and approved the final version.

## Conflicts of Interest

JM is in receipt of a Wellcome Trust Doctoral Studentship. She has also received research funding from Google, Vodafone, and the Digital Catapult. No funders were involved in the design, development, and writing of this research and therefore, no conflicts of interest are present. AM is also funded by the Wellcome trust. LM, KK, and IJ were all employed by NHSX at the time of writing.

### Multimedia Appendix 1

Semistructured interview guide.

[\[DOCX File, 40 KB - formative\\_v6i1e31623\\_app1.docx\]](#)

### Multimedia Appendix 2

Framework for the thematic analysis of semistructured interviews and focus groups.

[\[DOCX File, 44 KB - formative\\_v6i1e31623\\_app2.docx\]](#)

### Multimedia Appendix 3

Policy recommendations from the white paper.

[\[DOCX File, 21 KB - formative\\_v6i1e31623\\_app3.docx\]](#)

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## Abbreviations

- AI:** artificial intelligence
- CONSORT:** Consolidated Standards of Reporting Trials
- FG-AI4H:** Focus Group on Artificial Intelligence for Health
- GDHP:** Global Digital Health Partnership
- GPAI:** Global Partnership on AI
- HADCL:** Health Authority Data Collaboration Laboratory
- ITU:** International Telecommunication Union
- NCCID:** National COVID-19 Chest Imaging Database

**NHS:** National Health Service

**SPIRIT:** Standard Protocol Items: Recommendations for Interventional Trials

**WHO:** World Health Organization

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Original Paper

# Understanding Perceptions and Practices for Designing an Appropriate Community-Based Kangaroo Mother Care Implementation Package: Qualitative Exploratory Study

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## Abstract

**Background:** Low birth weight (LBW) is a common outcome of preterm birth, which increases the risk of an infant's morbidity and mortality. Approximately 20 million infants are born with LBW globally per year. Since a significant number of births in Pakistan take place at home, it is important to focus on the use of kangaroo mother care (KMC), the practice of skin-to-skin contact, in communities to prevent neonatal mortality and morbidity.

**Objective:** We employed a formative research approach to understand the context of communities and facilities with regard to neonatal care and KMC practice. The broader aims were to inform the design and delivery of culturally appropriate platforms to introduce KMC in communities, and develop effective recruitment and retention strategies of KMC in rural areas of the Dadu district in the Sindh province of Pakistan.

**Methods:** We conducted focus group discussions, in-depth interviews, and key informant interviews with families of LBW babies, community members, health care providers, and hospital administrators to identify barriers, enablers, and a knowledge base for KMC interventions.

**Results:** Newborn care practices in communities were found to be suboptimal. The community was generally unaware of the KMC intervention for the care of LBW babies. However, facility health care providers, the community, and family members were willing to provide KMC to improve outcomes. We found significant support from the community members and health care providers for KMC practices. Mothers were also ready to provide intermittent KMC. The administrative staff at the hospitals accepted the introduction of KMC practices for LBW babies.

**Conclusions:** KMC as a method of treating LBW babies is widely accepted in the community. This formative research provides strategically valuable information that will be helpful for developing effective implementation strategies by identifying common community practices for LBW babies, along with identifying the barriers and enablers to KMC practice.

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## KEYWORDS

kangaroo mother care; low birth weight; neonatal mortality formative research; Pakistan; newborn care

## Introduction

The neonatal period (first 4 weeks of life) is the most vulnerable time for child survival. Approximately 2.4 million infants die

within the neonatal period globally every year, with most deaths occurring in low-and middle-income countries (LMICs) [1,2]. The leading cause of deaths in neonates is attributed to complications that arise from preterm birth [3]. Preterm birth



has long-term effects on growth and neurodevelopment functioning, including an increased risk of cerebral palsy, impaired learning and hearing, and visual disorders [4]. Furthermore, preterm birth is associated with high economic and social costs due to the educational and medical needs of the neonate [3]. Low birth weight (LBW), defined as a birth weight <2500 g, is a common outcome of preterm birth, which increases the risk of an infant's morbidity and mortality [5]. The prevalence of LBW infants in developing countries (16.5%) is more than double that in developed countries (7%) [6].

Currently, Pakistan's neonatal mortality rate lies at about 44 deaths per 1000 live births [2]. The prevalence of LBW reported in various studies in Pakistan is in the range of 19%-30% [5]. Factors associated with LBW include the high prevalence of home-based deliveries in the absence of skilled birth attendants. Approximately one-third (34%) of all births in Pakistan take place at home, with a higher percentage of home-based deliveries in rural areas (41%); thus, it is important to focus on appropriate practices for LBW care in communities and rural settings. [7].

A newborn, particularly one born preterm or with LBW, is vulnerable and requires critical care. This challenge largely looms in LMICs where the rates of preterm and LBW babies are higher and the resources available for their care are scarce. Many health facilities are characterized by a lack of staff availability and training, along with ill-functioning equipment with nonexistent neonatal care units, which ultimately result in higher neonatal mortality [8,9]. Furthermore, essential neonatal care for small babies requires incubators and skilled personnel, which are unaffordable and inaccessible by most of the population in underdeveloped regions [10-12].

In response, the kangaroo mother care (KMC) method for the care of preterm and LBW babies was developed over 30 years ago, which is practiced through continuous and long-term skin-to-skin contact between the baby and an adult [13]. KMC is a gentle and effective method of caring for preterm and LBW babies, designed to increase the contact between parents and their infant, and has shown a 40% improvement in survival of preterm infants [14,15]. Advantages of KMC include the reduced risk of hypothermia [16]; improved rate and duration of breastfeeding [17]; early initiation of breastfeeding [18]; sustenance of the infant's physiological parameters, including respiratory rate and heart rate [19]; and improved mother-infant attachment and bonding [20]. Furthermore, KMC may improve an infant's head circumference growth and contribute to weight gain [21]. KMC also reduces parental distress related to their infant's well-being due to constant attachment [22].

The clinical efficacy and health benefits of KMC have been established in multiple settings of developed and developing countries. However, despite the evidence of its benefits, the uptake and implementation of KMC are limited in many developing countries, including Pakistan. Therefore, we conducted a formative assessment to evaluate the barriers and enablers associated with KMC uptake among families, communities, and health services related to newborn care practices in a rural area of Pakistan. These perspectives can help

to identify culturally acceptable ways of implementing KMC in the health facilities and communities of this region.

## Methods

### Study Design, Participants, and Setting

A qualitative exploratory study was conducted using focus group discussions (FGDs), key informant interviews (KIIs), and in-depth interviews (IDIs). Study participants included community members (mothers, grandmothers, and fathers), health care providers, lady health workers (LHWs), lady health visitors (LHVs), traditional birth attendants (TBAs), nurses, pediatricians, gynecologists, and *taluka* (subdistrict) hospital administrators. LHWs are first-line community health workers employed by the government to provide maternal newborn child health at the primary-care level and in the community. They provide an essential link between the formal health system and the community. LHVs are a trained cadre that are stationed in the facility and are responsible for conducting deliveries, recognizing high-risk pregnancies, and providing appropriate referrals. They are also trained in immediate newborn care. Mothers were selected for interviews if they had a newborn under 6 months of age and were residents of the project area. LHVs and nurses interviewed were required to have worked in the project area for at least 5 years. For FGDs, family members were required to have a baby in their household with a maximum age of 2 years. The study was conducted in three *talukas* (Nehar, KN Shah, and Johi) of the rural district Dadu in the Sindh province of Pakistan.

### Development of Interview Guidelines

The core research team comprising the principal investigator and coinvestigators developed the interview guidelines. The guidelines were developed in English and translated into the local language. The conceptual framework used for formulating the guidelines was adapted from a KMC formative study conducted in India [23]. Findings from a situation analysis of KMC in Pakistan were also integrated for developing key themes and questions [24]. The guidelines were pretested to check the clarity, accuracy, and flow of questions and probes, and reviewed in a 3-day-long workshop by experts in informative research from Aga Khan University, Pakistan. The experts included anthropologists, study investigators, physicians, and sociologists.

The interview guides were designed to evaluate the knowledge and perception of the community about KMC practices. They contained questions about the community's understanding of preterm birth complications, the prevailing beliefs and traditional practices regarding newborn care in general, and care of LBW newborns in particular. Questions about existing social support systems for mothers of newborns, the willingness of mothers to provide KMC, support available to mothers practicing KMC, and the willingness of community members to become KMC champions were also included in the guides. The hospital administrators of *taluka* hospitals were also asked about the potential role of health care providers in implementing KMC and suggestions for KMC implementation at the facility level.

## Pilot Testing

Before pilot testing, two training sessions were conducted for the data collectors. One was facilitated by a neonatologist well-versed in KMC. This training involved orientation to the concept of KMC and demonstration of the KMC technique. Participants were educated on various wraps and methods used to hold the baby and establish skin-to-skin contact. A practice session on the KMC position was carried out using a doll. The second training was carried out in a 3-day-long workshop on formative research methods by the core study team.

Following the training, pilot testing was conducted in a village with similar socioeconomic and demographic characteristics as those of the project area. Six mothers, one male community member, and one grandmother participated in the pilot. The results from the pilot were incorporated to modify the study instruments. Moreover, the KMC technique was demonstrated to nine mothers and one grandmother to evaluate the experience of securing the baby in the KMC position with the local KMC wrap.

**Table 1.** Details of qualitative assessments by community and health services members.

Qualitative assessment type	Community members	Members of health services
Focus group discussions (n=18)	Mothers (n=7), grandmothers (n=4), fathers (n=4), community elder (n=1)	Lady health workers (n=3)
In-depth interviews (n=9)	Mothers (n=2), grandmothers (n=2)	Nurses (n= 1), lady health visitors (n= 4)
Key informant interviews (n=8)	Not applicable	Pediatrician (n=1), gynecologist (n=1), traditional birth attendants/community midwives (n=3), taluka hospital administrators (n=3)

Verbal consent was provided by the study participants and recorded on tape. All FGDs, KIIs, and IDIs were conducted in Sindhi, the local language of the area, and were tape-recorded. The recordings were also transcribed in Sindhi. Notes of all sessions were taken by a note-taker in Sindhi.

A video of KMC being practiced was shown to all participants and their reactions were observed. The video was recorded and developed by a professional firm that was outsourced. A Term of Reference was developed for this purpose. The video was 10 minutes long and was recorded in the native language. The core study team, including the principal investigator and coinvestigators, developed the storyboard for the video. The conceptual model was based on the hypothesis that the adoption

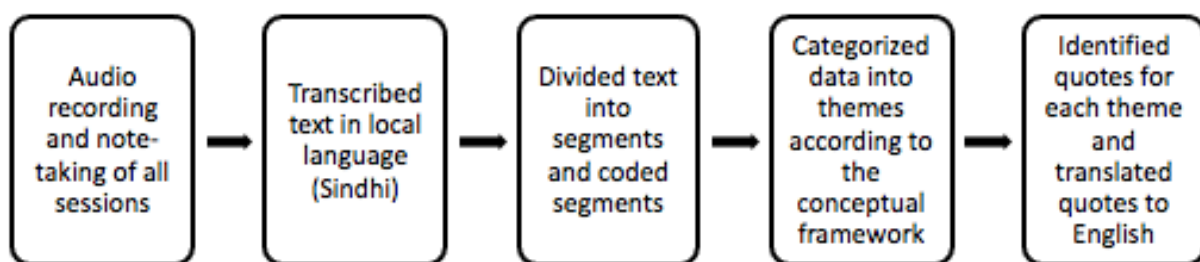
## Data Collection

Information was collected with the help of six data collectors, including two LHV's and four social scientists with a proven qualitative research background. LHV's are typically the first point of care during the reproductive health period. They have a formal education up to grade 10 and undergo a 2-year training program that comprises 1 year of training in midwifery and 1 year in pediatrics and tropical diseases. LHV's conduct deliveries at the household and facility levels and provide immediate newborn care. The social scientists had master's degrees in social sciences. All of the data collectors were from the same community and were fluent in the local language. Data were collected between August and November 2017.

Details of qualitative assessments are provided in Table 1. Each FGD comprised 8 to 10 participants and lasted 60 to 90 minutes. KIIs lasted for 35-40 minutes each, which were conducted under the aid of a semistructured topic guide. Additionally, nine IDIs were conducted with mothers, grandmothers, and LHV's/nurses.

of KMC by mothers and by the community at large would be predominantly influenced by factors at different levels: individual and community levels, health care provider, supportive environment, social and cultural factors, and existing practices. The script was originally written in English and then translated into the local language by the study investigators well-versed in both languages. The participating performers in the video were a mixture of professional actors and community members. The principal investigator accompanied the professional crew to the filming and ensured that correct KMC techniques were captured and relevant social aspects incorporated. Figure 1 shows the conceptual framework used to assess thematic areas.

**Figure 1.** Conceptual framework to assess thematic areas.



## Data Analysis

The inductive thematic analysis approach was used to analyze the data to determine the themes. First, the data collection team

and the investigators familiarized themselves with the data. For the nonnative investigators, the data were transcribed into the English language. Next, the data were coded based on the content to describe the most interesting and important findings.

The codes were then classified into common themes. Finally, the themes were reviewed and finalized based on the relevance to answering the research questions.

The process of data collection and analysis is presented in [Figure 1](#). The transcripts were divided into segments, which were then labeled with codes to categorize them and to further develop themes. Transcripts and notes were analyzed on NVivo (Version 11.0). Data were coded according to previously defined assessment areas and thematic contents. The inductive thematic analysis approach was used to analyze the data to determine the themes. First, the data collection team and the investigators familiarized themselves with the data. For the nonnative investigators, the data were transcribed into the English language. Emerging themes and subthemes were identified during this process. Next, the transcripts were divided into segments, which were then labeled with codes according to the themes and subthemes developed in the previous step. The data were further analyzed for main themes and subthemes during coding. The codes were then grouped into common themes. Finally, the themes were reviewed by the investigators and finalized based on the relevance to answering the research questions.

New themes were also identified according to the findings from the transcripts. Since all transcripts were in Sindhi, all data analysis was also performed in Sindhi. The analyzed quotes were then translated to English for reporting.

### Ethical Considerations

The study was approved by the Ethical Review Committee of Aga Khan University (ERC #2020-0321-8561). Informed consent was obtained from all participants before study commencement.

## Results

### Participant Characteristics

We interviewed a total of 184 respondents, including 43 (23.3%) men and 141 (76.6%) women. The respondents included mothers, fathers, women of reproductive age, grandmothers, elderly male members of the community, community village committee members, fathers, and community and facility health care providers (LHWs, LHVs, physicians, and TBAs). The participants ranged in age from 16 to over 50 years. A total of 66 mothers participated in the study. The mean age of the mothers was 31.9 (SD 7.3) years and that of the fathers was 30.3 (SD 9.0) years.

### Theme 1: Community Practices and Perception on Immediate Newborn Care for All Babies and LBW Babies

#### General Practices

Soon after birth, the newborn's umbilical cord is cut with a blade, and *Surmo*, oil, *Desi Ghee*, spirit, and betamethasone cream are applied to the umbilicus to prevent infections. It is a common belief that newborns are born "impure" and are covered with dirt and substances of the uterus; thus, bathing allows for purification. Once the baby is bathed and is cleared of

impurities, the call to prayer can be uttered. Uttering the call to prayer (*Azaan*) in a baby's ear is a sacred practice in Islam to enable starting one's life with the name of God: "When babies come out from mothers' bellies they are covered with impure substance and we wash them first and prepare them for *Azaan* because we are Muslims." [Grandmother]

Baby massage is widely reported as an essential component of immediate newborn care in the community. Some other unique practices include applying the saliva of the mother to the infant's ankles as "protection from evil spirits." The cultural concept of *chilla* (baby and mother dyad rooming-in) for approximately 40 days is extensively practiced in the community. It is believed that the newborn needs the mother to protect them against evil spirits. Some families even practice keeping sharp objects under the pillow to ward off evil spirits.

When mothers and grandmothers were enquired about the unique issues related to small babies and if they were able to differentiate small babies from normal-size babies, the majority were able to do so and characterized small babies as weak (*kamzor*), those born early (*sattria*), and those with LBW (*ghatwazan*). They were knowledgeable about the special needs of small babies; almost 70% of these respondents stated that such babies require extra care. Two-thirds of the women responded that these babies are slow, it is difficult to feed them, and they become cold very quickly, and therefore they defer the bathing practice in such babies beyond day 1 of life. Approximately half of the mothers and grandmothers stated that the *kamzor* babies are bathed at 2 to 3 days of age, and in the winters such babies' first bath is delayed to 2 weeks or even more. One-third of the mothers recognized small babies as "sick and unwell" when there is less movement or if the baby is cold (*kamzori*):

*If a baby is born ghat wazan waro (kamzor) we give the bath after 2 to 3 days.* [Mother]

*During the winter season, LBW babies are not given a bath and if they become sick doctors tell us not to give bath to the baby till they are well and breastfeeding.* [Mother]

#### Feeding Practices in LBW Babies

Exclusive breastfeeding is not common across the community, although the mothers and grandmothers were aware of its benefits and understood that breast milk was a nutritious diet, especially for LBW (*ghatwazan*) babies. Both mothers and grandmothers perceived that a small baby must be frequently breastfed. One mother explained, "I used to give my milk to my LBW baby after every 30 minutes unless he would fall asleep."

When an LBW baby is not feeding well or is unwell, they consult a doctor at a nearby health facility, where they are usually advised to give additional formula milk for extra calories.

*We visit doctors for treatment of weak [kamzor] babies and they tell that we must feed them our breast milk and also they tell us to feed formula milk [dabe*



*waro kheer] and medicines and drops for energy [multivitamins]. [Mother]*

The practice of giving goat milk to the baby in addition to breast milk was common, which was usually given in the evening hours: “When I gave birth to my baby, I fed him my milk and then I started feeding him goat-milk in the evening.” [Mother]

Regarding colostrum, we found mixed views, where some women were advised by doctors that it is equal to 100 injections (*teeka*) and that it keeps babies healthy, whereas others were advised that colostrum was thick (*kharr*) and dirty and must be discarded: “I had a baby who was born early [*sattria*] and I gave him colostrum [*ghantoo kheer peri khanj*], the doctors say that it is good for the health of the baby.” [Mother]

In addition, infants were frequently given prelacteal feeds such as cardamom (*nonehaal*) gripe water and (*ghutti*) for small babies to help the digestive system.

### **Community Traditions and Rituals for Keeping the Small Baby Warm**

LBW babies are generally wrapped in cotton wool and blankets immediately after birth up to 2 to 3 months of age owing to the fear of hypothermia (*thaand*). It is perceived by the community that wrapping them in warm clothing or cotton promotes their growth and well-being. *Kamzor* babies are given sunbaths to keep them warm: “When we have small babies, we keep them in cotton for some time and also wrap them in blankets.” [Grandmother]

LBW babies are considered weak and vulnerable, and oil massage is given less frequently compared to the frequency with a healthy normal-size baby; when it is performed on LBW babies, it is typically done gently with less force: “We massage LBW babies very less frequently and do it gently because they are weak [*kamzor*] and cannot bear the massaging.” [Mother]

### **Care-Seeking Practices for LBW Babies: Facility Providers' Views**

Hospital administrators shared that most communities consult TBAs and doctors when their newborn is unwell. Communities also seek care for LBW babies from TBAs and LHWs. Additionally, it is a common practice to seek assistance from neighbors and community elders and from mothers who have delivered an LBW baby in the past. According to physicians, the most common traditional practice prevailing in the community for the prevention of hypothermia in LBW babies is swaddling. The baby is swaddled in cotton or wool and placed near a wooden fire in the winter season. The health care providers considered this practice as unfavorable for exclusive breastfeeding and bonding.

### **Place of Delivery and Feasibility of Direct Skin-to-Skin Contact Immediately After Birth**

It is a custom for the mother-in-law or elderly male members of the family to decide the place of birth. Mothers are usually discharged from the hospital within hours of delivery. However, in the case of a Cesarean section, they remain admitted for 24 to 48 hours. When enquired about prolonging the hospital stay to learn and provide KMC, the majority of mothers were willing

to do so. However, the facility staff shared some challenges that included unavailability of meals for the attendant accompanying the mother, lack of security, unavailability of clean water, and lack of available washroom facilities. The family members were mindful of the attitude of staff toward patients, which largely determines the decision for early discharge and care-seeking practices. Limited finances also were raised as a major barrier to the hospital stay.

*We stay at the hospital according to doctor's advice; whatever he suggests we follow. [Mother, FGD-6]*

*Whatever days are required we can stay for the sake of the health of our baby, may it be for 6 days or more even unless our baby recovers completely. [Grandmother, FGD-2]*

## **Theme 2: Community Perceptions of KMC and Willingness to Adopt KMC Practice**

### **Perspectives of LHV and LHWs on KMC**

Some of the LHV were aware of the benefits of skin-to-skin contact and had heard about KMC in the training they received from a nongovernmental organization on newborn care. However, they were not confident to practice or teach mothers KMC in the community and facility: “We never practice it because of fear, and we do not know the steps of KMC.” [LHV]

They shared that they had never viewed the steps of KMC administration but after watching the KMC video, they thought this care was easy, practical, and would be beneficial for the growth and well-being of the baby.

The LHWs were not familiar with KMC practices. One of the LHWs said, “I have heard about KMC from my colleagues, but I have never seen it and never received any training.”

### **Physicians' Knowledge and Perception of KMC and its Feasibility**

The gynecologist and the pediatrician interviewed had somewhat better knowledge and understanding of KMC and were supportive of the practice. The general views among various health care practitioners were that KMC was a feasible, easy, and adaptable practice in present social and cultural settings in the community. They stated that the local culture encourages other family members, including the husband, mother-in-law, and sisters-in-law, to share the mother's responsibility during the *chilla* days, and that this supportive family system would facilitate KMC practices at the household level and improve sustainability: “We see mothers-in-law and husbands coming here to support baby and mothers, family members assist each other.” [Pediatrician]

### **Willingness to Practice KMC and Reactions to the KMC Video and Pictures**

The majority of mothers and grandmothers were excited and intrigued while watching the video as they had never heard of or seen such practice. As the video was developed in a similar setting to the project site, they expressed happiness and felt connected to the language and the performers in the video. Many believed that KMC appeared to be an effective method as it would *keep the baby warm and close to the mother*. Mothers

and grandmothers called this practice “*Chhati laen*” (placing on chest) and agreed that the practice would help enhance bonding between the baby and the mother and also enhance breastfeeding. When enquired about its acceptance, the grandmothers expressed that the KMC method will likely be culturally acceptable.

*Yes sister [baji], it is a good way, the baby will get more and more breastmilk and will become healthy.* [Mother]

*It is free treatment; no need to spend money, we can also do it at home when we are free.* [Father]

*Yes, this is a good way, a baby will have enough mother-milk, a baby will feel emotionally good, and will gain weight.* [Grandmother]

### **Views of Mothers and Grandmothers on the Duration and Feasibility of Practicing KMC**

Most mothers agreed to administer KMC for an average of 6-8 hours a day without any support from their husbands and other family members. However, they felt that continuous 24-hour KMC would not be possible. They shared their concerns of “backaches” if they were to hold the baby in this position for long hours, especially soon after delivery. They also felt “unsafe” with the baby (skin-to-skin contact) on their chest while sleeping and were concerned about “suffocating” the baby during sleep. Several mothers reported concerns about difficulties in practicing KMC in the summer when excessive heat and humidity cause a lot of perspiration and make KMC administration uncomfortable for both the baby and mother. Many grandmothers were worried that the baby will have sweat rashes. They also expressed anxiety in carrying the baby in this position with a cloth wrapped around their waist and thought that while performing household chores such as sweeping the floor, animal rearing, and washing dishes, they may drop the baby or that the baby may slip out of the wrap.

However, nearly all mothers were still willing to try and practice KMC as they recognize the benefits of this method for their child’s well-being and good health (*suthto*).

*I would like to carry the baby with me when the weather is cold, not sure if I want the baby so close to me all the time.* [Mother]

*It is a nice and easy method, and I can do it for 2 hours in the morning, 2 hours in the evening, and 2 or more hours in the night. But it seems difficult when I am performing household chores such as sweeping and washing clothes.* [Mother]

*Adi, I can do the KMC when I am doing chores such as sewing or cutting vegetables, but it seems difficult doing when I am sweeping.* [Mother]

*Although I am busy all the time, I can help my wife with KMC and hold the baby skin to skin contact for 2 to 3 hours in a day.* [Father]

### **Challenges and Enablers Perceived by the Community for KMC Practices**

As the Dadu district has very hot summers, many mothers stated that providing KMC during the daytime may be difficult, but they could hold the baby in the KMC position during the evening and at night. Several mothers suggested that this challenge could be overcome if they were provided with a loose robe (*cholo*) with a zipper or front buttons. The modified garment would make it more comfortable for practicing KMC.

### **Traditional Community Practice of Chilla and Applicability to KMC Practice**

*Chilla* is a traditional practice deeply rooted in the rural areas of the country, especially in the provinces of Sindh and Punjab. *Chilla* delineates “care for a birth-giving-woman” in the community. This is the immediate period after delivery and varies from 15 to 40 days. During this period, the mother and baby dyad remain together to ensure bonding and adequate breastfeeding, and the mother is provided time to rest and recuperate her energy. In the first 7 days, she is not allowed to do any household chores. Subsequently, she can perform small tasks that do not require substantial exertion. She is not allowed to carry heavy objects or do fieldwork. *Chilla* is similar to the practice of *attur* in rural Bangladesh; however, their concepts are unique. *Attur* reflects a state of impurity of a delivering woman, whereas *chilla* is purely a social support system during the postpartum period, where family members and *dais* (TBAs) provide support to the woman within a household setting. Several respondents, including grandmothers, expressed that the period of *chilla* would facilitate KMC practice.

*Dai [TBA] comes to wash my clothes and my baby’s clothes and massage my body for some days.* [Mother]

*During chilla, days woman is taken care of, she is provided food and she does not do anything but rest till 21 days.* [Grandmother]

*Adi, we rest for 21 days and can do this [KMC] during that time.* [Mother]

We interviewed three hospital (*taluka* facility) administrators to understand their knowledge and perception of KMC practice for LBW babies. One of the hospital administrators who was from the local community and was a public health expert was aware of the KMC intervention and its benefits. He was of the view that KMC practices can be introduced in the local setting and that the video on KMC would serve well for the uptake. The remaining administrators were unaware of KMC: “The main benefits of KMC include exclusive breastfeeding and prevention of hypothermia.” [Administrator]

### **Theme 3: Integral Support Systems in the Community to Foster KMC Practices**

#### **Family and Community Support for KMC**

When enquired as to whether other family members such as the grandmother or the father would help in providing KMC, several fathers stated that they would be willing to provide KMC while the mother attends to household chores and the majority were ready to carry the baby in the KMC position for 1 to 2 hours during the daytime.



The mothers believed that with extended family support they could try to provide skin-to-skin contact for a maximum of 10 hours a day: “My sister-in-law, my mother-in-law shall also do KMC to my baby if needed.” [Mother]

The majority of facility staff had never heard of KMC; however, after viewing the video, they were supportive and said that although KMC is a new practice for the community, it is a simple and natural method to keep the baby safe and warm.

The LHWs were confident that there is adequate family support for the mother and newborn to facilitate KMC practice. Elaborating on the various tasks to be shared, they stated that other family members, especially a sister-in-law, can prepare food, wash clothes and utensils, clean floors, attend to other children, and also help in cattle rearing and animal dung collection: “Sisters-in-law, cosisters-in-law, the brother-in-law’s wife, and mothers-in-law can provide support to a KMC-practicing mother by taking care of other household chores.” [LHW]

Community elders play a pivotal role in decision-making at the village level and can function as enablers for KMC uptake. The elders were willing to provide their services for KMC advocacy. They were also happy to organize support groups to facilitate KMC practices in the village.

*With the formation of support groups and monitoring committee, one can easily be notified of the birth of LBW baby in the village. This will increase coordination among villagers to provide support for mothers with LBW babies and would be a good deed to do.* [Elder, FGD]

### **TBAs’ Perception and Support for KMC**

The TBAs are an old and trusted cadre of health care providers that provide maternal and newborn care and also deliver social support from this platform to the community. They are trusted members of the rural society, and their advice is taken seriously by community elders and decision-makers. They live at the pregnant woman’s house and provide care to the mother and baby dyad during childbirth and the postnatal period. When enquired about their thoughts on KMC, they were not happy with the concept of KMC and considered it as a risky practice. They thought that the baby may slip and fall and they were

therefore reluctant to support its practice. Similarly, neighbors were also unwilling to provide skin-to-skin contact to the newborn; however, they were happy to assist in supporting housework. A mother told us that “*Dai* [TBA] comes to massage my body for few days and she helps me to look after my other children.”

### **Pilot Testing of KMC Practice**

We carried out a pilot study with 9 mothers to evaluate their experience of providing KMC with a local wrap. We used a soft long cloth of cotton material that the women usually wear for modesty locally named *Bhadhno*, *Rao/Dupatta*, or *Ajrak*

All mothers and one grandmother practiced KMC using *Rao/Dupatta/Ajrak* as the KMC wrap. They were trained in binding the local wrap. They felt comfortable holding the baby in the KMC position in the wrap and shared that their babies were safe and relaxed in the KMC position. The KMC wrap was liked by the mothers, as it was very easy to wear and soft to the skin, and most importantly easily available; they expressed that “we don’t need to buy anything also.”

When enquired of any religious or social taboo, we were informed that there were no religious or cultural barriers to practice KMC if they are adequately covered.

When asked “how they felt” with the baby in direct skin-to-skin contact on the chest, the common response was “I feel happy and peaceful, my baby is on my chest and protected.” However, there were concerns of tightness on wearing a shirt over the wrap. Some suggestions were shared, including the availability of a loose robe (*cholo*) with a wide neck (*galo*) and open front that would make the baby and the mother more comfortable and allow for longer hours in maintaining the KMC position.

With babies on the chest (ie, in KMC position), mothers were asked to lie down and incline on the bed, walk and perform some simple household chores, and share their feelings and experience. Overall, the mothers were comfortable and felt good.

### **Enablers and Barriers for KMC Implementation**

The enablers and barriers promoting and limiting KMC uptake in communities identified through this formative research are summarized in [Textbox 1](#).

**Textbox 1.** Enablers and barriers contributing to kangaroo mother care (KMC) implementation.

#### Enablers

- Family members are willing to provide KMC to low birth weight (LBW) babies.
- There exists a caring social support system within the family for a woman giving birth, particularly during the “*chilla*” period, where the baby and mother dyad room-in and the family members ensure that the mother is rested, provided good nutrition, and her daily chore responsibilities are taken over by close family members.
- Community elders are willing to create support groups to facilitate KMC.
- Health care providers understand the benefits of KMC and are willing to support mothers in practicing it.
- Since families take advice from health care providers on health-related matters, it is beneficial for these providers to support, promote, and advise on KMC.
- There is support from religious leaders for the practice as it facilitates breastfeeding and mother and baby attachment.
- The use of diapers is a usual practice in the community that would facilitate keeping the baby dry and in a KMC position for long hours.
- The mother is willing to provide intermittent KMC with a maximum of 2 hours at a time in KMC position.
- Multigravida women are happy to provide support and counseling to young mothers and show interest to demonstrate and administer KMC to the baby.

#### Barriers

- There is no additional community or traditional birth attendant support to provide KMC.
- The community and health care providers generally are not aware of KMC practice and its benefits.
- There is practically no facility in the district where KMC is presently being practiced.
- Health care providers are scarce, especially pediatricians and obstetricians that can provide comprehensive maternal and newborn care at *taluka* hospitals.
- Immediate bathing practices due to social and cultural beliefs may delay the initiation of KMC and could predispose babies to hypothermia.
- KMC is difficult to practice during the day in the summer months due to extreme weather conditions.
- Women are not confident in moving about and carrying out household chores with the baby in the KMC position and fear that the baby may slip out of the wrap. This was considered a significant challenge by the community.
- Keeping the baby in KMC position during the night while sleeping is considered dangerous for the baby.
- Early recruitment of newborns for KMC from the facility would be difficult as the families are typically discharged within a few hours of delivery.
- There is reluctance to practice 24-hour continuous KMC.
- No one had heard of the animal kangaroo or knew how it held its baby.

## Discussion

### Principal Findings

Implementation of KMC in Pakistan has remained elusive until recently, unlike other LMICs where national guidelines for the practice were published as early as 2014 [25]. Most studies have reported the experience of hospital-based KMC in neonatal units with scarce literature on sustainability at the community level. Our study was carried out to evaluate and understand the community and facility drivers and barriers to the implementation of KMC in the country for establishing a sustainable KMC intervention model. The study included perspectives on the beliefs, traditions, family responses, health care providers’ input, and community support for KMC. In addition, we also assessed care-seeking and how an LBW baby is perceived by the family and community.

We found an overall willingness to practice KMC and implement the practice of skin-to-skin contact with the use of a local wrap (*dupatta/chaddar* that the women adorn for modesty) to secure the baby in the KMC position. Our findings

are similar to those of a study carried out by Mazumder et al [26] in rural India, where the majority of mothers and grandmothers were happy to practice KMC despite challenges.

The promising finding of our study was the enthusiasm and agreement to practice KMC by the mothers and grandmothers interviewed. They believed in the benefits of KMC and considered it as a healthy practice that would help the LBW baby grow healthy and strong, and protect them from cold. Comparable receptive behavior to KMC practices has been reported in both the local and regional literature on KMC [27-29].

However, almost all of the women who participated in our study were anxious and reluctant to practice continuous KMC, especially during the night hours. They were comfortable giving 1 to 2-hour sessions and a maximum of 8 hours of KMC in a single day. Although the practice of KMC has existed in several countries, there is no evidence on the optimal duration of KMC practice for positive outcomes. Several studies have used a variable duration of KMC practice to demonstrate the impact on reducing mortality in LBW babies. A community KMC pilot

study in Bangladesh reported a reduction in neonatal mortality with only 7 hours of skin-to-skin contact in the first 2 days of life and fewer hours in subsequent days [30]. Similarly, a qualitative study performed in Indonesia by Mustikawati et al [27] showed that mothers of LBW babies after discharge from hospital practiced KMC for 3 hours per day, and twice and once a day.

We identified several inappropriate newborn care practices in the community that have been reported in other published studies. Such practices include early bathing, prelacteal feeding, delayed breastfeeding, use of formula feeds (especially in LBW babies), and providing suboptimal thermal care [31–33]. Some babies are bathed in a traditional norm using immersive bathing immediately after delivery to prevent a bad odor, whereas others are wiped with a damp cloth as a sacred necessity to offer the call for prayer [34]. These traditional practices may serve as barriers to implementing KMC immediately after birth. Nevertheless, the introduction of KMC immediately after birth may enable the replacement of suboptimal practices. At the same time, a strong community awareness program on safe newborn care practices and community mobilization would be required to implement KMC and sensitize the community to safe newborn care. There is sufficient evidence in the literature highlighting the role of health care providers in engaging with the community, especially during the antenatal and postnatal periods. A pilot study performed in India by Rasaily et al [28] demonstrated the positive impact of community mobilization through trained health workers and information, education, and communication provision during antenatal visits on KMC acceptance and practice.

We found mixed perceptions and practices on colostrum, as some women discarded the colostrum due to its thickness and dirty color, while others fed their babies colostrum knowing its impact on immunity and health. The overall opinion of the community was that breastmilk is nutritious and should be offered, even though exclusive breastfeeding practice is uncommon in the community, even for LBW babies. Several mothers were prescribed formula milk (*ka doud*) by the health care providers in clinics and facilities. Similar findings have been reported in qualitative studies from India, Bangladesh, and Indonesia regarding the use of formula feeds [27,34,35]. In Uganda, despite being aware of exclusive breastfeeding, mothers fed babies additional food, including millet or soy porridge, in the hopes of increasing their weight [36]. They also reported differences in feeding practices for LBW babies born in facilities and at home. LBW babies born at facilities were more likely to be exclusively breastfed, whereas babies born at home were more often offered prelacteal feeds, possibly due to a weak suck reflex [36]. In Bangladesh, neonates were given prelacteal feeds, formula milk, and porridges [34]. To improve health outcomes in neonates, it is imperative that newborns, particularly LBW babies, are exclusively breastfed to reduce morbidities and improve their neurodevelopment outcomes [37].

A systematic review performed by Seidman et al [38] highlighted the barriers and enablers of KMC, which found that the most popular enabler of KMC implementation for the preterm infant was family support and mother-infant attachment. Another study on KMC practices in LBW babies at a

tertiary-care hospital reported that KMC facilitated warmth, weight gain, and longer sleep hours, and was acceptable by mothers [39]. Moreover, KMC has been associated with significant reductions in neonatal mortality according to an overview of systematic reviews [40].

We found that the postpartum period could be utilized to provide KMC to an LBW baby. *Atur* is a concept in Bangladesh, which is very similar to *chilla* (rooming-in) in Pakistan. This is a 30–45-day-long period where the mother and baby dyad room-in and rest to recover from delivery exhaustion and to encourage breastfeeding and bonding. In Pakistan, this period could be beneficial for mothers in providing KMC to neonates as close family members and friends carry out household chores for the mother [34].

A multicountry analysis on bottlenecks for KMC implementation in 12 countries in Africa and Asia as part of the Every Newborn Action Plan progress concluded that a weak health workforce was a significant bottleneck in 9 of the 12 countries [24]. According to an unpublished report from our department, many barriers to KMC were found, including disagreements from health care providers in the effectiveness of practicing KMC to prevent hypothermia and sepsis. Pakistan has a staggering rate of malnutrition and infectious diseases, and historically the focus has been on these illnesses over issues such as LBW, hypothermia, and neonatal care. Consequently, KMC has not gained acceptance by the health care providers and community until recently (unpublished data of the first author SA, 2014). Strong support systems for mothers and trained health workers can improve the implementation of KMC [38]. Health workers can educate and increase mothers' knowledge and confidence to practice KMC. The initiation of KMC immediately after birth in the facility by trained health care providers has resulted in sustainable practices in the community in African countries. Studies in Ghana and Nigeria have reported sustainable KMC practices at home following discharge from the hospital [41,42]. In our study, the LHVs were not knowledgeable about KMC and had never observed KMC in the facility, despite its ease and benefit for the growth and well-being of an LBW baby. However, health care providers deemed KMC to be a feasible, easy, and adaptable practice in present social and cultural settings in the community. Women have support available from their families, which can be utilized to practice KMC.

Most of the research in this field has solely focused on accounts by mothers practicing KMC, since cultural gender roles prevent fathers' involvement in KMC [38]. Before this formative study, we found an unfavorable perception among health care providers and public health specialists in the country for male involvement in providing skin-to-skin contact (unpublished situation analysis report on KMC, first author SA, 2014). This study and the previous literature highlight a critical role of male members in social dynamics and family power structures. We found that fathers were willing and could play a substantial role in the adoption of KMC in the household and for continued practice.

TBAs also play an important role in the birth of a child. KMC was supported in communities in Bangladesh through the role of *dhoronis*, similar to the TBAs in Pakistan. *Dhoronis* play a significant role during childbirth, from delivering the baby to

assisting mothers with caring for the baby and doing household chores, and in facilitating KMC to the newborn [34]. The roles across the two countries were similar for the TBA cadre; however, the TBAs in the Dadu district were not comfortable with the idea of mothers providing KMC. This may be due to their perception that empowering mothers with KMC may reduce their importance in providing care to the baby and mother dyad.

To implement KMC in the future, communities at large must be educated on safe care practices for LBW babies with a special focus on exclusive breastfeeding, bathing, and the benefits of skin-to-skin contact [43]. Family members, including fathers, are willing to provide KMC. This willingness can be applied to ensure collective efforts for KMC implementation and sustainability. A mobilization program will maximize the provision of KMC hours by the mother, father, and grandmother. To do so, the implementation teams must be aware of the dynamics of support systems within and outside the family. One approach to formulating a national program for KMC implementation is identifying and training community members to be local KMC champions [24]. The tradition of *chilla* can serve as an ideal window of opportunity to implement KMC with counseling and supervision in our setting.

During the demonstration and practice of KMC wrapping by mothers, we recognized the necessity of close liaison, supervision, and a strong support system within the community. The potential of local KMC champions could be explored for offering a source of continuous support to the mothers. A special focus from the mobilization team is also needed to ward off apprehensions about the KMC wrap among mothers and grandmothers, and the safety it poses for newborns. From local dressing patterns, it is inferred that some modification in the form of loose shirts with broad necklines and open fronts may be required. Moreover, establishing newborn inpatient care services at the *taluka* hospitals is required to institute KMC at the facility level.

### Conclusion

The practice of KMC is widely accepted in communities given that it aligns with culturally suited enablers. Families and community elders, including male members, are willing to assist, encourage, and facilitate KMC. Although the adoption of KMC can be facilitated, it would require assistance and counseling from health care providers and community health workers. The government needs to invest in improving newborn care services at hospitals to encourage facility-based KMC.

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### Authors' Contributions

The study was conceptualized by SA. The data collection process was supervised by TS and IM. The first version of the manuscript was jointly drafted by SA, IM, and MB. Subsequent and final drafts were critically reviewed and edited by ZM, SZ, MU, IM, AH, SS, and ZB. All authors have reviewed, read, and approved the final version.

### Conflicts of Interest

None declared.

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## Abbreviations

- FGD:** focus group discussion
  - IDI:** in-depth interview
  - KII:** key informant interview
  - KMC:** kangaroo mother care
  - LBW:** low birth weight
  - LHV:** lady health visitor
  - LHW:** lady health worker
  - LMIC:** low- and middle-income country
  - TBA:** traditional birth attendant
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Original Paper

# Perceptions of Educational Needs in an Era of Shifting Mental Health Care to Primary Care: Exploratory Pilot Study

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## Abstract

**Background:** There is an unmet need for mental health care in Canada. Primary care providers such as general practitioners and family physicians are the essential part of mental health care services; however, mental health is often underestimated and underprioritized by family physicians. It is currently not known what is required to increase care providers' willingness, comfort, and skills to adequately provide care to patients who present with mental health issues.

**Objective:** The aim of this study was to understand the need of caregivers (family members overseeing care of an individual with a mental health diagnosis) and family physicians regarding the care and medical management of individuals with mental health conditions.

**Methods:** A needs assessment was designed to understand the educational needs of caregivers and family physicians regarding the provision of mental health care, specifically to seek advice on the format and delivery mode for an educational curriculum to be accessed by both stakeholder groups. Exploratory qualitative interviews were conducted, and data were collected and analyzed iteratively until thematic saturation was achieved.

**Results:** Caregivers of individuals with mental health conditions (n=24) and family physicians (n=10) were interviewed. Both the caregivers and the family physicians expressed dissatisfaction with the status quo regarding the provision of mental health care at the family physician's office. They stated that there was a need for more educational materials as well as additional support. The caregivers expressed a general lack of confidence in family physicians to manage their son's or daughter's mental health condition, while family physicians sought more networking opportunities to improve and facilitate the provision of mental health care.

**Conclusions:** Robust qualitative studies are necessary to identify the educational and medical management needs of caregivers and family physicians. Understanding each other's perspectives is an essential first step to collaboratively designing, implementing, and subsequently evaluating community-based mental health care. Fortunately, there are initiatives underway to address these need areas (eg, websites such as the eMentalHealth, as well as the mentorship and collaborative care network), and information from this study can help inform the gaps in those existing initiatives.

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**KEYWORDS**

mental health; Canada; qualitative research; caregiver; family physician; mentorship

## *Introduction*

Family physicians are most often the first point of contact for patients presenting with mental health illnesses. Unfortunately, mental health is often underestimated and underprioritized by family physicians [1,2]. In total, 75% of mental health visits are related to mood and anxiety disorders, and the majority of these mental health visits occur in the primary care setting [3,4]. Family physicians are central to address mental health illnesses in their communities as they often have the advantage of a previously established relationship, ease of access, and can be seen in much less time than a wait to see a psychiatrist [5]. To date, it is unclear what is needed to increase family physicians' willingness, comfort, and skills to provide care to this complex patient population. Furthermore, it is not known what needs must be addressed to ensure successful and clinically effective transitions in care for patients with schizophrenia to be treated in primary care settings. The literature on health care interventions is clear in that education alone is not a solution to service care provision. Collaborative care models have been shown to improve access to mental health care, individual and population outcomes, and cost-effective care [6]. Yet, there is a dearth of literature to guide educational interventions geared toward the management of schizophrenia in primary care.

Qualitative needs assessments can unlock potential solutions to building capacity within the primary setting for the assessment, treatment, and management of mental health conditions. The objective of this needs assessment was to better understand the education and information needs of (1) caregivers of patients with mental health needs in primary care, with a focus on early recognition, diagnosis, and treatment of schizophrenia, bipolar mood disorder, and depression; and (2) family physicians' perceptions of barriers to care.

## *Methods*

### **Design**

A needs assessment is a systematic process to collect and analyze information on a target group's needs or "gaps" between current and desired situations. Performing a needs assessment is well accepted as an essential first step in the educational process [7]. Calls for innovative strategies in needs assessment methodology have been made in the medical literature over an extended period. A social constructivist approach focuses our study design to permit for collaborative dialogue to promote understanding and learning among and between stakeholder groups [8]. The current needs assessment employed a qualitative approach to capture the experiences and rich details provided by the 2 stakeholder groups, caregivers and family physicians.

### **Sampling and Procedure**

The participants were selected through a purposive and snowball sample strategy. Two focus groups with patient caregivers were

created. In total, 24 caregivers took part in each of the 2 focus groups. The gender composition of the groups was predominately female with only 1 male participant. All of the women in the focus groups were mothers of adolescent or adult children with mental health conditions and ranged in age from 38 to 72 years. The male in the second focus group was a caregiver for his brother-in-law. Each of the focus groups lasted for 2 hours and followed a semistructured focus group protocol. The focus group protocol was developed from a review of the relevant literature and from expert input from team members MC (a clinical psychiatrist) and MSJ (a family physician). Further, interview questions were vetted with the Canadian Schizophrenic Society to ensure applicability and clarity for use with caregivers. Family physicians affiliated with the Faculty of Medicine at the University of Ottawa were invited to participate in a semistructured interview. In turn, the agreeing participants nominated colleagues who might be willing to participate in an interview. The interview guide was developed from a review of the relevant literature and from expert input from several family physicians associated with the University of Ottawa's Faculty of Medicine. A total of 10 family physicians took part in a 30-minute interview. The clinical experience level of family physicians ranged from 1 year to 24 years.

### **Data Analysis**

Data collection and analysis were an iterative process and continued until no new themes arose. In qualitative studies, data saturation occurs when the researchers are no longer obtaining new information or themes. Interviews were audio recorded and transcribed verbatim. Qualitative data analysis techniques were consistently applied to the focus group and interview data. This analysis included 2 of the research team members (SS and AJ) who participated in all coding meetings and the application of inductive coding techniques. Themes were generated directly from the data sets.

### **Ethical Considerations**

Ethics approval was obtained from the University of Ottawa's Research Ethics Board.

### **Study Rigor**

To promote study rigor, all transcripts were sent back to the participants for review and face validation. Two forms of triangulation were employed to achieve a balanced perspective and enhance the reliability of the conclusions: (1) data source triangulation (using multiple data sources and informants); and (2) investigator (using more than 1 person to collect, analyze, and interpret data).

## *Results*

### **Characteristics of Caregivers and Family Physicians**

Participant characteristics are presented in [Tables 1](#) and [2](#).

**Table 1.** Participant characteristics: caregivers.

Participant ID	Gender	Relationship to patient
C-001	Female	Mother
C-002	Female	Mother
C-003	Female	Mother
C-004	Female	Mother
C-005	Female	Mother
C-006	Female	Mother
C-007	Female	Mother
C-008	Female	Mother
C-009	Female	Mother
C-010	Female	Mother
C-011	Female	Mother
C-012	Female	Mother
C-013	Female	Mother
C-014	Female	Mother
C-015	Female	Mother
C-016	Female	Mother
C-017	Female	Mother
C-018	Female	Mother
C-019	Female	Mother
C-020	Male	Brother-in-law
C-021	Female	Mother
C-022	Female	Mother
C-023	Female	Mother
C-024	Female	Mother

**Table 2.** Participant characteristics: family physicians.

Participant ID	Gender	Years in practice
FP-001	Male	6
FP-002	Male	12
FP-003	Female	1
FP-004	Male	3
FP-005	Male	8
FP-006	Male	10
FP-007	Female	5
FP-008	Male	20
FP-009	Male	19
FP-010	Male	10
FP-011	Male	6
FP-012	Male	24

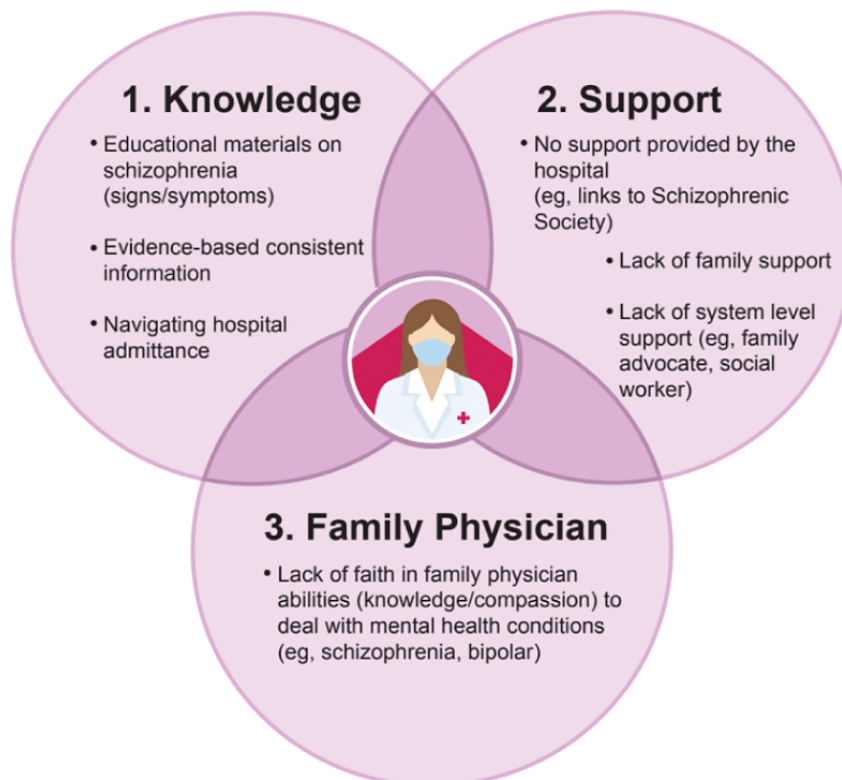


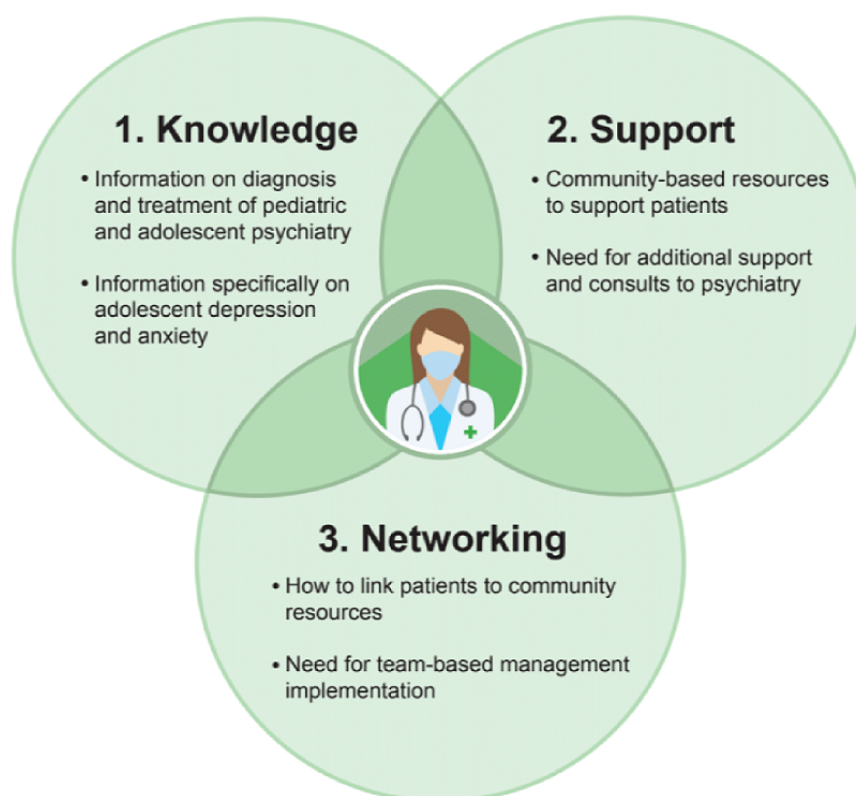
## Caregivers' and Family Physicians' Perception of Needs

Based on caregiver focus group data and family physician interview data, [Figures 1 and 2](#) present the three main themes that pertained to each stakeholder group's perceived needs. [Table 3](#) presents each group's preferred format of education materials, and [Table 4](#) presents each group's preferred method of delivery of educational materials. Prototypical qualitative quotes are provided to illuminate the themes. As shown in [Figure](#)

[1](#), when asked about their overall needs in caring for their loved ones who suffer mental health conditions, three interrelated themes were provided from caregiver interviews: (1) the need for more knowledge, which included educational materials on the signs and symptoms of schizophrenia, evidence-based and consistent information on schizophrenia and bipolar conditions, and how to navigate hospital admissions; (2) the need for more support, which included support at the family, local hospital, and system-wide supports; and (3) wanting more support from family physicians for mental health medication management.

**Figure 1.** Caregiver perceptions of needs.



**Figure 2.** Family physician perceptions of needs.**Table 3.** The preferred format of education materials by stakeholder groups.

Caregiver	Family physician
Networking opportunities (in person or virtual)	Self-learning modules
Availability of support staff (eg, social workers, family advocate)	Lists of referral options
Peer support groups (face-to-face)	Support materials (eg, decision trees “if- then”)
Education sessions (eg, training sessions, lectures, seminars)	Hard copy resources (eg, Hamilton Depression Scale, Psychiatry checklists, PHQ9, CanMat Guidelines—pocket guide for depression)
System-level supports (eg, On Track, Mobile Crisis Unit, ACT [Assertive Community Treatment])	Social networks for referral or information

**Table 4.** The preferred method of delivery by stakeholder groups.

Caregiver	Family physician
Easy-to-use materials (eg, copy the “common signs and symptoms of stroke” for schizophrenia)	<ul style="list-style-type: none"> <li>• Documents (eg, decision trees, lists of medications with associated side effects, pocket style guides)</li> <li>• Websites such as eMentalHealth, Centre for Addiction and Mental Health, Canadian Mental Health Association, and other major mental health organizations</li> <li>• Ottawa Depression Algorithm</li> </ul>
Education sessions (eg, [Name] Hospital has a 2-day information session for families)	<ul style="list-style-type: none"> <li>• Self-learning modules</li> </ul>
Web-based peer social networking	<ul style="list-style-type: none"> <li>• Professional online networking or referral services</li> <li>• Project ECHO (Extension for Community Healthcare Outcomes)</li> <li>• Collaborative mental health networks of the Ontario College of Family Physicians</li> </ul>

Many caregivers explained their frustrations with the process of actually having their loved ones admitted to the hospital. The following quotes are prototypical statements from participant caregivers:

### Knowledge

*My biggest complaint, most of you have heard me talk about it but what do you have to do to get someone admitted. Do you have to kill someone to get into [psychiatric hospital name]?*

### Support

*They [hospitals] should also have the knowledge to tell us about the supports, about On Track, about ACT (Assertive Community Treatment), some things are out there that could help us all. I've never been to anything except when I met [name], by chance, and found out about [name] and the sessions put on by the Schizophrenia Society of Ontario.*

*I am glad that I am here for my son because the system, what is out there for you, huh, we've never been able to get a caseworker. I am his caseworker. I got lucky and was connected to Dr [name] at the early episode clinic. I am concerned about what will happen when I am older or not around. What will happen then? There are no supports!*

### Family Physician

*Interviewer: What was your first point of contact with the system?*

*Caregiver: We took our son to our General Practitioner (GP), we talked to him. Our son was an honour student and suddenly he started not being interested in school and sleeping all the time. This is funny...now...but I remember the GP telling me not to worry and he said, "well at least it's not something like schizophrenia" which is eventually what the diagnosis was. He recommended us to a psychologist.*

*Interviewer: How many times did you take your son back to the GP?*

*Caregiver: About three more times...until he had a major break then we took him to the emergency at the Royal [Ottawa]. That's when there was a real emergency here... I probably saw the doctor with [son's name] about seven times in six months. His symptoms weren't obviously psychiatric. He was having vision anomalies but his vision was fine. Finally, he did have a complete break and I couldn't get him into CHEO (Children's Hospital of Eastern Ontario) and he was completely psychotic by then. I had to go to work one day so I asked my Mom. I said, 'listen he hasn't slept in a couple of days and that is not healthy, could you take him to the doctor [our GP] to get him a sedative while we wait for his assessment...he had to sleep. I came back from work that evening and he got a diet! He's got a diet. I said to my Mom, 'what did you tell him?'. They said that he was looking a little thin. Well, yeah, he's not eating*

*because he thinks the food is poisoning him so now he has a diet. [Son's name] says, 'the diet is the answer. If I eat this and at 10 am I eat a muffin I will be fine...a diet is an answer...it's all good now, Mom.'. Yeah, that was the help we got at the GP's office.*

Family physicians' needs were not all that different from those of caregivers. [Figure 2](#) illustrates the three interrelated themes from the family physician interviews: (1) the need for more knowledge, particularly about pediatric and adolescent psychiatric conditions; (2) the need for additional support from the community and for psychiatry consults; and (3) the need for networking in terms of linking patients to community resources and the implementation of team-based management options.

### Support

*I recently had a 39-year-old female with the following diagnoses join my practice: post-traumatic stress disorder with psychotic hallucinations, major depression with psychotic features, schizophrenia and 2 weeks later BAD. On Seroquel 200 mg HS, Olanzapine 10 mg HS and the new addition of Aripiprazole 10 mg as per emergency psychiatrist with decreasing doses and eventual discontinuation of Quetiapine. Patient is engaging in high-risk behaviour. I am unable to find a psychiatrist for follow-up. What is my next step?*

### Knowledge

*It would be helpful to have a list of community resources or even self-help resources. People who are mentally unwell are not going to access eHealth! Honestly, these people [mentally ill] are the bane of my existence... this is not why I went into medicine.*

### Networking

*I joined this practice a little over a year ago. This is a rural community, and I am not from here...I honestly am not so sure who or where I can refer my patients. Most of them end up going to emerg.*

Caregivers and family physicians were asked about their preferred format of educational materials or knowledge. The 2 stakeholder groups were more similar than different in the preferred formats for materials ([Table 3](#)), though caregivers tend to prefer more face-to-face interaction over virtual formats. [Table 3](#) illustrates the preferred methods of educational material delivery by stakeholder group. Caregivers and family physicians both reported preferences for both hard copy materials as well as online learning modes.

[Table 4](#) illustrates the preferred methods of educational material delivery by stakeholder groups. Caregivers and family physicians both reported preferences for both hard copy materials as well as online learning modes.

## Discussion

### Principal Results

The objective of this needs assessment was to better understand the education and information needs of (1) caregivers of patients with mental health needs in primary care, with a focus on early recognition, diagnosis, and treatment of schizophrenia, bipolar mood disorder, and depression; and (2) family physicians' perceptions of barriers to care. In this study, caregivers and family physician needs regarding caring for people with mental health conditions were generally similar. That is, both groups sought information such as related disease-specific symptoms and treatment options, and access to system-level psychiatric oversight. In terms of modes of delivery and educational formats for delivery, caregivers and family physicians were decisive in their preferred approaches.

The majority of caregivers had preferences for face-to-face delivery but were open to easy-to-use materials such as those developed for other diseases (eg, stroke). In keeping with adult learning principles, general practitioners desired self-learning modules with a focus on a decision tree type list of medications and side effects [9].

Most Canadians who receive mental health care do so in primary care settings, where collaborative care models have been shown to improve access to mental health care, individual and population outcomes, and cost-effective care [6]. Collaborative care involves providers from different specialties, disciplines, or sectors working together to offer complementary services and mutual support to ensure that patients receive the most appropriate service from the most appropriate provider in the most suitable location, as quickly as necessary, and with minimal obstacles [10].

The most empirically supported models of care are based on Wagner's chronic care model, yet they are typically implemented without evaluation. This is a crucial problem because the poor implementation of collaborative care yields worse experiences and outcomes of care [6]. Patient engagement becomes central to ongoing research, design, and implementation of collaborative care. Working in partnership with patients and their caregivers can provide unique insights into their needs and how programs should be designed, evaluated, and improved.

Caregivers have asked for improvement-oriented interventions such as educational sessions. This need is not a new one and has been available in the psychiatry literature since the mid-1980s [11]. Such education sessions include psychoeducational models of family therapy that include all-day survival skills workshops initially for families of schizophrenic patients. In these workshops, professionals share with families what is and is not known about the illnesses and seem to consolidate, in a multiple family setting, the connecting process they begin with each family. The format can serve as an excellent framework for similar psychoeducational workshops with families of patients with other mental illnesses. Though the workshops have been found to have positive outcomes [12], they have not gained a lot of traction in practice likely due to a

lack of consistent funding [13]. Currently, there are existing initiatives that attempt to fill these needs, which will be discussed in the following section.

### Initiatives and Resources

#### Need for Educational Materials

1. eMentalHealth [14], which is a comprehensive mental health website that provides information about mental health. It is also a resource directory on where to find help. eMentalHealth is targeted to both the general public and primary care providers, and it has been positively evaluated [15].
2. The Ottawa Depression Algorithm [16], which is a website designed to make it easy for primary care providers to diagnose and manage depression in an online decision tree format.

#### Need for Networking or Mentorship Opportunities

1. The Collaborative Mental Health Network is an initiative of the Ontario College of Family Physicians and provides mentorship support for family physicians to support patients with mental health needs.
2. Project ECHO (Extension for Community Healthcare Outcomes), which is a best practice in providing distance education about a variety of topics. In the province of Ontario, Project ECHO is funded by the Ministry of Health and provides networking and teaching in topics such as mental health.
3. There is a Project ECHO for adult mental health [17] as well as for child and youth mental health [18].

The information from this study will help inform existing initiatives and identify gaps where improvements can be made.

### Strengths and Limitations

The strengths of our study include the richness of the data obtained through firsthand accounts from key stakeholder groups. Caregivers spoke in detail about the difficulties they encountered accessing care for their loved one. In turn, family physicians voiced their concerns for a system with a lack of resources and a general dearth of information regarding psychiatric treatment options.

The limitations of our study include the small sample size of participants, which limits the generalizability of our findings. Despite the efforts to include male participants in the caregiver focus groups, our sample was predominantly female. Further, the purposive and snowball sampling strategy may create a self-selection bias in our data; as the focus groups included individuals who were willing to participate voluntarily, the results may be positively biased in favor of the study's intent.

### Conclusion

This needs assessment demonstrated that caregivers' and family physicians' needs about the care and medical management of individuals with mental health conditions may not be so different. Collaboratively designed and carefully developed educational materials, delivered in preferred formats, are an important step toward effective collaborative care. As family physicians and primary care teams are better equipped to manage



patients with mental health conditions, and as caregivers are better informed and supported, our hope is that “first encounters” at the primary care setting can be skillfully managed and that care can be better executed over the longer term.

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## Conflicts of Interest

None declared.

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## Abbreviations

**ACT:** Assertive Community Treatment  
**CHEO:** Children's Hospital of Eastern Ontario  
**ECHO:** Extension for Community Healthcare Outcomes  
**GP:** general practitioner



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Original Paper

# Short-Term and Long-Term Renal Outcomes in Patients With Obesity After Minimally Invasive Versus Open Partial Nephrectomy for the Treatment of Renal Cancer: Retrospective Study

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## Abstract

**Background:** Obesity is significantly associated with renal cell carcinoma. Surgery is the preferred treatment for demarcated lesions of renal cell carcinoma; however, obesity increases the complexity of surgical outcomes. Minimally invasive surgical techniques are preferred over open partial nephrectomy (OPN), but controversy remains regarding the most efficacious technique in patients with obesity.

**Objective:** This study aims to determine whether minimally invasive partial nephrectomy (MIPN) or OPN better preserves renal function and investigate short- and long-term renal outcomes in patients with obesity undergoing a partial nephrectomy.

**Methods:** We conducted a retrospective chart review of 242 adult patients aged  $\geq 18$  years who underwent MIPN or OPN between January 1, 2005, and December 31, 2016, at the University of Arkansas for Medical Sciences. Using creatinine as a measure of kidney function, patients' preoperative levels were compared with their postoperative levels in 2-time frames: short (3-6 months postsurgery) or long ( $>6$  months). The primary outcome was the change in creatinine values from preoperative to  $>6$  months postoperatively in patients with obesity. Secondary outcomes included the change in creatinine values from preoperative to 3 to 6 months postoperatively in patients with obesity who underwent MIPN versus OPN. We also analyzed the creatinine values of nonobese patients (BMI  $<30$ ) who underwent partial nephrectomy using the same time frames. Unconditional logistic regression was used to estimate crude and multivariable-adjusted odds ratios (ORs) and 95% CI to observe associations between surgery type and changes in creatinine values from while stratifying for obesity.

**Results:** A total of 140 patients were included in the study, of whom 75 were obese and 65 were nonobese. At  $>6$  months after MIPN (n=20), the odds of patients with obesity having a decrease or no change in creatinine values was 1.24 times higher than those who had OPN (n=13; OR 1.24, 95% CI 0.299-6.729;  $P=.80$ ). At 3 to 6 months after MIPN (n=27), the odds were 0.62 times lower than those after OPN (n=17; OR 0.62, 95% CI 0.140-2.753;  $P=.56$ ). In the nonobese group, at 3 to 6 months after undergoing minimally invasive surgery (n=18), the odds of having a decrease or no change in creatinine values was 4.86 times higher than those who had open surgery (n=21; OR 4.86, 95% CI 1.085-21.809;  $P=.04$ ). At more than 6 months after MIPN (n=14), the odds were 4.13 times higher than those after OPN (n=11; OR 4.13, 95% CI 0.579-29.485;  $P=.16$ ).

**Conclusions:** We observed a nonstatistically significant preservation of renal function in patients with obesity who underwent OPN at 3 to 6 months postoperatively. Conversely, after 6 months, the same was true for MIPN, indicating the long-term benefit of MIPN. In the nonobese group, MIPN was favored over OPN.

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**KEYWORDS**

renal outcomes; renal cell carcinoma; minimally invasive vs open partial nephrectomy; obesity; kidney; cancer; surgery; retrospective; outcome; short-term; long-term

## Introduction

### Background

Because of the negative impact obesity has on quality of life coupled with the associated increase in morbidity and mortality, obesity is one of the most significant modifiable health issues facing the United States and is reaching epidemic proportions [1-5]. As of 2016, obesity affects 13% adults worldwide, of which 39.8% are in the United States alone [6,7]. Furthermore, obesity is a major risk factor for other comorbidities, such as diabetes, heart disease, and cancer [8-12]. Particularly, the chance of acquiring renal cell carcinoma (RCC) is significantly higher in the obese population [13-15]. RCC is one of the top 10 cancers diagnosed in the United States. It is estimated that there will be 76,080 new cases of kidney cancer in 2021, which is higher than the estimated value for 2020 [16].

To preserve nephrons and, in turn, preserve renal function, partial nephrectomy has become the preferred option to radical nephrectomy when removing small renal tumors [14,17-19]. Although the more traditional open partial nephrectomy (OPN) is still performed, many have opted for minimally invasive surgical techniques, such as laparoscopic partial nephrectomy (LPN) or robotic partial nephrectomy (RPN), because of their shorter hospital stays and operating times [20]. With increased precision, dexterity, and 3D capabilities, RPNs are more commonly performed than OPNs or LPNs [21,22].

As obesity rates continue to rise, the treatment and management of renal cancer in the obese population poses a unique challenge. Because of the increased likelihood of postoperative complications, both medical and surgical techniques must be assessed to establish the best practice for patients with obesity. Although increased BMI adds another level of difficulty for physicians performing partial nephrectomies, the procedure is considered especially advantageous in this population [20,23]. RPNs have become a more favorable approach in the general population; however, there is still controversy regarding the most efficacious surgical technique in patients with obesity. Furthermore, several studies have found comparable short-term (<3 months postoperatively) outcomes in kidney function between patients with without obesity who underwent partial nephrectomy, but there are very limited data on long-term kidney function (>6 months postoperatively) [24,25].

### Objective

Because patients with obesity are already at risk of chronic kidney disease (CKD), maintaining renal function is a high priority [26]. Our goal is to investigate long-term renal outcomes in patients with obesity for up to 4 years after undergoing either MIPN or OPN. The gold standard for measuring renal function and diagnosing CKD is the estimated glomerular filtration rate (eGFR). However, there is still evidence that eGFR using the CKD epidemiology collaboration equation is not accurate in patients with obesity with a BMI >40 [27]. Because patients

with obesity are our target study population, we decided to compare patients' baseline creatinine levels before surgery to creatinine levels at 3 to 6 months (short term) and >6 months (long term) postoperatively. Although creatinine should not be used as the only factor to determine kidney health, our main goal is to determine whether patients maintained or improved their kidney function. Serum creatinine can be affected by age, race, sex, and BMI; therefore, we controlled and adjusted for these variables in our statistical model. On the basis of our results, we hope to contribute data regarding the optimal surgical approach, offering improved preservation of long-term kidney function in the obese population. This information may provide guidance to surgeons when deciding which surgical approach is the most appropriate for this population.

## Methods

### Study Design

The Institutional Review Board of University of Arkansas for Medical Sciences (UAMS) approved a retrospective chart review, conducted to identify patients with obesity aged  $\geq 18$  years who underwent OPN, LPN, or RPN for the treatment of renal cancer between January 1, 2005, and December 31, 2016, at UAMS. This study was conducted in accordance with all applicable government regulations and UAMS research policies and procedures. This retrospective study used existing data, and there was no direct contact with the study participants. A waiver of informed consent was approved by the institutional review board as there was no more than minimal risk to the participants, and the waiver did not adversely affect the rights or welfare of the subjects. The longest follow-up data that we found in patient charts were for 4 years, and the number of patients who had data this far out postoperatively was limited.

### Patient Selection

Originally used in the study by Webb et al [25], a previously existing institutional data set of partial nephrectomies was updated using patient charts from January 1, 2005, to May 4, 2011. A new subset of patients from May 5, 2011, to December 31, 2016, was added to the existing institutional database. All patient data, including both demographic and surgical data, were collected by retrospective chart review using an electronic medical records system. Patients were deidentified, and data were stored in a passcode-protected Microsoft Excel file. A system set was in place to find the specific information needed for each patient, so all data entries were consistent. The study was conducted in 2018. As this was an existing database and we wanted to analyze these data with a longer timeline (>6 months), we included patients who underwent surgery until 2016 to ensure that enough time was allotted postoperatively to evaluate long-term data. If patients who underwent surgery in 2017 or 2018 were included, many may not have fallen into the correct timeline. Patients were excluded if they had a previous radical nephrectomy, or if a planned partial nephrectomy was converted to a radical nephrectomy

intraoperatively. A total of 242 patients were identified who met the criteria of being >18 years and having undergone a partial nephrectomy for the treatment of renal cancer. Patients were further excluded if they did not have a preoperative creatinine value, a postoperative creatinine value, or if a full medical history could not be found, which would list any comorbidities.

### Surgical Approach

During this time, 3 urologists performed partial nephrectomies. All patients were consulted by a urologist in the clinic to determine whether OPN, LPN, or RPN (with LPN and RPN combined together as minimally invasive or MIPN) would be the most effective surgical approach for the patient. All 3 surgeons performed all the 3 surgical approaches. Decisions were made as per patient consent from discussions with their urologist regarding the risks versus benefits of each approach. The minimally invasive technique of choice was purely laparoscopic from 2005 to 2007. There were no laparoscopic surgeries after 2014, as there was a shift from the laparoscopic approach to the robotic approach. The shift began in 2008, with gradually more robotic surgeries and fewer laparoscopic surgeries. Both approaches are considered minimally invasive. With our timeline spanning the era of laparoscopic surgery, the slow transition to robotic surgery, and the era of almost exclusively robotic surgery as the minimally invasive approach, it was necessary to combine the cohorts. As with any new surgical technique, a learning curve needs to be considered. All patients were scheduled for regular outpatient follow-up after partial nephrectomies, regardless of the approach. No group was scheduled to be followed more or less frequently. Most follow-ups included an iStat creatinine blood draw or a basic metabolic panel.

### Primary Outcome

The primary outcome was the change in creatinine values from preoperative to >6 months postoperatively in patients with obesity who underwent MIPN versus those who underwent OPN. Preoperative creatinine values were obtained for every patient, and subsequent creatinine values were followed up for 4 years.

### Secondary Outcomes

Secondary outcomes included the change in creatinine values from preoperative to 3-6 months postoperatively in patients

with obesity who underwent MIPN versus those who underwent OPN. These findings were used to analyze the short-term effects on renal function. The change in creatinine values from preoperative to 3-6 months and >6 months postoperatively in patients without obesity who underwent MIPN or OPN were also studied as a secondary outcome. In both patient populations, differences in patient characteristics, tumor location, tumor size, pathology, age, average clamp time (defined as the time from which the renal artery was clamped to the time it was unclamped), estimated blood loss, and length of hospital stay were analyzed.

### Statistical Analysis

Various analyses were performed on the patients' creatinine concentrations. Creatinine values preoperatively, at discharge, 3 to 6 months postoperatively, and at >6 months after discharge were dichotomized into either <1 mg/dL or  $\geq 1$  mg/dL. Dummy variables were created for creatinine values during the 3- to 6-month and >6-month postoperative periods by subtracting the postoperative creatinine levels from the preoperative creatinine levels. A second dummy variable was created to record the difference in creatinine from preoperative to its corresponding postoperative time. The dichotomous variable indicated whether the individual's creatinine level had increased, decreased, or had no change since the preoperative period.

Differences in patient characteristics between surgical approach types were evaluated using chi-square tests for categorical variables and *t* tests for continuous variables (Table 1). BMI was calculated using the following formula:  $BMI = (\text{weight [kg]} / \text{height [m]}^2)$ . BMI of <30 was defined as nonobese and BMI of  $\geq 30$ , as obese. Variables evaluating sex (male and female) and race (European American and African American) were treated as dichotomous variables, and those evaluating age, as a continuous variable. Comorbidities hypertension, diabetes mellitus, prior kidney complications, and smoking status were combined to create 1 ordinal comorbidity variable. Each of the abovementioned comorbidities was labeled as a yes-no variable, except for smoking, which had the addition of a *prior smoking* label. These variables were then summed according to the total number of yes responses (and the number of prior responses for smoking) to create a single, continuous comorbidity variable and limit the multicollinearity of these comorbidities.

**Table 1.** Patient characteristics by surgical approach and obesity status.

Characteristic	Obese		<i>P</i> value	Nonobese		<i>P</i> value
	MIPN <sup>a</sup> (n=50)	OPN <sup>b</sup> (n=25)		MIPN (n=36)	OPN (n=29)	
<b>Age (years), mean (SD)</b>	57 (10.63)	55 (11.67)	.38	56 (14.73)	58 (12.96)	.51
Missing, n <sup>c</sup>	0 <sup>d</sup>	0		0	0	
<b>Race</b>			.65			.20
European American, n (%)	43 (87.76)	21 (84.00)		27 (84.38)	26 (96.30)	
African American, n (%)	6 (12.24)	4 (16.00)		5 (15.62)	1 (3.70)	
Missing, n <sup>c</sup>	1	0		4	2	
<b>Sex</b>			.41			.22
Male, n (%)	27 (54.00)	16 (64.00)		24 (66.67)	15 (51.72)	
Female, n (%)	23 (46.00)	9 (36.00)		12 (33.33)	14 (48.28)	
Missing, n <sup>c</sup>	0	0		0	0	
<b>Tumor location</b>			.045			.85
Left, n (%)	26 (52.00)	19 (76.00)		17 (47.22)	13 (44.83)	
Right, n (%)	24 (48.00)	6 (24.00)		19 (52.78)	16 (55.17)	
Missing, n <sup>c</sup>	0	0		0	0	
<b>Tumor size (cm), mean (SD)</b>	2.85 (1.65)	3.97 (2.15)	.04	3.25 (1.76)	3.58 (1.54)	.41
Missing, n <sup>c</sup>	2	2		0	1	
<b>Pathology</b>			.18			.26
Benign, n (%)	10 (20.00)	2 (8.00)		9 (25.00)	4 (13.79)	
Malignant, n (%)	40 (80.00)	23 (92.00)		27 (75.00)	25 (86.21)	
Missing, n <sup>c</sup>	0	0		0	0	
<b>Stage</b>			.37			.83
Stage 1, n (%)	33 (66.00)	21 (84.00)		23 (63.88)	18 (62.06)	
Stage 2, n (%)	3 (6.00)	1 (4.00)		2 (5.56)	2(6.90)	
Stage 3, n (%)	2 (4.00)	1 (4.00)		0 (0.00)	1 (3.45)	
Stage 4, n (%)	0 (0.00)	0 (0.00)		0 (0.00)	1 (3.45)	
Missing, n <sup>c</sup>	12	2		9	7	
<b>Length of stay (days), mean (SD)</b>	3 (1.31)	5 (3.33)	<.001	3 (1.81)	4 (1.29)	.08
Missing, n <sup>c</sup>	0	0		0	0	
<b>Average clamping time (min), mean (SD)</b>	24.00 (11.79) <sup>e</sup>	31.36 (11.47) <sup>f</sup>	.05		31.43 (11.08) <sup>e</sup>	.007
Missing, n <sup>c</sup>	11	11		4	8	
<b>Estimated blood loss (dL), mean (SD)</b>	132.50 (238.74)	325.00 (338.63)	<.001		275.00 (271.69)	.07
Missing, n <sup>c</sup>	0	1		0	2	

<sup>a</sup>MIPN: marginally invasive partial nephrectomy.

<sup>b</sup>OPN: open partial nephrectomy.

<sup>c</sup>Number of patients without a recorded variable.

<sup>d</sup>Missing data has been entered as 0.

<sup>e</sup>Warm ischemia.

<sup>f</sup>Cold ischemia.



Unconditional logistic regression was used to estimate crude and multivariable-adjusted odds ratios (ORs) and 95% CIs to observe associations between surgery type and changes in creatinine values from preoperative concentrations while stratifying for obesity. Logistic regression was used because of the small sample size limitations, amplified by the stratification of obesity. Creatinine values were not normally distributed; therefore, logistic regression was used to observe the relationship between creatinine differences and the 2 surgery types. Potential confounding variables for the association between surgery type and changes in creatinine level were included in the multivariable logistic regression models. Confounding variables were selected based on prior knowledge and a 10% change in the beta coefficient (results not shown). Although covariates such as length of stay in the hospital, average clamping time, and estimated blood loss were statistically different (Table 1), they could not be included in the model because of the model's inability to converge due to small sample sizes. The most parsimonious model was used to estimate associations between surgery type and changes in creatinine while stratifying by obesity status, with covariates including age, sex, race, comorbidities, and preoperative creatinine values. Each analysis was 2-sided, with *P* values of less than .05. All analyses were performed using the SAS version 9.3 (SAS Institute).

### Sensitivity Analysis

A sensitivity analysis was performed to determine whether LPN and RPN produced similar results; however, the models could

not converge because of the small sample size. If the patients who underwent LPN were removed, then the sample size would not be large enough to run the analysis.

## Results

### Overview

After controlling for race, sex, age, comorbidities, and available creatinine values, data for 140 patients, of whom 75 were obese and 65 were nonobese, were analyzed.

As presented in Table 1, there were statistically significant differences in tumor location (*P*=.045), tumor size (*P*=.04), length of stay (*P*≤.001), and estimated blood loss (*P*≤.001) in patients with obesity who underwent MIPN versus those who underwent OPN. Patients without obesity who underwent MIPN demonstrated a statistically significant (*P*=.007) shorter average clamp time than patients without obesity who underwent OPN. Patients who underwent MIPN had warm ischemia, whereas patients who underwent OPN had cold ischemia during tumor resection.

Table 2 shows mean creatinine values of obese and patients without obesity preoperatively, at discharge, 3 to 6 months postoperatively, and at >6 months after OPN or MIPN. As noted in Table 3, 44 patients with obesity and 39 patients without obesity had creatinine levels at 3 to 6 months. Furthermore, Table 4 shows that 33 patients with obesity and 25 patients without obesity had creatinine levels at >6 months.

**Table 2.** Patient mean creatinine values by surgical approach and obesity status.

Period	Obese			Nonobese		
	MIPN <sup>a</sup> (n=50)	OPN <sup>b</sup> (n=25)	<i>P</i> value	MIPN (n=36)	OPN (n=29)	<i>P</i> value
<b>Preoperative creatinine (mg/dL), mean (SD)</b>	0.96 (0.36)	1.12 (0.50)	.11	0.97 (0.35)	1.06 (0.42)	.38
Missing, n <sup>c</sup>	0 <sup>d</sup>	0		0	0	
<b>Creatinine at discharge (mg/dL), mean (SD)</b>	1.11 (0.45)	1.45 (1.38)	.11	1.12 (0.41)	1.01 (0.39)	.30
Missing, n <sup>c</sup>	1	0		0	1	
<b>Creatinine at 3-6 months (mg/dL), mean (SD)</b>	1.10 (0.292)	1.41 (0.858)	.17	1.06 (0.483)	1.03 (0.408)	.83
Missing, n <sup>c</sup>	23	8		18	8	
<b>Creatinine at &gt;6 months (mg/dL), mean (SD)</b>	1.12 (0.303)	1.16 (0.661)	.81	1.14 (0.648)	0.95 (0.333)	.38
Missing, n <sup>c</sup>	30	12		22	18	

<sup>a</sup>MIPN: minimally invasive partial nephrectomy.

<sup>b</sup>OPN: open partial nephrectomy.

<sup>c</sup>Number of patients without a recorded variable.

<sup>d</sup>Missing data have been entered as 0.

**Table 3.** Change in 3- to 6-month creatinine values.

Obesity status	Unadjusted				Adjusted <sup>a</sup>			
	Participants, n (%)	Surgery type	OR <sup>b</sup> (95% CI)	P value	Participants, n (%)	Surgery type	OR (95% CI)	P value
<b>Obese</b>	17 (68)	OPN <sup>c</sup>	1 (reference)	N/A <sup>d</sup>	17 (68)	OPN	1 (reference)	N/A
	27 (54)	MIPN <sup>f</sup>	0.83 (0.224-3.103)	.79	27 (54)	MIPN	0.62 (0.140- 2.753)	.56
<b>Nonobese</b>	21 (72)	OPN	1 (reference)	N/A	20 (69)	OPN	1 (reference)	N/A
	18 (50)	MIPN	5.20 (1.317-20.539)	.02	18 (50)	MIPN	4.86 (1.085-21.809)	.04

<sup>a</sup>Adjusted for age, sex, race, comorbidities, and preoperative creatinine values.

<sup>b</sup>OR: odds ratio.

<sup>c</sup>OPN: open partial nephrectomy.

<sup>d</sup>N/A: not applicable.

<sup>e</sup>MIPN: minimally invasive partial nephrectomy.

**Table 4.** Change in <6 month creatinine values.

Obesity status	Unadjusted				Adjusted <sup>a</sup>			
	Participants, n (%)	Surgery type	OR <sup>b</sup> (95% CI)	P value	Participants, n (%)	Surgery type	OR (95% CI)	P value
<b>Obese</b>	13 (52)	OPN <sup>c</sup>	1 (reference))	—	13 (52)	OPN	1 (reference)	—
	20 (40)	MIPN <sup>e</sup>	2.17 (0.521-9.017)	.29	20 (40)	MIPN	1.24 (0.229-6.729)	.80
<b>Nonobese</b>	11 (38)	OPN	1 (reference)	—	11 (38)	OPN	1 (reference)	—
	14 (39)	MIPN	3.56 (0.651-19.412)	.14	14 (39)	MIPN	4.13 (0.579-29.485)	.16

<sup>a</sup>Adjusted for age, sex, race, comorbidities, and preoperative creatinine values.

<sup>b</sup>OR: odds ratio.

<sup>c</sup>OPN: open partial nephrectomy.

<sup>d</sup>N/A: not applicable.

<sup>e</sup>MIPN: minimally invasive partial nephrectomy.

## Primary Analysis

For our primary outcome, at >6 months after minimally invasive surgery (n=20), the odds of patients with obesity having a decrease or no change in creatinine values were 1.24 times higher than those who had open surgery (n=13). However, this difference was not statistically significant ( $P=.80$ ).

## Secondary Analysis

At 3 to 6 months after minimally invasive surgery (n=27), the odds of patients with obesity having a decrease or no change in creatinine values were 0.62 times lower than those who had open surgery (n=17); however, this too was not statistically significant ( $P=.56$ ).

At 3 to 6 months after minimally invasive surgery (n=18), the odds of patients without obesity having a decrease or no change in creatinine values were 4.86 times higher than those who had

open surgery (n=21), which was statistically significant ( $P=.04$ ). At >6 months after minimally invasive surgery (n=14), the odds of patients without obesity having a decrease or no change in their creatinine values were 4.13 times higher than those who had open surgery (n=11), which was not statistically significant ( $P=.16$ ).

## Discussion

### Principal Findings

When evaluating the efficacy of OPN and MIPN using creatinine levels postoperatively, our results did not show a significant difference in long-term renal function in patients with obesity. However, our results showed a nonsignificant improvement in renal function at 3 to 6 months postoperatively in patients with obesity who underwent OPN. Conversely, after 6 months postoperatively, there was a nonsignificant improvement in

renal function in patients with obesity who underwent MIPN. Although our study set out to observe patients with obesity after these different surgical approaches, we also observed patients without obesity as a secondary outcome and found a statistically significant result regarding neutral or better renal function after MIPN. In the nonobese group, MIPN at 3 to 6 month and >6 months postoperatively was favored over OPN, with only the 3- to 6-month range being statistically significant.

We hypothesize that patients without obesity are able to compensate better and earlier with the nonsurgical kidney because they are more likely to be healthier and have fewer comorbidities. In addition, the patients without obesity who underwent MIPN had a more significantly reduced clamp time than that of patients without obesity who underwent OPN, which could have contributed to better renal function. Other possible explanations for our results include the effects of pneumoperitoneum on renal function, impact of the type of ischemia, learning curve in performing MIPN in the early study period, and the small sample size. When selecting follow-up periods for establishing what defines as *long-term*, the urology department was consulted; it was agreed that 6 months was a good break point for long-term kidney function because short term is most often determined as 2 to 3 months post operation. Because there is no formal structure for long-term follow-up after a partial nephrectomy, it is possible that the experience that the surgeons had with patients losing follow-up between 6 months and 1 year could have contributed to the time periods they recommended for analysis. When choosing the cutoff for BMI, we recognized that there could be differences between obesity and severe obesity; however, we did not have the sample size to break down the data into further groups. It would be ideal for future studies to have a larger sample size to assess more specific obesity categories.

Although partial nephrectomy has become the preferred option over radical nephrectomy for small renal tumors, a reduction of approximately 20% in renal function has been found in patients undergoing partial nephrectomies [14,17-19,28,29]. The amount of remaining healthy kidney tissue after nephrectomy is recognized as the most important factor for future renal function [30]. There have been conflicting results in recent literature comparing long-term renal function after MIPN with OPN. When comparing 866 patients undergoing either OPN or RPN, Yu et al [31] found that RPN preserved renal function better by analyzing preoperative eGFR to postoperative eGFR at 6 to 8 months. Another study by Wang et al [32] compared 360 patients undergoing either OPN or RPN showed no difference in eGFR over the long term. However, they specifically examined complex renal tumors. Furthermore, Choi et al [33] found that eGFR using diethylenetriamine pentaacetate renal scintigraphy was lower after open surgery than after robotic surgery when analyzing data up to 1 year postoperatively. However, 1 to 4 years postoperatively, eGFR between the 2 groups was comparable. When specifically examining long-term renal function in patients with obesity after partial nephrectomy, existing literature is limited and conflicting. One multi-institutional retrospective review evaluated long-term renal function and CKD predictors 1 year after MIPN in patients with obesity and did not find BMI or

operative technique as a predictor of progression to CKD [20]. Another study comparing the outcomes of 237 patients with obesity undergoing either RPN or OPN found no significant difference in eGFR between the 2 surgical groups. The median eGFR follow-up time was approximately 2 years, indicating some insight into long-term renal function [34]. Several studies have evaluated short-term complications in the obese population, but data on long-term kidney function are lacking [24,25]. One of the reasons we believe the results are so scarce and inconsistent is that there is no set protocol standard in the assessment of successful outcomes of surgery. Some studies focused on intraoperative complications, while others looked at postoperative complications, and others used readmission as their only qualification.

### Limitations

Our study is retrospective, which is a limitation of our study. No group was scheduled for follow-up in clinic more or less than another; however, many patients stopped showing up for their appointments, and the reason for this is unknown because this study was retrospective. Another limitation of retrospective studies is the risk of bias. We aimed to address selection bias, measurement bias, and confounding bias to decrease the effect of these biases during a retrospective study. To address selection bias, every patient aged >18 years who underwent a partial nephrectomy for the treatment of renal cancer were eligible for inclusion. The decision for partial nephrectomy versus radical nephrectomy could not be controlled because this was a retrospective study; however, the most desirable approach at this institution was partial nephrectomy if possible. The surgical approach of each partial nephrectomy (MIPN vs. OPN) could not be controlled or randomized, given the nature of the study. The decision for the approach was made between the patient and the physician.

To address measurement bias, every patient included in the study analysis had a preoperative creatinine level and postoperative creatinine level. Patients were assessed in groups depending on the time frame of the postoperative creatinine values available in their charts. We divided patients in 2 groups by 3- to 6-month postoperative, which is considered a short-term outcome in renal function and >6-month postoperative, which is considered long term. Preoperative and postoperative creatinine values were checked multiple times to ensure that the correct values were entered into the database. If these values were incorrect, the results would be affected because the main outcome depended on calculating the difference in preoperative and postoperative creatinine values.

To address confounding bias, we controlled for comorbidities, especially those that affect kidney function, that are common among the obese population. Just as there is an increased risk of RCC in the obese population, there is also a higher risk for diabetes and hypertension, both of which can affect kidney function. When gathering data, we documented pre-existing health conditions for each patient, including diabetes and hypertension, and smoking status. These comorbidities were controlled for during statistical analysis. If the above confounding variables were not controlled for, we could not be certain that the changes in creatinine were due to the surgical

approach. Patients were excluded if they had a previous radical nephrectomy, as this would dramatically affect the results; however, we did not control for other previous abdominal surgeries, which may have contributed to some bias.

In addition, 3 different surgeons performed all 3 surgical approaches (open, laparoscopic, and robotic) to partial nephrectomy at our institution during this period. All 3 surgeons were trained at different locations. Surgeons' techniques and experiences may have contributed to some bias. Considering the importance and impact of these procedures, a prospective study is needed. This would help attrition, and it would also help us track the loss of attrition. With a prospective study, we could better follow up recurrence rates, creatinine values, eGFR, proteinuria, and newly acquired medical conditions.

Another limitation of our study was that we were unable to assess the amount of lost renal volume during surgery, which is an important predictor of long-term renal function. For a surgeon, the primary focus is to preserve renal function while optimally decreasing the tumor burden. It would be helpful to know exactly how much renal volume was lost in each case,

which would only be available consistently if we had conducted a prospective study.

### Future Work

For academic purposes, we would like to observe eGFR and creatinine levels in every patient during follow-up after a partial nephrectomy for at least 1 year and extend this period for as long as possible. Anticipated barriers are the cost of time, overuse of resources, and attrition. The lack of an integrated system and follow-up protocols make it difficult to follow these patients long-term. With the understanding that there will be some limitations as there are multiple individual variables, we hope for a prospective study and a meta-analysis to help determine a surgical approach that is superior in preserving the greatest amount of long-term renal function in patients with obesity. It is important to examine both short-term and long-term outcomes to reveal a more optimal surgical approach that would decrease the risk of CKD in this susceptible population.

### Conclusion

When evaluating the efficacy of OPN and MIPN using creatinine levels postoperatively, our results did not show a significant difference in long-term renal function in patients with obesity.

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### Conflicts of Interest

None declared.

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## Abbreviations

**CKD:** chronic kidney disease  
**eGFR:** estimated glomerular filtration rate  
**LPN:** laparoscopic partial nephrectomy  
**MIPN:** minimally invasive partial nephrectomy  
**OPN:** open partial nephrectomy  
**OR:** odds ratio  
**RCC:** renal cell carcinoma  
**RPN:** robotic partial nephrectomy  
**UAMS:** University of Arkansas for Medical Sciences

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Original Paper

# Designing an Adaptive Adolescent Physical Activity and Nutrition Intervention for COVID-19–Related Health Challenges: Formative Research Study

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## Abstract

**Background:** With rates of childhood obesity continually increasing, effective physical activity and nutrition interventions are needed. Formative research is used to tailor interventions to different cultural and geographic contexts and can be vital in adapting intervention strategies in the face of significant disruptive circumstances (like COVID-19).

**Objective:** We conducted formative research via in-person and web-based focus groups among middle schoolers and parents to better understand the facilitators and barriers to physical activity and fruit and vegetable consumption and to inform the design of a large intervention for a low-income, urban setting in the US Midwest.

**Methods:** We conducted 2 phases of qualitative focus groups with parents (n=20) and 6th-9th grade middle schoolers (n=23). Phase 1 was conducted prior to the COVID-19 pandemic in late 2019, and phase 2 was conducted during the COVID-19 pandemic in the summer of 2020. Focus groups were transcribed and thematically coded using the Dedoose software.

**Results:** The main facilitators of physical activity prior to the pandemic included the opportunity to have fun, peer influence, competition (for some), and incentives, while the main barriers to physical activity were time constraints and social discomfort. The main facilitators of eating fruits and vegetables included parental influence, preparation technique, and convenience, while barriers included dislike of vegetables, time constraints, and preparation or freshness. During the pandemic, facilitators of physical activity remained the same, while additional barriers to physical activity such as lack of motivation and limited time spent outside of the home were reported. For fruit and vegetable consumption, both facilitators and barriers remained the same for both time periods. Additionally, for some participants, the pandemic offered an opportunity to offer more fruits and vegetables to middle schoolers throughout the day.

**Conclusions:** Some themes identified were common to those reported in previous studies, such as peer influence on physical activity and parental influence on fruit and vegetable consumption. Novel themes such as lack of motivation to be active and limited time outside the home helped improve intervention adaptation, specifically during the COVID-19 pandemic. The continuity of formative research after a major unexpected change in the intervention context can be essential in targeting areas of an intervention that can be retained and those that need to be adjusted.

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**KEYWORDS**

intervention; physical activity; nutrition; adolescents; formative research; COVID-19; exercise; young adult; teenager; focus group; qualitative; interview; urban; barrier

## **Introduction**

Inactivity, poor nutrition, and obesity are pervasive and growing problems among children in the United States. In 2019, 71.3% of middle schoolers did not meet the recommendations of 60 minutes of moderate to vigorous physical activity daily—an increase from 67.6% in 2011 [1]. Fruit and vegetable consumption follow similar trends as physical activity. Among adolescents in 9th-12th grade, 41.8% consumed less than one fruit and 40.7% less than one vegetable per day in 2019, compared to 38.7% (<1 fruit) and 35.8% (<1 vegetable) in 2001 [2]. These deteriorating rates of physical activity and fruit and vegetable consumption are reflected in the growth of childhood obesity, which has increased from 14.8% in 1999 to 21.2% in 2018 for 12-19-year-old adolescents [3]. Further, racial minority and socioeconomically disadvantaged youth are at an increased risk to be overweight or obese [4]. Although evidence is limited and lacking for middle schoolers, recent research has indicated that the COVID-19 pandemic has negatively impacted physical activity and nutrition for other populations [5-7], indicating that it has also likely exacerbated negative physical activity and fruit and vegetable consumption trends seen among middle schoolers. In response, the US Department of Health and Human Services established the Youth Engagement in Sports: Collaboration to Improve Adolescent Physical Activity and Nutrition (YES Initiative), specifically aiming to increase physical activity and consumption of fruits and vegetables [8].

Physical literacy and fitness, motivation, positive attitude, as well as friends and family were all found to be dominant facilitators of physical activity for youth [9-13]. The nature of the activity has also been identified as a facilitator of physical activity; for example, being fun was the primary feature, while competition appears to be a facilitator for youth who are already active [10,14]. Similarly, numerous barriers for youth to being more physically active are supported by the literature. Common barriers include availability or access to physical activity programs [9,14]; past negative experiences associated with physical activity; appropriate resources available; inactive, inappropriate level, or nonmeaningful sessions; and nonsupportive environments, which were just some notable barriers identified in a review of the literature [10]. Lacking the necessary skills for youth's preferred activity was also identified as a significant barrier [13]. Body image or gender-based sociocultural norms were identified as specific barriers for adolescent females [10]. Despite the breadth of research on this topic, it is important to tailor interventions to youth's characteristics, interests, and circumstances [9,10].

Previous research has identified a number of facilitators of fruit and vegetable consumption for youth. A review by Patrick and Nicklas [15] found that both family and availability are strong facilitators of fruit and vegetable consumption. Other research identified self-efficacy and benefits were predictors of fruit and vegetable consumption for a sample of minority high school students, whereas social support was a predictor for nonminority

students [16]. Lucan et al [17] found that health, taste, and preferences were the top facilitators of fruit and vegetable consumption. In a nationally representative sample of teenagers, it was found that normative belief was a strong predictor for male fruit and vegetable consumption, while perceived barriers were strong predictors of female fruit and vegetable consumption [18]. Costs, availability, and preferences rank as the top barriers to fruit and vegetable consumption [17].

Interventions to increase physical activity may be particularly important in the middle school years. For example, only 7.9% of middle schools in the United States provide daily physical education for the entire school year [19], indicating a need for additional physical activity programming for this age group. Participation in sports may be an effective strategy to help youth meet the current physical activity guidelines [20,21]. Since sport participation disparities exist by race, socioeconomic status, and gender [22,23], it is important that interventions address barriers to participation specific to these at-risk populations.

A critical component of developing an effective intervention is formative research, which aims to identify how to best implement aspects of a program to the context of its stakeholders [24]. Formative research is an iterative process to ensure that components of an intervention are informed by the direct experiences and opinions of the local population it intends to benefit [24]. Previous research suggests that a 2-phase formative research process is ideal to satisfy the immediate need of the information to proceed with intervention development and implementation as well as providing an opportunity to gain follow-up as additional needs and challenges are identified [25]. In our case, these phases were separated by the onset of the COVID-19 pandemic, presenting even more challenges in implementing an intervention originally designed for the in-person school setting.

Research on the barriers to and facilitators for physical activity and fruit and vegetable consumption specific to middle schoolers is lacking; this gap in literature is particularly important because this is a pivotal time for developing health habits. Therefore, the overall objective of this paper is to describe how formative research informed a large-scale intervention that meets the goals of the YES Initiative for middle schoolers prior to and amid a global pandemic. More specifically, we aim to describe formative research findings from a 2-phase process, their impact on intervention implementation, and how both formative research and intervention implementation pivoted due to COVID-19-related challenges.

## **Methods**

### **Design**

We conducted a series of qualitative focus groups, separately with middle school students and their parents, in 2 phases (before and after the onset of COVID-19). Compared to surveys, focus groups allow for rich, open-ended responses about

participants' ideas and experiences that we needed to help shape intervention components in the early stages of development. Compared to individual interviews, focus groups served as an efficient way to gather perspectives of a large sample and offered the advantage of interaction among participants, which can help illuminate areas of common experience and formulate consensus around programmatic recommendations [26]. Further, segmentation of each study population (parents and students) may increase the openness, comfort level, and ability of participants to relate to each other's experiences, allowing for richer responses than if groups were mixed [27].

Both phases of focus groups aimed to gain a deeper understanding of the following topics: (1) facilitators and barriers to physical activity, (2) parent/student recommendations for increasing physical activity through sports/activities, (3) facilitators and barriers to fruit and vegetable consumption, and (4) parent/student recommendations for increasing fruit and vegetable consumption through a fresh produce and nutrition education intervention. Focus group guides were informed by the social-ecological model [28] and social cognitive theory [29] (Multimedia Appendix 1). The social-ecological model offers a multi-level perspective to examine factors influencing behavior at the individual and environmental (family, school, and community) levels. Embedding selected elements of social cognitive theory within our framework provided further direction on specific influences to examine at the individual level (self-efficacy, interests, motivations, experiences) and environmental (social support, opportunity) levels. Further, both theories have been used in combination to inform past formative research and successful interventions in healthy lifestyles among adolescents [25].

## Recruitment

All procedures were approved by the Institutional Review Board at the University of Missouri-Kansas City prior to study commencement. Initial procedures were updated to reflect protocol changes necessary to accommodate COVID-19 risk mitigation (ie, virtual focus groups via Zoom); updated procedures were approved prior to commencement of phase 2 focus groups. Phase 1 focus groups were conducted in-person in December 2019, and phase 2 focus groups were conducted virtually in the summer of 2020 (June-August). Participants in each phase were unique.

Participants in the first phase were recruited prior to implementing the intervention through the local children's hospital's daily newsletter and represented 8 school districts in the metropolitan area. A total of 4 focus groups were conducted in this phase in December 2019—2 with parents (n=5, n=6) and 2 with middle schoolers (n=6, n=6).

The second phase of focus groups was conducted in June-August 2020, after participating schools were closed due to COVID-19 and the intervention was suspended. Participants in this phase were recruited from middle schoolers enrolled in control and intervention groups and were invited to participate via email. Recruitment emails sent by research staff indicated that focus groups would take place virtually via zoom and that participants would need the necessary technology to participate. Four focus groups were conducted in this phase—2 with parents (n=2, n=3)

and 2 with middle schoolers (n=4, n=6). In this phase, an additional Spanish-speaking parent focus group (n=4) was conducted in response to interest expressed by parents who had previously been unable to participate owing to language barriers. Participants in each phase, both parents and middle schoolers, received a US \$30 gift card.

## Data Collection and Analysis

All focus groups were conducted by members of the research team trained in focus group moderation for formative research (EAH, KAP, ESDM, EMMS). For in-person focus groups in phase 1, participants gave informed consent and completed a demographic survey on paper prior to the start of the discussion.

Virtual focus groups in phase 2 were designed to assess the transferability of findings identified in the first phase of focus groups to the changing intervention context presented by COVID-19. Themes that were approaching saturation from phase 1 were included in the guide for phase 2 for the purposes of confirming initial findings but not to explore in great depth (eg, influence of friends). New subtopics that emerged in phase 1 and did not yet reach saturation were added to the guides for the second phase for exploration in greater depth, specifically issues surrounding body image and use of recipes. Phase 2 also included new topics related to COVID-19, specifically (1) the pandemic's impact on physical activity and fruit and vegetable consumption and (2) recommendations for web-based program adaptation.

Participants in phase 2's virtual focus group gave informed consent over the phone and completed a demographic survey online prior to the scheduled discussion session. During the discussion, participants had the option of using video or audio only and could use the chatbox. Recordings were made only of audio and chatbox content. For Spanish groups, all consent forms and focus group guides were translated by bilingual members of the research team (KAP and ESDM) according to a 9-step process [30,31].

Verbatim transcripts were produced for English-speaking focus groups using the automatic transcription feature in Zoom and then manually improved for accuracy alongside the audio-recording. For Spanish-speaking groups, verbatim transcripts were produced manually by the bilingual research team members and then translated into English. Transcripts were uploaded to the Dedoose app for analysis [32]. An initial coding tree was developed based on the starting theoretical frameworks (social-ecological model, social cognitive theory) and discussion guide topics. Three coders coded the same first 4 transcripts from phase 1 independently, using a combination of deductive coding based on the initial coding tree, while also allowing for adjustment and addition of the thematic subcodes inductively [33]. The coding team met to debrief and synthesize codebook revisions, resolve discrepancies (with the senior author serving as the final arbitrator), and synthesized a final codebook for the remaining phase 1 transcripts, which were coded independently. The same codebook was applied to the phase 2 transcripts by independent coders, while adding new codes inductively as needed, which were integrated into the final codebook after group consensus. Summary outputs were examined by participant type and time of collection, discussed,

and synthesized into themes. Throughout data collection and analysis, the study team tracked thematic saturation through memoing and debriefing, determining saturation through consensus.

## Results

### Demographics of the Participants

Table 1 outlines participants' demographics. The mean parent participant age was 41 years, and the mean middle schooler

participant age was 13 years. Participants (parents and middle schoolers) predominantly spoke English (16/20, 80% and 23/23, 100%; respectively). The majority of parents were females (19/20, 95%), but the majority of middle schoolers were males (13/23, 57%). Parents and middle schoolers were predominantly non-Hispanic (15/20, 75% and 16/23, 70%; respectively) and White/Caucasian (14/20, 70% and 12/23, 52%; respectively).

**Table 1.** Demographic characteristics of the focus group participants.

Characteristics	Parents (n=20)	Middle schoolers (n=23)
<b>Language, n (%)</b>		
English	16 (80)	23 (100)
Spanish	4 (20)	0
Average age, median (IQR)	41 (31-64)	13 (11-15)
<b>Gender, n (%)</b>		
Male	1 (5)	13 (57)
Female	19 (95)	9 (39)
Prefer not to answer	0 (0)	1 (4)
<b>Race, n (%)</b>		
White/Caucasian	14 (70)	12 (52)
Black or African American	2 (10)	5 (22)
Multiracial	0	1 (4)
Other	4 (4)	4 (18)
I prefer not to answer	0 (0)	1 (4)
<b>Ethnicity, n (%)</b>		
Non-Hispanic	15 (75)	16 (70)
Hispanic	4 (20)	5 (22)
I prefer not to answer	1 (5)	2 (8)
<b>Focus group type, n (%)</b>		
In-person	11 (55)	12 (52)
Virtual	9 (45)	11 (48)
<b>Grade level, n (%)</b>		
6th	N/A <sup>a</sup>	3 (13)
7th	N/A	8 (35)
8th	N/A	6 (26)
9th	N/A	6 (26)

<sup>a</sup>N/A: not applicable.

### Physical Activity

The main facilitators of physical activity were similar before the pandemic and amid the pandemic and included having fun, peer influence, competition (for some), and incentives. The main barriers were time constraints, social discomfort, and additionally during the pandemic, limited time spent outside of home.

### Facilitators

In phase 1, middle schoolers and parents cited peer influence and socialization as the strongest motivator for physical activity. Students enjoyed being active if it meant having fun with friends they were comfortable with, although they also noted they enjoyed meeting new people through physical activity.



...When we play with friends it makes it more fun. When you know the people that you're playing with or against. [Phase 1, male student]

Some middle schoolers and parents noted students' desire for competitive sports and games.

...I like to play to win and I just play to have fun, but I like to play to win. [Phase 1, male student]

...He has this mindset of drive and focus and winning and competition. And I don't know what to do with it but let him play. [Phase 1, English-speaking female parent]

In phase 2, peer and social influence were again noted as the strong motivators for physical activity. Similar to sentiments in phase 1, middle schoolers emphasized enhanced enjoyment of activities played with peers they considered friends.

...It's more fun when you play against your friends because with strangers you don't feel as comfortable. [Phase 2, female student]

Parents and students again emphasized the potential benefits of competition and incentives. Amid pandemic-related restrictions, some middle schoolers described how they continued to seek competitive environments, and parents suggested ways for the intervention to preserve the social aspect of competition as motivation for physical activity.

...I went against my friend to see who gets the most steps in a day. [Phase 2, male student]

...Maybe given them an incentive, so now that they are still young get motivated to do some type of activity because now, many cannot get together. They could get together to know each other, if they were about the same age, do some type of challenge. But virtually, incentivize them so they want to participate virtually. [Phase 2, female parent]

### Barriers

In phase 1 focus groups, barriers to physical activity were often related to time constraints and restrictive social factors. For example, some students struggled with finding time to participate in physical activity while managing homework and other obligations. Although previously noted as a facilitator for many middle schoolers, competitive environments were noted by others as creating potential conflicts among peers.

...I play for my school volleyball team and there is drama between some people on the team. So that was kind of affecting some people and made it a little less enjoyable to play. [Phase 1, female student]

Others expressed the fear of feeling "awkward" in competitive environments, with anxieties about not knowing how to play the sport, making an error, or not being as good at the sport as their peers.

...If you're not good at it, and maybe those people that you play against are good at it, then it's not as fun. [Phase 1, male student]

In phase 2, participants described how COVID-19 decreased physical activity among middle schoolers overall.

...their physical activities [has] definitely slowed down. I mean, they still do go outside and stuff, but they don't play the way they used to. [Phase 2, female parent]

Barriers to physical activity still included time and social constraints, and additionally, a decrease in motivation to remain active when in-person schools and activities were suspended.

...Like you don't feel like being like, like during quarantine or whatever you didn't feel like going outside a lot, you just wanted to be inside a lot. You just felt like being inside like laying on your bed. [Phase 2, female student]

Participants described additional COVID-19–related barriers, including the loss of opportunity for structured physical activity in the school environment and parental reluctance to let children venture far outside the home owing to the risk of contracting the virus.

...Yes, when they would come from school, they would also go outside with their bicycles. But now with the pandemic that they are here, with the school [online] they do not want to go out. They say that they have a lot of homework and they have who knows what. However, when she was going to school, they would give her an hour and all the stairs going up and down, all that helped a lot. Now, no matter how much I tell her [to be active] she doesn't want to. [Phase 2, female parent]

...What I've noticed is definitely a difference, since we've been more hibernated this year than normal like even if they go outside and stuff, but it's not the same as well. I mean, like, I wouldn't let them go to the park forever [...] I have started at least letting them go sometimes because it's, you know, they, like I said, they love being outside, but it's just such a weird time. [Phase 2, female parent]

### Parent and Student Recommendations

As an extension of motivation by competition, parents and students suggested the benefit of incentives, challenges, or activity goals as intervention components, emphasizing the importance of connecting friends through these activities. Middle schoolers in phase 1 also said an ideal intervention would include a variety of participation options, including different sports and games and competitive and noncompetitive choices.

### Fruit and Vegetable Consumption

The main facilitators of eating fruits and vegetables included parent influence, preparation technique, and convenience, which were similar to that reported before the pandemic and amid the pandemic. The main barriers to eating fruits and vegetables included middle schoolers disliking vegetables, time constraints, and preparation or freshness.

### Facilitators

Findings from phase 1 suggested that middle schoolers were aware that fruits and vegetables are good for their overall health. Parents reported needing to take a major role in encouraging

their children to eat fruits and vegetables. They also noted that the cooking method or preparation technique (eg, cutting, peeling, adding dressing) determined if their child ultimately consumed them.

*...I will puree anything that needs onions or tomatoes. If you get the immersion blender and make it almost like a sauce they never know. They will eat it. [Phase 1, female parent]*

*...When it comes to fruits, honestly, I have to cut down the oranges, so they eat them, otherwise they don't eat them. [...] I need to push them so they eat the fruits and vegetables. [Phase 2, female parent]*

In phase 2, parents continued to be a primary influence on their children's fruit and vegetable consumption. With school being held virtually and many parents working remotely, parents were able to offer vegetables conveniently and more frequently.

*...One of the things that I've done during the quarantine [...] I start out the day by cutting up fruits and vegetables and putting them out on the kitchen counter. So that they're always available. So as my son walks through the kitchen like yesterday morning he comes down for breakfast, and he grabbed cucumbers off the counter. [Phase 2, female parent]*

Phase 2 also included additional discussion about recipes, which parents reported using regularly, appreciating those that made healthy meal preparation simple and convenient. English-speaking parents appeared to be more open to new recipes, while Spanish-speaking parents tended to seek out familiar recipes.

*...As long as it's something simple and quick and easy and I don't have to get out and run to the store. [Phase 2, English-speaking female parent]*

*...We actually do food prep on Sunday. My kids will help me on that. [...] We like to try new recipes every time we cook. [We will] put them in the freezer so that when we head out, it's easy to just say, throw it in the oven and it'll be ready by the time we get home from any after school activity. [Phase 2, English-speaking female parent]*

*...Sometimes, I use recipes from YouTube when I see them. Or sometimes I called my sisters to ask them how to cook something I want to make and they tell me how to make it. [Phase 2, Spanish-speaking female parent]*

### Barriers

As a chief barrier in both phase 1 and 2, parents and middle schoolers discussed how children are often not fond of fruits and especially vegetables. When middle schoolers were asked about their frequency of fruit and vegetable consumption on a scale of 1 to 10, one student responded with the following quote regarding his fruit and vegetable consumption.

*...Because I don't get any of the fruits and vegetables at school because they don't taste good and they make you get a fruit or vegetable. And an apple juice counts*

*[as a fruit], so I just get an apple juice. [Phase 1, female student]*

Students also expressed their dislike for fruits and vegetables provided in school meals due to lack of freshness, bad taste, and lack of variety.

*...[Schools should] spend a little more money on making it more fresh, or buying them from better sources, I'd probably say. And just make them more local, and I think a lot more people want to eat fruits and vegetables at school if they tasted better. [Phase 1, male student]*

Additionally, parents believed that constraints on their own time limited their ability to prepare healthy meals for their children. Further, parents identified time with their children's grandparents as a negative influence, as they tended to be more permissive, allowing their children to eat unhealthy foods.

### Parent and Student Recommendations

Parents and students emphasized that an intervention should promote healthy eating as a fun and engaging activity. Parents felt that if the children could prepare recipes themselves, that would give them a sense of pride and they would more likely eat the food. Students specifically talked about creating a cooking competition or a challenge where all students can be involved, as well as utilizing appetizing pictures and social media to engage students.

### Integrating Formative Research Findings Into Intervention Design

Findings from both phases of the focus groups helped to inform the intervention prior to and during the COVID-19 pandemic. The key themes and subsequent intervention strategies are summarized in Table 2. Phase 1 focus groups affirmed many proposed intervention strategies such as offering an intramural sports program (to create a motivating social environment) with rotating sport offerings (to ensure a variety of activities with competitive and noncompetitive options). We also aimed to achieve a positive social environment through positive sport coach training and referral incentives to increase friend participation. Gift cards incentives were also provided for meeting individual participation goals, facilitating motivation from goal setting without the pressure of peer competition for those who cited it as a barrier. Each youth was also provided a wearable, wrist-mounted accelerometer to measure physical activity and track steps, providing additional opportunity for goal setting and competition according to participant preferences.

By offering the program after school, we were able to reduce time constraint barriers with strategies such as utilizing an existing late-departing school bus. We also partnered with a local hospital's "mobile market" bus to deliver fresh fruits and vegetables weekly, providing participants enough fruits and vegetables to make a meal for a family of 5 individuals. When COVID-19 interrupted the initial intervention plans, phase 2 focus groups helped determine how to adapt the intervention in light of the changing facilitators and barriers. Shortly after, we began offering live "Move Sessions" through Microsoft teams, allowing middle schoolers to engage with physical

activity coaches and their peers. In response to parents' mention of their child's notable decline in physical activity during the pandemic, we expanded the Move Session offerings to 7 sessions per week, including multiple afternoon/evening options and 1 weekend option. We continued incentives for completing participation challenges. To increase exposure and variety, we

provided all middle school participants with sports equipment (ie, jump rope, baseball and glove, yoga mat). Weekly produce distributions were maintained by making basic modifications (ie, no-contact drive-through, masks), and a weekly newsletter was developed to provide healthy recipes coordinated with the produce distribution.

**Table 2.** Key themes and subsequent intervention strategies.

Themes	Intervention strategies
<b>Physical activity</b>	
Friend and peer influence	The intervention is free and open to all middle schoolers at a given school, with no try outs and regardless of level of ability. This easily allows for friends to participate (year 1 and 2).
Competition or goal setting	We utilize activity trackers to provide opportunity for individual goal setting and personal competition (year 1 and 2). This sport sampling intervention allows for skill development and concludes with a scrimmage to allow for low-stakes competition between peers (year 1).
Incentives	Middle schoolers can earn incentives (ie, gift cards) for reaching participation goals (year 1 and 2).
Fun	Sport offerings rotate ever 2 weeks to keep the programming fun and new (year 1 and partially implemented in year 2). Provide all middle schoolers with sports equipment (ie, jump rope, baseball and glove, yoga mat) to increase exposure and variety (year 2).
Time constraints	The intervention takes place at the middle schoolers' respective schools that eliminates additional transportation needs and travel time and concludes prior to other potential evening activities (year 1). Move Session offerings were expanded to 7 virtual sessions per week, including multiple afternoon/evening options and 1 weekend option (year 2).
Motivation	All coaches are trained in positive sport coaching to ensure a positive, inclusive, and motivating environment (year 1 and 2).
<b>Fruit and vegetable consumption</b>	
Parental time constraint	Providing weekly produce packages has the potential to eliminate additional grocery trips (year 1 and 2).
Disliking fruits and particularly vegetables	Each produce package contained common staple fruits and vegetables that tend to be well-liked as well as more unique or less accessible fruits to expand middle-schooler exposure.
Recipes	Newsletters with recipes related to the produce selection are included with each produce bag (year 2).
Preparation of fruits and vegetables	Newsletters that were included with each package of produce included preparation tips related to produce in the weekly package (year 2).

## Discussion

### Principal Findings

This formative research study informed the creation of a large-scale physical activity and nutrition intervention and its adaptations amid the onset of COVID-19. Overall, the main thematic findings from pre-pandemic focus groups were highly transferrable to the pandemic times, including primary motivators for participation in physical activity (peer influence, goal setting, or competition) and many barriers to consuming fruits and vegetables. However, later focus groups revealed that the pandemic introduced new facilitators (increased parental involvement in fruit and vegetable consumption) and challenges (declining motivation and limited structure for physical activity that needed to be incorporated into the revised intervention).

### Physical Activity

#### Facilitators

In both phases, we found that peer influence and socialization were the most commonly cited motivators for physical activity. These findings are consistent with previous findings that suggest that peer influence significantly impacts physical activity behavior over time in children [9-12]. Having fun also emerged as a dominant theme for physical activity participation, similar to that reported in other studies [10,13]. Despite the role peers play, our study found that parents had an increased role in facilitating physical activity during COVID-19, reflecting prior evidence that supports parental involvement can increase youth physical activity [9,10,29].

#### Barriers

Barriers to physical activity uncovered in our data were also similar to those reported in previous studies, such as time commitment (ie, homework obligations) [13,34], and for some, a counterproductive competitive environment for physical activity [10,13]. Our study further revealed that COVID-19

exacerbated these existing barriers and created additional barriers such as reduced physical activity and motivation to be active. These qualitative findings provide context for recent quantitative studies that confirm decreases in physical activity for children during the COVID-19 pandemic and more so for middle-school-aged children (age 9-13 years) compared to younger children (age 5-8 years) [35].

### ***Parent and Student Recommendations***

Students and parents suggested leveraging competition and goal setting as a strategy to increase physical activity. As such, incorporating wearable activity monitors that allow for self-tracking may provide an opportunity for both competition and goal setting. Previous research indicates that wearable activity monitors may be a particularly beneficial strategy to increase physical activity among students who are less active to begin with [36]. Lastly, participants also recommended the use of incentives to motivate middle schoolers. Although not widely studied in youth, evidence does suggest that providing financial incentives as done so in our intervention can increase physical activity among youth [37] but may be limited in sustaining long-term behavior change in sedentary adolescents [38].

### **Fruit and Vegetable Consumption**

#### ***Facilitators***

Parents reported high levels of influence over their middle schooler's food choices, controlling food availability and rules, as noted in previous studies [39,40]. This parental control often facilitated fruit and vegetable consumption; however, parents also mentioned struggling to get their child to eat vegetables, and they used presentation, preparation technique, and convenience to encourage healthy eating. The pandemic seemed to allow increased opportunity for parental control, as some parents mentioned offering more fruits and vegetables throughout the day. These findings align with other research that the pandemic potentially has had a positive effect on dietary behaviors in children [41].

#### ***Barriers***

Middle schoolers reported liking very few vegetables, which aligns with that reported in previous research [40]. Yet, unlike that reported in other research, middle schoolers in this study reported knowing the benefits of eating healthy; therefore, it does not seem to be a significant barrier for this population [40]. Middle schoolers made specific complaints about the preparation and freshness of fruit and vegetable offered at schools, indicating that school-level changes may be needed to increase fruit and vegetable consumption. This may indicate that middle schoolers lack a supportive environment for fruit and vegetable consumption at school—an important factor in facilitating fruit and vegetable consumption [42].

### ***Parent and Student Recommendations***

Both parents and students alike suggested that a nutrition intervention should be a fun and engaging activity. One way to achieve this is through the promotion of cooking at home. In a review of the literature, researchers found that youth overall enjoyed cooking programs [43], and previous research suggests that cooking at home is associated with several nutritional benefits for youth [44]. Further, youth who are involved with cooking at home are more likely to enjoy cooking as an adult [45]. Parents also suggested novel approaches such as cooking challenges and using social media to engage students. There is currently a lack of research on these topics but they may have promise and should be explored.

### **Strengths and Limitations**

This study was strengthened by its qualitative methodology that allowed for deeper probing than alternative quantitative approaches. The inclusion of focus groups before and after a major interruption to intervention roll-out allowed for the adaptation of the intervention as well as a unique demonstration of the essential role of formative research to address unforeseen midprogram challenges. It also demonstrated the feasibility of shifting focus group data collection and intervention strategies to virtual platforms. This study was further strengthened by the inclusion of both English- and Spanish-speaking families.

As this was a formative research study intended to adapt an intervention to a specific context, results cannot be generalized from the limited sample size to the broader population of middle school students and parents. Sampling from phase 1 and phase 2 also differed demographically, as phase 1 participants were sampled at large and phase 2 directly from the schools involved in the intervention. Further, phase 2 focus groups were held virtually, meaning that participation and findings may have been different compared to an in-person setting (such as in phase 1). Although virtual focus groups allowed for participation among individuals for whom in-person sessions were not feasible, they required a conducive at-home environment (few distractions, good internet connection). Differing preference for use of chatbox and video may also have had different impacts on engagement and responses among participants.

### **Conclusions**

Our formative focus group discussions informed the creation of a large-scale physical activity and fruit and vegetable consumption intervention and its successful adaptation during the onset of COVID-19. These findings offer a feasible and targeted approach to increasing physical activity and fruit and vegetable consumption in middle school students through both a school-based in-person and virtual intervention. Moreover, this study demonstrates the importance of planned multi-phase formative data collection throughout a project. Future research must examine the efficacy of the intervention developed based on these findings.



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## Authors' Contributions

ARG conceptualized the study, wrote the manuscript, and performed the literature review. JSL conceptualized the study and contributed to manuscript writing. KAP collected data, analyzed data, and contributed to manuscript writing. ESDM and EMMS collected the data and analyzed the data. RPS oversaw the research efforts. EAH conceptualized the focus groups and contributed to manuscript editing.

## Conflicts of Interest

None declared.

Multimedia Appendix 1

Focus group discussion guides.

[\[DOCX File, 77 KB - formative\\_v6i1e33322\\_app1.docx\]](#)

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## Abbreviations

**YES Initiative:** Youth Engagement in Sports-Collaboration to Improve Adolescent Physical Activity and Nutrition

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Original Paper

# COVID-19 Preventive Behaviors and Health Literacy, Information Evaluation, and Decision-making Skills in Japanese Adults: Cross-sectional Survey Study

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## Abstract

**Background:** Health literacy is important for the prevention of COVID-19 transmission. Research in Japan shows that health literacy is related to skills in evaluating information and decision-making (skills that are not necessarily limited to information about health). Such basic skills are important, particularly when individuals encounter new health issues for which there is insufficient evidence.

**Objective:** We aimed to determine the extent to which COVID-19 preventive behaviors were associated with health literacy and skills in evaluating information and making decisions.

**Methods:** A web-based questionnaire survey was conducted using a Japanese internet research company. The measures comprised 8 items on COVID-19 preventive behaviors, health literacy items (European Health Literacy Survey Questionnaire), 5 items on information evaluation, and 4 items on decision-making process. Pearson correlations between these variables were calculated. Multivariable analyses were also conducted using the COVID-19 preventive behavior score as a dependent variable.

**Results:** A total of 3914 valid responses were received. COVID-19 preventive behaviors were significantly correlated with health literacy ( $r=0.23$ ), information evaluation ( $r=0.24$ ), and decision-making process ( $r=0.30$ ). Standardized regression coefficients (health literacy:  $\beta=.11$ ; information evaluation:  $\beta=.13$ ; decision-making:  $\beta=.18$ ) showed that decision-making process contributed the most.

**Conclusions:** Although comprehensive health literacy is necessary for COVID-19 preventive behaviors, the skills to evaluate a wide range of information and to make appropriate decisions are no less important. Opportunities for people to acquire these skills should be available at all times.

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## KEYWORDS

coronavirus; COVID-19; health literacy; health information; decision-making; health promotion; prevention; behavior; survey; evaluation

## Introduction

Health literacy is as important for the prevention of COVID-19 virus transmission as it is for the prevention of noncommunicable diseases [1]. Messages and materials about COVID-19 incorporate unusual vocabulary and phrases, and

the number of COVID-19-related cases and deaths may be interpreted differently by people within a particular region or country [2]. Without adequate health literacy, people are unable to distinguish fact from fiction, and their behavior may be affected by unreliable information [3]. Low health literacy and information gaps may contribute substantially to the rapid spread

of fear and anxiety [4]. Conversely, high health literacy can “flatten the curve” (ie, slow infection rates) of COVID-19 infections [5].

Research shows that health literacy, which has been measured in a variety of ways for a diverse range of topics, is associated with knowledge and behavior related to COVID-19: participants with less comprehensive health literacy expressed more confusion about COVID-19–related information [6], and a study [7] on digital health literacy related to COVID-19 found that college students who were better at evaluating reliability and determining the relevance of the information that they received used more reliable public websites rather than search engines or social media.

Similarly, adolescents with higher comprehensive health literacy who were asked to respond to the pandemic situation were more likely to be knowledgeable, more likely to wash their hands, less likely to socialize with friends, and more likely to report higher health-related quality of life [8]. Higher levels of infectious disease–specific health literacy or COVID-19–related health literacy are associated with greater implementation of COVID-19 preventive behaviors [9,10].

Several studies [11–13] have investigated the relationship between health literacy not associated with COVID-19 and COVID-19–related behaviors, mental health, and quality of life. In a study [11] of the Australian general public using the Single Item Literacy Screener that reported differences in knowledge, attitudes, and behaviors, participants with lower health literacy had more difficulty understanding COVID-19 symptoms, infection-prevention behaviors, and government information. In a study [13] using the comprehensive health literacy scale developed by the European Health Literacy Project [12], chronically ill patients with greater health literacy engaged more in COVID-19 preventive behaviors [13]. Similarly, in a study [14] that assessed comprehensive health literacy in an outpatient setting, greater health literacy was associated with lower depression and greater health-related quality of life, even when COVID-19 symptoms were suspected. In addition, a study [15] of medical students found that higher comprehensive health literacy was associated with lower fear of COVID-19 [15]. Among health care workers, higher comprehensive health literacy is associated with better infection prevention and control procedures, healthier lifestyles [16], and better mental health and quality of life [17], even during the COVID-19 pandemic.

Thus, health literacy, whether related to COVID-19 or not, plays an important role in the response to COVID-19. In Japan (as in other countries), fake news and information without scientific basis (such as “The new coronavirus is very heat-sensitive and can be cured by drinking hot water” and “There is a shortage of toilet paper due to the shortage of masks”) have been circulated on the internet and social media, highlighting the importance of health literacy [18]. In addition to broadcasting the number of new COVID-19 infections and deaths, the news media in Japan have broadcast daily pandemic-related information on issues, such as whether health or economy should be prioritized, an increase in bankruptcies and suicides owing to job loss, whether the Tokyo Olympics should be held, which factors have delayed vaccine development and inoculation, and

whether government and administrative responses have been inadequate. During a pandemic, there is little time to improve health literacy because governments and citizens must act immediately; therefore, the challenge is to prepare individuals and society for a situation that requires immediate response and containment [1,19].

It is likely that, in Japan, the response to COVID-19 is related to health literacy, but no studies have investigated this. Individual preventive behaviors are important in responding to COVID-19. According to the World Health Organization [20] and the Japanese Ministry of Health, Labor, and Welfare [21], such behaviors include avoiding contact with the virus by maintaining social distancing, wearing masks, and disinfecting hands. Furthermore, to avoid infecting others, individuals with a high temperature or COVID-19 symptoms should rest and stay at home. Theoretically, individuals with greater health literacy should find it easier to obtain relevant health-related information and make appropriate decisions about these behavioral choices; however, health literacy depends, not only on individual ability, but also, on interactions between individuals and the environment. Therefore, the environment must also be conducive to making appropriate behavioral choices. Individuals may find it more difficult to obtain information and make decisions in response to a new disease because the environmental context is more uncertain.

A recent study [22] in Japan demonstrated that comprehensive health literacy is associated with skills in evaluating the reliability of information and decision-making (skills that are not necessarily limited to information about health). In particular, health literacy and the skills to properly evaluate the reliability of new, uncertain, and rapidly changing information (including political and socioeconomic aspects) and to make decisions are required to cope with pandemics and infodemics. The World Health Organization [23] defines an infodemic as “too much information including false or misleading information in digital and physical environments during a disease outbreak.” It would be useful to understand the extent to which information evaluation and decision-making skills are required and which skills are needed to enable individuals to be prepared and respond to emergency situations such as the COVID-19 pandemic. Therefore, the purpose of this study was to determine the extent to which COVID-19 preventive behaviors in Japanese individuals are related to health literacy and to the skills to evaluate and make decisions based on general information from the media (eg, the internet, television, and newspapers).

## Methods

### Participants

Participants were recruited from individuals registered with a Japanese internet research company (Nippon Research Center Ltd) that, as of the time of this study, had approximately 1.4 million voluntarily registered participants. We aimed to collect data from a minimum of 4000 individuals aged 20 to 69 years. In January 2021, potential respondents (n=22,115) were randomly selected and invited via email to participate in a cross-sectional web-based anonymous questionnaire.



In determining potential participants, we tried to match participants' genders, age groups, and regions (we divided the country into 8 regions) to the results of the 2015 Japanese census [24]. We accepted emailed responses from potential participants until we reached the target number for gender, age group, and region.

## Measures

### COVID-19 Preventive Behaviors

The questions on COVID-19 preventive behaviors were developed using World Health Organization [20] and Japanese Ministry of Health, Labor, and Welfare [21] guidelines on preventing infection.

To ensure that the questions were as comprehensible as possible, we selected text from easy-to-understand recommendations written for citizens on Japanese government and administrative webpages.

These items were "Use a mask, tissue, handkerchief, or sleeve to cover your mouth and nose when coughing or sneezing," "Wear a mask when the distance between people is likely to be less than 2 m (meters)," "Wash your hands with soap or alcohol-based disinfectant before meals or upon returning home from outside, etc.," "Try maintaining a minimum distance of 2 m (meters) from people," "Rest if you are not feeling well," "Ventilate the room," "Avoid touching your eyes, mouth, or nose after contact with doorknobs, railings, desks, light switches, etc.," and "Take your temperature." A 5-point scale (5, always; 4, often; 3, sometimes; 2, rarely; 1, never) was used for response options (see [Multimedia Appendix 1](#)). The total score was calculated; higher scores indicated greater frequency of engaging in COVID-19 preventive behaviors.

### European Health Literacy Survey Questionnaire

The Japanese-language version of the European Health Literacy Survey Questionnaire (HLS-EU-Q47), which is a comprehensive, concept-based measure of most aspects of health literacy for the general population that allows for national and international comparisons [12,25-27], has been used and validated in Japan and in other Asian countries [26,27]. The HLS-EU-Q47 comprises 47 items assessing 12 subdomains of health literacy formed by 4 information processing competences of individuals (accessing, understanding, appraising, and applying) and 3 health contexts (health care, disease prevention, and health promotion). The survey response categories were all phrased similarly to "On a scale from very easy to very difficult, how easy would you say it is to understand why you need health screenings?" and were ranked on a 4-point scale (1, very difficult; 2, fairly difficult; 3, fairly easy; 4, very easy) and included the response option "don't know/not applicable"; this response was coded as a missing value.

The health literacy score was standardized for each participant on a metric between 0 and 50 using the formula [12]:  $(MEAN - 1) \times (50 / 3)$ , where *MEAN* is the mean of all item responses.

### Information Evaluation

Based on 5 criteria (accuracy, authority, objectivity, currency, and coverage) for judging the quality of information sources

[28-32], 5 items were used to determine whether participants were able to evaluate the information [22]. We asked respondents to rate how often they checked the following aspects of the information they accessed on the internet, television, newspapers, magazines, or other media: (1) the source of the information, (2) the qualifications of the people and organizations providing the information, (3) whether the information advertised products or services, (4) when the information was created, and (5) how the information differed from other information. A 5-point scale (5, always; 4, often; 3, sometimes; 2, rarely; 1, never) was used for response options (see [Multimedia Appendix 2](#)). Total and item scores were calculated. The internal consistency reliability was excellent (Cronbach  $\alpha=.92$ ) and construct validity was demonstrated by the results of a confirmatory factor analysis, which produced a single factor. Higher scores indicated greater information evaluation frequency and skill.

### Decision-making Process

We assessed whether the essential aspects of the process of determining all the available options, knowing the pros and cons of each option, comparing them based on values and preferences, and making a choice were implemented, which is necessary for informed decision-making. For this purpose, we developed 4 items for each aspect based on the Shared Decision-Making Process scale [33]. Items on this scale are limited to 2 options; therefore, we created items that were not limited to health decisions and had a wider range of options. We asked respondents to rate how often they implemented the following aspects when they made important decisions: (1) make sure they have all the options, (2) know the pros of each option, (3) know the cons of each option, and (4) compare the pros and cons of each option and clarify what is important to them. As with the information evaluation items, we used a 5-point scale (5, always; 4, often; 3, sometimes; 2, rarely; 1, never; see [Multimedia Appendix 2](#)). Total and item scores were calculated; higher scores indicated greater decision-making frequency and skill. The reliability was excellent (Cronbach  $\alpha=.93$ ), and construct validity was demonstrated with confirmatory factor analysis, which produced a single factor [22].

### Demographic Characteristics

The following demographic characteristics were analyzed: gender, age, level of education, occupation, and prefecture status (under a state of emergency or not under a state of emergency). At the time of the survey, the Japanese government had declared a state of emergency because of the COVID-19 pandemic in 11 of the 47 prefectures, including the Tokyo metropolitan area [34]. The main points of this state of emergency plan were shortening the opening hours of restaurants and bars, reducing the number of employees in offices by 70%, avoiding nighttime outings, and limiting events.

### Statistical Analysis

We examined the distribution of responses to each COVID-19 preventive behavior items. Reliability and validity were verified, and Cronbach  $\alpha$  values were calculated to examine internal consistency. For construct validity, confirmatory factor analysis



was conducted to examine construct validity; the comparative fit index, the root mean square error of approximation, and the standardized root mean square residual were used as model fit indices. A comparative fit index value  $\geq .95$  represents a good fit, and a value  $\geq .90$  is generally considered to indicate acceptable model fit [35,36]. Root mean square error of approximation and standardized root mean square residual values  $< .05$  represent good fits, and values  $< .08$  are acceptable [35,36].

To determine which participants scored higher on COVID-19 preventive behaviors, we conducted multiple linear regression analysis (general linear model) with this variable as the dependent variable and demographic characteristics (gender, age group, education, occupation, and prefecture status) as independent variables.

To determine the extent to which the variables *health literacy*, *information evaluation*, and *decision-making process* can independently explain COVID-19 preventive behaviors, we conducted hierarchical multiple linear regression analysis with the COVID-19 preventive behavior score as the dependent variable and scores on health literacy, information evaluation,

and decision-making process as independent variables; demographic characteristics (gender, age group, education, occupation, and prefecture status) were used as control variables.

Data were analyzed using SPSS and Amos software (version 27.0; IBM Corp).

### **Ethics Approval and Consent to Participate**

The study received prior approval from the Research Ethics Committee of St. Luke's International University, Japan (20-A076) and was conducted in accordance with the guidelines of the Declaration of Helsinki. Participants voluntarily signed a web-based informed consent form that was approved by the institutional review board.

## **Results**

### **Participants**

There were 3914 valid responses (Table 1). These included responses with less than 20% of missing values on all health literacy items, which enabled health literacy scores to be calculated as per the original HLS-EU-Q47 survey [12]. Data for these individuals were included in the analysis.

**Table 1.** Characteristics of study participants.

Characteristic	Participants (n=3914) or value
<b>Gender, n (%)</b>	
Men	1953 (49.9)
Women	1961 (50.1)
<b>Age (years), n (%)</b>	
20-29	567 (14.5)
30-39	721 (18.4)
40-49	891 (22.8)
50-59	785 (20.1)
60-69	950 (24.3)
Age, mean (SD)	46.9 (13.6)
<b>Highest level of education, n (%)</b>	
Junior high school	86 (2.2)
High school	981 (25.1)
2-year college	858 (21.9)
College or university	1806 (46.1)
Graduate	183 (4.7)
<b>Occupation, n (%)</b>	
Self-employed	191 (4.9)
Managerial and administrative	166 (4.2)
Professional and technical	463 (11.8)
Other (routine and manual)	1367 (34.9)
Part-time	474 (12.1)
Homemaker	652 (16.7)
Student	131 (3.3)
Unemployed	470 (12.0)
<b>Prefecture status, n (%)</b>	
Under a state of emergency	2387 (61.0)
Not under a state of emergency	1527 (39.0)
Health literacy score, mean (SD)	27.4 (9.4)

## Distribution of Responses

The item that received the highest percentage of *always* responses was cough etiquette (Table 2), followed by wearing a mask when close to someone, and handwashing. The most infrequently performed behavior was temperature taking (*always* response: 853/3914, 21.8%; *often* response: 717/3914, 18.3%).

The 3 most frequently performed behaviors had mean scores representing *often* (ie, >4): cough etiquette (mean 4.4, SD 1.0), wearing a mask when close to someone (mean 4.3, SD 1.0), and handwashing (mean 4.1, SD 1.2). The mean total preventive behavior score was 30.1 (SD 6.4).

**Table 2.** Responses for COVID-19 preventive behavior items.

Items	Responses, n (%)					Score, mean (SD)
	Always	Often	Sometimes	Rarely	Never	
1. Use a mask, tissue, handkerchief, or sleeve to cover your mouth and nose when coughing or sneezing	2408 (61.5)	890 (22.7)	368 (9.4)	158 (4.0)	90 (2.3)	4.4 (1.0)
2. Wear a mask when the distance between people is likely to be less than 2 m (meters)	2234 (57.1)	992 (25.3)	418 (10.7)	162 (4.1)	108 (2.8)	4.3 (1.0)
3. Wash your hands with soap or alcohol-based disinfectant before meals or upon returning home from outside, etc	2033 (51.9)	930 (23.8)	489 (12.5)	266 (6.8)	196 (5.0)	4.1 (1.2)
4. Try maintaining a minimum distance of 2 m (meters) from people	845 (21.6)	1479 (37.8)	986 (25.2)	440 (11.2)	164 (4.2)	3.6 (1.1)
5. Rest if you are not feeling well	1217 (31.1)	1059 (27.1)	805 (20.6)	497 (12.7)	336 (8.6)	3.6 (1.3)
6. Ventilate the room	1037 (26.5)	1133 (28.9)	986 (25.2)	506 (12.9)	252 (6.4)	3.6 (1.2)
7. Avoid touching your eyes, mouth, or nose after contact with doorknobs, railings, desks, light switches, etc	1035 (26.4)	1111 (28.4)	857 (21.9)	495 (12.6)	416 (10.6)	3.5 (1.3)
8. Take your temperature	853 (21.8)	717 (18.3)	932 (23.8)	798 (20.4)	614 (15.7)	3.1 (1.4)

### Reliability and Validity of the Total COVID-19 Preventive Behavior Score

We confirmed the reliability and validity of the total COVID-19 preventive behavior score (Cronbach  $\alpha=.83$ ). The comparative fit index was 0.963, the root mean square error of approximation was 0.073 (95% CI 0.067- 0.079), and the standardized root mean square residual was 0.035, which indicated acceptable fit. Error covariances were observed between 2 sets of items with similar wording in Japanese (set 1: items 1 and 2, set 2: items 5 and 8), but confirmatory factor analysis factor loadings were

>0.45 for all items, and a unidimensional structure was confirmed.

### Multiple Linear Regression

For COVID-19 preventive behaviors, scores were higher for women than for men ( $P<.001$ ), and participants with higher levels of education had higher scores ( $P<.001$ ) (Table 3). Participants in occupational, managerial, and administrative jobs had the highest preventive behavior scores, and participants who were unemployed had the lowest scores ( $P<.001$ ). Participants in prefectures under a state of emergency had higher preventive behavior scores ( $P<.001$ ).

**Table 3.** Multiple linear regression results for COVID-19 preventive behaviors as the dependent variable.

Variables	Estimated marginal mean (95% CI)	F test (df)	P value
<b>Gender</b>		141.9 (1,3913)	<.001
Men	28.4 (27.9, 28.8)		
Women	31.2 (30.7, 31.7)		
<b>Age (years)</b>		.7 (4,3913)	.63
20-29	29.7 (29.1, 30.3)		
30-39	29.9 (29.4, 30.5)		
40-49	29.6 (29.1, 30.2)		
50-59	29.6 (29.1, 30.2)		
60-69	30.0 (29.5, 30.5)		
<b>Highest level of education</b>		4.6 (4,3913)	.001
Junior high school	28.0 (26.6, 29.3)		
High school	29.7 (29.3, 30.1)		
2-year college	30.4 (30.0, 30.9)		
College or university	30.2 (29.9, 30.6)		
Graduate	30.6 (29.7, 31.6)		
<b>Occupation</b>		6.0 (7,3913)	<.001
Self-employed	29.3 (28.4, 30.3)		
Managerial and administrative	31.5 (30.5, 32.5)		
Professional and technical	29.1 (28.5, 29.7)		
Other (routine and manual)	29.6 (29.2, 30.1)		
Part-time	29.8 (29.2, 30.4)		
Homemaker	30.4 (29.8, 31.0)		
Student	30.0 (28.8, 31.2)		
Unemployed	28.6 (27.9, 29.2)		
<b>Prefecture</b>		33.1 (1,3913)	<.001
Under a state of emergency	30.4 (30.0, 30.8)		
Not under a state of emergency	29.2 (28.8, 29.6)		

### Hierarchical Multiple Linear Regression

Pearson correlations (Table 4) between COVID-19 preventive behaviors and health literacy, information evaluation, and decision-making process were  $r=0.23$  ( $P<.001$ ),  $r=0.24$  ( $P<.001$ ), and  $r=0.30$  ( $P<.001$ ), respectively.

An examination of the change in health literacy from model 1, in which only health literacy was entered as an independent

variable, to model 3, which included all 3 variables, showed that the standardized regression coefficient approximately halved (model 1:  $\beta=.20$ ; model 3:  $\beta=.11$ ), whereas the changes for information evaluation (model 2:  $\beta=.15$ ; model 3:  $\beta=.13$ ) and decision-making process (model 1:  $\beta=.20$ ; model 3:  $\beta=.18$ ) were less pronounced; both standardized regression coefficient remained similar even after controlling for health literacy.

**Table 4.** Hierarchical multiple linear regression analysis of COVID-19 preventive behaviors, controlling for demographic variables (gender, age, education, occupation, and prefecture status).

Independent variable	Correlation		Model 1 <sup>a</sup>			Model 2 <sup>b</sup>			Model 3 <sup>c</sup>		
	<i>r</i>	<i>P</i> value	$\beta$	<i>t</i> value	<i>P</i> value	$\beta$	<i>t</i> value	<i>P</i> value	$\beta$	<i>t</i> value	<i>P</i> value
Health literacy	0.23	<.001	.20	13.0	<.001	— <sup>d</sup>	—	—	.11	6.8	<.001
Information evaluation	0.24	<.001	—	—	—	.15	8.3	<.001	.13	7.4	<.001
Decision-making process	0.30	<.001	—	—	—	.20	11.3	<.001	.18	9.9	<.001

<sup>a</sup> $R^2=0.12$ , and adjusted  $R^2=0.12$ ;  $F(18,3913)=30.6$ ,  $P<.001$ .

<sup>b</sup> $R^2=0.18$ , and adjusted  $R^2=0.18$ ;  $F(19,3913)=45.3$ ,  $P<.001$ .

<sup>c</sup> $R^2=0.19$ , and adjusted  $R^2=0.19$ ;  $F(20,3913)=45.9$ ,  $P<.001$ .

<sup>d</sup>Data not included.

## Discussion

This study demonstrated that health literacy was associated with COVID-19 preventive behaviors. However, information evaluation and decision-making process skills, which are not limited to health information, showed a similar strength of association with preventive behaviors. Because the assessment of health literacy in this survey focused mainly on daily health information, it may reflect the ability to cope with common diseases, including familiar infectious diseases and may be inadequate to assess responses to pandemics caused by new viruses (or infodemics). In situations in which the evidence is insufficient or not immediately communicated in an easy-to-understand manner, skills in information evaluation and decision-making process (not necessarily limited to health information) are important.

The decision-making process showed the strongest association with preventive behaviors in all analyses, even after controlling for health literacy and information evaluation. The results show that an engagement in COVID-19 preventive behaviors is associated with rational decision-making skills. To make rational decisions (ie, decisions that are purposeful and have clear reasons), an individual must engage in the process of generating options, comparing the pros and cons of those options, and selecting the option that best fits their values. The importance of this process has been demonstrated in business and health, both of which require individuals to regularly make important decisions [37]. This process is essential to the practice of shared decision-making in health, which is a collaboration between health care professionals and consumers [38]. Similarly, in evidence-based health care, consumer values and decision-making preferences are as important as evidence [39]. Furthermore, the Ottawa Decision Support Framework [40] states that to improve the quality of decision-making, individuals must make choices according to the perceived importance of the pros and cons of each option.

To implement COVID-19 preventive behaviors, we first need to know what the options are and which behaviors lower or raise the risk. Then, we need to be able to evaluate the balance and trade-offs between infection-prevention behaviors and work, connections with family and friends, stress, and mental health. To make decisions appropriate to their personal values, people need to be familiar with making decisions that clarify their

values on a regular basis; it may be difficult to clarify personal values on the spur of the moment. Some international comparative studies [41-43] have shown that Japanese people have low self-esteem in decision-making and tend to make intuitive decisions rather than rational decisions. Therefore, this is an opportunity to draw attention to the importance of rational decision-making skills.

The association between preventive behaviors and information evaluation and decision-making skills that we found may indicate that the lack of these skills leads to a higher risk of infection. These differences could result in individual disparities in new health issues, which could be greater for infectious diseases as people infect others around them. In making important decisions, it is necessary to ensure that the information on which the decision is based is sufficiently reliable to determine the pros and cons of each option and to identify which pros and cons are important. However, in a survey [22] in Japan, only approximately 30% to 50% of respondents answered that they always or often made decisions in such a manner. Furthermore, more than 40% of respondents reported that they did not have the opportunity to learn these skills. Therefore, it is necessary to create an environment in which everyone can learn these skills. Respondents who had had the opportunity to learn these skills usually acquired them from the internet (approximately 40%), followed by television (approximately 30%), and newspapers and magazines (approximately 15%). It may therefore be useful to consider providing information through these media [22].

Our findings also indicate that individuals who lack skills in information evaluation and decision-making do not receive sufficient reliable information to enable decision-making. Transparent, honest communication is important to control the pandemic [4]. It would be useful to develop a website or social media source where people could obtain the latest reliable and easy-to-understand information and make decisions. In Japan, there is no organization equivalent to the US Centers for Disease Control and Prevention, and no clear source of information in the event of an infectious disease or pandemic; therefore, a solution to this problem is needed.

In addition to providing information and services that are easy to understand, there is a need to support decision-making, especially for individuals with poor decision-making skills. One early initiative was the creation of a decision aid by the



Gerontological Society of America to enable people to determine whether to interact with people and participate in activities outside the home [44]. To prepare for pandemics, it is necessary to create a system that can rapidly develop and disseminate such a tool.

This study had several limitations. It is possible that there was some sample selection bias. Participants may have been skewed toward a high level of internet literacy because of the use of a web-based survey. Recruitment of respondents was based on self-selection from a group of individuals who had previously expressed a desire to participate in research projects. The responses were limited to approximately the first 4000 people; therefore the sample may have included only individuals who were most active on the internet (eg, frequently checking email). Although users familiar with the internet and social media may find it easier to obtain health information, they may become confused by the large amount of often contradictory health information available. There is evidence that internet literacy is not the only factor that determines whether people access health information using electronic sources [45]. The results of our study suggest that even people with sufficient internet literacy also need health literacy, information evaluation skills, and decision-making skills to take appropriate health action in response to an infodemic.

Items were created from 5 information evaluation criteria; however, these were just representative items; many alternative,

more detailed items could have been chosen (eg, the affiliation of the author of the information). However, rather than covering a wide range of content, the goal was to identify the core aspects of information evaluation associated with COVID-19 preventive behaviors. These issues also apply to the 4 decision-making items. For example, the description *decision-making* includes clarification of the problem before checking the options, as well as action and evaluation after the decision is made. However, because we used the shared decision-making process as a reference, we focused on the process required to make a decision, assuming that the problem was already apparent. The aim was, not to create a scale to cover all skills needed in the decision-making process, but, to determine if specific key points were related to COVID-19 preventive behaviors.

This study was also limited because it used cross-sectional data, which does not allow a firm conclusion to be drawn.

For new nonroutine health challenges, for example, understanding and using preventive behaviors during a pandemic such as that of COVID-19, the ability to evaluate all information and make appropriate decisions is required. However, because some people experience difficulty with this, there is a substantial need to provide reliable and easy-to-understand information and to support people in choosing appropriate actions by creating an environment that allows individuals to learn information evaluation and decision-making skills at any age.

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## Authors' Contributions

KN designed the study and contributed to writing the manuscript. KN had full access to all study data and takes responsibility for the integrity of the data and the accuracy of the data analysis. KH performed data collection. YY contributed to the study design. All authors contributed to the questionnaire development process. All authors read and approved the final manuscript.

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## Conflicts of Interest

None declared.

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### Multimedia Appendix 1

Questionnaire on COVID-19 preventive behaviors (Japanese version).

[[DOCX File, 17 KB - formative\\_v6i1e34966\\_app1.docx](#)]

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### Multimedia Appendix 2

Questionnaire on information evaluation and decision-making process skills (Japanese version).

[[DOCX File, 35 KB - formative\\_v6i1e34966\\_app2.docx](#)]

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## Abbreviations

**HLS-EU-Q47:** European Health Literacy Survey Questionnaire

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Original Paper

# Collaborative Research and Development of a Novel, Patient-Centered Digital Platform (MyEyeSite) for Rare Inherited Retinal Disease Data: Acceptability and Feasibility Study

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## Abstract

**Background:** Inherited retinal diseases (IRDs) are a leading cause of blindness in children and working age adults in the United Kingdom and other countries, with an appreciable socioeconomic impact. However, by definition, IRD data are individually rare, and as a result, this patient group has been underserved by research. Researchers need larger amounts of these rare data to make progress in this field, for example, through the development of gene therapies. The challenge has been how to find and make these data available to researchers in the most productive way. MyEyeSite is a research collaboration aiming to design and develop a digital platform (the *MyEyeSite platform*) for people with rare IRDs that will enable patients, doctors, and researchers to aggregate and share specialist eye health data. A crucial component of this platform is the *MyEyeSite patient application*, which will provide the means for patients with IRD to interact with the system and, in particular, to collate, manage, and share their personal specialist IRD data both for research and their own health care.

**Objective:** This study aims to test the acceptability and feasibility of the MyEyeSite platform in the target IRD population through a collaborative patient-centered study.

**Methods:** Qualitative data were generated through focus groups and workshops, and quantitative data were obtained through a survey of patients with IRD. Participants were recruited through clinics at Moorfields Eye Hospital National Health Service (NHS) Foundation Trust and the National Institute for Health Research (NIHR) Moorfields Biomedical Research Centre through their patient and public involvement databases.

**Results:** Our IRD focus group sample (n=50) highlighted the following themes: *frustration with the current system* regarding data sharing within the United Kingdom's NHS; positive *expectations* of the potential benefits of the MyEyeSite patient application, resulting from increased access to this specialized data; and concerns regarding data security, including potentially unethical use of the data outside the NHS. Of the surveyed 80 participants, 68 (85%) were motivated to have a more active role in their eye care and share their data for research purposes using a secure technology, such as a web application or mobile app.



**Conclusions:** This study demonstrates that patients with IRD are highly motivated to be actively involved in managing their own data for research and their own eye care. It demonstrates the feasibility of involving patients with IRD in the detailed design of the MyEyeSite platform exemplar, with input from the patient with IRD workshops playing a key role in determining both the functionality and accessibility of the designs and prototypes. The development of a user-centered technological solution to the problem of rare health data has the potential to benefit not only the patient with IRD community but also others with rare diseases.

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## KEYWORDS

MyEyeSite; inherited retinal diseases (IRD); rare diseases; genetics; ophthalmology; digital health; eye data; GDPR; subject access request (SAR); mobile phone

## Introduction

### Inherited Retinal Diseases and Challenges in Accessing Eye Data

Inherited orphan rare eye diseases are genetic eye diseases that have not been adopted for drug development. This group of conditions includes inherited retinal diseases (IRDs), an umbrella term for lifelong genetic conditions that affect the retina. Although *rare diseases* may be individually rare, they are collectively common, with 1 in 17 people being affected by a rare disease at some point in their lives [1]. IRDs are a leading cause of blindness in children and working age adults in the United Kingdom and other countries, with an appreciable socioeconomic impact [2,3]. People with IRD face a range of challenges that are both directly and indirectly related to their eye condition. These may include a delayed or inconclusive diagnosis (which can be especially challenging for children with IRD and their caregivers) and no access to curative treatment, difficulty accessing specialist clinicians with expertise in their condition, a lack of awareness from others regarding their eye condition, and a myriad of other disease-specific quality of life issues [4,5].

Eye care for IRD is highly specialized, requiring complex genetic information as well as large amounts of clinical data, including high-dimensional ophthalmic images, such as optical coherence tomography scans, taken over the course of a patient's lifetime [6,7]. Therefore, although rare eye diseases are often analyzed at a great level of detail (deeply phenotyped), these specialized data tend to be *siloed* and fragmented across multiple specialist sites, making it difficult for doctors (most often ophthalmologists) to access all relevant data regarding a patient before an appointment. Doctors are often reliant on patients to collate their data from various sources and bring it with them to an appointment. In the United Kingdom, patients are not given easy access to their medical records, which has led to a culture of private digital data *hacks*, including taking photos of medical letters and computer screen displays and bringing these to a medical appointment. We do not believe that this is an acceptable situation as it introduces risks with regard to patient data confidentiality and information governance (IG), which could be mitigated by providing more robust and efficient systems for sharing patients' health data. Furthermore, it runs contrary to the principles of the UK General Data Protection Regulations, which state that data should be made available in an "accessible, concise and intelligible format" and "disclosed securely" [8].

Difficulty accessing IRD data is further compounded by the lack of publicly available natural history information for specific gene mutations relevant to IRD and poor knowledge regarding the correlation between clinical observations (objective measures) and first-hand experiences of IRD reported by the affected people (subjective measures) [9]. The incidence of the early stage disease remaining undetected or being misdiagnosed [10] because of lack of data makes it more difficult to ascertain the prevalence of these diseases, especially at a genetic level. Streamlining the process of secure health data sharing at both national and international levels while delivering data with the required level of clinical and technical details for clinical and research purposes is a challenge. However, it has the potential to transform health outcomes [11] and positively affect the cost of IRD both for individuals and health services [2]. It is also likely to accelerate the process of therapeutics discovery, including gene therapies [12,13], through enhanced recruitment in clinical trials, an ambition that aligns with the United Kingdom national health research strategy to create the best research for the best health [14].

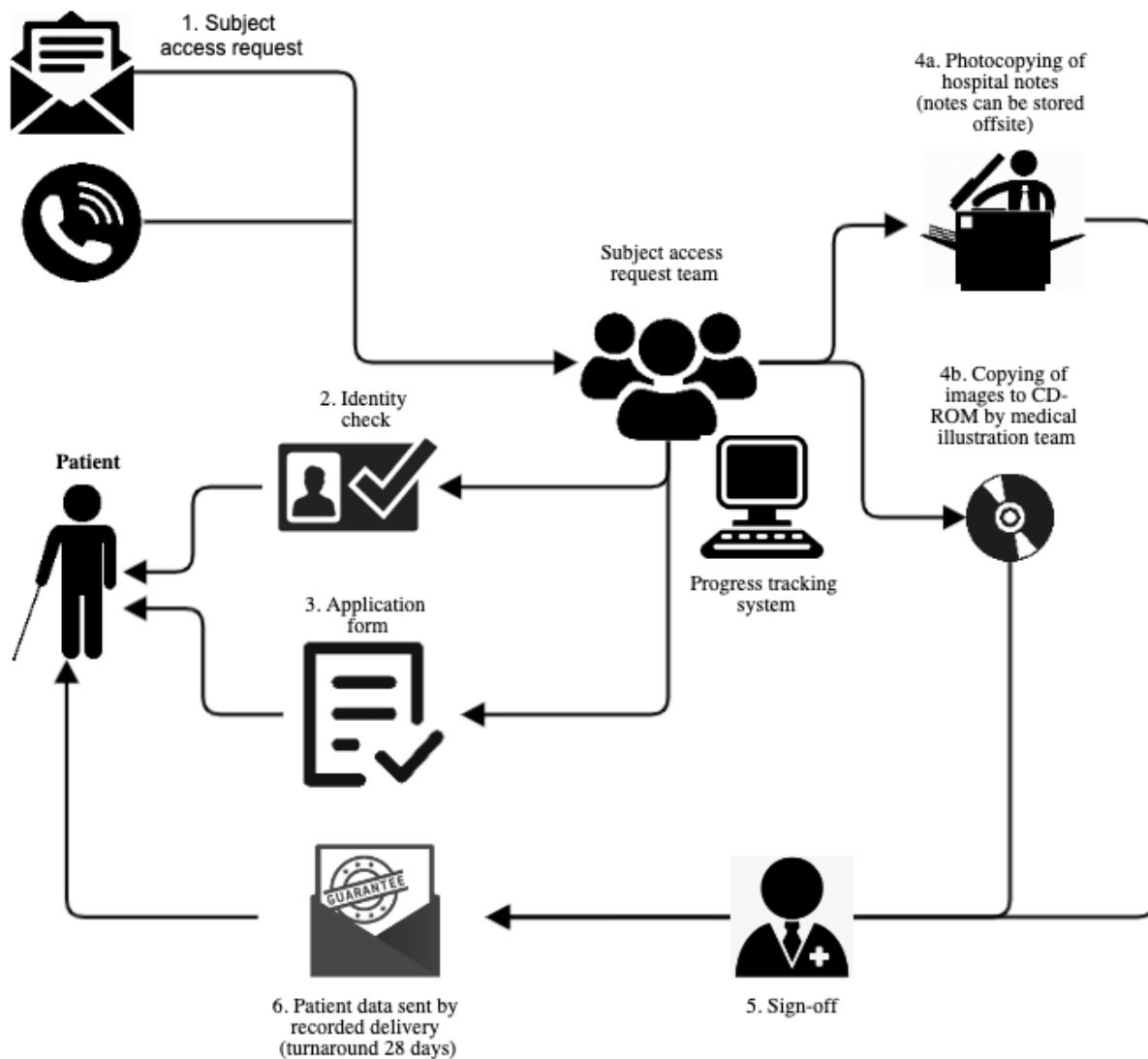
As IRDs are individually rare, there is a lack of disease-specific data for every IRD, which is suitable for research. The available data are widely dispersed and difficult to consolidate. This is a limiting factor in research, and as a result, the patient with IRD population is underserved compared with patients with more common disorders. To address these issues, researchers need access to comprehensive, linked, longitudinal phenotypic, and genomic data in a suitable format. The data need to be extracted from patient registries across the United Kingdom National Health Service (NHS) hospital systems and other sources, linked to genomic data and prepared (coded) for research. Patient registries are an essential tool for increasing current knowledge regarding rare diseases [15,16]; however, the way the registry is designed and organized is key. Attention must be paid to making the data findable, accessible, interoperable, and reusable and to IG and data quality, among other aspects, of the database architecture [17].

Patients have the right to access their data, as laid out by the General Data Protection Regulations [8,18,19]. Obtaining personal copies of detailed medical data requires the patient to submit a subject access request (SAR) to an individual NHS Hospital Trust, a procedure that requires a response within 4 weeks. The data returned to the patient is often in the form of photocopied paper notes and a CD of images, if available (Figure 1). Although the SAR process is unsustainable at scale, it stands to reason that the person best placed to initially access a

complete individual data set is the patient with IRD. The experiences of living and dealing with a rare disease [20] make patients with IRD a particularly motivated population to catalyze digital innovation for patient benefit. Therefore, we propose an

IG-compliant platform and application (MyEyeSite) for digitally processing, sharing, and storing eye data at the necessary scale and speed, which is managed by patients with IRD without the need for special expertise.

**Figure 1.** Example of subject access request process at Moorfields Eye Hospital National Health Service Trust.



### The MyEyeSite Project: Aims and Approach

The MyEyeSite project is a collaboration among Moorfields Eye Hospital NHS Trust, Loft Digital, and University College London Institute of Ophthalmology, which began work on a feasibility study funded by the Health Data Research United Kingdom in 2019. This project adopted user-centered design principles and a particularly patient-centered approach as

fundamental to its methodology. In striving to address the myriad of challenges of data linkage across the NHS outlined above (detailed in [Multimedia Appendix 1](#) [2,21-27]), the project set out to establish digital tools and streamlined workflows to help individuals in the IRD community access and make the best possible use of their eye health data through 5 specific aims ([Textbox 1](#)).

**Textbox 1.** Aims of the MyEyeSite platform and patient application.

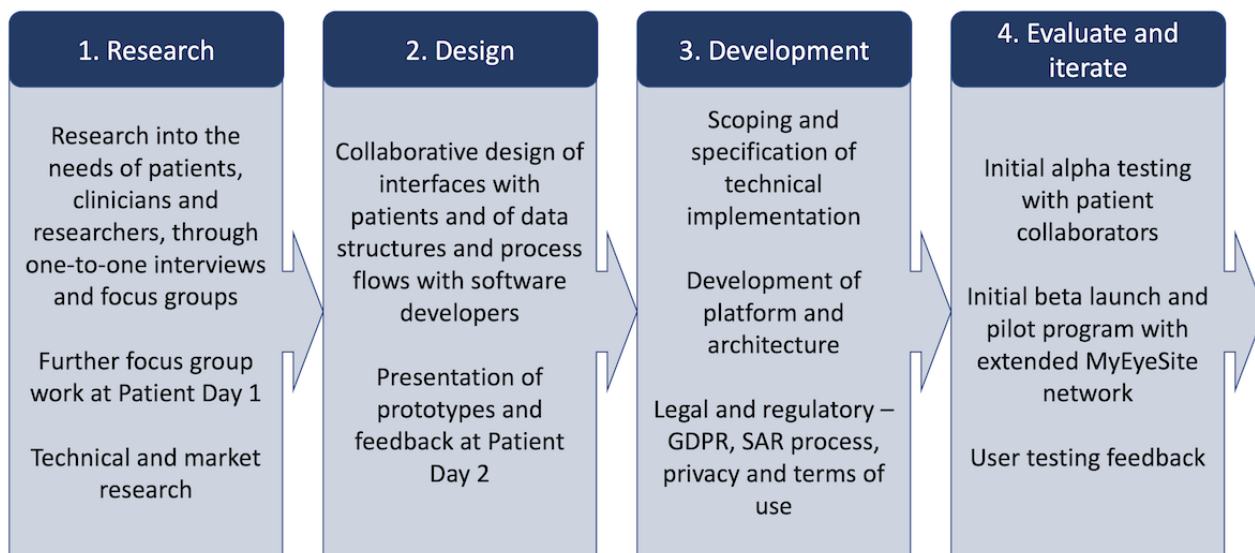
**Aims of the MyEyeSite platform and patient application**

- To aggregate consented rare disease data into a centralized electronic location
- To exploit the unique position of the patient as pivotal in this process through the subject access request system and ensure their access to their own data for self-management of their care (this also meant ensuring that the MyEyeSite patient application was fully accessible to those with severe sight impairment)
- To enable access to the data for clinicians and researchers in a safe and compliant manner so as to increase research on inherited retinal diseases
- To facilitate the communication of data and, therefore, knowledge between secondary and tertiary treatment centers to enhance treatment
- To develop a model of data curation that could be an exemplar for rare diseases in other medical specialties

The scope of the initial program of work was to evaluate the feasibility of the endeavor from a range of perspectives (involving user, market, technical, and security research) and to develop a prototype of the proposed platform and patient

application that could be tested on smartphones, tablets, or desktop computers. The process for this phase of development is outlined in [Figure 2](#).

**Figure 2.** High-level schematic of the work program to develop the MyEyeSite platform. GDPR: General Data Protection Regulation; SAR: subject access request.



An enriched picture of future objectives and uses for the technology was also established based on use-case scenarios ([Textbox 2](#); [Figures 3 and 4](#)).

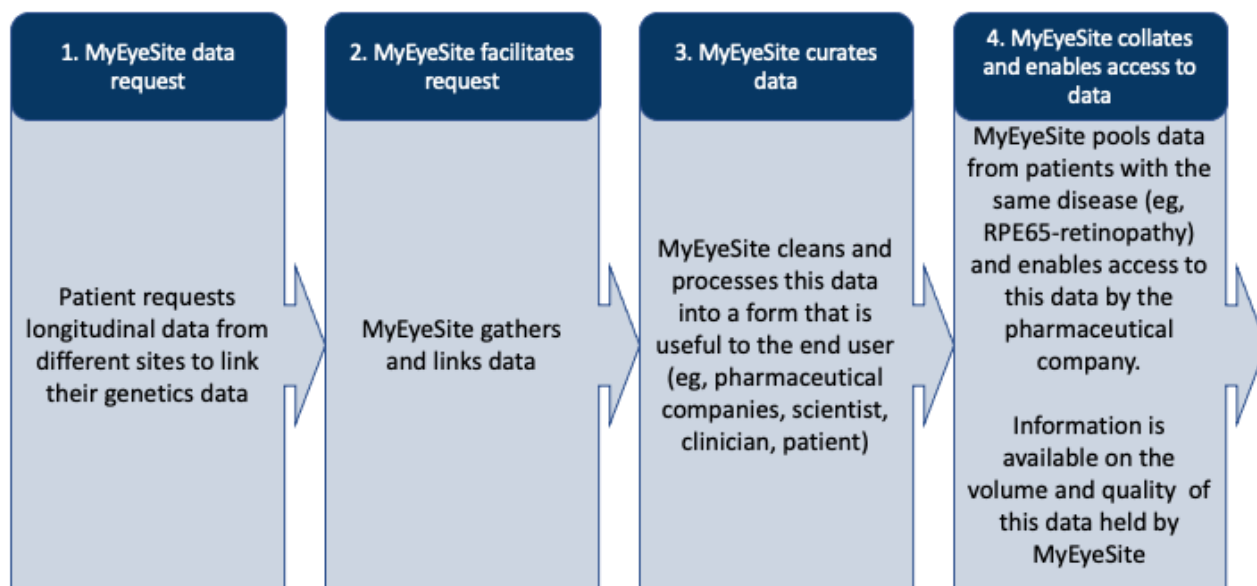
The MyEyeSite *use case* is outlined in [Figures 3 and 4](#).

**Textbox 2.** Intended uses of the MyEyeSite platform.

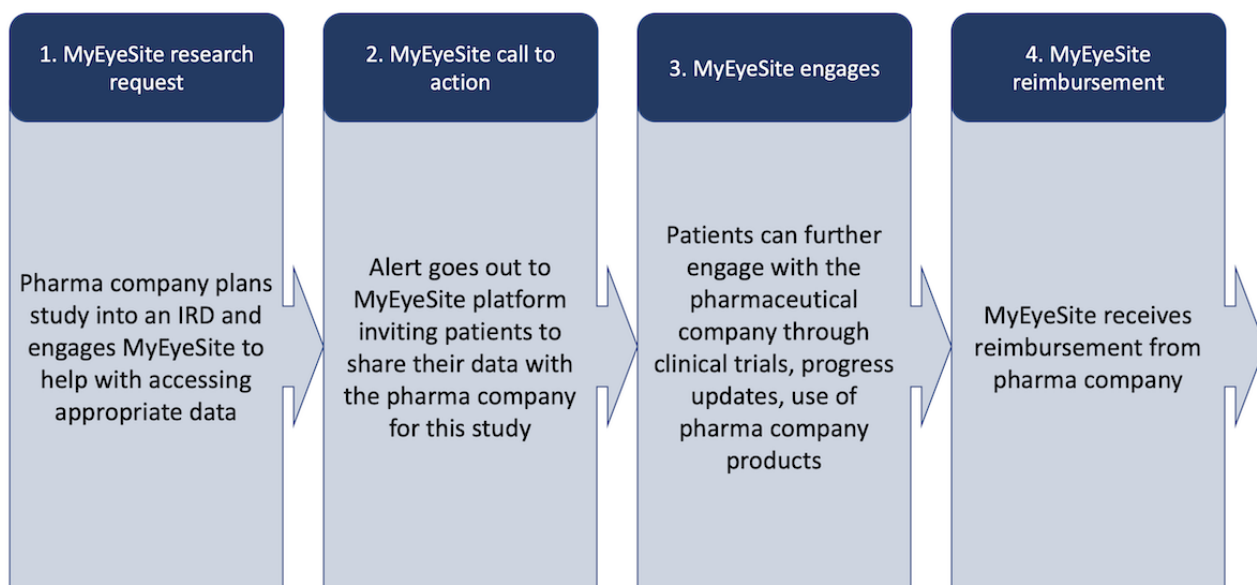
**Intended uses of the MyEyeSite platform**

- To facilitate subject access requests from patients to hospitals for disease-appropriate data
- To provide a framework for hospitals to respond efficiently to such patient requests
- To allow patients to access their own data in an informative way, robust to sight impairment
- To provide pooled data on consented patients for research purposes

**Figure 3.** MyEyeSite: patient data request process.



**Figure 4.** MyEyeSite: researcher data request and engagement process. The request example used here is from a pharmaceutical company. IRD: inherited retinal disease.



The underlying strategy of the MyEyeSite platform is to connect groups of patients with IRD with similar conditions and uniquely valuable data sets to research projects and clinical trials with the potential to restore sight using a patient-centered methodology.

**The MyEyeSite Project: Patient Engagement Study Design and Objectives**

There is a high expectation among patients regarding the quality of communication between health care providers and themselves [28,29], and this is consistent with the shift in medicine toward patient-centered care. Thus, it has become the accepted best practice to engage patients in the design process of eye care interventions [30-35]. A study involving patients with retinitis pigmentosa, a relatively common phenotype within IRD, showed

that engagement strategies significantly affected the vision-related quality of life and emotional health, with disengagement having a particularly negative effect [36]. Furthermore, the UK Medical Research Council guidance on developing complex interventions states that the best practice is “to develop interventions systematically, using the best available evidence and appropriate theory, then to test them using a carefully phased approach, starting with a series of pilot studies targeted at each of the key uncertainties in the design, and moving on to an exploratory and then a definitive evaluation” [37].

The first phase of developing the MyEyeSite platform intervention focused on engagement with our target population: the patient with IRD community. We aimed to follow the principles set out in the UK government’s Department of Health and Social Care’s policy paper [38], which describes the involvement of users throughout the research, design, and build process.

The objective of this study was to test the acceptability and feasibility of the MyEyeSite platform. For the purposes of developing the MyEyeSite platform, stakeholders were engaged via multiple methods, which included individual interviews, focus groups, a web-based survey, professional networks, conference presentations, and public engagement events. Participants provided verbal and written consent for their data to be used for this project. According to the UK NHS Health Research Authority and Medical Research Council guidelines on defining research [39], this pilot study was not deemed a formal research study, and so, NHS ethical approval was not required.

## Methods

### Thematic Analysis of Focus Groups and Workshops

#### Recruitment

Patients with IRD were specifically recruited for MyEyeSite focus groups, technology design, and user research workshops via specialist retinal clinics at the Moorfields Eye Hospital in London and across the United Kingdom, patient charities (The Macular Society, Retina United Kingdom, Bardet–Biedl Syndrome United Kingdom, and Fight for Sight), and a patient registry held by the National Institute for Health Research (NIHR) Moorfields Biomedical Research Centre.

#### Patient and Public Involvement and Thematic Analysis

Focus groups were conducted with 5 participants in each group in June 2019 at a patient and public involvement event in London. Following the interviews, a sample size of 20 was

finalized when no new codes or themes were identified, and it was concluded that saturation had been reached. A total of 2 technology design workshops were held in November 2019 and attended by a further 30 participants to discuss the MyEyeSite patient application design prototype, which had been prepared in Adobe XD. The application interface was presented to the participants on a large screen that they were able to access either directly or by taking a photo of the screen on their mobile device and magnifying that image to suit their personal needs. Screen-reader technology was also used in these workshops.

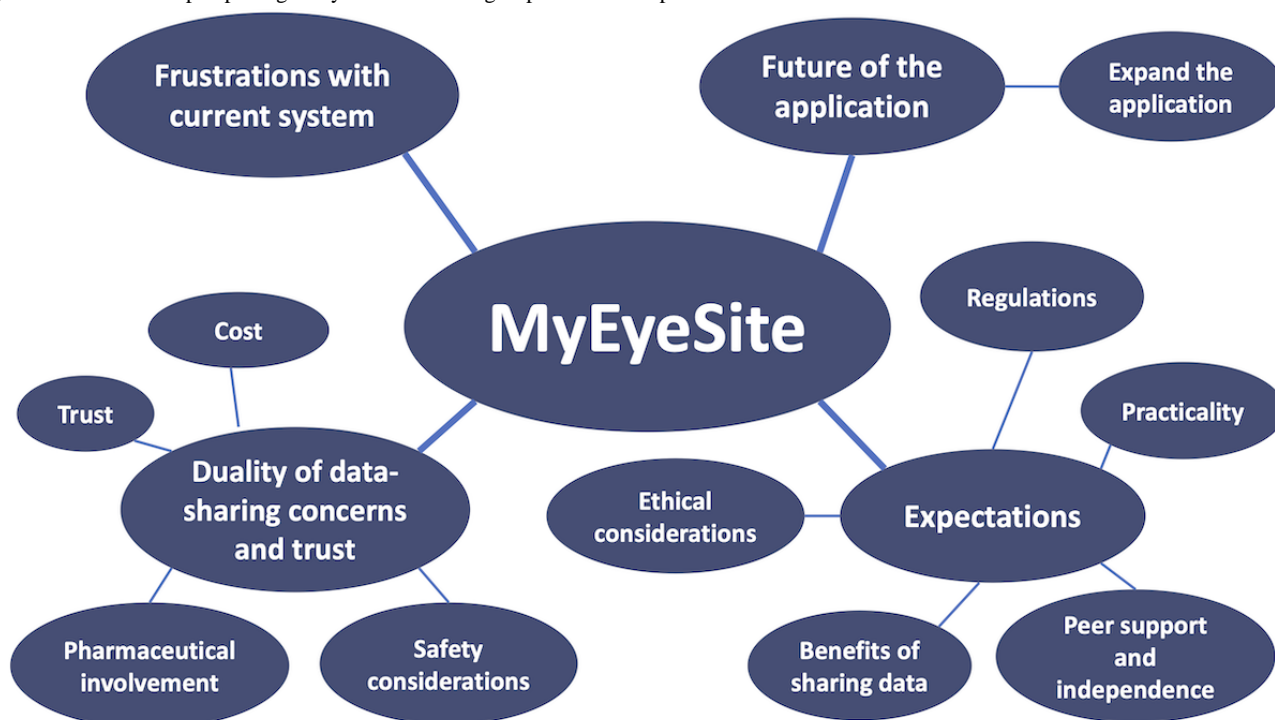
The 50 participants ranged in age from 10 to 75 years. The group was informed of the purpose of the discussions, how the data would be used, and how to withdraw from the group. Informed consent was obtained for participation and use of their data to develop MyEyeSite. The discussions followed a semistructured guide exploring how the patients would feel regarding their clinical data being stored on a digital platform and subsequently being used for research. Patients’ experiences and concerns regarding sharing data with universities and pharmaceutical companies were also investigated. The focus groups (moderated by RMG, ARW, NN, SS, and SVDS) averaged 58 (SD 1.2) minutes and were audio taped and transcribed verbatim, with participants deidentified using pseudonyms. A short film demonstrating some of these approaches is available to view as a QuickTime (Apple, Inc) video file in [Multimedia Appendix 2](#).

An inductive thematic analysis was conducted to analyze the data following the Braun and Clarke 5-step guide [40,41]. This method was chosen to analyze the qualitative (transcribed) data for the following reasons: it is a useful method for working within the participatory research paradigm (with participants as collaborators), it can usefully summarize the key features of a large body of data, it can generate unanticipated insights and allow for social as well as psychological interpretations of data, and its results are generally accessible to the educated general public.

The transcripts were read and reread to understand the depth of the data and then transferred into NVivo (version 12 QSR International), a computer-assisted qualitative data analysis software tool for organizing, storing, and analyzing transcribed data [42], where the codes were initiated. Following this, the codes were combined into themes. The creation and discussion of the themes took place during face-to-face meetings between the authors to make sure that those themes were applicable to the codes, true to the data set, and reflective of the meaning that the participants intended. Finally, the themes were defined, transcript quotations were chosen to illustrate the themes, and a *thematic map* was produced ([Figure 5](#)).



**Figure 5.** Thematic map depicting analysis of the focus group and workshop discussions.



### Web-Based Survey of Patients with IRD

We conducted an anonymous Google Forms survey ([Multimedia Appendix 3](#)) of views within the IRD community regarding the sharing of eye data, which was circulated via patient charities, eye clinics, social media, and our project's website.

## Results

### Qualitative Results

The thematic analysis of the focus group and workshop discussions outlined four main themes ([Figure 5](#)): (1) frustration with the current system, (2) expectations from a digital application, (3) duality of concerns and trust, and (4) future of the MyEyeSite platform.

#### **Theme 1: Frustrations With the Current System**

The IRD focus group participants expressed frustrations with the current NHS eye data system, which stores their data locally in each hospital and does not allow these data to be easily accessed and shared across hospitals. Patients highlighted the need to have easy access to their data so they could share it with other health care providers involved in their care. Some reported that they kept all of their paper hospital records with themselves so that they could bring them to every eye clinic appointment. They expressed interest in having all their digital data in one electronic location, which they could access through an application such as the MyEyeSite patient application. The following quotation from a patient with IRD highlights an instance where she relocated to a different geographic area, which resulted in the loss of all her eye data, including her family history map of IRD:

*From a personal perspective as well, we wouldn't have lost our data and my mother would be able to*

*know which side of the family all this came down from. So, if I'd have had that data we would still have that along with my letters from 1995. Yeah so, you will not lose your own data because it's so important to you whereas we are just 1 in 60 million people in the United Kingdom. [Participant 6]*

#### **Theme 2: Expectations of the MyEyeSite Patient Application**

##### **Benefits of Sharing Data, Peer Support, and Independence**

Participants felt that there would be real benefits to using a patient-focused application for tackling the current issues of disaggregated NHS data, which would obviate the need to make individual, institutional data requests via a SAR process. They felt that an application might allow them to participate in research trials with potentially positive health outcomes as a result of accelerated research processes. Participants also described a sense of increased agency and being empowered to manage their conditions through a central place where they could self-administer changes in their personal details and be in control of their own health data, including how it was used in research:

*But if they got in touch with that particular patient and explained the reason why they want to copy it, and then we can give that permission, so it's granted by the patient. [Participant 4]*

The desire for an application to facilitate a sense of community through the linkage of patients with similar eye conditions was strongly expressed:

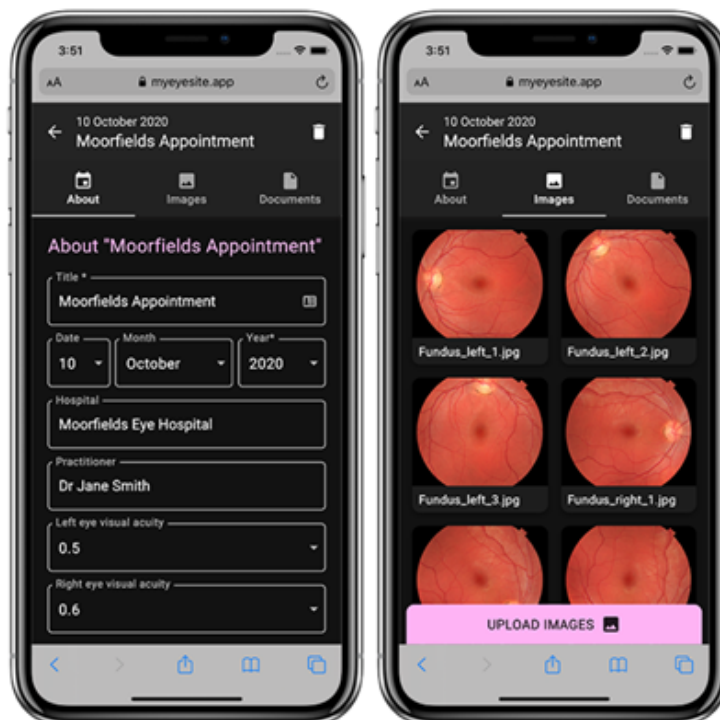
*I mean there's a great need for people to know that there are other people around that have the same problem or a similar problem. There's great need. [Participant 5]*

*I was going to say...is there any value in links maybe? If you suddenly feel totally isolated and you've just been told that you'll lose your eyes and nothing can be done, however these links may be of use to you in your area. [Participant 3]*

### Practicality of the Application: Accessibility

The user research workshop sessions, which tested the *front-end* design of the patient application (Figure 6; Multimedia Appendices 4 and 5), highlighted diverse accessibility requirements, even within the patient with IRD group.

**Figure 6.** Example of the MyEyeSite patient application front-end design for a smartphone.



Patients had different requirements of the visual display according to their diagnosis, level of disease progression, and disability from vision loss. Detailed discussions led to an expansion of the available accessibility features so that, in addition to user-friendly fonts and common color options (normal, high contrast, and dark mode), settings were introduced for users who have difficulty perceiving specific colors. Some patients relied on a screen-reader software such as Job Access With Speech (Freedom Scientific, Inc) [43] to access information. It was also apparent that some older adults found it difficult to access or navigate the applications because of a lack of experience with digital tools, as well as vision problems. These individuals often relied on their neighbors, friends, or families for assistance.

Participants felt that any application should be accessible both on their smartphones and via a desktop (using a web browser) and expressed the need to have their data available in lay terms that avoid medical jargon. User-friendly access to the application could also allow them to perform some simple analyses and plot graphs to self-monitor their condition.

### Practicality of the Application: Functionality

Sharing of data in an anonymized form was perceived as a necessary safety feature by participants:

*I would be happy to share my clinical information if it helps research or...but then maybe to disconnect my personal sort of data away from that. [Participant 3]*

*If people want to access that anonymous data that's got genetic information and my age or whatever it might be, but nothing else that identifies me, you don't have to ask me every time for that. [Participant 6]*

Participants expressed a desire to have an easy *opt-in* and *opt-out* option to take part in research studies and receive notifications to let them know whether they were eligible to participate and whether there were any significant findings from the research in which they participated:

*The other bit for me was the research piece, which was to say anonymised data; people can access my clinical data [but] I would want to make sure individual [research] requests come through to me. [Participant 6]*

### Regulations and Ethical Considerations

Participants suggested a form of recognition or incentives for sharing their data with parties external to the NHS and called attention to the need for clear policies, strict controls, and security systems in any digital technology to protect their personal details from people who might use it for unethical purposes. In particular, they asked for transparency and traceability regarding access to their data, as highlighted by the following quotations:

*So, knowing, I suppose, where that data's going, who's got the data, or what it could be used for, the potential research...just knowing kind of an overview of what it's for, what the reason this is for, then*

people can make that decision. I think it's important. [Participant 1]

If, for example, I was contacted by say an outside agency, an organisation, whether it was a researcher or if I was being, you know, [added] into some clinical trial and the clinical team wanted access to that, I would want to be asked, I would want to know exactly what that meant before I gave my consent. [Participant 3]

Participants raised further ethical concerns regarding decision-making around data sharing outside the NHS and power of attorney agreements with regard to data sharing for minors or severely sight-impaired patients:

You take away the competition don't you if you give them [pharma company] exclusivity. Then they can take their time and they might [take] another ten years over it. [Participant 7]

If somebody's got power of attorney already, does that mean automatically they now get access to this sort of thing? Because power of attorney means I can do what I need to do for you financially, but does that mean they can also access this or because I've gone doolally or whatever it is, I might have said, okay go do what you need to do - is this separately controlled or is it covered by that piece of the legality? [Participant 8]

### **Theme 3: Duality of Concerns Around Data Sharing and Trust**

Trust was identified as a key requirement for any data sharing agreement. Participants were motivated to share their data with clinicians, as they felt that this would contribute to finding a cure for their conditions:

I'm happy for the doctors, the opticians, the clinical side of people that I see, I would want them to have access to my information. That's absolutely fine. And it's for the right reasons. They're looking for a cure so it's all good isn't it? [Participant 3]

On the other hand, participants acknowledged the need for a balance between data accessibility and security:

So, for me the app, I like the idea of it. I like the idea of the bigger picture, which is, you know, what [we're] talking about, that kind of having that data that can help future research. I really like that sort of idea, but it's the security of it...it's just like if you lose your phone or—could this be manipulated in some way? It could be misused in some way. [Participant 5]

As patients we would want to make sure the app is secure. We would want a secure platform and some assurances behind that. I think the ability that the patient controls the access to whoever and is reminded on a regular basis you've given that access to people, to review it. [Participant 11]

I want to be able to see a log of who has accessed it and when. [Participant 9]

I think giving somebody a period of access with that: okay I'm happy to let that person be able to see it for three months, I'm happy to let that person see it for six months. Or, every year they come back and go, did you remind yourself that you actually had given permission to these people to access your data? Do you want to turn it on or off for anyone? [Participant 6]

To address some of these concerns, an external organization was invited to perform penetration testing on the application, and the messaging system between clinicians and patients was also improved to keep the patients better informed and help them feel more secure.

### **Theme 4: Future of the MyEyeSite Platform**

Some participants felt that if a platform for IRD data were developed, then as many patients as possible should be encouraged to use it to gain the most benefit for the community. Hence, they would support international data sharing, as it would allow the creation of larger data sets:

And to get to individualised care we have to have sharing of data in big groups of people because these diseases are all rare. I mean, achromatopsia there's only 35 people in the UK. So, you know, that needs to be international, I think. [Participant 1]

## **MyEyeSite Survey Analysis and Quantitative Results**

### **Demographic and Diagnostic Survey Data**

The MyEyeSite survey was completed by 80 participants between April 2019 and June 2020. Of these 80 participants, 71 (89%) identified as White, 9 (11%) as Asian or Asian British, and 1 (1%) as *other*. Of the 80 respondents, 40 (50%) identified as female, and 66 (83%) were equally distributed across the ages of 25 to 65 years. The highest levels of educational attainment among the respondents were as follows: 34% (27/80) had an undergraduate university degree, 25% (20/80) had a nonuniversity college qualification, 23% (18/80) had a postgraduate university degree, 10% (8/80) reported secondary school as their highest educational level, 6% (5/80) had technical or vocational education, and 4% (3/80) had primary school level education.

Of the 80 survey respondents, 98% (n=78) specified their IRD diagnoses as follows: 53% (n=42) had retinitis pigmentosa, 15% (n=12) had Stargardt disease, 25% (n=20) had *other* IRD diagnoses, and 5% (n=4) reported that they were *not sure* of their IRD diagnosis. A breakdown of the 25% (n=20) of patients reported *other* IRD diagnoses.

With regard to the prevalence of additional eye conditions to IRD, cataract was the most common, affecting 19% (15/80) of participants, followed by 5% (4/80) having age-related macular degeneration and 10% (8/80) of respondents (2 for each condition) reporting glaucoma, retinal detachment, uveitis, and dry eyes. On a scale of 1 to 5, with 1 being fully sighted and 5 being severely sight impaired, 26% (21/80) of respondents self-assessed their level of sight at level 5, 21% (17/80) at level 4, 29% (23/80) at level 3, 10% (8/80) at level 2, and 6% (5/80) at fully sighted (1 person did not respond to this question).

### Patients' Current Access to Personal Health Data

Currently, the only route by which patients can access their personal health data from a hospital in the United Kingdom is by making a SAR. Only 18% (14/80) of surveyed respondents had attempted to retrieve their health data this way and 6% (5/80) had not heard of a SAR before. Of those 14 who had performed a SAR, 50% (n=7) had found the process *extremely difficult* (level 5 on a Likert scale of 1-5) or very difficult (level

4), and for 8 (57%) respondents, the process was either wholly or partly unsuccessful in achieving their intended purpose.

The reasons for the completion of the SAR have been listed in [Textbox 3](#). All patients who had independently made a SAR self-assessed their vision at level 4 or 5 on the 1 to 5 scale of vision, with 1 being fully sighted and 5 being severely sight impaired. The MyEyeSite platform is able to accommodate all the reasons they gave for making a SAR, as well as those of nonpatients ([Textbox 3](#)).

**Textbox 3.** Reasons given for making a subject access request for hospital data.

#### Reasons for giving a subject access request

- To get my son's genetic testing information (he has Stargardt disease)
- To gather insight for the MyEyeSite project
- For my own curiosity
- To have photos of my retina scans
- For fertility/genetics consulting via Genetics
- French clinical trial
- To support the claim for personal independence payment
- For curiosity and for information when I was pregnant with my son
- I wanted copies of my records to understand what they comprised and understand more about my condition
- Asked to by project team and personal interest
- Hearing test data required by another hospital

### Patients' Access to Personal Health Data Using MyEyeSite

Of the 80 surveyed respondents, 85% (n=68) were motivated to have a more active role in their eye care and to share their data for research purposes using a secure technology, such as a web or mobile app. Approximately 14% (11/80) of respondents were unsure whether they would want greater involvement in their own eye care, with 82% (9/11) being >35 years of age. All the survey respondents had access to the internet; however, the 9 respondents were born before 1985 and so would not have

grown up with smart technology, a factor that may have had a bearing on their uncertainty regarding data use via smartphone technology. Only 1% (1/80) of respondents wanted no change in the level of their involvement in their own eye care. Of the 80 respondents, 79 (99%) owned a smartphone, and 76 (95%) used apps.

Of the 80 respondents, 44 (55%) had no concerns regarding storing or sharing their health data in a web application or mobile app, whereas 35 (44%) expressed a variety of concerns, as presented in [Textbox 4](#).

**Textbox 4.** Additional information on respondents' concerns regarding the use of a health data application.

#### Additional information

- The effort it might take to get my data from multiple sources into the app
- One of the concerns I have is that this type of information may be shared across social media platforms and could cause upset, misinterpretation, and unnecessary anxiety.
- Third parties getting access such as insurance companies; anything that can hinder my options or impact me financially
- The accuracy of the data and whether it is kept up to date or not (a subject access request is a point in time snapshot for example—as more visits and images happen will this be kept up to date)?
- My concern is that this service would not be available as both a phone app and a regular browser-accessible application for those of us that have great difficulty interacting with smaller devices.
- I would have serious concerns if data were shared with any pharmaceutical companies or equipment manufacturers or suppliers without my consent.
- Genetic information in a phone app
- Many reputable companies have suffered data breaches so you will too.



## Discussion

### Principal Findings

This patient engagement study demonstrates that patients with IRD find it acceptable and highly desirable to be actively involved in managing their own data for increased use in research and in their own eye care. It also demonstrates the feasibility of involving patients with IRD in the detailed design of a technological solution to the problem of paucity in these uniquely valuable data sets. Through qualitative evidence, we identified the specific tradeoffs that patients might find agreeable in practice between the benefits and concerns of eye data sharing. Furthermore, quantitative evidence demonstrated that a substantial proportion (68/80, 85%) of our respondents from the IRD community would like a more active role in their eye care and share their data for research purposes using a secure technology, such as a web application or mobile app. These findings build upon previous studies that suggest that public support for future research uses of data requires greater awareness raising, combined with opportunities for public engagement and deliberation [44]. The findings are also in keeping with a recent large research study of non-eye-specific rare disease patients in Europe [45], which showed that, regardless of the disease severity and sociodemographic profile, patients were supportive of data sharing to foster research and improve health care. However, their willingness to share data came with a specific requirement to respect their privacy, choices, and need for information regarding the use of their data.

This study indicates a clear and unmet need for a collaboratively designed technological solution to clinical data sharing and increased opportunities to participate in health data research within the IRD community. Despite this unmet need, to date, only 18% (14/80) of the study respondents attempted to access their hospital eye health data through the SAR process, and 58% (8/14) of those found this process wholly or partly unsuccessful in achieving their intended purpose.

### Comparison With Prior Work

In 2016, the US-based charity Foundation Fighting Blindness created *My Retina Tracker*, an international web-based registry for people affected with IRD and their unaffected genetic relatives, which allows the sharing of anonymized data with participants, researchers, and clinicians [16]. *My Retina Tracker* now has 15,700 active patient members, of whom 9% are from the United Kingdom. In the United Kingdom itself, however, there has been no comprehensive shared eye data resource available to the wider community in which the data are adherent to the NHS IG policy and the Information Commissioner's Office regulations at the point of care in addition to being accessible to eye patients (who may be visually impaired).

As with the *My Retina Tracker* Registry, the *MyEyeSite* platform is aimed at accelerating the discovery of therapeutics for IRDs by providing researchers with more efficient identification and selection and enhanced pooling of this rare and hard to find data sourced from around the world. However, the *MyEyeSite* platform also offers a rare opportunity for patients to *take ownership* of the use of their health data, not

only for research but also for their ongoing health care, thereby acknowledging the desire for agency so widely expressed in this study. By moving beyond patients as assets [46], *MyEyeSite* centralizes the patient as pivotal in gathering together their personal health data from numerous varied databases, in part through the SAR process, with the added benefit of incrementally reducing the need for such individual, institutional data requests and the cost to the NHS of servicing them. *My Retina Tracker* requires an extensive amount of text data to be manually entered into the web-based registry system, whereas *MyEyeSite* aims to streamline and simplify this process by automating the SAR process and facilitating the electronic transfer of clinical data, such as optical coherence tomography images, to the platform.

Furthermore, through meaningful collaboration in determining the functionality and accessibility of the technology itself, the user-led methodology by which the *MyEyeSite* platform and patient applications have been developed has ensured that as many patients' needs as possible have been addressed while adhering to all due data use compliances. Critically, patients' ongoing autonomy over consenting to their data being used through the *MyEyeSite* platform for particular research is transformative when compared with the current model operating within the NHS, which assumes consent for all purposes and removes patient data from all NHS-related research if a patient chooses to opt-out of sharing their data.

The UK Biobank is a large-scale biomedical database and research resource that contains in-depth genetic and health information from half a million UK participants [47]. Although this database is regularly augmented with additional data and is globally accessible to approved researchers, it is not accessible to patients and crucially not linked with their valuable clinical ophthalmic imaging data. *MyEyeSite* aims to collaborate with the UK Biobank to provide patients access to their stored data and facilitate linkage with their hospital clinical data.

### Limitations

Our survey size of 80 patients was an adequate sample size for this feasibility study, in which we engaged and collaborated with our population of rare eye disease patients. We are currently recruiting a larger sample size for the next phase of the study to implement a prototype of the *MyEyeSite* platform within our hospital clinical population. Furthermore, we will perform a power calculation to determine the sufficient sample size to conduct a health technology assessment study comparing the novel *MyEyeSite* intervention with standard care.

Although the *MyEyeSite* platform will reduce the need for repeated SAR applications and repeated acquisition for consent to share data by giving control of their eye data to the individual patient, each SAR procedure still necessitates meticulous work on the part of the hospital staff in retrieving, deidentifying, and releasing that data.

### Conclusions

The user-led design process used to develop the *MyEyeSite* platform highlighted the unmet need and strong desire of patients with IRD for enhanced access to their health data and a greater involvement in how these data are used for both health care and



research purposes. It also brought to our attention the issue that very few hospitals are equipped to deal with an increasing volume of SAR processes in a timely manner and that evidently, the process does not scale with new or repeated requests.

We conclude that sharing data electronically via a hospital portal or a third-party platform such as MyEyeSite is likely to be the most secure and potentially accessible solution (especially for the visually impaired) to the myriad of challenges of health data sharing at both national and international levels. However, current internal IG regulations in several UK hospitals appear to favor paper correspondence as the mode of communication. Therefore, at the present time, our implementation of the MyEyeSite platform relies on patients uploading and storing their own data and using MyEyeSite as a platform for sharing.

Once available, the MyEyeSite platform will enable patients to gain direct access to their medical records and easily share them

for future consultations or second opinions. They will gain insights into their own rare conditions and monitor their progress, treatment, and follow-up. We anticipate that this will improve clinical decision-making and patient outcomes and enhance choice and efficient delivery of health care, even when it is distributed across many health providers and laboratories.

The MyEyeSite platform offers the capacity to connect groups of patients with similar conditions and uniquely valuable data sets to commercial research projects through a system that is managed by the patients themselves. This strategy will facilitate access to a centralized international database of genetic variants, supporting rare disease research and clinical trials that have the potential to restore sight and transform lives. We believe that this model of data curation could be an exemplar for rare diseases in other medical specialties.

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## Acknowledgments

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## Authors' Contributions

ARW, NN, RMY, and NP conceived the idea of the project. ARW, NN, RMG, NP, SS, SVDS, and RMY developed the concept for the project, including the technical planning and design phases. RMG, SS, NN, SVDS, JC, and ARW designed and delivered patient or stakeholder engagement and user experience research, with CH and AP significantly contributing to the user experience research. RMG performed the data collection. RMG, DS, and NP performed the data analysis and drafted the manuscript. RMG and JC critically revised the manuscript, and all authors contributed to the final version of the manuscript.

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## Conflicts of Interest

None declared.

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### Multimedia Appendix 1

Challenges in linking health service data for patient benefit.

[[DOCX File, 19 KB - formative\\_v6i1e21341\\_app1.docx](#) ]

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### Multimedia Appendix 2

QuickTime video of MyEyeSite patient and public involvement activity.

[[MP4 File \(MP4 Video\), 39145 KB - formative\\_v6i1e21341\\_app2.mp4](#) ]

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### Multimedia Appendix 3

Google Forms survey questions (plain text version) circulated to inherited retinal diseases patients.

[[DOCX File, 25 KB - formative\\_v6i1e21341\\_app3.docx](#) ]

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### Multimedia Appendix 4

MyEyeSite patient app mobile phone user interface showing the Appointments page.

[[PNG File, 304 KB - formative\\_v6i1e21341\\_app4.png](#) ]

## Multimedia Appendix 5

MyEyeSite patient app mobile phone user interface showing retinal images selected for upload to the application.

[PNG File , 672 KB - formative\_v6ile21341\_app5.png ]

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## Abbreviations

**IG:** information governance  
**IRD:** inherited retinal disease  
**NHS:** National Health Service  
**NIHR:** National Institute for Health Research  
**SAR:** subject access request  
**UCL:** University College London

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Original Paper

# Assessment of Patient Journey Metrics for Users of a Digital Obstructive Sleep Apnea Program: Single-Arm Feasibility Pilot Study

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## Abstract

**Background:** Despite the importance of diagnosis and treatment, obstructive sleep apnea (OSA) remains a vastly underdiagnosed condition; this is partially due to current OSA identification methods and a complex and fragmented diagnostic pathway.

**Objective:** This prospective, single-arm, multistate feasibility pilot study aimed to understand the journey in a nonreferred sample of participants through the fully remote OSA screening and diagnostic and treatment pathway, using the Primasun Sleep Apnea Program (formally, Verily Sleep Apnea Program).

**Methods:** Participants were recruited online from North Carolina and Texas to participate in the study entirely virtually. Eligible participants were invited to schedule a video telemedicine appointment with a board-certified sleep physician who could order a home sleep apnea test (HSAT) to be delivered to the participant's home. The results were interpreted by the sleep physician and communicated to the participant during a second video telemedicine appointment. The participants who were diagnosed with OSA during the study and prescribed a positive airway pressure (PAP) device were instructed to download an app that provides educational and support-related content and access to personalized coaching support during the study's 90-day PAP usage period. Surveys were deployed throughout the study to assess baseline characteristics, prior knowledge of sleep apnea, and satisfaction with the program.

**Results:** For the 157 individuals who were ordered an HSAT, it took a mean of 7.4 (SD 2.6) days and median 7.1 days (IQR 2.0) to receive their HSAT after they completed their first televisit appointment. For the 114 individuals who were diagnosed with OSA, it took a mean of 13.9 (SD 9.6) days and median 11.7 days (IQR 10.1) from receiving their HSAT to being diagnosed with OSA during their follow-up televisit appointment. Overall, the mean and median time from the first televisit appointment to receiving an OSA diagnosis was 21.4 (SD 9.6) days and 18.9 days (IQR 9.2), respectively. For those who were prescribed PAP therapy, it took a mean of 8.1 (SD 9.3) days and median 6.0 days (IQR 4.0) from OSA diagnosis to PAP therapy initiation.

**Conclusions:** These results demonstrate the possibility of a highly efficient, patient-centered pathway for OSA workup and treatment. Such findings support pathways that could increase access to care, reduce loss to follow-up, and reduce health burden and overall cost. The program's ability to efficiently diagnose patients who otherwise may have not been diagnosed with OSA is important, especially during a pandemic, as the United States shifted to remote care models and may sustain this direction. The potential economic and clinical impact of the program's short and efficient journey time and low attrition rate should be further examined in future analyses. Future research also should examine how a fast and positive diagnosis experience impacts success rates for PAP therapy initiation and adherence.

**Trial Registration:** ClinicalTrials.gov NCT04599803; <https://clinicaltrials.gov/ct2/show/NCT04599803>

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**KEYWORDS**

obstructive sleep apnea; virtual care; remote care; OSA diagnosis; sleep apnea; OSA; underdiagnosed; feasibility; patient-centered; treatment pathway; diagnostic; eHealth

**Introduction**

Obstructive sleep apnea (OSA) is a prevalent sleep-related breathing disorder affecting up to 1 billion people worldwide [1]. OSA is associated with many common and costly comorbidities such as hypertension, diabetes, stroke, asthma, depression, and other cardiovascular and cerebrovascular conditions [2]. Untreated OSA is associated with an increased risk of morbidity and mortality and can result in the worsening of comorbid conditions as well as diminished quality of life [2,3]. Untreated OSA may also be associated with motor vehicle accidents and accidents in the workplace [4]. In addition to the impact on clinical outcomes, untreated OSA is associated with increased health care utilization and can result in increased direct and indirect costs (eg, workplace productivity, absenteeism, and presenteeism) [5,6].

Given the potential clinical and economic impact, it is important for individuals with OSA to be diagnosed efficiently, to receive treatment, and to stay adherent to treatment [7,8]. For most patients with moderate-to-severe OSA, first-line therapy is positive airway pressure (PAP) therapy [9]. Despite the importance of diagnosis and treatment, OSA remains a vastly underdiagnosed condition; this is partially due to current OSA identification methods and a complex and fragmented diagnostic pathway [10]. Traditionally, polysomnography (PSG) has been used to diagnose OSA, which requires a patient to stay overnight at a sleep clinic [6]. The traditional pathway is labor-intensive, requires a great deal of effort and proactiveness by the patient, and is dependent on sleep lab capacity and staffing. Home sleep apnea tests (HSATs) are a viable alternative to PSG, as they reliably and cost-efficiently diagnose OSA, do not require patients to stay overnight at a sleep clinic, and are less expensive than PSG [7,11]. Even so, a variety of considerations such as appointment availability, challenges surrounding in-person appointments for evaluation, picking up, and dropping off testing equipment, and prolonged waits to receive results may impact progress through diagnostic and treatment pathways [12,13]. Furthermore, education about OSA and support for patients during the diagnostic process are often lacking. Taken together, the numerous steps and the involvement of multiple health care providers in the traditional pathway predispose to a fractured experience, high attrition rates, and barriers to OSA diagnosis and treatment in a timely and patient-centered manner.

With the advancement of telemedicine and digital technologies, virtual care methods are increasingly being used to diagnose and treat sleep disorders [14,15]. The COVID-19 pandemic rapidly catalyzed the adoption of telemedicine and nontraditional health care delivery methods across the United States [16,17]. Although there is an increase in the use of telemedicine and virtual care methods for OSA diagnosis and disease management, additional research is required to understand whether clinical outcomes for patients who receive care virtually differ from the outcomes for patients who receive it through traditional means (eg, in-person visits) [15]. One recent review

and meta-analysis found that, based on the results from 16 randomized controlled trials, telemedicine interventions were associated with increased PAP usage and PAP adherence for individuals with OSA [18].

A distinctive feature of the Primasun Sleep Apnea Program (PSAP) is that it can be applied to general clinical populations, which guides individuals completely virtually, with no in-person visits, through the OSA diagnosis process, onboarding them onto therapy and providing them with continuous support and care once therapy has been initiated. The patient journey experienced by the users of this program parallels what is experienced in traditional clinical practice, but by using a health information technology solution (including virtual appointments, an app, and a website). This platform focuses on improving the patient experience, promoting clinical efficacy, and reducing attrition rates through the diagnostic pathway. Independent features of this platform have also been proposed to increase access to care. This study was undertaken to understand the journey in a nonreferred sample of participants through a fully remote OSA screening and diagnostic and treatment pathway.

The objectives of this single-arm feasibility pilot study were to assess patient journey metrics, including time to physician evaluation and testing, as well as time to initiate therapy if recommended by the sleep physician, patient satisfaction, and program completion rates for users of this entirely virtual program.

**Methods****Study Design**

This prospective, single-arm, multistate feasibility pilot study of a fully virtual OSA assessment, diagnostic, and management platform aimed to assess the patient journey (eg, platform ease of use, time to diagnosis, time to initiate PAP therapy if clinically recommended, and pathway completion rates) as well as satisfaction. Study duration differed for each participant; duration depended on how long it took the participant to complete the diagnostic pathway and whether the participant continued onto the PAP therapy portion of the study. The PAP therapy study period was 90 days. The study followed the STROBE (Strengthening the Reporting of Observational Studies in Epidemiology) guidelines [19].

This study was conducted entirely virtually using the Baseline Platform, a comprehensive remote clinical studies platform for recruitment, consenting, screening, enrollment, data collection, and study monitoring. This study was approved by the Western Institutional Review Board and is registered on ClinicalTrials.gov (NCT04599803).

**Program Overview**

The virtual platform investigated in this study was the PSAP platform, which is intended to support and educate individuals at risk for OSA as they navigate the complex, multistep

assessment and diagnosis pathway in a more patient-centered, efficient, and entirely virtual way. The program facilitates preassessment, online scheduling, one-on-one video televisits with board-certified sleep physicians pretesting and posttesting, and an entirely remote diagnostic testing process for OSA. Education on healthy sleep and OSA is provided, and patients can reach out to a dedicated support team with questions at any point during the assessment and diagnostic process.

For cases in which OSA is diagnosed and PAP is prescribed as therapy, the PSAP is also intended to assist in getting the patient equipped with a PAP device and supplies, provide a supportive onboarding experience onto PAP therapy, address questions and concerns with real-time support, and help patients to become adherent to therapy. Health coaches are available to engage in two-way communications through the platform to provide educational information related to sleep, OSA, and PAP therapy, as well as to use motivational enhancement techniques and general support.

### Recruitment and Study Eligibility

Study participants were recruited through online registries and targeted digital advertisements in North Carolina and Texas. North Carolina and Texas were selected as study locations because of practical considerations around physician availability and related elements. Potential participants were first provided with a study overview on a web landing page. On this page, they were also given the option to consent to the Project Baseline Community Study [20]. Project Baseline Community Study is an online registry for individuals who are interested in opportunities to participate in health-related research, test new technology, and learn about their health. Once enrolled in the Project Baseline Community Study, the participant could proceed to an online preassessment tool to assess initial eligibility. This tool included the OSA-50, an established 4-question validated OSA screening questionnaire [21], as well as questions assessing shift worker status, pregnancy, supplemental oxygen use, and verification of access to platform-compatible devices. Individuals who appeared to be qualified were then asked to review and sign the study's specific informed consent form to participate in the study.

To be eligible for the study, the participants were required to be 18 years or older, speak and read English, live in North Carolina or Texas, own a compatible smartphone, have access to a computer with a camera, and have consistent access to electricity and internet. The participants were also required to have a high risk of OSA, based on the OSA-50 questionnaire (score of 5 or greater) [21]. The participants were excluded if they reported being previously diagnosed with OSA or certain other chronic sleep disorders (eg, central sleep apnea, complex sleep apnea, or chronic insomnia); being a shift worker; being or planning to become pregnant during the study period; being employed by the sponsor or by individuals working on Baseline Community; or using a home supplemental oxygen device.

To be eligible to continue onto the PAP therapy portion of the study, the participants must have completed the post-HSAT sleep medicine physician televisit by December 31, 2020. Additionally, they needed to have been diagnosed with OSA and prescribed PAP therapy by their sleep study physician.

### Procedures

Once deemed eligible, the participant completed a medical and sleep history questionnaire covering medical and sleep information as well as an Epworth Sleepiness Scale (ESS) for the sleep physician to review [22]. After completing the questionnaires, the participant was invited to schedule their first sleep televisit appointment using an online scheduling tool. During the first televisit appointment, the physician performed a sleep medicine consultation. If the sleep physician ordered HSAT as a result of the consultation, the HSAT order was placed through the PSAP platform.

The HSAT device used for this study was WatchPat One (Itamar Medical Ltd). Following HSAT completion, the patients received an emailed invitation to schedule a follow-up physician video telemedicine appointment to review HSAT results and plan for further care as appropriate and recommended by the sleep physician. At appropriate time points, the participants who were not suspected to have OSA, were suspected to have conditions requiring in-laboratory PSG testing, were not diagnosed with OSA, were recommended non-PAP treatment options, or chose not to proceed with PAP therapy were exited from the study and connected to additional local clinical resources when needed and appropriate.

The participants who were diagnosed with OSA during the study and prescribed a PAP device were instructed to download the PSAP app, which provides educational and support-related content. The PSAP app also guides the participants through the device-ordering and mask-selection process and schedules the delivery of a welcome kit, which includes comprehensive tools for starting PAP therapy, guiding and supporting the participants to successfully adhere to therapy.

The participant could access the tools and resources in the PSAP app to attain set-up support and begin using the PAP device. As the participants used the device over the next 90 days, they could reach out to health coaches via messaging with any questions or support they needed. The participants also had access to phone support during business hours.

There were 5 study surveys administered during the study period. These surveys assessed baseline demographic information, knowledge of sleep apnea prior to diagnosis, and satisfaction with the program. After the 90-day PAP therapy study period, the participants conducted a final study exit televisit appointment where they were provided guidance on how to continue therapy (if desired) outside of the study.

### Outcomes

The primary objective of this study was to assess patient journey metrics using a fully remote system for the diagnosis of OSA and onboarding of PAP therapy. The analysis presented in this publication focuses on the cohort of individuals who initiated the diagnostic pathway and examines the following key patient journey outcomes: time from the first televisit appointment to OSA diagnosis; time from OSA diagnosis to PAP therapy initiation; time from the first televisit appointment to when the patient receives the HSAT; time from when the participant receives the HSAT to OSA diagnosis; and the percent of

individuals who completed various stages of the diagnosis pathway.

Usability of the platform, as measured by retention and survey feedback, and program satisfaction were among some of the exploratory objectives of the study, which will be presented in this manuscript. Participant satisfaction with the program overall and with certain program features was measured using a standard 5-point Likert scale ranging from “very dissatisfied” to “very satisfied.”

### Sample Size and Statistical Analyses

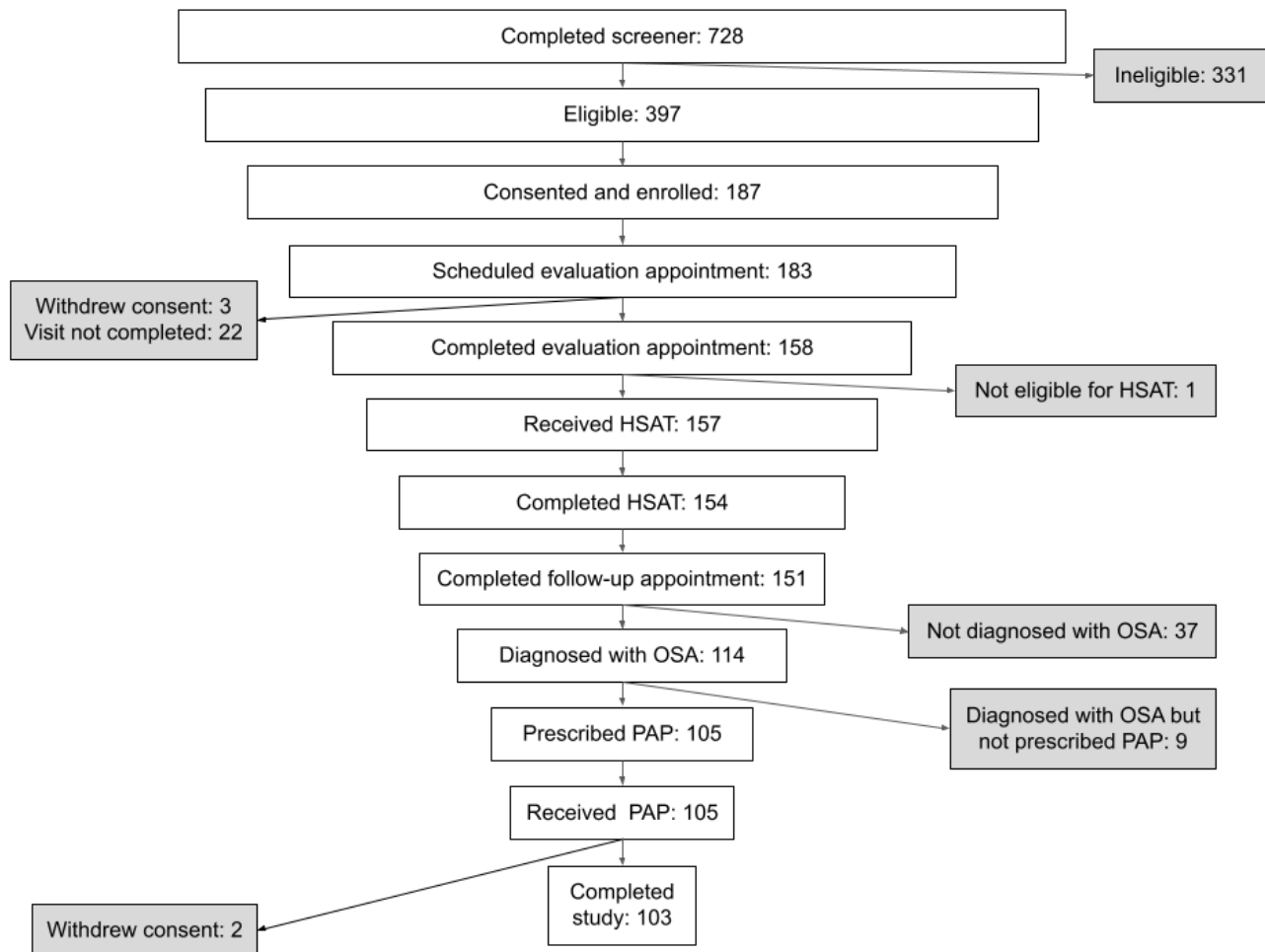
Given the preliminary nature of this pilot, we did not power the study to measure a specific difference in any of the outcomes. Our goal was to have a minimum of 50 individuals on PAP therapy.

Mean and standard deviation or proportions, when relevant, are reported for baseline demographics and clinical characteristics. For patient journey time metrics, the mean, standard deviation, median, and interquartile range are reported, and outliers examined. Moreover, attrition rates (ie, the proportion of individuals who dropped out of the diagnostic pathway) for various points in the diagnostic pathway are reported. All analyses were conducted in Python (version 3.6.13; Python Software Foundation).

## Results

### Study Sample

Figure 1 details recruitment and participant flows through the study. Study recruitment, screening, and enrollment took place between June 2020 and October 2020. Of the 687 individuals who completed the online screening questionnaire for eligibility, 57.8% (n=397) were eligible. A total of 71.5% (n=284) of the eligible individuals provided electronic informed consent for the study. Of the 284 individuals who provided consent, 85.9% (n=255) enrolled in the study. A total of 71.8% (n=183) of the enrolled participants scheduled their first televisit appointment. Of the 183 individuals who scheduled a first televisit appointment, 86.3% (n=158) completed their appointment; there were 25 individuals who initially scheduled an appointment but either canceled their appointment and never rescheduled or missed their first scheduled televisit appointment and never successfully completed it. Of the 158 individuals who completed their first televisit appointment, 99.4% (n=157) were determined appropriate for HSAT by the sleep medicine physician. Moreover, 1 individual was referred out of the study to in-laboratory testing for clinical suspicion of a different disorder. Of the 157 individuals who received an HSAT, 98.1% (n=154) successfully completed the HSAT and 96.2% (n=151) completed their follow-up televisit appointment. A total of 114 individuals were diagnosed with OSA, and 105 were prescribed PAP therapy. Of the 105 individuals who were prescribed PAP therapy as part of this program, all were able to download the PSAP app to order the PAP device. All 105 individuals received a PAP device during the study.

**Figure 1.** Participant flow through the pilot study; HSAT: home sleep apnea test; OSA: obstructive sleep apnea; PAP: positive airway pressure.

### Baseline Demographic and Clinical Characteristics

An overview of baseline demographics and self-reported clinical characteristics for the 158 individuals who completed the first televisit appointment is reported in [Table 1](#). The majority of this population were female (95/158, 60%), White (141/158, 89%), had an associate degree or higher (82/142, 58%), and were from Texas (103/158, 65%). The mean age of the population was 47 years (SD 10, range 24-72 years). At baseline, the participants reported an average ESS of 10.7 (SD 4.8), with about half of the study population having an ESS greater than

10 (80/158, 51%). Average BMI was 34.6 kg/m<sup>2</sup> (SD 8.3), and the majority of the population (105/158, 66%) were obese (BMI of at least 30 kg/m<sup>2</sup>). Top comorbidities included allergies (76/158, 46%), high blood pressure (60/158, 38%), and diabetes (30/158, 19%). A majority of the population had health insurance (107/142, 75%), had a primary care physician (107/158, 68%), and were at least somewhat familiar with sleep apnea prior to enrolling in the study (130/142, 92%). Approximately 6% (9/158) of this population had completed a sleep study previously.

**Table 1.** Key baseline demographics and self-reported clinical characteristics of those who initiated the diagnostic pathway (n=158).

Characteristics	Values
Age (years), mean (SD)	46.9 (10.4)
<b>Sex, n (%)</b>	
Female	95 (60)
Male	63 (40)
<b>Race or ethnicity, n (%)<sup>a</sup></b>	
White	141 (89)
Black	8 (5)
Hispanic	30 (19)
Asian	7 (4)
Native American	4 (3)
Other	6 (4)
<b>Geographic location, n (%)</b>	
North Carolina	55 (35)
Texas	103 (65)
<b>Comorbidities, n (%)</b>	
Allergies	76 (46)
High blood pressure	60 (38)
Diabetes	30 (19)
Bruxism	26 (17)
Swollen legs	20 (13)
Bronchitis or asthma	19 (12)
Thyroid issues	16 (10)
Migraine	16 (10)
Anemia	15 (9)
Dizziness or fainting	12 (8)
Chronic pain	11 (7)
Heart murmur	9 (6)
Temporomandibular joint syndrome	9 (6)
Arrhythmia	8 (5)
Mononucleosis	8 (5)
Concussion	7 (4)
Coronary artery disease	6 (4)
Epilepsy or seizures	4 (3)
Stroke	3 (2)
Heart attack	3 (2)
COPD <sup>b</sup>	3 (2)
Cognitive impairment	1 (1)
Other lung disease	1 (1)
Heart failure	1 (1)
BMI (kg/m <sup>2</sup> ), mean (SD)	34.6 (8.3)
<b>BMI (kg/m<sup>2</sup>), n (%)</b>	



Characteristics	Values
<18.5	0 (0)
18.5 to <25	13 (8)
25 to <30	40 (25)
30 to <35	35 (22)
35+	70 (44)
OSA-50 <sup>c</sup> , mean (SD)	7.2 (1.6)
ESS <sup>d</sup> , mean (SD)	10.7 (4.8)
<b>ESS, n (%)</b>	
0-5	30 (19)
6-10	48 (30)
11-12	19 (12)
13-15	41 (26)
16-24	20 (13)

<sup>a</sup>Does not sum to 100% because the participants were able to select multiple answer choices.

<sup>b</sup>COPD: chronic inflammatory lung disease.

<sup>c</sup>A validated obstructive sleep apnea questionnaire.

<sup>d</sup>ESS: Epworth Sleepiness Scale.

## Patient Journey Metrics

The main journey time results for this pilot are depicted in [Table 2](#). For the 157 individuals who were ordered an HSAT, it took a mean of 7.4 (SD 2.6) days and median 7.1 days (IQR 2.0) to receive their HSAT after they completed their first sleep medicine televisit appointment with the physician. For the 114 individuals who were diagnosed with OSA, it took a mean of 13.9 (SD 9.6) days and median 11.7 days (IQR 10.1) from receiving their HSAT to receiving a diagnosis of OSA from their physician at their follow-up televisit appointment. Of those who were diagnosed with OSA (n=114), mean journey times were 21.4 (SD 9.6) days from the first physician televisit appointment to the 2nd physician televisit when they received the diagnosis; and 8.1 (SD 9.3) days from the diagnosis until receiving their PAP device, if prescribed. Median journey times were explored as well in order to best assess for outliers (defined as 1.5 times IQR above the 75th percentile) ([Figure 2](#)). All 4 metrics show skewness of the distributions due to outliers, which were preserved in this analysis to reflect real-world scenarios such as shipping delays, holidays, and multiple missed

appointments. As such, these statistics reflect realistic distributions of patient journey times. There were no patterns detected in journey times over the course of the study. There was no significant difference in journey times between those with and without OSA diagnosis ( $P=.93$  using the Welch  $t$  test) ([Figure 3](#)). Overall, median patient journey times from first landing on the screening webpage to onboarding to PAP therapy were approximately under 6 weeks ([Figure 4](#)).

[Figure 2](#) demonstrates median, interquartile range, and outlier data (in days) for key journey metrics.

The chart in [Figure 3](#) depicts the key journey time metrics for each participant, with the length of the bar representing the number of days elapsed since 1st physician visit. The bars are ordered from top to bottom in chronological order for the first physician appointment.

[Figure 4](#) displays the median total journey times (in days) for the participants, from first landing on the screening website to completing 2 sleep physician televisits plus sleep testing, and to starting PAP therapy if diagnosed with OSA and recommended for PAP therapy.

**Table 2.** Mean, median, and range for key participant journey metrics (in days).

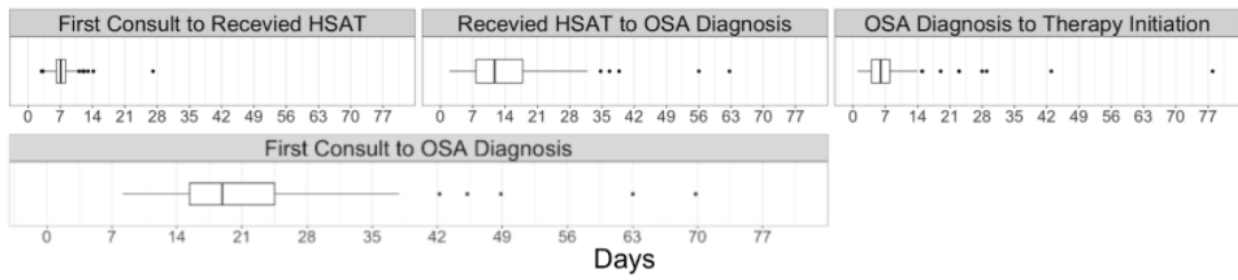
Milestone	Mean (SD)	Median (IQR)	Range
Days from the 1st physician visit to the 2nd physician visit (post-HSAT <sup>a</sup> ) (n=151)	21.1 (9.8)	18.8 (9.0)	7.1-71.1
Days from the 1st physician visit to receiving HSAT (n=157)	7.4 (2.6)	7.1 (2.0)	2.1-27.1
Days from OSA <sup>b</sup> diagnosis (2nd physician visit) to PAP <sup>c</sup> therapy initiation (n=105)	8.1 (9.3)	6.0 (4.0)	1-78

<sup>a</sup>HSAT: home sleep apnea test.

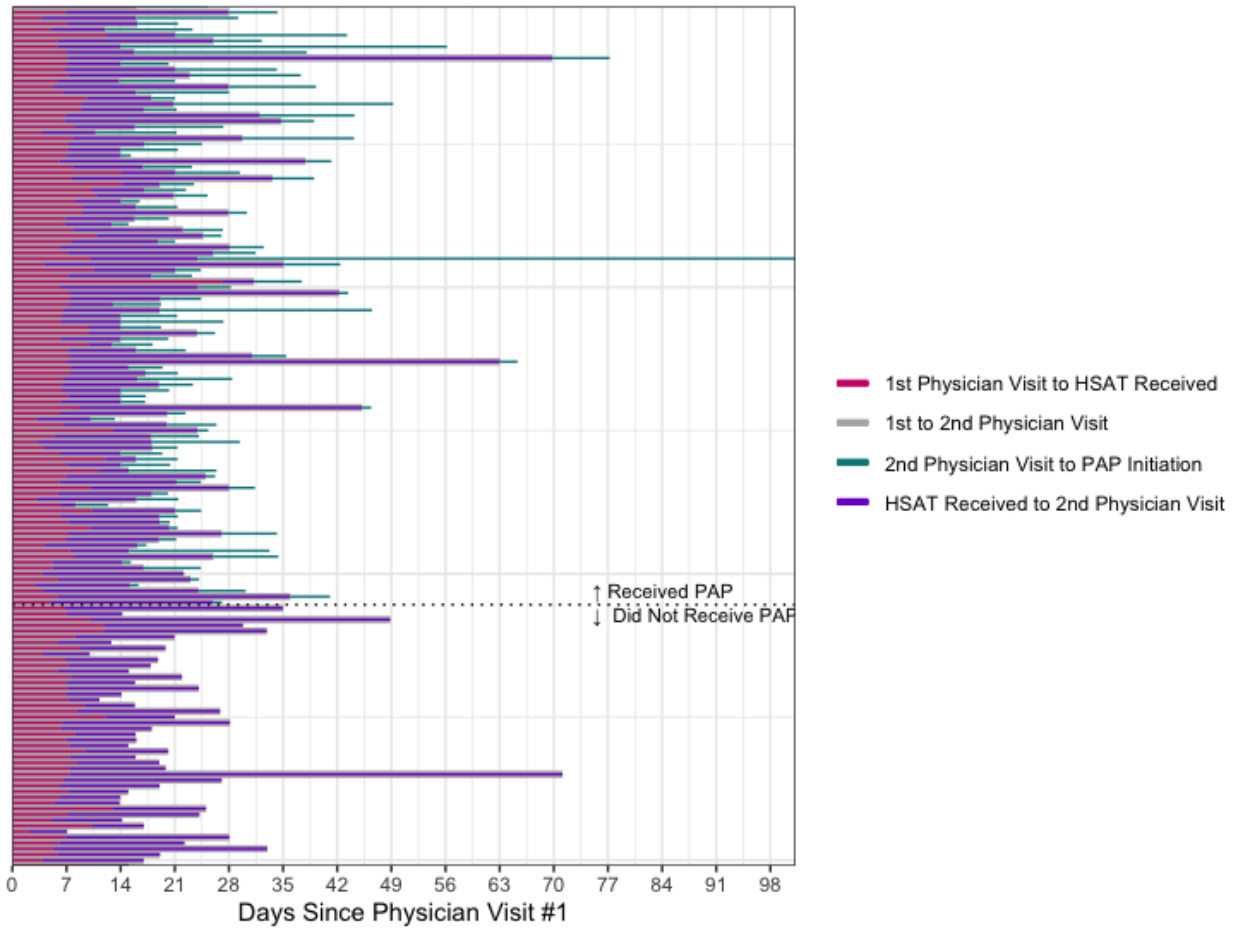
<sup>b</sup>OSA: obstructive sleep apnea.

<sup>c</sup>PAP: positive airway pressure.

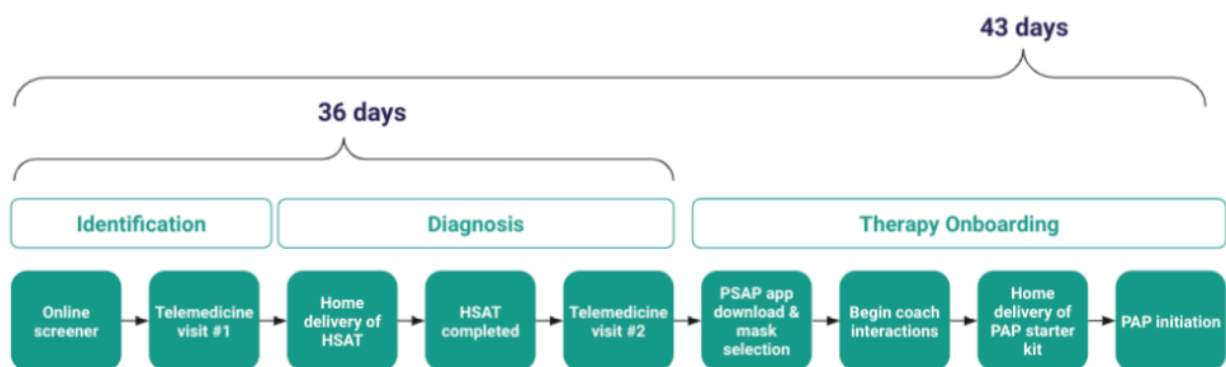
**Figure 2.** Outlier detection for key patient journey time metrics. HSAT: home sleep apnea test; OSA: obstructive sleep apnea.



**Figure 3.** Key patient journey time metrics. HSAT: home sleep apnea test; PAP: positive airway pressure.



**Figure 4.** Median total journey times in obstructive sleep apnea (from screening to onboarding to positive airway pressure). HSAT: home sleep apnea test; PSAP: Primasun Sleep Apnea Program; PAP: positive airway pressure.



## Program Satisfaction

A total of 100 participants (all with OSA, 99 of whom went on to use the PSAP app) provided satisfaction scores after the 2nd physician televisit. The mean satisfaction rating for the diagnostic portion of the program was 4.75 (SD 0.67) out of 5, corresponding to a “very satisfied” rating. Overall, 84% (n=84) of the participants provided a 5-out-of-5 satisfaction rating, with 2% (n=2) rating less than a 3 out of 5. In addition, 86% (n=86) of the participants reported that registering for the program was very easy (average rating of 4.78 out of 5, SD 0.65), and 77% (n=77) were very satisfied with the onboarding process (average rating of 4.69 out of 5, SD 0.69).

A total of 76 participants provided total program satisfaction scores at the conclusion of 90 days of PAP on our study. The mean satisfaction score for these participants was 4.3 (SD 1.0), and the median score was 5, corresponding to a “very satisfied” rating, with 6.6% of the participants (n=5) providing a rating of less than 3 out of 5. Overall, 81.6% (62/76) of the participants provided a 4 or 5 out of 5, corresponding to a “satisfied” or “very satisfied” rating.

## Discussion

### Principal Findings

Overall, the participants in our program were able to quickly and efficiently complete the OSA diagnostic pathway using PSAP. It took approximately 3 weeks from the initial televisit to OSA diagnosis and an additional 1 week from diagnosis to PAP therapy initiation. This includes scheduling and completing 2 televisit appointments, receiving, completing, and sending back an HSAT, the interpretation of the HSAT results by a board-certified sleep physician, and ordering and receiving a PAP device and the associated supplies. For purposes of comparison, the length of time it takes an individual to complete the OSA diagnostic pathway under standard of care is highly variable in the United States and largely depends on geographic location, physician availability, type of sleep test performed (HSAT or PSG), referral method, and other factors. Estimates show that it can take anywhere from weeks to over a year for an individual to eventually get diagnosed with OSA and initiate therapy in the United States [23]. For example, according to one analysis of a sleep center in Philadelphia, OSA diagnosis may take from 4 weeks to 8 months from initial referral to sleep evaluation and then an additional time for PAP initiation. The Veterans Health Administration facilities report that it can take about 8 to 9 months on average from initial referral to sleep evaluation [23]. One study examining a home management pathway for OSA in Canada found that the home management program reduced wait times from 152 days to 92 days, on average [24]. In the United Kingdom, the average wait time from initial physician referral to PAP initiation is approximately 14 months [23]. Therefore, compared to the limited evidence available, this program’s patient journey times are promising.

Attrition in traditional models of sleep care at each step of the pathway is also variable and underreported. In our study, among those who screened into an offer for an initial sleep physician evaluation and made an appointment through the platform, 86.3% completed the appointment. This is a no-show or

cancellation rate that compares favorably to reports describing this journey in clinical practice. For example, a recently published retrospective chart review of over 2000 sleep clinic visits found a no-show rate of 30.5% for the first clinic visit and an overall no-show rate of 21% [25]. The better attendance rate seen in this study may be related in part to the older mean age of the group and the fact that most had insurance, which may reflect being more connected to health care opportunities, generally. Moreover, long waits for appointments may traditionally drive no-shows, and delays in testing and diagnosis complicate the patient journey and interfere with ultimate treatment success [26]. In PSAP, appointments were available typically within 1-2 weeks at a variety of times including outside traditional office hours, and email reminders were sent prior to the appointments. The shorter wait times and email reminders may have been factors in the high show rates observed in this study.

Similarly, completion rates for HSAT were extremely high. Moreover, the completion rate for the 2nd physician televisit, the HSAT “results” televisit, was very high, at 98%. Though data are sparse on this metric in the published literature, the authors believe that the less-than-2% attrition following HSAT may indicate an ease-of-use advantage for clinical care.

Overall, these results are very promising, especially given that this study was conducted during the COVID-19 pandemic, an era marked by uncertainty, competing priorities, limited access to health care, and illness, not to mention delays in shipping and reduced supply availability. The program was able to effectively reach individuals and had very low attrition rates, with less than 5% of the study population lost to follow-up during the diagnostic period after completing their first appointment. The program received very positive feedback; most of the participants were satisfied to very satisfied with their experience with the program and the program’s ability to guide them through the complex OSA diagnostic pathway. This is especially meaningful considering world events during this study, which included the COVID-19 pandemic and related occupational economic, social upheavals which have been reported to interrupt medical care, as well as the widespread power outages in Texas due to weather in February 2021 [27].

### Strengths and Limitations

One of the major strengths of this study was its fully virtual nature. This allowed the study to mimic real-world settings as the study participants did not need to visit in-office clinics to complete study documents and provide study data. Instead, they interacted with PSAP as they would have outside the study. Our analyses also include all outliers from the study to appropriately demonstrate how the program may perform in the real world.

There were some limitations to this study. First, given that this was designed as a single-arm study with no control population, a direct comparison of the study participants’ patient journey experience through the OSA diagnostic pathway with standard of care was not possible. But as previously mentioned, standard of care is extremely variable, so a true generalizable control would be difficult to construct and examine. Despite not having a control group, the authors believe these results are extremely useful when assessing the value of this program. The study

population was also primarily female and White, and all participants were from North Carolina or Texas. Most participants reported having health insurance and a primary care doctor. Therefore, the results may not be fully generalizable to other populations. Future studies should examine the program in a more diverse population. The participants were also identified and recruited for the study through digital means, which may mean that our study population is not fully generalizable to the entire undiagnosed OSA population in the United States. However, given that the PSAP is a digital and app-based solution, this population may represent a new subgroup of the undiagnosed OSA population who would benefit from this solution and who may not necessarily be reached by standard care pathways. Regarding satisfaction scores, only the participants who were diagnosed with OSA or those who completed the app portion of the journey (for PAP treatment) filled out satisfaction surveys. Therefore, it is not possible to ascertain the degree of satisfaction with the program in the subgroup of participants who were not diagnosed with OSA in

this pathway, or who were diagnosed with OSA and were recommended treatments other than PAP therapy. This area certainly requires further study.

## Conclusions

In this single-arm feasibility pilot study, we assessed the patient journey for users of a fully virtual diagnosis and OSA management program. The results of this pilot study are promising when considering increasing access to care, improving inefficiencies and inconsistencies in diagnostic pathways, and reducing overall costs. The program's ability to diagnose patients who otherwise may have not been diagnosed with OSA is extremely important, especially during a pandemic as the country shifted to virtual and remote care models and may sustain this direction. The potential economic and clinical impact of the program's short and efficient journey time and low attrition rate should be further examined in future analyses. Future research also should examine how an efficient and positive diagnosis experience impacts success rates for PAP therapy initiation and long-term adherence.

## Acknowledgments

The authors thank all study participants and study collaborators for their important contributions.

## Conflicts of Interest

Primasun makes and owns the PSAP (Primasun Sleep Apnea Program) examined in this study. Primasun is a joint venture between ResMed and Verily Life Sciences. SK, ER, CD, and SSS work for Verily Life Sciences. AB and AVB work for ResMed.

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## Abbreviations

**ESS:** Epworth Sleepiness Scale

**HSAT:** home sleep apnea test

**OSA:** obstructive sleep apnea

**PAP:** positive airway pressure

**PSAP:** Primasun Sleep Apnea Program

**PSG:** polysomnography

**STROBE:** Strengthening the Reporting of Observational Studies in Epidemiology



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Original Paper

# Expert-Moderated Peer-to-Peer Online Support Group for People With Knee Osteoarthritis: Mixed Methods Randomized Controlled Pilot and Feasibility Study

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## Abstract

**Background:** Osteoarthritis (OA) is a major problem globally. First-line management comprises education and self-management strategies. Online support groups may be a low-cost method of facilitating self-management.

**Objective:** The aim of this randomized controlled pilot study is to evaluate the feasibility of the study design and implementation of an evidence-informed, expert-moderated, peer-to-peer online support group (My Knee Community) for people with knee OA. The impacts on psychological determinants of self-management, selected self-management behaviors, and health outcomes were secondary investigations.

**Methods:** This mixed methods study evaluated study feasibility (participant recruitment, retention, and costs), experimental intervention feasibility (acceptability and fidelity to the proposed design, including perceived benefit, satisfaction, and member engagement), psychological determinants (eg, self-efficacy and social support), behavioral measures, health outcomes, and harms. Of a total of 186, 63 (33.9%) participants (41/63, 65% experimental and 22/63, 35% control) with self-reported knee OA were recruited from 186 volunteers. Experimental group participants were provided membership to My Knee Community, which already had existing nonstudy members, and were recommended a web-based education resource (My Joint Pain). The control group received the My Joint Pain website recommendation only. Participants were not blinded to their group allocation or the study interventions. Participant-reported data were collected remotely using web-based questionnaires. A total of 10 experimental group participants also participated in semistructured interviews. The transcribed interview data and all forum posts by the study participants were thematically analyzed.

**Results:** Study feasibility was supported by acceptable levels of retention; however, there were low levels of engagement with the support group by participants: 15% (6/41) of participants did not log in at all; the median number of times visited was 4 times per participant; only 29% (12/41) of participants posted, and there were relatively low levels of activity overall on the forum. This affected the results for satisfaction (overall mean 5.9/10, SD 2.7) and perceived benefit (17/31, 55%: *yes*). There were no differences among groups for quantitative outcomes. The themes discussed in the interviews were *connections and support*, *information and advice*, and *barriers and facilitators*. Qualitative data suggest that there is potential for people to derive benefit from connecting with others with knee OA by receiving support and assisting with unmet informational needs.

**Conclusions:** Although a large-scale study is feasible, the intervention implementation was considered unsatisfactory because of low levels of activity and engagement by members. We recommend that expectations about the support group need to be made clear from the outset. Additionally, the platform design needs to be more engaging and rewarding, and membership should only be offered to people willing to share their personal stories and who are interested in learning from the experiences of others.

**Trial Registration:** Australian New Zealand Clinical Trials Registry ACTRN12619001230145; <http://anzctr.org.au/Trial/Registration/TrialReview.aspx?id=377958>

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## KEYWORDS

support group; online support group; knee; osteoarthritis; arthritis; online forums; patient education; self-efficacy; health literacy; self-management; qualitative

## Introduction

### Background

Osteoarthritis (OA) is a major cause of pain, disability, and health service use globally [1]. Prevalence and burden are predicted to increase because of population aging and rising obesity rates [1,2]. Recommended management emphasizes nonsurgical, nondrug treatment, including physical activity and weight loss [3-6], delivered through education and self-management support. Current management of the condition in Australia and worldwide has been found to be inconsistent with recommended practice [7-9]. Given these deficiencies with current care and the scale of the problem, additional, inexpensive, and scalable resources or services, which can help meet care needs and close care gaps, need to be explored.

A community survey by Arthritis Australia found that people who fare worse because of their joint pain are those who perceive they have received poorer care through lack of information and access to help rather than those who have worse disease severity or longer disease duration [10]. More recently, contextual factors, specifically *support and relationships* were found to be key influencers of how a person manages their OA [11]. Having supportive friends, role models, and opportunities to share experiences with others were all found to help people maintain independence. They also helped people stay active and adopt effective lifestyle self-management behaviors. Studies also suggest that support networks can be a source of health information [12]. Thus, improving life participation and satisfaction for people living with knee OA may be aided through having access to a social network that provides accurate information and greater feelings of support and connectedness, while also meeting individual needs.

Peer-to-peer online support groups (OSG) can be defined as “any virtual social space where people come together to get and give information or support, to learn, or to find company” [13]. OSGs can potentially be a low-cost method of providing peer support and information [12,14]. Groups can also provide

effective behavior change interventions [15]. They offer several advantages over face-to-face support groups in terms of accessibility, time, and financial cost to participants; running and maintenance costs; and the asynchronous nature of engagement [12,14,16]. In addition, participants may find it easier to disclose personal or sensitive information in a web-based environment rather than in person. Online group facilitation, as with web-based consulting, may be an increasingly feasible way of bringing patients with similar health problems together [17]. Studies on OSGs for other conditions support their effectiveness for improving emotional well-being, self-efficacy, and feelings of support [12,18,19]. Little is known about the effectiveness of OSGs for chronic painful musculoskeletal disorders or knee OA. Research is also needed to determine the features and functions needed to optimize engagement and hence effectiveness and to understand the mechanisms by which positive effects are achieved [12]. Existing evidence suggests that important features to include are perceived similarity among support group members (eg, having the same disease), credibility of information, access to experts or trained peer facilitators, and enjoyment [14].

### Objectives

We conducted a mixed methods randomized controlled pilot and feasibility study with people with knee OA who were provided with peer-to-peer support via an expert-moderated OSG and an OA information website. The comparison group were only provided with the OA information website. The primary objective is to determine the feasibility of delivering the OSG intervention in a trial setting. Feasibility was explored in terms of the study methods (participant *recruitment and retention* and *costs*) and the experimental intervention (perceived *benefit, satisfaction, and engagement* with the OSG). Secondary objectives include the impacts of participation in an OSG on psychological determinants of self-management and lifestyle behavior change, behaviors, and health outcomes compared with those of participants who only received web-based information.

## Methods

### Overview

The study was conducted in accordance with the published trial registration (ACTRN12619001230145), the conditions of ethics committee approval (University of Melbourne Human Research Ethics approval number: 1853275.4), and the Note for Guidance on Good Clinical Practice (CPMP/ICH-135/95). This report follows the guidance of the Consolidated Standards of Reporting Trials (CONSORT) extension for randomized pilot and feasibility trials [20], Consolidated Standards of Reporting Trials-eHealth [21], and Consolidated Criteria for Reporting Qualitative Research [22] for the qualitative research component [22]. Study participants provided verbal and digital informed consent.

### Study Design

The study was a 2-arm, pragmatic randomized parallel-groups design pilot and feasibility study with mixed methods analysis.

### Participants

Volunteers from Australia, who had self-reported clinically diagnosed knee OA were recruited from research databases, Facebook, and an advertisement on the Arthritis Australia website. Participants were eligible for the study if they (1) were aged >45 years, (2) self-reported having been diagnosed with knee OA by a physician or met the clinical criteria for knee OA (activity-related knee pain on most days, experienced pain for at least three months, and no morning joint-related stiffness lasting >30 minutes) [23], (3) could access and were willing to use the internet at least once a week, (4) were prepared to engage in an OSG if randomized to that group, (5) able to commit to completing baseline and follow-up questionnaires, and (6) able to give informed consent. Potential participants were excluded if they (1) had undergone previous knee replacement on their painful knee or were on the waiting list for knee surgery, (2) self-reported a diagnosis of rheumatoid arthritis or other inflammatory arthritis, (3) were currently participating in an arthritis support group, or (4) had another serious medical condition or upcoming medical procedures that in the opinion of the research staff would preclude participation. Screening was done in 2 stages via a web-based survey (Qualtrics) and a phone call (LS and GK).

### Study Procedures

Participant recruitment, the provision of consent, interventions, and assessments were all performed on the web. Following informed consent, participants completed the baseline questionnaire on a secure web-based platform designed to support data capture for research studies [24,25]—REDCap (Research Electronic Data Capture; Vanderbilt University)—hosted at the University of Melbourne. Full disclosure was provided, so participants were not blinded to the different types of web-based resources being compared in this study. As all impact assessments used self-report, the participants were the assessors and therefore were not blinded to treatment group allocation or intervention provided to both groups. A researcher not involved in generation or implementation of the randomization schedule revealed group

allocation via REDCap. Participants were then informed of their group allocation and how to access the relevant websites. For the OSG group, this is reflective of real life where participants were always aware of the format with which they received information and education or peer support and had preconceived views on the benefit and relative effectiveness of these options.

### Intervention and Control Conditions

Experimental group participants were provided membership to an OSG for people with knee OA (My Knee Community) and recommended a web-based patient education resource (My Joint Pain [26]) [27]. Control group participants received the My Joint Pain website recommendation only.

My Knee Community was a newly established, expert-moderated, peer-to-peer OSG hosted with Discourse web-based platform (Civilized Discourse Construction Kit, Inc). It provides an online discussion forum organized into categories (eg, *Living with knee osteoarthritis*) and threads (eg, *Cold weather and joint pain*). Before study commencement, the forum was reviewed and tested by approximately 15 stakeholders, including 3 individuals with knee OA. My Knee Community was then opened for membership (August 14, 2019) and promoted on Facebook; the Arthritis Australia website; the Centre for Health, Exercise and Sports Medicine webpage, and internet search engines (unpaid). It was a closed group, and interested people were screened via a web-based survey (Qualtrics) for self-reported knee OA and Australian location before being given member access. When pilot study recruitment commenced (December 11, 2019), there were 123 members and 84 posts, of which 12 were moderator posts.

My Knee Community members could add posts to threads or create new threads. The OSG was monitored (daily) and moderated (approximately weekly) by *experts*, who were health care professionals (mostly physiotherapists) with knowledge of evidence-based management of knee OA and a belief that people with knee OA can learn self-management skills. The moderator's roles included (1) removing any offensive posts or product advertisements, (2) posting information, such as new research findings or links to recommended knee OA resources, and (3) contributing to discussions by responding to questions and comments if they needed or requested a response from a health care professional.

All members were permitted to view and post as much or as little as they wanted, but members who were study participants were asked to log on to the My Knee Community at least once. Thus, one or more visits to the OSG constituted adherence to the experimental intervention protocol. All randomized participants' data were included in the analysis unless they were lost to follow-up. After the final follow-up questionnaire, experimental group participants could remain members of the My Knee Community and control group participants were offered membership.

My Joint Pain [26] is a freely available website managed by Arthritis Australia and developed for Australian users with joint pain. It provides information via factsheets, videos, and other tools, such as risk assessments. Some resources require signing up for access.



### Sample Size

The sample size of 60 for this study was based on recommended sample sizes for feasibility studies [28,29] and the recommended sample size for pilot studies using continuous variables and small (0.2) effect sizes [30]. The randomization schedule was computer generated in advance by a statistician not involved in the study according to a 2:1 ratio using random permuted blocks of varying sizes (4-10). Allocation was concealed in a password-protected software (REDCap). An unequal sample size between experimental and control groups was used because most of the research questions were related to the experimental group data. This strategy enabled more data to be collected from experimental group participants, particularly for the qualitative evaluations, for a smaller overall sample size but without compromising the ability to answer all feasibility questions. Finally, a target of 40 experimental group participants was estimated to be an adequate sample size for the qualitative components.

### Quantitative Evaluation—Feasibility of Study Methods and Experimental Intervention

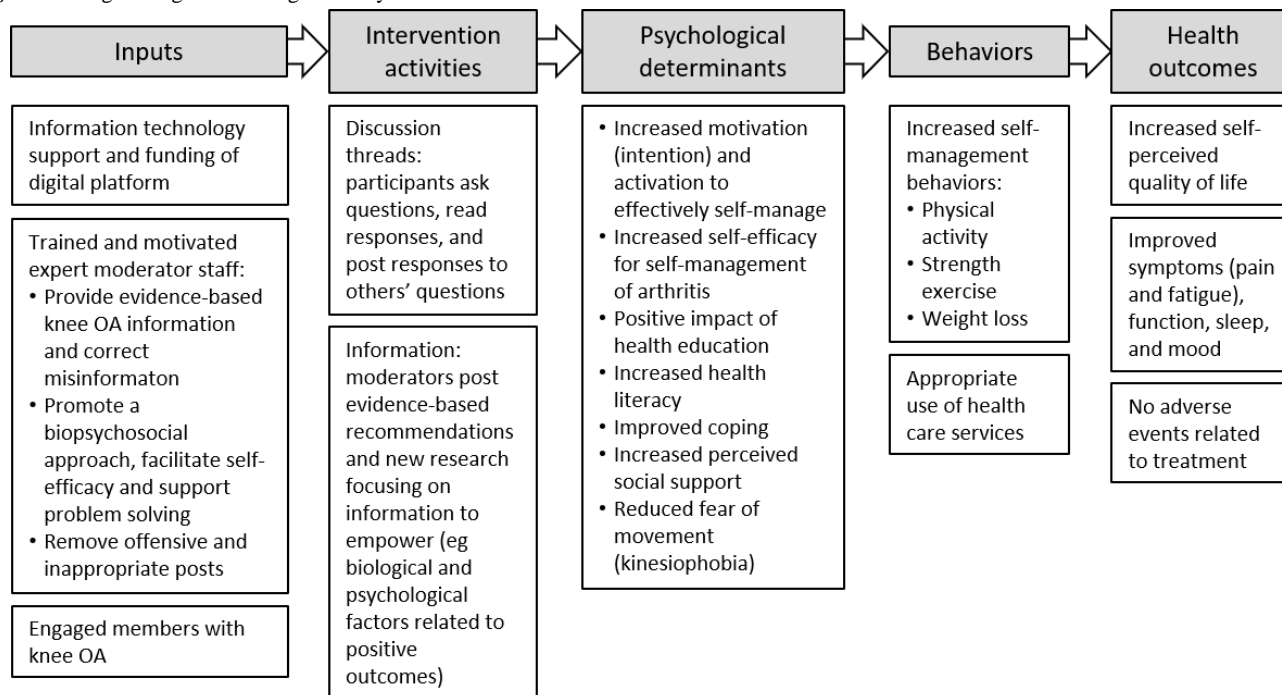
Data for the quantitative feasibility evaluation (ie, participant recruitment, participant retention, costs, perceived benefit, satisfaction, and engagement with the OSG) were collected after 3 months using a questionnaire or at the end of the trial (ie, for data analytics) and are reported descriptively (Multimedia Appendix 1). Participants completed baseline and follow-up questionnaires (3 months after randomization) for the impact evaluation. Questionnaires measured psychological determinants (motivation, activation, self-efficacy, health education impact, health literacy, coping, social support, and fear of movement),

self-management behaviors (physical activity, exercise, and weight loss), health outcomes (quality of life, pain, fatigue, function, sleep, mood, and global rating of change), and harms (related adverse events).

### Quantitative Evaluation—Psychological Determinants

Psychological determinants are constructs that were hypothesized to be important in the causal pathway through which an OSG can achieve increased uptake of effective self-management behaviors and improved health outcomes (Figure 1). Motivation was measured by asking participants to rate their level of agreement with statements about motivation to be more active or exercise or lose weight on 11-point numerical rating scales (NRS) [31]. Activation was measured using the Patient Activation Measure [32], and coping was measured using the Brief Coping Strategy Questionnaire [33], both of which have been shown to be valid measures in knee OA populations [33,34]. Self-management skills were measured using the Health Education Impact Questionnaire, which has high construct validity and reliability in a sample of individuals with chronic conditions including arthritis [35]. Health literacy was measured with the Health Literacy Questionnaire, which shows good reliability and validity in a broad Australian community sample [36]. Social support was measured using the Duke-University of North Carolina Functional Social Support Questionnaire [37], which has moderate reliability and validity in community-dwelling older Australians [38]. Fear of movement (kinesiophobia) was measured using the Brief Fear of Movement Scale for Osteoarthritis [39] and self-efficacy, using the Arthritis Self-Efficacy Scale [40]. Both measures were developed for individuals with knee and hip OA and demonstrate acceptable validity and reliability [39,40].

Figure 1. Program logic describing the study intervention. OA: osteoarthritis.



Physical activity during the past week was measured using the Incidental and Planned Exercise Questionnaire as well as by asking participants “How many days in the past week did you

do 30 minutes of moderate intensity physical activity?” The Incidental and Planned Exercise Questionnaire (past week) has good validity and reliability in a sample of older adults [41].



Strength exercise was captured similarly, with participants answering “How many days in the past week did you do leg strengthening exercises?” Participants were also asked “If you need to lose weight, how much effort are you currently making?” on a 11-point NRS.

Quality of life was measured using the Assessment of Quality of Life instrument [42], which has good validity in a sample of Australians with hip and knee joint disease [43]. Pain, fatigue, and sleep were measured by asking participants to rate each on a 11-point NRS. Measurement of pain in this way is recommended for OA clinical trials by the Osteoarthritis Research Society International [44]. There is evidence of validity for this measurement of fatigue [45] and sleep [46] albeit not yet in individuals with OA. Physical function was measured using the Western Ontario and McMaster Universities Osteoarthritis Index physical function subscale [47] and global change by a 7-point Likert scale asking about *overall change in knee condition since commencing in the study*. Both measures are recommended for use in OA clinical trials [44], and the Western Ontario and McMaster Universities Osteoarthritis Index is valid, reliable, and responsive in OA populations [47]. Finally, mood was measured using the Patient Health Questionnaire-9, which has high reliability and validity in arthritis populations [48].

Adverse events were collected by asking participants “Have you had any new health problems or symptoms, or have any of your existing health conditions or symptoms worsened since you started in the study?” Further details of the impact evaluation are provided in [Multimedia Appendix 2](#).

Data are reported descriptively by treatment group assignment. Between-group differences in change were statistically analyzed by linear regression modeling with follow-up value as the dependent variable and baseline value and group allocation as independent variables. This was to help identify outcomes that may favor the intervention group rather than to determine effectiveness. Statistical analysis was conducted using SPSS software (version 26; IBM Corp). If a participant chose not to engage at all with the OSG, they were considered a protocol violator; however, provided that they completed follow-up questionnaires, their data remained in the analysis, and all completers were analyzed according to their allocated group.

### Qualitative Evaluations

In total, 2 qualitative evaluations were nested within the study. The first qualitative evaluation used semistructured interviews and reflexive thematic analysis [49] to explore the perspectives and experiences of participants in the My Knee Community OSG. All experimental group participants were invited to participate in telephone interviews after completing their 3-month questionnaire. All participants who agreed were interviewed. The final sample was therefore not dictated by data

saturation. Interviews were conducted by an experienced interviewer (PKC, who is a research trial coordinator, woman with previous experience in OA research, trained in qualitative interview methods, and a part of the study team but not previously known to participants or involved in My Knee Community). The topics discussed included their experiences, perceived impacts, and perceived barriers and enablers to engagement. The interview guide ([Multimedia Appendix 3](#)) was developed directly from these study aims. Interviews were audio recorded and transcribed. Analysis of transcribed interviews was based on an inductive thematic approach informed by grounded theory [50]. This method involves the generation of hypotheses and theories from data through cumulative coding [51]. Transcripts were read separately by BJL and PKC after transcription then coded to identify topics and patterns of ideas within the data. Both researchers independently organized codes into categories before meeting to discuss ideas. To ensure credibility and confirmability of the data, another researcher (MP) read all transcripts before meeting with BJL and PKC to review initial themes and subthemes. A fourth researcher (TE) provided additional input and validation of final themes and subthemes. All analytical steps were performed using word processing software.

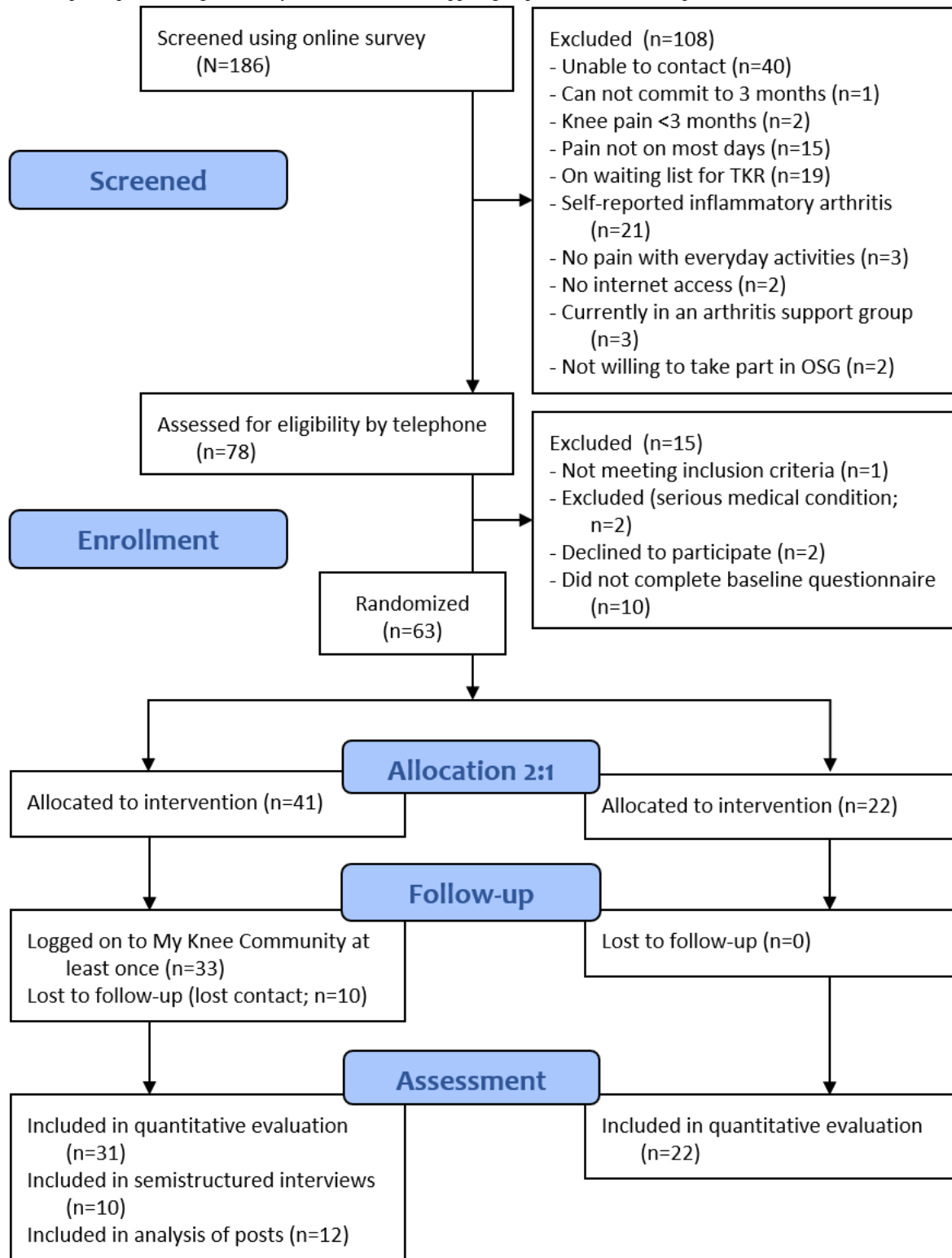
The second qualitative evaluation was a content analysis [52] of posts by study participants to understand how the OSG for people with knee OA was used by people living with the condition. This involved 2 researchers (BJL and TE) independently reading through all posts and coding the data to identify topics and initial patterns of ideas, which were then grouped into categories. Categories were given descriptive labels and reported as themes.

## Results

### Overview

A total of 186 volunteers were screened on the web, with 63 (33.9%) participants recruited (41/63, 65% participants allocated to OSG and 22/63, 35% participants, to control) between December 2019 and May 2020 ([Figure 2](#)). Participants (mean age 62.6 years, SD 11.2 years; 52/63, 83% were women; [Table 1](#)) included people living in different locations within Australia, including approximately 20% (12/63) in outer regional or remote areas. They had a range of educational levels and approximately half were in paid work. Duration of symptoms varied in participants from <1 year (6/63, 10%) to >10 years (14/63, 22%). A total of 5% (3/63) of participants had previously attended a self-management program, but none had previously participated in a support group. A total of 100% (22/22) of control participants and 76% (31/41) of OSG participants completed the follow-up questionnaire; 24% (10/41) of OSG participants were lost to follow-up ([Figure 2](#)).

**Figure 2.** Flow of participants through the study [18]. OSG: online support group; TKR: total knee replacement.



**Table 1.** Study participant characteristics (N=63).

Characteristics	Control group participants (n=22)	Online support group participants (n=41)
Age (years), mean (SD)	66.4 (7.6)	60.5 (12.4)
<b>Sex, n (%)</b>		
Female	18 (82)	34 (83)
<b>Region, n (%)</b>		
Major city	8 (36)	24 (59)
Inner regional	10 (46)	9 (22)
Outer regional	3 (14)	8 (20)
Remote	0 (0)	0 (0)
Very remote	1 (5)	0 (0)
<b>Highest level of education, n (%)</b>		
Some secondary or high school	1 (5)	4 (10)
Completed secondary or high school	0 (0)	7 (17)
Completed some further study (eg, Technical and Further Education)	9 (41)	16 (39)
Completed university: bachelor's degree	9 (41)	8 (20)
Completed university: master's degree	3 (14)	6 (15)
<b>Current employment status, n (%)</b>		
Work: full time (paid)	2 (9)	8 (20)
Work: casual (paid)	1 (5)	1 (2)
Work: part time (paid)	7 (32)	10 (24)
Unable to work because of health reasons	1 (5)	4 (10)
Retired (not because of health reasons)	11 (50)	15 (37)
Unemployed or not employed (eg, caring)	0 (0)	3 (7)
<b>Duration of knee pain symptoms, n (%)</b>		
<1 year	2 (9)	4 (10)
1 or 2 years	5 (23)	4 (10)
3-5 years	6 (27)	11 (27)
5-10 years	5 (23)	12 (29)
>10 years	4 (18)	10 (24)
<b>When first consulted a physician for knee pain, n (%)</b>		
<1 year ago	2 (9)	2 (5)
1 or 2 years ago	3 (14)	5 (12)
3-5 year ago	6 (27)	4 (10)
5-10 years ago	5 (23)	12 (29)
>10 years ago	2 (9)	8 (20)
<b>Previous participation, n (%)</b>		
Any support group	0 (0)	0 (0)
Any online support group	0 (0)	0 (0)
Any other self-management program	2 (9)	1 (2)
<b>Problems around other joints, n (%)</b>		
None	0 (0)	0 (0)
Head	0 (0)	2 (5)

Characteristics	Control group participants (n=22)	Online support group participants (n=41)
Neck	11 (50)	14 (34)
Back	10 (46)	22 (54)
Hip or hips	5 (23)	22 (54)
Foot, ankle, or ankles	11 (50)	17 (42)
Shoulder	6 (27)	6 (15)
Elbow or elbows	10 (46)	12 (29)
Hand, hands, wrist, or wrists	0 (0)	0 (0)

### Intervention Activities (Experimental Intervention Feasibility)

A total of 85% (35/41) of OSG study participants accessed My Knee Community at least once and therefore were considered adherent to the study protocol (Table 2). A total of 15% (6/41) of participants did not log in at all and approximately half logged in <3 times. Mean (SD) number of times visited per participant was 8.2 (SD 12.9; median 4, range 0-75). Only 29% (12/41) of participants posted, with the median number of posts per participant being 2 (range 1-5) for those who posted. During the study period (December 12, 2019, to August 31, 2020), there were 77 new members in the OSG (including the 35 new members who were study participants). Study participant engagement during the study period was consistent with the activity by members overall, that is, from the 200 total My Knee Community membership by the end of the study period, there were 922 total user visits during the study period (mean 4.6 per member) and 100 posts, with one-third being moderator posts and one-fourth being made by study participants (mean 0.3 post per member and mean 2.7 new posts per week). The topic with most reads and most replies was *Will exercise help my osteoarthritis?*, followed by *weight loss and reduction in pain: the evidence* and then *supplements to reduce inflammation*. The post with most likes was as follows:

*For me it's simple walking. I've gradually built up so now I can do 10-12km each walk. I walk at a pace of 6km/hr. I love it. In fact, I find my knee is more painful if I don't walk! The other benefits I've had is that I am now stronger in my legs and this has made it easier to do some movements that I found very painful before, like walking downstairs. The walking is free, and I also get to be outside which helps my mood.*

Comparing self-reported with software analytics data, participants either underestimated their number of log-ins or those who visited the OSG the most did not complete the follow-up questionnaire (Table 2). Perceived benefit was lower for the OSG intervention than for the information website, with 55% (17/31) of the OSG participants saying that they benefited from the My Knee Community but approximately three-fourth of the control group saying that they benefited from My Joint Pain (Table 2). Satisfaction was moderate, with an average

rating for overall satisfaction with the My Knee Community of 5.9/10 (SD 2.7) and satisfaction with specific aspects ranging from an average of 4.2/10 (SD 3.0) for *relationships developed with other participants* to 6.4/10 (SD 3.1) for *input from expert moderator* (Table 2).

For the qualitative content analysis of posts, 29 posts were made during the study period by 12 study participants who were My Knee Community members. From these, 4 themes were identified. The first theme included describing their successes (n=6 posts). These narratives included positive descriptions of management methods they use:

*In the past 18 months I have lost 18 kgs just through a few minor changes. The difference in my knees is remarkable, as well as my feet. I now am more active, and my doctor believes that I have avoided surgery. My knee pain is bearable, the only time it flares up is when I am inactive. [MKC9]*

The second theme included describing their struggle (n=6 posts). These posts described the difficulties people had coping because of their knee problem:

*I am in Melbourne and feeling the stress of not being able to really go anywhere. I'm not sleeping well, eating erratically and any exercise just feels like it's all 'too hard' atm. [MKC10]*

The third theme included what they do (n=9 posts), which included neutral narratives of management methods they use or their experiences of living with the condition:

*I experience the same with cooler weather and high humidity. Rather than take anything, I use Voltaren gel and the TENS machine, not necessarily in that order [MKC6]*

The fourth theme included appreciating something (n=7 posts). These generally short posts expressed thanks for a resource that was mentioned on the community forum:

*Great video guys. It made a lot of sense and motivated me. [MKC7]*

Only 1 of the 29 posts analyzed asked for advice:

*Has anyone tried Synvisc injections into their knee? [MKC9]*

**Table 2.** Experimental intervention feasibility.

Experimental intervention (online support group) feasibility	Participants
<b>Self-reported measures (n=31)</b>	
<b>Perceived benefit (My Joint Pain), n (%)</b>	
Do you think you benefited from using the information website? Yes	23 (74)
<b>Perceived benefit (My Knee Community), n (%)</b>	
Do you think you benefited from using the online support group? Yes	17 (55)
<b>How satisfied were you with the My Knee Community? (0-10 numerical rating scale: not at all satisfied to completely satisfied), mean (SD)</b>	
Overall	5.9 (2.7)
Quality of advice and information	4.9 (3.2)
Amount of information	6.3 (3.0)
Ease of use	5.9 (3.2)
Relationships developed with other participants	4.2 (3.0)
Input from expert moderator	6.4 (3.1)
<b>Engagement</b>	
<b>How many times did you visit My Knee Community over the past 3 months? n (%)</b>	
Never	3 (10)
1-2 times	10 (32)
3-5 times	14 (45)
6-10 times	3 (10)
>10 times	1 (3)
<b>How often did you read posts? n (%)</b>	
Never or rarely	7 (23)
Once every 2 or 3 weeks	22 (71)
Once or twice per week	2 (6)
>Twice per week	0 (0)
<b>How often did you post on the discussion board? n (%)</b>	
Never or rarely	28 (90)
Once every 2 or 3 weeks	3 (10)
Once or twice per week	0 (0)
>Twice per week	0 (0)
<b>Software analysis (n=41)</b>	
<b>Number of times visited, n (%)</b>	
Never	6 (15)
1-2 times	8 (20)
3-5 times	13 (32)
6-10 times	3 (7)
>10 times	11 (27)
Number of times visited, median times visited per participant (range)	4 (1-75)
Number of topics viewed, median topics per participant (range)	7 (0-35)
Number of posts read, median posts read per participant (range)	38 (0-164)
Number of posts created, median posts created per participant (range)	0 (0-5)
<b>Number of participants categorized, n (%)</b>	



Experimental intervention (online support group) feasibility	Participants
No participation <sup>a</sup>	6 (15)
Lurkers <sup>b</sup>	23 (56)
Posters <sup>c</sup>	12 (29)

<sup>a</sup>Did not log in to My Knee Community at all.

<sup>b</sup>Logged in but did not post.

<sup>c</sup>Logged in and posted at least once.

## Study Feasibility

A total of 94% (59/63) of participants were recruited from paid advertisements (Facebook and Instagram), with the remaining 4 recruited from free advertisements (university webpage, participant database, and word of mouth). Total cost of recruiting was Aus \$1086.20 (US \$772), which equates to Aus \$17.24 (US \$12) per participant recruited. Recruitment rate was 7.9 participants per week. A total of 84% (53/63) of participants completed the 3-month questionnaire. Retention was 100% (22/22) for the control participants and 76% (31/41) for the OSG participants. A total of 33 posts were made by the moderator during the study period, which equated to approximately 10 hours work over 8.5 months. Moderator posts were mostly news or research or OA resources but also included welcoming new members and responding to a member question. No posts were removed by the moderator. Administration of the platform, including managing license and enrolling new members, equated to approximately 0.5-1 hour/week, excluding initial setup and testing of the forum. Annual software license with educational institution discount was Aus \$15 (US \$11 normally Aus \$100/year [US \$71]).

## Psychological Determinants, Behaviors and Health Outcomes

The baseline and follow-up data for the psychological determinants, behaviors, and health outcomes are provided in [Multimedia Appendices 4-6](#). The study was not powered for within- or between-group statistical analyses, and the large number of analyses increased the risk of type 1 errors (false positives). There is no evidence supporting a clinically meaningful change in any of the measures within the OSG group and no between-group differences that suggest which outcomes may be positively affected by OSG participation. A total of 8 participants from each of the control (8/22, 36%) and experimental (8/31, 26%) groups reported overall improvement because of the intervention or interventions. No participant reported an adverse event that could have been related to the intervention or interventions. The 2 outcomes with the largest between-group differences in change favoring OSG were self-efficacy for pain (between-group difference in change 0.5 [95% CI -0.4 to 1.4]) and the health literacy domain of *navigating health care services* (between-group difference in change 0.3 [95% CI 0.0-0.5]).

## Qualitative Evaluation

A total of 10 people participated in the interviews about their perspectives of participating in an OSG for their condition: 8 (80%) women, mean age 63.2 (SD 7.7) years, mean visits 8.4

(SD 5.5; range 3-18); 5 (50%) interviewees did not post at all; and the remaining 5 (50%) posted between 1 and 4 times. The interviews lasted between 15 and 35 minutes. Three main themes were derived from the interview transcripts: connections and support, information and advice, and barriers and facilitators. These themes are comprehensively described from the data elicited in the interviews; however, the analysis does not suggest equal importance of all inferences. In addition, we report the perspectives from 1 or 2 participants when they presented a new or disparate view, but these views may not necessarily be consistent with the views of the entire sample or the knee OA population.

Under the theme of connections and support, interviewees talked about the importance of *support* from others in managing the condition more generally, the *benefits* of connecting with other people with OA, and *preferring to spectate* rather than connect. In relation to *support*, some specifically mentioned the need for emotional support. Interviewees talked about how useful it was to be able to talk to people other than their family or friends and health care professionals:

*Because it's a consistent pain problem, having a place to go to when the pain is bad for other suggestions or information or even just some reassurance, which is not bothering your GP and it's also not you complaining yet again to your family. Or maybe you don't want to [talk about it] because you don't want people in your workplace to realize it's inhibiting your life, you don't want them to think it's going to inhibit what you can do in the workplace. [OSGs are] a neutral place to be able to go and I think that's a real benefit and positive. [OSG10]*

Interviewees also talked about finding the *support* they received from health care professionals sometimes being inadequate, for example, because of the time constraints or costs of seeing health professionals:

*I know they've got their 15 minutes or their half hour, whatever they're charging for, but - doctors seem to be, in and out, thank you. They're happy to prescribe something, but I don't want to be prescribed anything. [OSG3]*

One interviewee said that they liked the idea of trying to *support* others by posting about their experiences on a forum. Finally, 1 interviewee said they felt "very supported" [OSG7] by the group moderator within the My Knee Community. It was not clear from the data whether these were disparate views or minor themes.

Some interviewees described *benefits* that they perceived they could gain from connecting with other people with OA. These included the reassurance that comes from knowing *you are not the only one*:

*So I personally found it extremely helpful, and it made me realize that no, there are other people out there with the same if not worse conditions that are still doing other things. [OSG8]*

*It's just about sharing your experiences I suppose and helping to put your troubled mind at rest if that makes sense. I mean I didn't have great expectations - it's just a reassurance that mentally...And other people are in the same position. [OSG1]*

*It was the personal comments that I really, I think, probably enjoyed the most...It's hard to explain, I felt part of this, but nothing on a personal level. Just that it was a group that I was part of. [OSG6]*

A specific *benefit* of connecting with other people with knee OA through the OSG mentioned by some interviewees was motivation to keep up their self-management. They derived encouragement from reading about other people who were still active despite their pain or their age:

*It's encouraged me to be more active and to be a bit more proactive about my self-care. [OSG10]*

*So being reminded about exercise, being reminded about the fact that those people were older and were doing a lot of exercise and pushing through their pain. Being reminded that being in pain doesn't make any difference to—it was not going to injure me any further, it was not going to make things worse, that it would make things better. All of those sorts of things were useful. [OSG2]*

Many interviewees *preferred to spectate* rather than contribute to discussions or connect with others on the OSG:

*I didn't even post anything, I just read...Well, I didn't really think I had anything to add. [OSG3]*

*I probably always thought I would do nothing because that's probably just my nature. I don't post on Facebook. I just look. [OSG6]*

*I enjoyed watching and listening and seeing what people were communicating on the chat, that was really interesting. [OSG10]*

Some had specific reasons for not posting, for example, they were not interested in social connections or relationships or they did not feel they fitted in:

*I probably didn't use it as much as I thought I would. Because a lot of people were talking about a lot more problems and things like that and I couldn't really associate with what they were saying...I think it probably was more involved for the higher pain threshold. [OSG5]*

One interviewee perceived that the people in the OSG were older [OSG2] and therefore they did not feel they could be a part of the group. Another interviewee said they did not post because they were older:

*I don't post anywhere really. I guess because I'm older. I don't know, just the privacy I suppose. [OSG6]*

Another interviewee was very clear that they did not want to connect with others, saying that they were not interested in emotional support or sympathy and just wanted to know how to *get rid of the pain* [OSG3]. Some interviewees suggested that they did not see the benefit in reading about other people's experiences:

*But people put up things that I've looked at, and gone oh yeah, well, good luck with that. [OSG1]*

In relation to the second theme of information and advice, interviewees talked about being *curious* about how others manage, wanting to *learn* about new management methods, and having *concern* about the accuracy of information being posted. *Curiosity* about what others were doing was the main reason for becoming a member of the OSG for some:

*I like to know a little bit about everything. So whatever was new, I had a look at. [OSG3]*

People were also motivated to *learn* through sharing information about things that help and receive "people's genuine opinions" [OSG6]:

*I do have a belief that I can work on it myself. I can, you know, learn to cope with it and get it better again. [OSG7]*

Some interviewees made the point that they were looking for treatment ideas that they were not receiving from health professionals:

*General advice because most of the health professionals, their answer is tablets or medications and stuff, and I'm a bit over that. [OSG4]*

Some interviewees said that people with knee OA often do not realize the other things they can do besides see health professionals, and meeting other people with the condition may be a way of learning about other strategies:

*A lot of people sort of-how can I explain-they suffer in silence thinking, "All right, it's just age," and that sort of thing, and they don't realize that there are opportunities there for them to get help to deal with it. [OSG8]*

Some of our interview participants found that hearing it from people with knee pain themselves encouraged them to try new things or be more active. Some mentioned they were managing a little bit better because of what they had learned:

*I am now seeking a bit more attention for my knee. I've just been putting up with it and been resigned to this is the way it's going to be. So [the OSG] has prompted me to be more active. [OSG10]*

Alternatively, some were more interested in the advice from experts (ie, the moderator or new research findings). Interviewees appreciated the resources (eg, videos and exercise programs) that were introduced to the group and some reported finding that they had benefited from them:

*By discovering those resources such as [painTRAINER]...that definitely helped me to find a way to manage my pain to my point that I don't have any at the moment. [OSG7]*

In contrast, some interviewees said they did not learn anything because they already knew most of the information; there was nothing new for them.

A few interviewees expressed some *concern* that the things people were posting about may not be helpful or “recommended” [OSG7]. They did not want to get involved in the discussions, and this concern meant that they were less keen on the OSG:

*I was just concerned that, you know, if they said, “Eat ants” other people might have gone and eaten ants because formic acid helps, or something [laughs]...There was someone who was sort of keeping an eye on it, but yes, to begin with I was just a bit concerned about, you know, “Whose advice do I follow?” [OSG7]*

The final theme was barriers and facilitators to engagement. *Barriers* included the perceived repetition within posts leading to much time reading. Conversely, the low level of activity on the site and infrequent new posts was also reported as contributing to reduced interest in engaging. One interviewee explained that they felt disappointed that they did not receive many replies to their post and that the conversations did not get going:

*So even when you make a comment...you might not get a comment or any feedback. [OSG2]*

Several interviewees commented on difficulties with accessibility, particularly on mobile devices, although most interviewees thought that the web-based format was easy to access. In terms of *facilitators*, interviewees talked about the advantages of being on the web and asynchronous rather than in person, for example, liking the flexibility of being able to use it a lot or just a little:

*And the fact that it is online and so you're not having to physically go somewhere to go to a meeting, or to go a session, makes it easily portable and accessible for people in all sorts of ways and means. [OSG10]*

Some of the study participants set up notifications, and occasionally the moderator would push out a notification to remind people to visit. Both these strategies were mentioned as being helpful by some of our interviewees. In terms of suggestions to facilitate engagement, 1 interviewee would have liked a scheduled release of new information, so they would know when to go on and look at what was new. Several people suggested that a reminder or a prompt such as a weekly summary might help to encourage more engagement.

## Discussion

### Principal Findings

This pilot study found that a trial of the effect of an evidence-informed, expert-moderated, peer-to-peer online support group for people with knee OA (My Knee Community)

is feasible in terms of study methods (recruitment, retention, and costs). Our findings suggest that future sample size calculations would need to allow for approximately 25% participant attrition given the 76% retention rate among our experimental group. However, our experimental intervention was not delivered to an acceptable extent as indicated by our measures of engagement and satisfaction. A total of 85% (35/41) of the participants adhered to the requirement to log on to the OSG at least once, which may seem to be an acceptable protocol adherence; however, given the overall lack of activity on the forum as well as the lack of activity by the study participant members, the dosage of any potentially important components would have been low. Only 55% (17/31) of the experimental group participants perceived benefit, and this was notably lower than for the control group's perceived benefit from the information website alone. Overall satisfaction was 5.9/10, which is relatively low compared with satisfaction scores in other OSG studies [53,54]. In relation to the qualitative evaluation, our data suggest that most people with knee OA perceive that they need informational support and, to a much lesser extent, emotional support. However, the participants did not find the My Knee Community OSG particularly useful in meeting these needs. Some participants liked hearing about how other people manage, but in general, they were not willing to share their own experiences. In terms of perceived benefits, some participants found that the OA resources posted by the moderators were useful as this information was not normally provided by health professionals. The low level of activity meant that people quickly drifted away from the group. Facilitators of engagement included identifying as someone who fitted into the group and being comfortable with the technology. In relation to the impacts, the study was not powered to detect a difference in effect, and the dosage of intervention components experienced by participants was low. Of the numerous measures, self-efficacy for pain and the health literacy domain of *navigating health care services* are suggested as target outcomes in future trials.

As with our findings, previous studies have shown that posts in OSGs can mostly be categorized as being supportive or informational [55,56]. Emotional support, positive feedback from others, and reinforcement of decisions was found to occur in other OSGs [55-58]. Unfortunately, there was little such peer-to-peer interaction in the My Knee Community. Nonetheless, our OSG helped some people to feel reassured and more motivated to actively self-manage. In relation to information, we found that some people favored the information from other people with knee OA, whereas others had a clear preference for information from the *experts*. Our earlier survey study indicated that trustworthiness of the organizing group and incorporating health professionals or expert peer leaders would be important to potential members [14], and this was substantiated by our findings. During the study period in our OSG, the most popular topics were related to exercise, followed by other treatment options, such as weight loss and supplements. Other studies have shown that people most often talk about medications and symptom management [12,59]. Differences may be due to the type of informational posts provided by the My Knee Community moderators.



It was clear from our study that most people prefer to be passive members rather than actively post and engage with other members. Despite this, our qualitative data indicate that many people know they need support and know about the benefits of connecting with others. Considerable evidence from the field of positive psychology shows the importance of talking to other people, including the value of talking to strangers [60]. Research shows that people often prefer not to connect with others, but they are happier if they do [60]. Perceived fear about conversation enjoyment and pessimism about how they will be perceived are typical barriers [60]. People who are more engaged in OSGs may experience greater gains in health literacy and self-esteem than those who post infrequently or only *lurk* [54,61]. Thus, efforts to promote the OSG as a safe place to share and express their feelings, respond positively to posts, and role model suitable posts may be warranted to encourage activity. On the other hand, research has shown that people can benefit from OSGs even if they avoid posting [54]. Posting behavior may be largely determined by personality traits and the nature of the condition (not life-threatening and relatively common in the community). These factors may influence both engagement and satisfaction with peer-to-peer OSGs for OA.

Our quantitative data indicated that self-efficacy and health literacy may be mechanisms by which OSGs can lead to improved health outcomes. This is supported by findings from previous studies, which suggest that the sharing of experiences in chronic condition on web-based communities helps improve health literacy and the quality of self-management plans [57,58]. In addition, multiple cohorts and observational studies of people with nonmusculoskeletal disorders have reported significant positive effects on self-efficacy following participation in OSGs [62-65]. Both health literacy and self-efficacy are considered foundational for effective chronic disease self-management [56,58,66,67]. Our qualitative data additionally suggest that people may benefit through increased motivation to actively self-manage (ie, feeling encouraged by other posts) and perhaps also simply through boosting their mood. The potential mechanisms require further investigation.

Our feasibility study has led us to consider some important modifications to our OSG before continuing to a full-scale intervention study. First, a critical mass of members may be needed in an OSG for knee OA to create an atmosphere that retains and benefits members. People tended to be reluctant to post, but at the same time, lack of activity was given as a reason to disengage. A large membership may mean that enough people become regular posters to maintain momentum and consequently the interest of the wider group. A larger membership might also lead to greater diversity of member characteristics and diversity of opinion [14], which might, in turn, lead to wider appeal. Second, we discovered that many of our study participants seemed to be motivated by curiosity or had a preconceived expectation of what they wanted to find out from the community. Both types were quick to disengage. Therefore, we recommend that expectations are clarified before people join by explaining that the My Knee Community is a forum for sharing experiences, discussing, and supporting each other (not just a knee OA information resource). For trial purposes, we recommend

focusing recruitment on people who are interested in sharing and supporting. As noted in a review on mechanisms of action in group-based health behavior change interventions, groups are not for everyone. Participant selection and matching are an important preliminary part of setting up effective groups, including effective online groups [15]. We found that inclusion of the moderator team was helpful for safety, responding to some types of questions, and for communicating trustworthy information and therefore recommend that this feature remains. This recommendation is consistent with our earlier survey study, which concluded that a moderator role is important for explaining complex topics and maintaining trustworthiness [14]. That study also highlighted the need for people to enjoy participating in the forum to maintain participation [14]. Therefore, we will consider some additional strategies to increase enjoyment and ongoing interest, for example, adding humor, changing the design to be more attractive, emailing weekly summaries, sending reminders or other notifications (but not too many), and improving accessibility (mobile phone interface) and ease of log-in.

### Limitations

This pilot study was not designed to evaluate impacts, and our findings are limited by the small sample sizes for both quantitative and qualitative analysis (only 10 out of 41 participants agreed to be interviewed) and the uncertainty about the dosage of the intervention that was delivered. These sources of bias are likely to underestimate the impact. Other limitations include error and noise inherent in the self-reported measures [68] and potential sampling bias because of our recruitment predominantly using social media. Both our strategies for recruiting My Knee Community members and study participants may not have reached the people most likely to benefit from an OSG, for example, people who are isolated or lack social support for other reasons and people who have lowest health literacy and access to health professionals and high value health care. The limitations to generalizability of the findings include the digital literacy requirements, inclusion based on self-diagnosis of knee OA according to clinical presentation, and the Australian health care context.

### Conclusions

Future research should consider cost as well as health benefits. Health benefits are likely to be small at best; however, because of the large number of people with knee OA and the relatively low cost and safety of OSG interventions, OSGs for OA may have value as part of a range of options. Importantly, we recommend that the intervention be delivered only to those inclined to engage with the format. Our study found a full trial of an expert-moderated, peer-to-peer online support group intervention to be feasible provided the OSG can engage members and facilitate active participation. OSGs are rapidly growing in popularity and may provide a range of benefits for several health conditions or chronic disease-related problems. This study contributes to evidence-informed implementation and use of OSGs for improving self-management behaviors and health outcomes for people with knee OA as well as future trial design.

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## Authors' Contributions

TE designed the study, wrote the protocol, managed the project, interpreted the data, and drafted the manuscript. KLB, DJH, BV, and PWH acquired funding, initiated the project, and contributed to the conceptualization and design of the study. BJL, MLP, KM, JE, LM, MB, CD, and CA also helped in the design of the study. DAM and TE managed the My Knee Community. LS, DAM, and GK recruited participants and collected quantitative data. BM, BG, and TE analyzed the quantitative data. PKC conducted the qualitative interviews. BJL, MLP, PKC, and TE analyzed the qualitative data. All authors reviewed and contributed to the final manuscript.

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## Conflicts of Interest

DJH provides consulting advice on scientific advisory boards for Pfizer, Lilly, TLCBio, Novartis, Tissuegene, and Biobone. KLB's institution receives grant funding for osteoarthritis research from the National Health and Medical Research Council, Medical Research Futures Fund, and Medibank. KLB receives royalties from UpToDate knee osteoarthritis clinical guidelines.

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### Multimedia Appendix 1

The evaluation plan related to study feasibility.

[\[PDF File \(Adobe PDF File\), 112 KB - formative\\_v6i1e32627\\_app1.pdf \]](#)

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### Multimedia Appendix 2

The evaluation plan related to the intervention impact mapped to the logic model components.

[\[PDF File \(Adobe PDF File\), 142 KB - formative\\_v6i1e32627\\_app2.pdf \]](#)

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### Multimedia Appendix 3

The qualitative interview guide.

[\[PDF File \(Adobe PDF File\), 99 KB - formative\\_v6i1e32627\\_app3.pdf \]](#)

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### Multimedia Appendix 4

Psychological determinants: summary measures and estimated mean differences in change (95% CI).

[\[PDF File \(Adobe PDF File\), 107 KB - formative\\_v6i1e32627\\_app4.pdf \]](#)

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### Multimedia Appendix 5

Behaviors: summary measures and estimated mean differences in change (95% CI).

[\[PDF File \(Adobe PDF File\), 79 KB - formative\\_v6i1e32627\\_app5.pdf \]](#)

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### Multimedia Appendix 6

Health outcomes: summary measures and estimated mean differences in change (95% CI).

[\[PDF File \(Adobe PDF File\), 83 KB - formative\\_v6i1e32627\\_app6.pdf \]](#)

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### Multimedia Appendix 7

CONSORT-EHEALTH (V 1.6.1) - Submission\_Publication Form.

[\[PDF File \(Adobe PDF File\), 2637 KB - formative\\_v6i1e32627\\_app7.pdf \]](#)

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## Abbreviations

**NRS:** numerical rating scale

**OA:** osteoarthritis

**OSG:** online support group

**REDCap:** Research Electronic Data Capture

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Viewpoint

# The Applied Data Analytics in Medicine Program: Lessons Learned From Four Years' Experience With Personalizing Health Care in an Academic Teaching Hospital

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## Abstract

The University Medical Center (UMC) Utrecht piloted a hospital-wide innovation data analytics program over the past 4 years. The goal was, based on available data and innovative data analytics methodologies, to answer clinical questions to improve patient care. In this viewpoint, we aimed to support and inspire others pursuing similar efforts by sharing the three principles of the program: the data analytics value chain (data, insight, action, value), the innovation funnel (structured innovation approach with phases and gates), and the multidisciplinary team (patients, clinicians, and data scientists). We also discussed our most important lessons learned: the importance of a clinical question, collaboration challenges between health care professionals and different types of data scientists, the win-win result of our collaboration with external partners, the prerequisite of available meaningful data, the (legal) complexity of implementation, organizational power, and the embedding of collaborative efforts in the health care system as a whole.

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**KEYWORDS**

digital health; data-driven care; multidisciplinary; lessons learned; eHealth; personalized medicine; data analytics; implementation; collaboration; hospital

## Introduction

The University Medical Center (UMC) Utrecht is one of the largest academic teaching hospitals in The Netherlands. It has been using an electronic health record (EHR) system since 2007 and has ample experience in unlocking these data. The use of these routine health care data in data-driven care provides an opportunity to further personalize health care. Therefore, the UMC Utrecht executed a hospital-wide innovation program to explore if analysis of routine care data can be used to directly improve health care for patients. Personalizing health care using data analytics and specifically artificial intelligence (AI) is demanding for any health care organization. We would like to share the most important lessons we have learned over the last 4 years to inspire and support others.

## Program Set-up

The Applied Data Analytics in Medicine (ADAM) program started in 2017 as a proving ground with funding from the UMC Utrecht Board of Directors with the goal to try to improve health care for patients, by using innovative data analytics tools to answer clinical questions based on available routine care data. The program was headed by a core team of 4 people, who were ultimately responsible for the results. ADAM was based on three basic concepts: the value chain, the innovation funnel, and the multidisciplinary team

### The Data Analytics Value Chain

The value chain runs from data to insight to action to value. For example, when heart rhythm is captured (data), an absent heart



rhythm can be found (insight), which warrants resuscitation (action) to save a life (value). Without action, value cannot be created.

### The Innovation Funnel

The innovation funnel consists of 7 phases with specific goals. In between the funnel phases, go and no-go moments can be found. The innovation funnel facilitated business-driven, controlled development for the project teams and prevented them from deviating from the clinical question. More importantly, the funnel provided the possibility to discontinue projects in an early stage of development. On an organizational level, the innovation funnel provided insight into the stage of development of the various data analytics projects.

### The Multidisciplinary Team

The multidisciplinary team always consisted of a patient, a health care professional, and a data scientist. The health care professional was the product owner of the data analytics project.

Data analytics proposals were prioritized based on relevance, feasibility, and scalability. In addition, educational value to contribute to a learning digital health care organization as a whole was a selection criterion. The multidisciplinary project team met weekly to discuss progress. Furthermore, cross-team meetings were organized to support interaction between teams. The project team organized project-specific expert sessions to discuss the project in a larger meeting with health care professionals or patients. To leverage lessons learned both within and outside the health care field, the program was established as a collaboration with different external business partners. As the UMC Utrecht only employed a few data scientists at the time, other parties (eg, external partners) provided data science expertise. The use of AI was optional and was seen as a means to an end. The program was extended twice, and total of 11 projects and 9 different external partners collaborated over 4 years' time (Table 1). We organized 3 public seminars to spread our knowledge, and the infrastructure, activities, and interactions within the program provided the basis for 5 master's degrees in fields other than health care.

**Table 1.** Projects of the Applied Data Analytics in Medicine (ADAM) program.

Specialty	Clinical goal
Cardiology	To support shared decision-making in cardiovascular risk management using a dashboard within the electronic health record system [1]
Rheumatology	To support the decision of whether or not to taper medication, based on risk of rheumatoid arthritis flares [2]
Psychiatry	To support a more personalized choice of antipsychotic medication
Neonatology	To support the decision to start antibiotics without a positive blood culture, as an early warning for neonatal sepsis
Microbiology	To support the decision to obtain a urine sample to lower unnecessary cultures
Gynecology	To support planning schedules in both the neonatal intensive care unit and the maternity ward by predicting capacity
Radiology	To obtain the infrastructure (hardware and software) to be able to apply artificial intelligence in radiology
Anesthesiology	To prioritize patients based on a visualized patient status overview
Intensive care medicine	To support ICU <sup>a</sup> planning by predicting ICU capacity
Neonatology	To support the decision of whether or not to start a procedure on a neonate based on sleeping patterns

<sup>a</sup>ICU: intensive care unit.

## Lessons Learned

### Lesson 1. Clinical Practice as Both a Starting and End Point

Each data analytics project was based upon a relevant clinical question, provided by a health care professional [3]. We stimulated focus on this question by making the health care professional the product owner of the multidisciplinary project team. At the same time, this guaranteed the commitment of the health care professional. Moreover, the health care professionals received partial dispensation from clinical duties to participate in the program. In addition, the IT (information technology) department was involved from the start of the program, to facilitate expertise on data architecture and infrastructure that enabled both data extraction and model development, as well as interaction with the EHR system.

### Lesson 2. Health Care Professionals and Data Scientists Do Not Speak the Same Language

Health care professionals and data scientists each brought in specific expertise within their own frame of reference [4]. We therefore provided an objective project lead to further encourage collaboration. The project lead, for example, asked clarifying questions about the meaning of specific terms. We deliberately spent a considerable amount of time explaining medical processes and medical terminology to data scientists, for example, by drawing on the diagnostic or therapeutic process (where does the decision support system fit in this scheme? What decision will be ultimately supported?). A visit to the outpatient clinic or hospital ward proved to be of great value.

### Lesson 3. Data Professionals With Varying Expertise Are Needed

Data scientists in health care often choose a health care job consciously and are idealistic. One of the most important ways of keeping them excited was to provide them with diverse and

challenging tasks: our data scientists worked on different projects at the same time, and we valued and encouraged the team spirit. We soon discovered that more roles were needed in addition to data scientists. Considerable effort was needed to collect and clean the data to preprocess it for data analysis (data stewards, data engineers). We also needed software developers, as well as UX (user experience) and UI (user interface) designers later on during development.

#### **Lesson 4. External Partners Are Partners, Not Just Suppliers**

In our collaboration with external partners, we always aimed for a win-win situation. Partners pointed out the strategic benefits of working together with a hospital, indicating their willingness to invest in the relationship. All of our data scientists worked in the same project room. Because some partners provided company-specific expertise, this was a challenging way of collaborating. It was therefore crucial to discuss, for example, intellectual property before the project started (intellectual property was in principle allocated to the UMC Utrecht).

#### **Lesson 5. Available Data Need to Be Unlocked in a Meaningful Way**

The collection of data in health care nowadays takes place in closed electronic health care systems that are not designed to enable reuse of data. The data need to be unlocked and, to prevent the “garbage in = garbage out” phenomenon, transformed into meaningful data in a workable format. In making these data analysis tables, domain knowledge, as well as knowledge of the medical process and technical knowledge of the EHR structure, are needed. Data stewards with combined knowledge were a valuable addition to the multidisciplinary teams. For example, we could build on the ample experience and available data from the Utrecht Patient Oriented Database [5]. In addition, sufficient data were needed for both epidemiologic determinants, as well as outcomes. In the project that aimed to personalize antipsychotic therapy, we, for example, couldn't find a way to determine therapeutic success from the EHR, so the project was discontinued after the exploration phase. AI was not always needed for a successful project; for example, the successful model to predict flares in rheumatology was based on a joint modeling technique from classic epidemiology [2].

#### **Lesson 6. Implementation Is Versatile and Complex**

If insights do not lead to action, value cannot be created and the data analytics project is essentially a waste of effort. Implementation of data analytics tools requires organizational changes that must not be underestimated. The multidisciplinary team, the expert sessions, and a UX researcher supported the changing health care processes at the UMC Utrecht. As the health care sector has fully embraced the concept of shared decision-making, the action that will be taken is the result of a shared decision. We therefore involved patients from the start of the clinical decision support tool, which supplemented the

projects with important alternative perspectives. In addition, medical technology is always ahead of laws and regulations, for example, in the development of medical devices. Several partner departments in our hospital were of great value by pointing out the scope and leeway of legislation to support innovations. Next to “is this possible?” and “is this allowed?” we always answered the ethical question “do we want this?” in our projects.

#### **Lesson 7. Organizational Power Is Essential**

A large academic hospital is home to a lot of expertise, yet this often leads to a bureaucratic decision-making process. We had the advantage of being a program under the direct supervision of our Board of Directors, with a core team that had the authority to make decisions and the funding to carry them out. We were therefore prioritized by partner departments such as legal, privacy, and ethics. Without organizational power, it is difficult to run successful innovative projects.

#### **Lesson 8. You Cannot Do Anything Alone, You Have to Do It (Carefully) Together**

Data analytics projects demand far-reaching collaboration. Health ministries could serve to bring inspiration and support to the current innovative health care climate. Academic medical centers should reach out and connect to smaller institutions because, for example, their academic population leads to underrepresentation of certain patient groups. Health care insurance companies should consider investing in projects that do not yield value directly to hospitals but are of value to the health insurance premium payers or society as a whole. The health care sector should find a way to collaborate with external partners that are for-profit, yet also possess a valuable network to valorize swiftly. As an example, the ADAM project IMAGR closed a contract to bring to the market a platform for radiology analysis using AI that connects to various existing radiology systems [6].

The experiences of our program led to the establishment of a new digital health department in the UMC Utrecht in early 2020. This department functions as a “hub” for digital health in the broadest sense, to further encourage and support the digital transition of the UMC Utrecht. The new department specifically appeals to the clinical departments: this is where medical processes take place and where data analytics is implemented in a responsible way. The positioning of the new department, close to the Board of Directors, provides the organizational power to make this happen.

Patients nowadays expect to be able to use personalized services always and everywhere. In 1959, the first article was published in which the author discussed computers supporting clinical decision-making [7]. Now, over 50 years later, it is about time for a flexible, digitally supported health care organization that facilitates personalized care at the right time and the right place, perhaps not with a personal computer on the doctor's desk but with a mobile phone in hand.

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## Authors' Contributions

SH and WWvS developed the concept. SH wrote the manuscript, and TRP and WWvS contributed to the manuscript.

## Conflicts of Interest

None declared.

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## Abbreviations

**ADAM:** Applied Data Analytics in Medicine  
**AI:** artificial intelligence  
**EHR:** electronic health record  
**IT:** information technology  
**UI:** user interface  
**UMC:** University Medical Center  
**UX:** user experience

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Original Paper

# A Telemedicine-Guided Self-Collection Approach for PCR-Based SARS-CoV-2 Testing: Comparative Study

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## Abstract

**Background:** Large-scale, polymerase chain reaction (PCR)-based SARS-CoV-2 testing is expensive, resource intensive, and time consuming. A self-collection approach is a probable alternative; however, its feasibility, cost, and ability to prevent infections need to be evaluated.

**Objective:** This study aims to compare an innovative self-collection approach with a regular SARS-CoV-2 testing strategy in a large European industrial manufacturing site.

**Methods:** The feasibility of a telemedicine-guided PCR-based self-collection approach was assessed for 150 employees (intervention group) and compared with a regular SARS-CoV-2 testing approach used for 143 employees (control group). Acceptance, ergonomics, and efficacy were evaluated using a software application. A simulation model was implemented to evaluate the effectiveness. An interactive R shiny app was created to enable customized simulations.

**Results:** The test results were successfully communicated to and interpreted without uncertainty by 76% (114/150) and 76.9% (110/143) of the participants in the intervention and control groups, respectively ( $P=.96$ ). The ratings for acceptability, ergonomics, and efficacy among intervention group participants were noninferior when compared to those among control group participants (acceptability: 71.6% vs 37.6%; ergonomics: 88.1% vs 74.5%; efficacy: 86.4% vs 77.5%). The self-collection approach was found to be less time consuming (23 min vs 38 min;  $P<.001$ ). The simulation model indicated that both testing approaches reduce the risk of infection, and the self-collection approach tends to be slightly less effective owing to its lower sensitivity.

**Conclusions:** The self-collection approach for SARS-CoV-2 diagnosis was found to be technically feasible and well rated in terms of acceptance, ergonomics, and efficacy. The simulation model facilitates the evaluation of test effectiveness; nonetheless, considering context specificity, appropriate adaptation by companies is required.

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**KEYWORDS**

self-sampling; telemedicine; test strategy effectiveness; simulation model; SARS-CoV-2; COVID-19

## Introduction

Numerous campaigns for COVID-19 vaccination have been initiated worldwide, but the pandemic continues to spread. Emerging variants of SARS-CoV-2, as well as reports of breakthrough infections, underline that public health mitigation measures, including testing strategies, need to be continued. In terms of sensitivity, nucleic acid amplification tests (NAATs) are standard for SARS-CoV-2 detection in respiratory samples obtained by medical personnel (ie, regular testing approach) [1]. However, the implementation of professional, large-scale routine testing is limited owing to high organizational costs and intensive efforts entailed. The authorization of lateral-flow SARS-CoV-2 antigen tests enables the implementation of self-testing strategies (ie, self-testing approach), which improves the turnaround times of test results. Due to the absence of amplification steps, the analytic sensitivity of lateral-flow antigen tests is substantially inferior to that of a NAAT-based approach, particularly when the viral load is low in early or late stages of disease progression [2].

A self-collection approach based on NAAT performed on self-collected swabs could combine the advantages of regular testing and self-testing approaches. Previous studies have shown that the sensitivity of SARS-CoV-2 polymerase chain reaction (PCR) testing using self-collected swabs was comparable to swabs collected by health care professionals, with an acceptable impact on the test sensitivity [3-7]. Self-collection reduces the use of resource-intensive testing centers and personal protective equipment, and it eliminates the requirement of swab collection by medical personnel. Furthermore, the willingness of individuals to undergo testing might be increased as the time required for testing is expected to be lesser, and self-collected swabs are considered to be more convenient for the operator [8]. Structured evaluations of different testing strategies are required to compare their feasibility, costs, and infection-prevention capabilities.

In this prospective, two-arm feasibility study, we aimed to compare a telemedicine-guided self-collection approach with a regular testing approach involving a sample collected by a health care professional for PCR-based SARS-CoV-2 diagnostics, primarily focusing on the feasibility, and secondarily on the acceptance, ergonomics, and efficacy of the testing strategy implemented onsite at a large European industrial manufacturing company in Germany. For the self-collection approach, we developed a telemedicine-guided approach, which included obtaining electronic consent, electronic registration, and communication of the SARS-CoV-2 PCR test result. Testing approaches in companies aim to reduce the infection risk arising from undetected but infectious employees. In this study, none of the SARS-CoV-2 PCR tests performed in the employees returned positive. We performed health economic modeling to analyze potential effects of different testing strategies and developed a shiny app to enable people to run simulations using different medical assumptions.

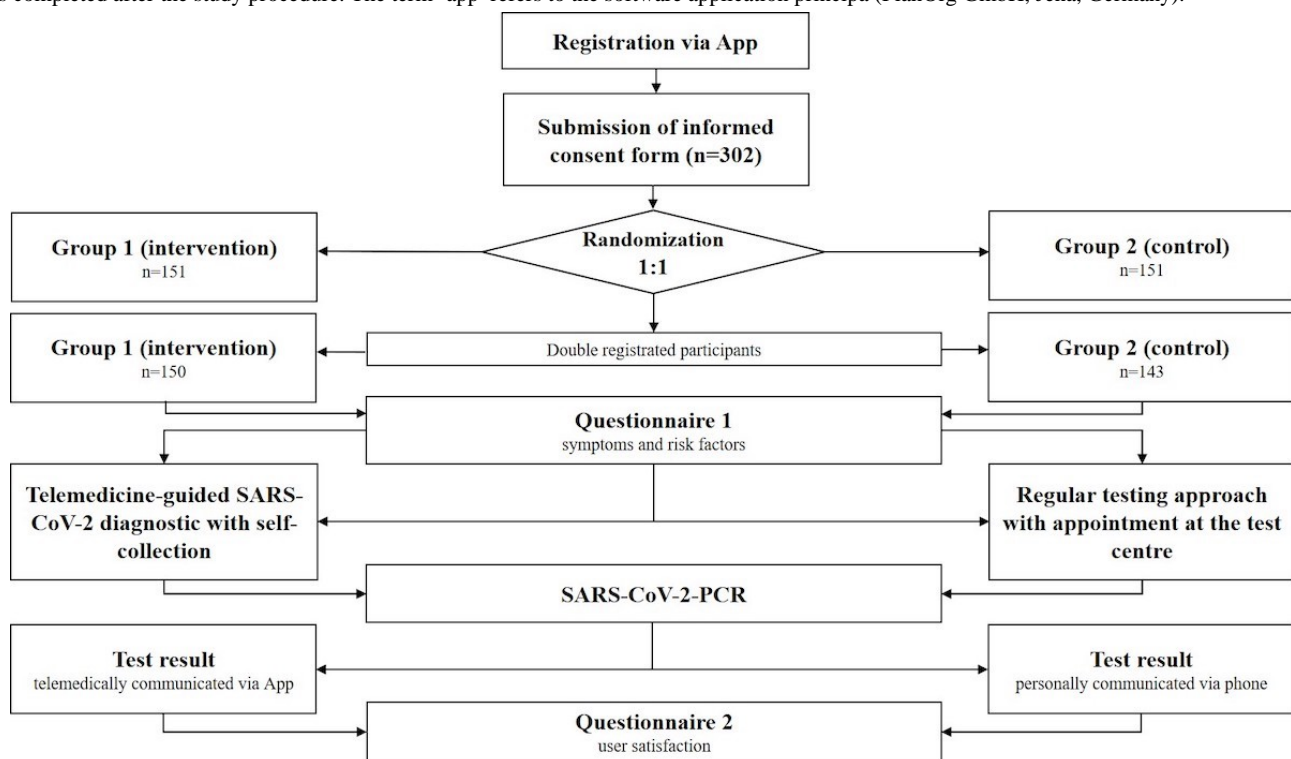
## Methods

### Study Design and Participants

The process flow of this prospective, interventional, open-label, controlled, two-arm feasibility trial is illustrated below (Figure 1). Between November 11, 2020, and December 11, 2020, all employees of Siemens F80, SYKATEC GmbH, and Valeo Siemens eAutomotive Germany GmbH were invited to participate in this study (see Figure S1 in Multimedia appendix 1 for the advertisement flyer). The main inclusion criteria were the ability to download and use the user application of the software app *principa* (PlanOrg GmbH), which is part of the hospital information system and clinical workplace system at the University Hospital rechts der Isar (Technical University of Munich, Germany). The app could be downloaded using a study-specific quick response (QR) code with a deep link to the Android or Apple store. Upon registration, electronic consent was obtained from all participants, following which they were randomized 1:1 into two study groups using the Java function *SecureRandom* (algorithm: SHA1PRNG). Participants in group 1 (intervention group; telemedicine-guided SARS-CoV-2 diagnostic testing with self-collection) were asked to collect a prepacked self-collection kit, including the United Nations' recommendation of dangerous goods (UN 3373) compliant packaging kit (cardboard and container) with a prepaid shipping label, printed instructions (see Figure S2 in Multimedia Appendix 1), and a swab (FLOQSwabs 552C Regular Flocked Swab with an 80-mm breakpoint, Copan). The risk factors for and the symptoms of SARS-CoV-2 infection were self-reported using the app (see Table S1 in Multimedia Appendix 1). A short explanatory video was made available in the app for demonstration to the participants (see Multimedia Appendix 2). Participants self-collected an oropharyngeal swab, scanned the individualized unique code of the shipping kit, and mailed the kit to the study center at University Hospital rechts der Isar for analysis. SARS-CoV-2 PCR test results were provided via the app; in addition, the PDF report could be exported for personal use. Group 2 participants (control group; regular testing approach via appointment at the test center) were asked to book an appointment via phone for SARS-CoV-2 testing at a test center located at the study site. After assessment of SARS-CoV-2-specific risks and symptoms by a staff member, a nasopharyngeal sample was collected (REST Clinical Virus Transport Medium [CTM] swab, Rapid & Easy System Technology; Noble Biosciences, Inc.) by trained medical staff. The samples were shipped to the study center and processed as described for group 1. SARS-CoV-2 PCR test results were exclusively provided by phone and without any hard copy. Upon communication of the test results, participants in both groups were asked to evaluate the respective testing strategy and app by using a visual slider on a 7-point Likert scale (0=strong disagreement, 6=strong agreement) within the app. The questionnaire items were based on the National Aeronautics and Space Administration (NASA) Task Load Index [9] for evaluating the effort and the Website Analysis and Measurement

Inventory for evaluating user satisfaction. The time required for the entire sample collection procedure was assessed in minutes. The completion of the questionnaire was facultative.

**Figure 1.** Process flow. Upon registration and informed consent, participants were randomized into a self-collection (intervention) and regular testing (control) group. Swabs from participants of both groups were submitted to the study center and SARS-CoV-2 polymerase chain reaction (PCR) was performed. Questionnaire on the symptoms and risk factors was completed before conducting the procedure, whereas the questionnaire on user satisfaction was completed after the study procedure. The term ‘app’ refers to the software application *Principia* (PlanOrg GmbH, Jena, Germany).



### Ethics Approval

This study was approved by the ethics committee at the Technical University of Munich, School of Medicine, University Hospital rechts der Isar, Munich, Germany (approval 603/20-SH) and conducted in accordance with the Declaration of Helsinki.

### Primary and Secondary End Points

The primary end point was the proportion of participants for whom self-collection, virological diagnosis, and reporting of the test result were successfully conducted, and the statements made by the participants in response to the questionnaire did not indicate any uncertainty with respect to interpretation of the test results (see Table S2 in [Multimedia Appendix 1](#) for details). The secondary end points were (1) the proportion of participants for whom virological findings were available but uncertainty regarding the interpretation was reported, and (2) patient-reported outcomes, including acceptance, ergonomics, and efficacy. The statements of group-specific questionnaires were assigned to these three outcomes (see Table S4 in [Multimedia Appendix 1](#)). Threshold values were defined to transfer the ratings into a dichotomous scale (favorable rating >3 points; unfavorable rating ≤3 points). A favorable rating for more than 70% of all the statements was interpreted as a satisfactory outcome.

### Diagnostic Procedures

All virological diagnostics were performed by the expert staff of the Institute of Virology, Technical University of Munich. Nucleic acids were extracted using the mSample Preparation System DNA kit (Promega), and a standard protocol was followed on an m2000sp device for RNA and DNA extraction (Abbott). SARS-CoV-2\_N1 and SARS-CoV-2\_N3 primer and probe sets were used for amplification on an ABI 7500 real-time PCR cyclers (Thermo Fisher Scientific), following the protocol of the Division of Viral Diseases, National Center of Immunization and Respiratory Diseases, Centers for Disease Control and Prevention (accreditation authority No. D-ML-14063-02-00) [10].

### Sample Size Calculation

For calculation of the sample size, we assumed that 50% of the participants met the criteria for the primary end point. A confidence level of 95% and a specified CI of 0.08 resulted in 151 participants per group (n=302). Dropouts were not considered because they were represented in the fraction of the participants to whom the test results were not successfully communicated. Recruitment was stopped when the calculated sample size was reached.

### Simulation Model for Evaluation of the Effectiveness of Test Strategy

We developed a simulation model that facilitates evaluation of the effectiveness of distinct COVID-19 test strategies. We modeled the risk of infection that arises from individuals with

SARS-CoV-2 infection who do not present typical COVID-19 symptoms. This implies that the model solely focuses on the risk of infection that arises from undetected, presymptomatic, and asymptomatic COVID-19 cases. Test strategies that are targeted on individuals without COVID-19 symptoms represent a measure taken to reduce this risk. The developed simulation model considers a period of 4 weeks (28 days) and relies on several medical assumptions. Based on expert ratings and a review of the relevant literature, we assumed that COVID-19 symptoms appear on the third day of infection [11,12]. We assumed 20% asymptomatic infections [13] and postulated that infected individuals are infectious for 10 days [14]. Furthermore, we assumed a 7-day incidence rate of 100 and 20% immune individuals. The main outcome of the simulation model was the average number of infectious but undetected individuals working onsite per day, which can be interpreted as a measure of the risk of formation of infection clusters within the company. Considering a scenario without any testing strategy as the benchmark, the model allows us to calculate and compare the measurements of relative risk reduction for different testing strategies. In our simulation model, test strategies are defined by five parameters. For this study, we considered a population of 10,000 individuals (workers) and assumed that 80% of susceptible individuals actually participated in the testing program. In addition, we assumed that participants were tested once per week. We assumed these parameters to be equal for both testing programs used in this study. The other two parameters defining a testing program are closely related to the test performed and are therefore of particular importance in this study. The first parameter is test sensitivity, which is supposed to be higher in the case of the regular testing approach. Prior research indicates a sensitivity of 90% for the regular testing approach and 80% for the self-collection approach [5-7,15]. However, because the exact difference remains unknown, we report simulation results for four different levels of test sensitivity: 70%, 80%, 90%, and 100%. The second parameter that is relevant in this study is the number of days taken to communicate the test results to the program participants (ie, turnaround time). Unfortunately, the trial conducted does not provide a clear indication of the turnaround time of both testing approaches. In fact, the turnaround times may differ between the two approaches. Therefore, we ran our simulations for four different turnaround times: 0, 1, 2, and 3. Because we differentiate between the four sensitivity levels and the four turnaround times, we report the results for a total of 16 simulation scenarios. The comparison of the obtained results allows us to gain insights into the potential effectiveness of the testing approaches. Due to the stochastic nature of our simulation model, the result of one simulation run is subject to uncertainty. To address this uncertainty, we ran each of our 16 simulations 1000 times, and accordingly, the mean of the obtained simulation results is presented.

Few of our assumptions and model input parameters might vary from time to time and/or are context specific. Therefore, we developed an interactive R Shiny web application (R Studio version 4.0.5; R Foundation for Statistical Computing), which enables users to customize the model input parameters and run simulations on their own. The developed simulation tool is integrated in a website. The website also contains a detailed

description of the simulation model and displays the R function written and used to run the simulations in this study.

It must be noted that the potential reduction in the risk implied by the simulation results is only applicable if the employees follow hygiene standards as if there were no testing programs implemented at their company. Furthermore, large-scale testing of asymptomatic individuals in a situation of low COVID-19 prevalence will lead to a large share of false-positive test results, which might necessitate the unjustified quarantining of many individuals. This potentially leads to a productivity loss and might disturb the employees unnecessarily. The declining rigorosity of the hygiene measures or the lack of trust in the test results could decrease the effectiveness of the testing strategies. Because the effectiveness of risk reduction measures depends on individual compliance, every large-scale testing program should be accompanied by an information campaign explaining the interpretation and the consequences of positive and negative test results. The developed simulation tool was integrated in a website [16].

## Statistical Methods

The distributions of quantitative and qualitative data are presented as the absolute and relative frequencies or medians (range), respectively. Fisher's two-sided exact test or Pearson's chi-squared test were performed on the categorical variables, and Wilcoxon rank-sum test was performed on quantitative parameters. Statistical hypothesis testing was performed on the two-sided exploratory 0.05 significance levels. RStudio (version 4.0.2; R Foundation for Statistical Computing) was used for all statistical analyses.

## Availability of Data and Material

All self-collection instructions, questionnaires, and comments of the questionnaires are provided in [Multimedia Appendices 1 and 2](#). All raw data are available from the corresponding author on request.

## Results

### Baseline Characteristics of Study Cohort

In this study, 302 employees registered and consented for participation. In all, data of 293 unique participants were available for analysis because 9 employees registered twice, as duplicate registrations were not technically prevented by the app. Groups 1 and 2 consisted of 150 and 143 participants, respectively, of which 21.3% (n=32) and 18.2% (n=26), respectively, were female. The median age for both the groups was 42 years (range: 20-61 years in group 1 and 23-64 years in group 2). The completion rate of the symptom and risk factor questionnaire (see Table S1 in [Multimedia Appendix 1](#)) was 64% (n=96) in group 1 and 45.4% (n=65) in group 2. In group 1, 51% (n=49) of the participants reported at least one and 21% (n=20) of the participants reported at least two typical symptoms of COVID-19 (ie, fatigue, tiredness, cough, shortness of breath, rhinitis, loss of smell, loss of taste, sore throat, headache, limb pain, shivering, diarrhea, elevated temperature, and temperature  $\geq 38^{\circ}\text{C}$ ), in contrast to at least one reported symptom in 29% (n=19) and at least two reported symptoms in 2% (n=1) of group 2 participants. This resulted in significantly fewer symptomatic



participants in group 2 ( $P=.01$ ) during the assessment. Similarly, group 1 participants reported significantly more symptoms for the last 48 hours and 14 days ( $P<.001$ ). Predefined risk factors (ie, active or past history of smoking, cardiovascular disease, diabetes mellitus, immunosuppressive therapy, and immunodeficiency) for severe COVID-19 were reported by 44% ( $n=42$ ) of group 1 participants and 60% ( $n=39$ ) of group 2 participants ( $P=.06$ ).

**Primary Study End Point**

SARS-CoV-2 test results were successfully communicated to a total of 270 participants without any significant difference in the results between the two groups (139/150, 92.7% in group 1 vs 131/143, 91.6% in group 2). The results were not successfully communicated to 7.3% (11/150) and 8.4% (12/143) of the participants in groups 1 and 2, respectively ( $P=.91$ ). None of the SARS-CoV-2 PCR results returned positive. The proportion of participants with positive primary study end point (ie, test results were successfully transmitted and participants' responses to the questionnaire did not indicate uncertainty with respect to the interpretation of the test result; see Table S2 in Multimedia Appendix 1) was 76% (114/150) in group 1 and 76.9% (110/143) in group 2 ( $P=.96$ ). The median age of the participants with positive primary end point was 41 (range 20-61) years in group 1 and 43 (range 23-63) years in group 2.

**Secondary Study End Points**

A questionnaire evaluating user satisfaction (see Table S2 in Multimedia Appendix 1) was completed by 73.3% (110/150) of the participants in group 1 (response rate: 87/118, 73.7% for male; 23/32, 71.9% for female participants) and 71.3% (102/143) of the participants in group 2 (response rate: 85/117, 72.6% for male and 17/26, 65.4% for female participants). Of all the participants evaluated for user satisfaction, 16.7% ( $n=25$ ) in group 1 and 14.7% ( $n=21$ ) in group 2 indicated uncertainty regarding the test result. The age was comparable to that of participants with a positive primary end point: 42 (range 26-60) years for group 1 ( $P=.30$ ) and 38 (range 24-64) years group 2 ( $P=.24$ ). Furthermore, gender was not significantly related to the reporting of uncertainty about the virological test result obtained in either group (group 1:  $P=.20$ ; group 2:  $P=.99$ ).

Based on the assessment of the responses to the questionnaire, acceptance was favorably rated by 71.6% (78/109), ergonomics

by 88.1% (96/109), and efficacy by 86.4% (95/110) of the participants in group 1 (see Table S4 in Multimedia Appendix 1). Age was not significantly associated with the favorable evaluation of any of the outcomes (acceptance:  $P=.41$ , ergonomics:  $P=.30$ , efficacy:  $P=.71$ ). Further, the evaluation of outcomes was not significant with respect to gender (women compared with men, acceptance:  $P=1.0$ , ergonomics:  $P=.73$ , efficacy:  $P=.73$ ). In group 2, acceptance of the regular testing approach was favorably evaluated by 37.6% (38/101), ergonomics by 74.5% (76/102), and efficacy by 77.5% (79/102) of the participants. The study procedure was estimated to consume an average of 23 (median 15, range 5-90) minutes by participants in group 1 compared with 38 (median 30, range 3-180) minutes for those in group 2 ( $P<.001$ ).

**Analysis of Program Effectiveness**

A simulation model was developed to evaluate the effect of COVID-19 test strategies on the infection risk arising from undetected but infectious employees. We ran 16 simulations for four different levels of the test sensitivity and four different turnaround times. The mean relative risk reduction scores and the corresponding 95% CIs for these 16 simulations are tabulated below (Table 1). The results shown in the table can be interpreted as follows: given the assumptions described in the Methods section, a test strategy using a SARS-COV-2 PCR test with a sensitivity of 90% and featuring a turnaround time of 1 day has the potential to decrease the risk of infection posed by undetected but infectious workers onsite by 17.89%. All other aspects remaining constant, a higher test sensitivity or a lower turnaround time increases the effectiveness of the testing strategy. Assuming that the turnaround time is comparable for both the regular approach and the self-collection approach, one might conclude that the regular approach is slightly more effective than the self-collection approach. Depending on the turnaround time selected, the difference in the relative risk reduction score ranges between 1.21% and 3.29%. The self-collection approach would be more effective than the regular testing approach, if the turnaround time in the self-collection approach is 1 day lesser than that of the regular approach. To enable people to run simulations with different medical assumptions and to evaluate alternative testing strategies, we developed an interactive R Shiny app [16].

**Table 1.** Simulation results for relative risk reduction and impact of test sensitivity and turnaround time. Each cell of the table depicts the mean of 1000 relative risk reduction scores and the corresponding CI. In each simulation run, a population of 10,000 individuals was considered. The assumptions (see Methods section) include that 80% of the susceptible individuals participate in the testing program once a week. Turnaround time refers to the time taken to communicate the test result after testing.

Turnaround time (days)	Relative risk reduction across various levels of test sensitivity (%), mean (95% CI)			
	100%	90%	80%	70%
0	27.64 (27.24-28.05)	25.22 (24.81-25.63)	21.93 (21.53-22.32)	19.28 (18.91-19.65)
1	20.08 (19.72-20.43)	17.89 (17.53-18.24)	15.75 (15.40-16.08)	14.02 (13.68-14.35)
2	14.13 (13.81-14.44)	12.72 (12.41-13.02)	11.61 (11.32-11.91)	9.83 (9.54-10.11)
3	10.51 (10.25-10.77)	9.68 (9.43-9.93)	8.47 (8.23-8.71)	7.27 (7.06-7.49)

## Discussion

This study aimed to compare the feasibility, acceptance, ergonomics, and efficacy of an innovative telemedicine-guided self-collection approach with a regular SARS-CoV-2 testing approach implemented onsite at a large European industrial manufacturing company in Germany.

### Principal Results

Given the comparable rates of successful communication of test results in both the study groups, our data show that the telemedicine-guided self-collection approach for SARS-CoV-2 diagnostics, including registration, swab self-collection, shipping, and communication of SARS-CoV-2 PCR test result, is technically feasible. The ratings of acceptability, ergonomics, and efficacy for the self-collection approach were noninferior compared with those of the regular testing approach, with the limitation that the ratings were based on different questions for groups 1 and 2 (see Table S2 in [Multimedia Appendix 1](#)). Furthermore, the self-collection approach was rated as significantly less time-consuming than the regular testing approach. Neither gender nor age had an effect on the uncertainty regarding the study results or the acceptability, ergonomics, and efficiency ratings. Moreover, a favorable rating for acceptance and efficacy did not affect the outcome and performance of the study procedures, suggesting that a telemedicine-guided self-collection approach for SARS-CoV-2 diagnostics can be applied even among less motivated individuals.

Intriguingly, none of the 293 SARS-CoV-2 PCR tests returned positive. This might be ascribed to a low pretest probability, because all the employees were invited to participate, independent of any prevalent risk contacts or COVID-19 symptoms. Furthermore, the diagnostic laboratory was working at capacity during the second wave of the pandemic, and specimens from patients were prioritized, leading to a delay of study-specific diagnostics and the possible degradation of viral nucleic acid.

Our simulation results suggest that both the testing approaches have the potential to reduce the risk of infection posed by infectious but undetected individuals. Owing to lower sensitivity of self-collected swabs [3], the self-collection approach tends to be slightly less effective than the regular testing approach, whereas the time taken to communicate the test result is the same for both approaches. However, due to the high workload of the virological laboratory at the time of this study, we could not assess the time taken to communicate the test result, hindering a clear assessment of the testing approaches used in this study.

The costs pertaining to the investigated testing approaches vary depending on context-specific factors, including the costs for PCR tests, supply of medical staff, information technology (IT) infrastructure, and onsite time associated with testing. Therefore, a detailed cost evaluation is not within the scope of this study. However, to estimate the costs pertaining to the two testing approaches examined in this study, we conducted back-of-the-envelope calculations for the large central European

manufacturing company. Interestingly, the costs of the two testing approaches mainly differ with respect to the five types of costs: costs for medical staff, hygiene costs, productivity loss, shipping costs, and IT costs. The proportion of these five types of costs indicates the testing approach that is more cost effective. The regular testing approach showed higher costs for medical staff, hygiene, and productivity loss than the self-collection approach. In contrast, the self-collection approach entailed higher shipping costs and costs for setting up and operating the app than the regular testing approach. The main share of the app costs was fixed, however, leading to a decrease in the costs per test in proportion to the number of tests conducted in the case of the self-collection approach. Therefore, the self-collection approach might be more favorable for large testing programs. Our back-of-the-envelope calculations indicate that the self-collection approach can be substantially less expensive than the regular approach for large testing programs. However, we recommend that the companies calculate the cost of testing approaches individually, considering context-specific factors.

### Limitations

This study has several limitations. The age and gender did not significantly differ between the two study cohorts, suggesting an appropriate comparability of the results. However, the male participants outnumbered the female participants, which can be ascribed to a predominantly higher male workforce at the Siemens site. The study cohort did not include participants above 64 years of age. The questionnaires on user satisfaction were not completed by 40 and 41 participants in group 1 and group 2, respectively. In future studies, efforts should be made to increase the questionnaire completion rates. The primary end point was defined both as the successful communication of the test result and the lack of reported uncertainty regarding the test result in the questionnaire (see Table S2 in [Multimedia Appendix 1](#)). We note that the user satisfaction questionnaires were not completed by all participants. Therefore, it is possible that few participants might have felt insecure regarding their test results and avoided reporting it. To assess the validity of our results, we repeated our analyses by assuming that the nonresponse to the questionnaire is equivalent to the uncertainty regarding the test results. This approach did not significantly change the results of our primary analysis (see Table S5 in [Multimedia Appendix 1](#)). COVID-19 symptoms were less often reported in group 2, which might be attributed to nondisclosure of symptoms at the workplace. The risk factors for COVID-19 were more frequently reported in group 2, which is possibly related to assessment by the medical staff. The responses in the questionnaire for symptoms and risk factors were incompletely transmitted by the app for few participants in group 2. Furthermore, the software app should be upgraded to prevent double registrations. Due to the abovementioned high workload in the virological laboratory at the time the study was performed, turnaround times were delayed, and the results could not be provided in 23 cases (7.8%), which might have affected the satisfaction of those participants. Four participants commented that the alignment of the Likert scale was not clear; however, the interpretation of all the participants was correct. The ambiguity was clarified in the app during the course of the study.



Nonetheless, we cannot exclude that the visual slider was occasionally moved inversely.

The simulations conducted to assess the effectiveness of the regarded testing approaches rely on several assumptions that are partially based on the expert ratings of the participating investigators. Therefore, bias cannot be excluded. Furthermore, the simulation model assumed few factors, such as a constant incidence rate and immunity rate within the specific period of 4 weeks. The developed simulation model as well as the developed Shiny app exclusively focuses on the risk of infection posed by undiagnosed but infectious individuals. Superspreading events as well as secondary transmissions by index patients were not considered in this model.

### Comparison With Prior Work

Several recent studies evaluated the diagnostic reliability of self-collected versus professional-collected specimen for the detection of SARS-CoV-2 and found comparable sensitivities [3-7]. To the best of our knowledge, telemedicine-guided self-collection approaches in a home-based setting followed by PCR-based SARS-CoV-2 testing have not been investigated to date.

### Conclusions

This study provides evidence that a telemedicine-guided self-collection approach for SARS-CoV-2 diagnostic testing is technically feasible, and this approach is favorably rated in terms of acceptance, ergonomics, and efficiency. Our data indicate that the resources, expense of time and labor, and personal contacts can be considerably reduced through a telemedicine-guided, self-collection approach when compared with a regular PCR-based testing strategy. Nonetheless, the risk reduction in a self-collection approach is expected to be slightly lower because the test sensitivity of the self-collected swabs is inferior to that of professional-collected swabs. Self-test approaches based on lateral-flow antigen tests may be a cost-effective alternative to PCR-based strategies and should be investigated in future studies because the test sensitivity appears to be secondary to the turnaround time regarding the risk reduction. The app-based platform we provide here may serve as the basis for enhanced connectivity in future digital approaches of personalized medicine. Indeed, the easy-to-use design combined with potential coupling with other health care interfaces may provide benefits beyond the COVID-19 pandemic.

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### Authors' Contributions

CDS, UP, ML, and S Würstle conceived and designed the study. S Werfel produced the instruction video. S Würstle, RF, MM, and DH were involved in the practical part of the study. DH and UP performed laboratory analysis and interpretation. S Würstle, SH, and DH acquired the data; CDS verified the collected data together with S Weidlich and AH. S Würstle, SH, and JH analyzed and interpreted the data. MH and ML contributed to the health economic aspects. MH developed the R Shiny app. JE, MH, S Würstle, and CDS were the major contributors in writing the manuscript. ML, UP, CDS, JS, S Weidlich, S Werfel, AH, and RMS revised the manuscript. All authors read and approved the final manuscript.

### Conflicts of Interest

CDS reports grants, personal fees, and nonfinancial support from AbbVie, Apeiron, Gilead Sciences, Janssen-Cilag, GSK/ViiV Healthcare, and MSD; grants and personal fees from BBraun and Eli Lilly; grants from Cepheid; and personal fees from Formycon—outside the submitted work. S Weidlich reports personal fees and nonfinancial support from Gilead Sciences and Janssen-Cilag outside the submitted work. All other authors declare that they have no conflicts of interest.

#### Multimedia Appendix 1

Supplementary figures and tables.

[[DOCX File, 309 KB](#) - [formative\\_v6i1e32564\\_app1.docx](#) ]

#### Multimedia Appendix 2

Self-sampling instruction video.

[[MP4 File \(MP4 Video\), 60416 KB](#) - [formative\\_v6i1e32564\\_app2.mp4](#) ]

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## Abbreviations

- CTM:** Clinical Virus Transport Medium  
**IT:** information technology  
**NAAT:** nucleic acid amplification test  
**NASA:** National Aeronautics and Space Administration  
**PCR:** polymerase chain reaction  
**QR:** quick response  
**UN 3373:** United Nations' recommendation of dangerous goods

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## Short Paper

# Toward Using Twitter Data to Monitor COVID-19 Vaccine Safety in Pregnancy: Proof-of-Concept Study of Cohort Identification

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## Abstract

**Background:** COVID-19 during pregnancy is associated with an increased risk of maternal death, intensive care unit admission, and preterm birth; however, many people who are pregnant refuse to receive COVID-19 vaccination because of a lack of safety data.

**Objective:** The objective of this preliminary study was to assess whether Twitter data could be used to identify a cohort for epidemiologic studies of COVID-19 vaccination in pregnancy. Specifically, we examined whether it is possible to identify users who have reported (1) that they received COVID-19 vaccination during pregnancy or the periconception period, and (2) their pregnancy outcomes.

**Methods:** We developed regular expressions to search for reports of COVID-19 vaccination in a large collection of tweets posted through the beginning of July 2021 by users who have announced their pregnancy on Twitter. To help determine if users were vaccinated during pregnancy, we drew upon a natural language processing (NLP) tool that estimates the timeframe of the prenatal period. For users who posted tweets with a timestamp indicating they were vaccinated during pregnancy, we drew upon additional NLP tools to help identify tweets that reported their pregnancy outcomes.

**Results:** We manually verified the content of tweets detected automatically, identifying 150 users who reported on Twitter that they received at least one dose of COVID-19 vaccination during pregnancy or the periconception period. We manually verified at least one reported outcome for 45 of the 60 (75%) completed pregnancies.

**Conclusions:** Given the limited availability of data on COVID-19 vaccine safety in pregnancy, Twitter can be a complementary resource for potentially increasing the acceptance of COVID-19 vaccination in pregnant populations. The results of this preliminary study justify the development of scalable methods to identify a larger cohort for epidemiologic studies.

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**KEYWORDS**

natural language processing; social media; COVID-19; data mining; COVID-19 vaccine; pregnancy outcomes

## Introduction

COVID-19 during pregnancy is associated with an increased risk of maternal death, intensive care unit admission, and preterm birth [1]; however, in the United States, uptake of COVID-19 vaccination during pregnancy is low [2]. Surveys indicated that the most common reason for refusing COVID-19

vaccination during pregnancy was a lack of safety data [3], which are limited because people who were pregnant were excluded from preauthorization clinical trials. The Centers for Disease Control and Prevention (CDC) recently released the first US data on COVID-19 vaccine safety in pregnancy, based on postvaccination health information reported by participants voluntarily enrolled in V-safe [4]. According to the CDC, although the preliminary data do not indicate any obvious safety

signals, continued monitoring is needed, especially in early pregnancy and the periconception period (within 30 days before the last menstrual period). The CDC suggests that additional evidence of COVID-19 vaccine safety in pregnancy is critical for increasing the acceptance of COVID-19 vaccination in pregnant populations [2].

In the United States, 42% of people aged 18-29 years and 27% of people aged 30-49 years use Twitter [5]. Our prior work [6] demonstrated that Twitter data can be used to assess outcomes associated with medication exposure during pregnancy. Therefore, we hypothesized that Twitter could also be a source of data for assessing outcomes associated with COVID-19 vaccination received during pregnancy. Although user-generated Twitter data may be subject to potential limitations similar to those that the CDC has discussed regarding their participant-reported data [4] (eg, selection bias, reporting bias, misreporting, small sample size, limited information on other risk factors), the current availability of other sources of data is very limited. The objective of this preliminary study was to assess whether Twitter data could be used to identify a cohort for epidemiologic studies of COVID-19 vaccination in pregnancy. In particular, we explored whether it is possible to identify users who have reported (1) that they received COVID-19 vaccination during pregnancy or the periconception period, and (2) their pregnancy outcomes.

## Methods

The Institutional Review Board of the University of Pennsylvania reviewed this study and deemed it exempt from human subjects research under Category 4 of Paragraph b of the US Code of Federal Regulations Title 45 Section 46.101 for publicly available data sources (45 CFR §46.101(b)(4)).

To facilitate a preliminary assessment of self-reports of COVID-19 vaccination on Twitter, we developed 6 handwritten, high-precision regular expressions designed to match tweets mentioning that the user received at least one dose of COVID-19 vaccination ([Multimedia Appendix 1](#)). In prior work [7], we developed an automated natural language processing (NLP) pipeline that detects tweets from the Twitter streaming application programming interface that announce a user's pregnancy, and then collects all of their publicly available tweets on an ongoing basis. We deployed the 6 regular expressions on the collection of these users' tweets that were posted through to the beginning of July 2021. To help determine if users were vaccinated during pregnancy (or the periconception period), we manually compared the timestamp of the tweets that matched the regular expressions with the timeframe of their prenatal period. To help estimate the timeframe of the users' prenatal period, we drew upon an automated NLP tool, developed in our

prior work [8], that uses a rule-based approach to search tweets for reports of the baby's gestational age, due date, or date of birth, and extracts an estimate of the beginning and end dates of pregnancy based on the specific information in the tweet.

For users who posted tweets with a timestamp indicating they were vaccinated during pregnancy or the periconception period, we drew upon additional automated NLP tools, developed in our prior work [9-11], that use supervised classification to search tweets for reports of adverse pregnancy outcomes, including miscarriage, stillbirth, preterm birth, low birth weight, birth defects, and neonatal intensive care unit admission. To reduce the potential reporting bias in assuming that the lack of tweets self-reporting an adverse pregnancy outcome represents the lack of an adverse outcome, we also deployed an automated NLP tool, developed in our prior work [12], to search users' tweets for reports that the baby was born at a gestational age of at least 37 weeks (ie, that the user is at least 37 weeks pregnant, or that the due date is in 3 weeks or less) and a weight of at least 5 pounds and 8 ounces. A gestational age of at least 37 weeks indicates the lack of miscarriage or preterm birth. A birth weight of at least 5 pounds and 8 ounces indicates the lack of low birth weight or, as a report of live birth, miscarriage, or stillbirth. If we did not automatically detect a tweet explicitly reporting a gestational age of at least 37 weeks, we manually analyzed tweets posted during this time for evidence that the user was still pregnant.

## Results

We manually verified the content of tweets detected automatically, identifying 150 users who reported on Twitter that they received at least one dose of COVID-19 vaccination during pregnancy or the periconception period. [Table 1](#) presents examples of tweets that we used to identify these 150 users. For example, user 1 reported being 16 weeks pregnant on June 15, 2021, and therefore our automated tool [8] estimated that pregnancy began on February 23, 2021. User 1 reported receiving COVID-19 vaccination on March 24, 2021, which is approximately 1 month into the pregnancy. User 2 reported being 13 weeks pregnant on June 21, 2021, and our automated tool [8] estimated that the pregnancy began on March 22, 2021. User 2 reported receiving COVID-19 vaccination on March 6, 2021, which corresponds to the periconception period. The tweets in [Table 1](#) also show that some users reported the vaccine manufacturer (eg, "#PfizerVaccine") or dose number (eg, "second vaccine"), which can help distinguish mRNA vaccines from other types. Based on our estimates of the prenatal period for these 150 users, 90 (60.0%) of their pregnancies may have been ongoing. We manually verified at least one reported outcome for 45 of the 60 (75%) completed pregnancies. [Table 2](#) presents the outcomes reported by these 45 users.



**Table 1.** Sample tweets indicating that COVID-19 vaccination was received during pregnancy or the periconception period.

Tweets	Timestamp	Pregnancy start	Pregnancy end
<b>User 1</b>			
I am bringing a life into this world and that is pretty darn incredible. #16weekspregnant	June 15, 2021	February 23, 2021	November 30, 2021
Got my first dose of the COVID vaccine today and feeling so excited and grateful for science	March 24, 2021	February 23, 2021	November 30, 2021
<b>User 2</b>			
I'm awake because I'm 13 weeks pregnant and...well..."morning sickness"	June 21, 2021	March 22, 2021	December 27, 2021
Got my #PfizerVaccine last night!	March 7, 2021	March 22, 2021	December 27, 2021
<b>User 3</b>			
93 days till my due date	April 17, 2021	November 11, 2020	August 18, 2021
So I just got my second vaccine. So far I feel fine... I'm praying it stays that way all day	March 1, 2021	November 11, 2020	August 18, 2021
<b>User 4</b>			
I'm 8 months pregnant. My family drove down to Tampa with me just in case baby shows up early	June 9, 2021	October 9, 2020	July 16, 2021
Happy to report I received the Moderna vaccine today	March 6, 2021	October 9, 2020	July 16, 2021

**Table 2.** Self-reported pregnancy outcomes for Twitter users who received COVID-19 vaccination during pregnancy or the periconception period (N=45).

Self-reported outcome	Outcomes, n (%) <sup>a</sup>	Sample tweet
<b>Adverse outcomes</b>		
Neonatal intensive care unit (NICU)	5 (11)	I made a small human. So that's pretty cool. Now for a few weeks of NICU time.
Preterm birth (<37 weeks)	4 (9)	She was born Jan. 11th...3 months early...stayed in the hospital until about 2.5 weeks ago...
Low birth weight (<5 pounds, 8 ounces)	1 (2)	He weighed 3 lbs 9 ounces @ birth & we didn't have 1 thing that came close to fitting him.
Miscarriage	1 (2)	In the last 4 weeks, I've had a miscarriage...family death...pet death...my car broke down...finals...
Stillbirth	0 (0)	N/A <sup>b</sup>
Birth defect	0 (0)	N/A
<b>Normal outcomes</b>		
Term (≥37 weeks) <sup>c</sup>	39 (87)	He made his debut at #37weeks. We got to the hospital by 6:15am, fully dilated by 7:45am, and he was here at 8:22am!
Normal birth weight (≥5 pounds, 8 ounces)	7 (16)	He arrived via c/section last night at 8:49pm. He was 7 lbs 11 oz. I can't believe he's mine!

<sup>a</sup>Multiple outcomes were identified for some pregnancies; therefore, the sum and percentage of the total outcomes are greater than 45 and 100%, respectively.

<sup>b</sup>N/A: not applicable.

<sup>c</sup>Pregnancies were included for which we did not find subsequent tweets explicitly indicating live birth.

## Discussion

### Principal Findings

Our study demonstrates that there are users who report on Twitter that they were vaccinated during pregnancy, including in early pregnancy and the periconception period, and that many

of them report their pregnancy outcomes. Therefore, the results of this study justify the development of scalable methods to identify a larger cohort on Twitter for epidemiologic studies of COVID-19 vaccination in pregnancy. The 150 users in this study were identified based on tweets posted through the beginning of July 2021. Since identifying these users, we have redeployed the 6 regular expressions for detecting tweets that

self-report COVID-19 vaccination and our NLP tool that estimates the timeframe of the prenatal period [8] on users' tweets [7] collected through November 2021. Even using the regular expressions alone, we have automatically identified approximately 2000 additional users who posted a matching tweet and have an estimated due date in 2021 or 2022. In future work, we will manually verify their tweets to determine the inclusion of these additional users in our cohort of people who received COVID-19 vaccinated during pregnancy or the periconception period. Therefore, the small size of the initial cohort—150 users—seems to largely reflect the point of time in which this study began, rather than the larger-scale utility of Twitter data.

Our preliminary results suggest that reports of preterm birth and miscarriage are largely unaffected by a potential reporting bias, given that we detected a gestational age of at least 37 weeks for 39 of the 40 (98%) completed pregnancies for which we did not identify a preterm birth or miscarriage. However, reports of low birth weight may be affected by a potential reporting bias, given that we detected a birth weight of at least 5 pounds and 8 ounces for only 7 of the 44 (16%) completed pregnancies for which we did not identify a low birth weight. Given our

initial small sample of Twitter users, it is not surprising that we did not detect any reports of birth defects or stillbirth, which have an incidence in the United States of 3% [13] and less than 1% [14], respectively. Nonetheless, our prior work [9-11] demonstrates that users do report these rare outcomes on Twitter. Although a full comparison is beyond the scope of this study, out of the total number of pregnancies with a reported gestational age of at least 20 weeks, the proportion of preterm births reported on Twitter (9.09%) is similar to both the incidence in the United States prior to the COVID-19 pandemic (10.23%) [15] and the proportion reported by V-safe participants (9.4%) [4].

## Conclusions

Given the limited availability of data on COVID-19 vaccine safety in pregnancy, Twitter can be a complementary resource for continued monitoring and potentially increasing the acceptance of COVID-19 vaccination in pregnant populations. Directions for future work include developing methods to detect a larger cohort, and performing an epidemiologic study comparing their pregnancy outcomes to those of users who have announced their pregnancy on Twitter [7] but gave birth prior to the availability of COVID-19 vaccines.

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## Authors' Contributions

AK developed the regular expressions, analyzed the Twitter data for pregnancy outcomes, and wrote the manuscript. KO analyzed the Twitter data to identify users who received COVID-19 vaccination during pregnancy and edited the manuscript. GGH guided the overall study design and edited the manuscript.

## Conflicts of Interest

None declared.

## Multimedia Appendix 1

Regular expressions for detecting tweets that self-report COVID-19 vaccination.

[[TXT File, 1 KB](#) - [formative\\_v6i1e33792\\_app1.txt](#)]

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## Abbreviations

**CDC:** Centers for Disease Control and Prevention

**NLP:** natural language processing

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Original Paper

# The Impact of the COVID-19 Infodemic on Depression and Sleep Disorders: Focusing on Uncertainty Reduction Strategies and Level of Interpretation Theory

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## Abstract

**Background:** During the COVID-19 pandemic, information diffusion about the COVID-19 has attracted public attention through social media. The World Health Organization declared an infodemic of COVID-19 on February 15, 2020. Misinformation and disinformation, including overwhelming amounts of information about COVID-19 on social media, could promote adverse psychological effects.

**Objective:** This study used the Psychological Distance and Level of Construal theory (CLT) to predict peoples' negative psychological symptoms from social media usage. In this study, the CLT intended to show peoples' psychological proximity to objects and events with respect to the COVID-19 pandemic. Furthermore, this study links the uncertainty reduction strategy (URS) and CLT for COVID-19-related preventive behaviors and affective reactions to assess their effects on mental health problems.

**Methods:** A path model was tested (N=297) with data from a web-based survey to examine how social media usage behaviors are associated with URS and psychological distance with COVID-19 (based on the CLT), leading to preventive behaviors and affective reactions. Finally, the path model was used to examine how preventive behaviors and affective reactions are associated with mental health problems including anxiety and sleep disorder.

**Results:** After measuring participants' social media usage behavior, we found that an increase in general social media usage led to higher use of the URS and lower construal level on COVID-19. The URS is associated with preventive behaviors, but the CLT did not show any association with preventive behaviors; however, it increases affective reactions. Moreover, increased preventive behavior showed negative associations with symptoms of mental health problems; that is, depression and sleep disorder. However, the affective reaction tends to be positively associated with depression and sleep disorder. Owing to the infodemic of COVID-19, the psychological perception of the pandemic negatively influenced users' mental health problems.

**Conclusions:** Our results imply that the information from social media usage heightened concerns and had a lower construal level; this does not facilitate taking preventive actions but rather reinforces the negative emotional reaction and mental health problems. Thus, higher URS usage is desirable.

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**KEYWORDS**

COVID-19; social media; infodemic; construal level theory; uncertainty reduction strategy; depression; sleep disorder; preventive actions, affective reaction; infodemiology; misinformation; uncertainty; strategy; mental health; sleep; prevention; survey; usage; behavior

## Introduction

### Background

The COVID-19 pandemic is still ongoing worldwide after the World Health Organization (WHO) declared it a pandemic on March 11, 2020 [1]. Moreover, the second wave of the COVID-19 pandemic in European countries occurred in the summer of 2020 [2,3]. The WHO reported that most confirmed COVID-19 cases and deaths occurred in the United States [4]. COVID-19 introduced nonpharmaceutical interventions (NPIs) into people's lives, which negatively impacted their everyday life, including activities such as working, studying, schooling, shopping, and dining [4-6]. A large majority of people's everyday life changed to telecommuting (working remotely) and web-based learning. The NPI lifestyle pattern (ie, limited offline activities) have possibly impacted people's psychological responses, including anxiety, depression, and sleep disorder [7].

For over 20 years in the history of pandemics—including the severe acute respiratory syndrome pandemic in 2002, A/H1N1 influenza pandemic in 2009-2010, and the Middle East Respiratory Syndrome pandemic in 2015, along with the current COVID-19 pandemic—health care workers' psychological symptoms have been mostly examined [8,9]; however, relatively few studies focused on ordinary people's psychological symptoms [10]. Compared to previous pandemic outbreaks, the COVID-19 pandemic has occurred uniquely in the age of social media. As a result of these changes and self-isolation, people's social lives, especially their communication strategies, have experienced unprecedented changes. During self-isolation, people made videos of user-generated content (UGC) or pictures of their lives with the hashtags “#quarantine” and “#viewfromquarantine” [11]. Citizens in a state of confinement can experience psychological constraints and express fixation on the state of the disease and psychological disorders including sleep disorder and depression [8]. Social media usage led to the emergence of a novel situation called “infodemic” [12-17]. The impact of infodemics on social media users' psychological perception—that is, construal level [18]—has been barely considered for the pandemic. Furthermore, the information contagion has a complex association with negative feelings; however, individual differences such as frequent social media usage and the uncertainty reduction strategy (URS) have not been considered.

How social media usage behavior and excess information regarding COVID-19 impact the users' mental problems, including their URS (also known as their “information-seeking strategy”), still needs to be further examined. Since the onset of the pandemic, the following questions have been raised: (1) could social media usage increase concerns regarding COVID-19 and reduce the psychological distance between perceivers and COVID-19? (2) Among these associations, do individual differences such as URS impact further reactions

such as preventive behavior, and do they help maintain mental health?

To answer these questions, we investigated how psychological symptoms are impacted by the URS and the perception of the Psychological Distance and Level of Construal theory (CLT) [19] during the COVID-19 pandemic [20]. We also examined how preventive behaviors and affective reactions are associated with the CLT and URS.

### CLT and Hypothetical Distance With Social Media Usage

The psychological distance that was examined with the CLT explains how people perceive an event or an object by their subjective feeling of distance. Trope and Liberman [21] defined the psychological distance as “the perception of when an event occurs, where it occurs, to whom it occurs, and whether it occurs.” Psychologically, a more distant form of an event or object is described as being more abstract and of a “higher construal” level. In contrast, a more proximal form of an object or event is shown to be more concrete and specific; that is, of a “lower construal” level [18,22]. This tendency can be applied to social perception [23], decision-making, and self-control [24]. In CLT research, known dimensions of the CLT are temporal, spatial, social, and hypothetical distance. Among them, hypothetical distance is mainly an applied dimension in the domain of consumer behavior research [13,25] and health communication in the context of mediated communication [26]. Hypothetical distance is based on *whether* the event could be happening or not, which implies “the likelihood of a target event happening” [27] or the probability level. The COVID-19 pandemic could be interpreted as a hypothetical dimension. As COVID-19 news and information is acquired from social media, frequent social media users perceive that they are closer to the event, and they feel that their community or residency is at a higher risk of COVID-19. Because the CLT describes how people experience psychological distance and how it affects attitudes, perception, and behaviors, the CLT has been considered a valuable framework for understanding a pandemic [20].

Altered news consumption patterns and UGC disseminations [28-31] have also been observed on social media during the COVID-19 pandemic. During emergency situations, social media could be a major channel of news consumption [28,30] and the primary source of news from neighbors and the community during the pandemic; for example, Nextdoor.com [32]. Three different types of altered patterns of information acquisition were observed: (1) mobile news adoption [29], (2) news consumption via social media, including Twitter [31], and (3) UGC contents from social media. The first case of mobile adoption allows people to consume the news incidentally, whenever and wherever they wish. The second pattern relates to news recommended by other users such as friends from social networking sites and a personalized recommendation system



in social media platforms. In the third pattern, with emergent processes such as COVID-19 outbreaks, users have become news sources, creating their own news to elucidate their real-time situation.

Filtered and recommended news curated by computer recommendation systems is difficult to ignore. Such curated news accurately targets the users' preferences on the basis of their social media usage behavior; that is, reading time, preferring topics, commenting, pressing "like" buttons, and following, including real-time topics [33] and user location [34]. Location information from location-based systems have facilitated studies on CLT and SNSs. For example, proximity effects (ie, geographic, social, and temporal proximity) on audiences' expression of terrorism and the CLT approach have been studied during the Boston Marathon [35].

Furthermore, the impact of information consumption on social media about COVID-19 has been defined as an "infodemic" [13,17]—greater the amount of information regarding the pandemic acquired from social media, the more excessive perceived sensitivity among users. UGC helped information to be broadcasted in real time with regard to the COVID-19 outbreak—even faster than legacy media. This UGC showed devastating impacts of COVID-19; for example, how contagious COVID-19 could be, how quickly these infected people develop symptoms, and disease outcome including death. Thus, perceivers who see those UGC and circulated the news on social media about the pandemic may get frightened. Moreover, increased social media usage behavior may provide more chances of being exposed to more information and news about COVID-19. This may lead to greater concern among users with regard to the pandemic than among those who have not been exposed to social media.

Increased social media usage may lead to feelings of proximity to COVID-19, while social media users remain exposed to the updated information regarding the pandemic. Thus, their perception of the possibility of infection is higher; in other words, the hypothetical distance from COVID-19 is lesser than among those with lower social media usage.

Therefore, we propose the following research question (RQ) and hypothesis:

*RQ1:* To what extent does information acquisition on social media associate concerns regarding COVID-19 with CLT and URS?

*H1:* Higher information acquisition through social media usage is positively associated with the CLT on COVID-19.

### Preventive Behaviors and Emotional Reactions

Consuming more COVID-19 news through social media can significantly result in psychological proximity with the pandemic. Once individuals apply a lower construal level to the event, they use more concrete representations. They perceive the event as being more proximal to them, focusing on the *how* and evoking the negative emotion [20]. Conversely, the others have a higher construal level to the event, having more abstract representations and perceiving the event or object distantly from the self. A higher construal level is known to lead people to

focus on the *why*. For example, if the pandemic occurred geographically distant from the perceivers (ie, other countries or continents) and had a time lag (ie, a couple months ago), one would think of social, political, and structural reasons, including the mechanism of contagion (ie, airborne aerosol-mediated transmission of SARS-CoV-2 [36]) and preventive methods (ie, wearing protective equipment including masks, gloves, and goggles and avoiding visiting public areas). In contrast, suppose the pandemic event occurred closer to the place recently. In that case, the perceivers are likely to focus on how to avoid a dangerous situation (eg, pay attention to other methods of contagion) and how to reserve everyday necessities (ie, food, water, toilet paper, and other essentials). Although people acquire information regarding how to prevent COVID-19, social media users could acquire deviant stories such as panic-buying at grocery stores or cases of rapid development of symptoms. Bowen [20] also explained how people interpret the pandemic and its impact on behaviors with an example of grocery shopping in a pandemic. Bowen [20] highlighted emotional evoking by each construal level; at higher construal levels, the abstracted and macro view evokes thankfulness during grocery shopping and thoughts on how the agricultural pipeline was maintained during the pandemic. However, the lower construal level approach generates anxiety among people on the issue of transmission from unknown sources or safety guidelines (ie, maintaining a 6-foot distance). When an individual becomes aware of the safety guidelines—for example, knowing that failing to maintain a 6-foot distance from others can increase the chance of infection—that person now not only knows how vital it is to maintain distance but also realizes the severity of COVID-19, which further increases anxiety. To extend this construal level to preventive behaviors, the lower construal level makes people focus on specific entities; in doing so, they tend to avoid the infection, but it is quite difficult for them to think about preventive behaviors associated with people with a higher construal level [20]. As Bowen [20] suggested, when people had a lower construal level, they reacted negatively and could not think of preventive behaviors.

To examine the application of CLT on the COVID-19 pandemic and the extent to which the lower construal level impact preventive behaviors and reinforce negative affective reactions, the following RQ and hypotheses are proposed.

*RQ2:* To what extent does construal level affect preventive behavioral actions (ie, wearing masks, using sanitizer, and avoiding attending public spaces)? Furthermore, to what extent does it reinforce affective reactions (ie, fear, difficulties, stress, and negative feelings)?

*H2A and H2B:* A lower construal level (shortened hypothetical distance) has (a) a negative association with preventive behaviors and (b) a positive association with emotional reactions.

However, though the participants were exposed to information regarding COVID-19, those with URSs could have preventive health behavioral information and may lower their concerns and negative psychopathological impacts such as those of depression, anxiety, and sleep disorder.

## Linking URS to Information-Seeking and Prevention Behaviors

The uncertainty reduction theory (URT) is used for information-seeking behaviors when uncertainties arise, utilizing many strategies to seek information about others [37] to reduce social anxiety caused by revealing users' identity to those who are anonymous [38]. However, the extended URT has been applied to affection in mediated communication and the digital world [39] and in seeking health information [40]. When health-related information is not adequately acquired from the traditional medical professions, uncertainties arise, and then web-based information becomes the main source. Substituting the conventional information source, web-based information can be sought and shared by users to evaluate and verify [41]. Using the URS to information-seeking strategies, Berger [37] initially identified three types of knowledge-seeking techniques that an individual might use to minimize uncertainty: interactive, active, and passive knowledge-seeking techniques. First, interactive knowledge-seeking techniques are those in which the individual actively interacts directly with the target person and provides input. Second, active knowledge-seeking refers to whether an individual obtains information about a target from a second party that is more familiar with the target. Finally, passive knowledge-seeking techniques entail the person observing the target discreetly. Ramirez et al [42] explained extractive knowledge-seeking strategies, in which a person "draws upon a vast storehouse of written comments provided by targets" to acquire information and minimize confusion, using increasing information archived and retrievable on the internet [43]. Considering the URS in the current "infodemic," the passive and extractive knowledge-seeking strategies may be applied. The passive and extractive knowledge-seeking strategy used here leads to examine how excessive social media usage may result in higher URS usage.

We argue that the URS in the communication domain is possible to link with the concern of COVID-19 outbreaks to obtain preventive knowledge. Furthermore, people with higher URS usage may have less emotional reactions, and having a URS leads to control mental health problems.

Therefore, we propose testing the following RQ and hypotheses:

*H3:* Increased information acquisition through social media usage is positively associated with URS usage.

*RQ3:* To what extent does the URS affect preventive behavioral actions (ie, wearing masks, using sanitizer, and avoid attending public space) and affective reactions (ie, fear, difficulties, stress, psychological burden, and negative feelings)?

*H4A and H4B:* The weighted URS shows a (a) positive association with preventive behaviors and (b) negative association with affective reactions.

## The Negative Psychological Symptoms: Depression and Sleep Disorder

The COVID-19 pandemic involves multiple factors such as an ever-increasing number of confirmed cases, depletion of protection equipment and daily necessity, feeling isolated, and lack of support. A combination of these multiple factors may instigate mental burden and the feeling of anxiety. However, most of those factors can be known through media coverage, including social media. Through social media usage, the acquired COVID-19 news and UGC result in shortening of the hypothetical distance with it, leading to negative emotional reactions such as stress, psychological burden, and anxiety. The feeling of stress and burden shows a higher association with psychological disorders—depression and sleep disorder.

During this critical COVID-19 situation, people are at risk of developing mental health symptoms. The multidimensional threatening situation can be known through widespread media coverage and social media. The sensational news from social media in users' smartphones always delivers provocative and devastating news based on the personalized recommendation features of social media or recommendations by other users. However, altered information acquisition and consumption with social media and the mobile environment may result in a different psychological distance of construal level for the pandemic situation by the level of social media usage. Furthermore, individuals with a URS may be influenced to have more preventive information, leading to preventive behaviors such as wearing gloves and masks or avoiding attending public spaces. Those preventive behaviors may decrease the feeling of depression and sleep disorder. In sum, the overwhelmed information may contribute to these frequent social media users' mental burden, while the URS reduces the mental health problem.

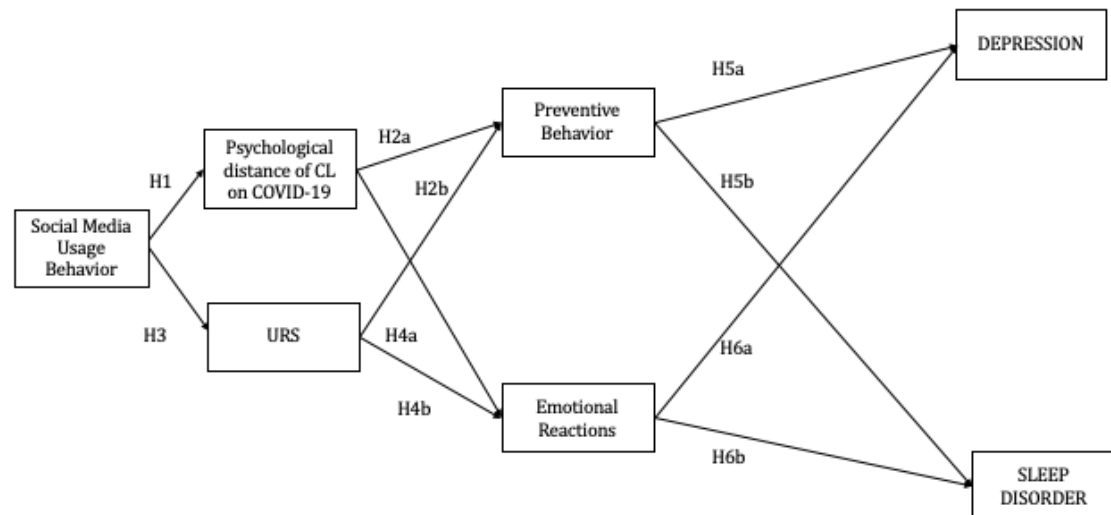
Therefore, we propose the following RQ and hypotheses that are indicated in the proposing path model of [Figure 1](#):

*RQ4:* To what extent did the participants' self-reported mental health symptoms—that is, depression and sleep disorder—were affected by COVID-19 and preventive behaviors?

*H5A and H5B:* Increased preventive behaviors of COVID-19 indicate negative associations with mental health symptoms: (a) depression and (b) sleep disorder.

*H6A and H6B:* Affective reactions on COVID-19 indicate positive associations with mental health symptoms: (a) depression and (b) sleep disorder.

**Figure 1.** Proposed path model. CL: construal level; URS: uncertainty reduction strategy.



## Methods

### Participants and Procedure

To measure the general populations' perception of COVID-19 and their psychological response, we adopted a web-based cross-sectional survey through Amazon Mechanical Turk (AmTurk) to collect data. The Turk represents the general US population in terms of age and ethnicity more accurately than the college survey pool. Furthermore, the participants' motivation and ability are better than those of the college sample [44-46].

Through the AmTurk advertisement, the participants could begin answering the web-based survey by clicking the participation agreement button on the web-based consent form. The survey questionnaire included questions on social media usage behavior, psychological distance on COVID-19, preventive behavior and emotional reactions, the Center for Epidemiology Scale for Depression (CES-D), and the Pittsburgh Sleep Quality Index (PSQI).

We used WarpPLS (version 7.0; ScriptWarp Systems) to not only examine the path model we proposed but also test the fitnesses of the hypothesized model.

### Measurements

The survey questionnaire included questions on social media usage behaviors, concern regarding COVID-19, a modified URS, a hypothetical distance of COVID-19, COVID-19 preventive behaviors, affective reactions, psychological symptoms, the CES-D, and the PSQI.

### Social Media Usage Behavior

To measure social media usage behavior, we adopted suitable questions from questionnaires such as the Media Technology Usage and Attitude Scale [47], the Digital Natives Assessment Scale [48], and social media and digital natives. Example statements include "I send 'links' of contents to others using social media," "I expect the social media that I visit regularly to be constantly updated," and "I use the social media every

day" (Cronbach  $\alpha=.92$ ). Answers were based on 7-point Likert scales (1=never, 7=always).

### URS

The URS measurement [40] has been modified for this study; example statements include "I use the Internet and social media to find information regarding prevention for the COVID-19," "I use the Internet and social media to find the symptoms of COVID-19 that were not discussed yet," "I use the Internet and social media to seek alternative treatment or medical information regarding COVID-19 cure," and "I use the Internet and social media to find the right information about the COVID-19" (Cronbach  $\alpha=.87$ ).

### Psychological Distance of Construal Level on COVID-19

To measure the hypothetical distance of construal level on COVID-19, the question asked was "How is the COVID-19 situation in your residence area?" and the answers were provided on a 7-point Likert scale ranging 1=mild to 7=severe, 1=good to 7=bad, and 1=positive to 7=negative. For the question "Do you feel that your residential area is near to the impact of COVID-19?" the answers were based on a 7-point Likert scale ranging 1=near to 7=far (reversed coding was applied; Cronbach  $\alpha=.87$ ).

### COVID-19 Preventive Behaviors

The preventive behaviors consist of the following statements: for example, "Worn a face mask," "Washed/Sanitized hands," "Worked or studied at home," "Avoided in-person contact with high-risk people" (Cronbach  $\alpha=.85$ ). Their answers ranged 1=never to 7=always [49].

### Emotional Reactions

To measure the participants' affective reactions, the following questions were asked: "How often do you feel afraid of COVID-19?" "Do you feel that you are safe from the COVID-19?" "How often do you feel that you lack companionship?" "How often do you feel isolated from others?" "How often do you feel left out?" "How much has your sleep been interrupted or disturbed by concern about the outbreak?" and "How much difficulty do you have obtaining the food that

you need because of the COVID-19 pandemic or social distancing rules?" (Cronbach  $\alpha=.86$ ), and the answers were based on 7-point Likert scales [49].

### ***Depression (CES-D) and Sleep Quality (PSQI)***

The CES-D was used to measure depression symptoms, and the PSQI was used to measure sleep disorder symptoms. Detailed items and their reliability are reported in [Tables 1](#) and [2](#).

### **Statistical Power**

Statistical power was estimated on the basis of the sample size. When a significance level of .05 (range .001 to  $-.50$ ) was used, and the required power level was 0.80 (range 0-0.99), the minimum absolute significant path coefficient in the model was 0.15, the inverse square root methods required a minimum sample size of approximately 275 to run the path model, and the 297 participants of this study are above stipulated sample size threshold.

## **Results**

To examine how social media usage and individual differences are associated with the impact of psychological responses, a path model analysis using WarpPLS (version 7.0) [43-45] software was executed.

In total, 296 participants (106 male and 191 female) were included in the path model analyses. The ethnicity of participants included White (157/297, 52.9%), African American (45/297, 15.2%), Asian American (35/297, 12.1%), American Indian or Alaska Native (54/297, 18.2%), Native Hawaiian or Pacific Islander (2/297, 0.67%), and others (3/297, 1.01%). Their age distributions are reported in [Table 1](#), and one of the participants refused to answer.

Measurements with items and their reliability are reported in [Tables 2](#) and [3](#).

**Table 1.** Participant age distribution (N=296<sup>a</sup>).

Age (years)	Participants (N=296, 99.7%), n (%)
18-24	13 (4.6)
25-34	168 (56.6)
35-44	67 (22.6)
45-54	28 (9.4)
55-64	18 (6.1)
65-74	2 (0.7)
Total	296 (99.7)

<sup>a</sup>One (0.3%) missing participant refused to reveal his/her age.

**Table 2.** Items and reliability of mental health measurements.

Items	Cronbach $\alpha$
<b>Center for Epidemiology Scale for Depression</b>	.93
1. I was bothered by things that usually don't bother me	
2. I did not feel like eating; my appetite was poor	
3. I felt that I could not shake off the blues even with help from my family or friends	
4. I felt I was just as good as other people	
5. I had trouble keeping my mind on what I was doing	
6. I felt depressed.	
7. I felt that everything I did was an effort	
8. I felt hopeful about the future	
9. I thought my life had been a failure	
10. I felt fearful	
11. My sleep was restless	
12. I was happy	
13. I talked less than usual	
14. I felt lonely	
15. People were unfriendly	
16. I enjoyed life	
17. I had crying spells	
18. I felt sad	
19. I felt that people dislike me	
20. I could not get "going"	
<b>Pittsburgh Sleep Quality Index</b>	.87
a. Cannot get to sleep within 30 minutes	
b. Wake up in the middle of the night or early morning	
c. Have to get up to use the bathroom	
d. Cannot breathe comfortably	
e. Cough or snore loudly	
f. Feel too cold	
g. Feel too hot	
h. Have bad dreams	
i. Have pain	



**Table 3.** Items and reliability of measurement.

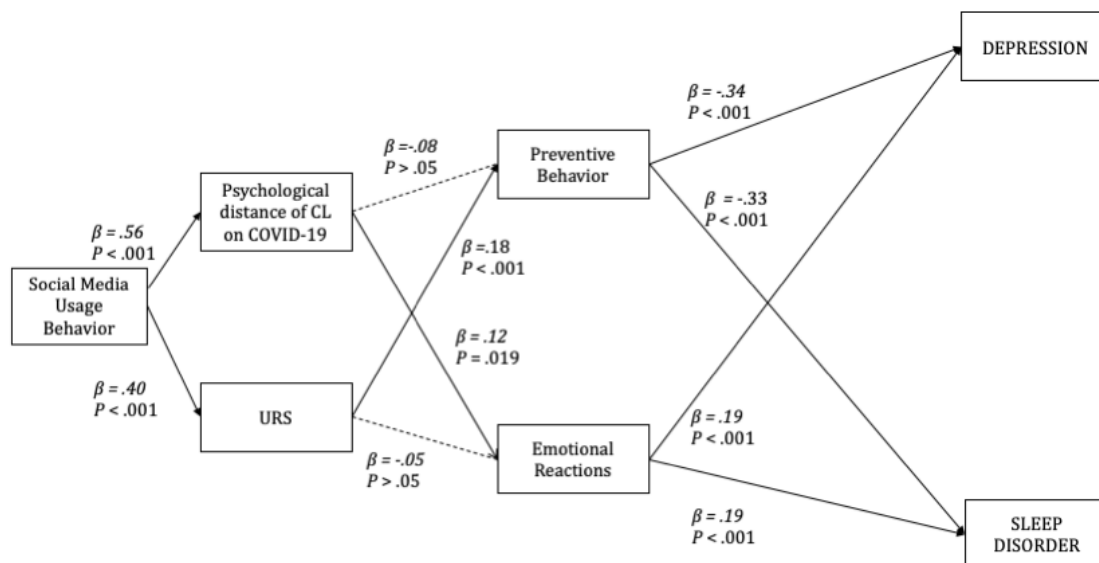
Items	Cronbach $\alpha$
<b>Social media usage</b>	.92
Read and comment or write feedback (for example, on the opinion board, RT on Twitter or on the Facebook)	
I send “links” to contents to others using social media	
I habitually surf around information/contents	
I surf around and click whatever get my attention	
I do not particularly look for information/news and just “surf” habitually.	
Watch TV shows, movies, etc. on a computer.	
I feel it is important to be able to access the social media any time I want.	
Technology will provide solutions to many of our problems.	
<b>Hypothetical distance: construal level on COVID-19</b>	.87
<b>How is the COVID 19 situation in your residence area?</b>	
Mild-severe	
Good-bad	
Positive-negative	
Do you feel that your residence area is near to the impact of COVID-19? (Near-far <sup>reversed</sup> )	
Do you feel that your neighbors are under the impact of COVID-19? (Impactful-not impactful <sup>reversed</sup> )	
Do you feel that you are under the impact of COVID-19? (Near-far <sup>reversed</sup> )	
<b>Uncertainty reduction strategy</b>	.87
I use internet and social media to find information regarding prevention for the COVID-19	
I use internet and social media to find the symptoms of COVID-19 that were not discussed yet	
I use internet and social media to seek alternative treatment or medical information regarding COVID-19 cure	
I use internet and social media to find right information about the COVID-19	
<b>Preventive behaviors</b>	.85
Worn a face mask	
Washed/sanitized hands	
Worked or studied at home	
Cancelled/postponed work or school activities	
Prayed	
Avoided public places/crowds	
Avoided in-person contact with high-risk people	
Cancelled/postponed travel	
<b>Affective reactions</b>	.86
How often do you feel that you lack companionship?	
How often do you feel isolated from others?	
How often do you feel left out?	
How much has your sleep been interrupted or disturbed of concern about the outbreak?	
How much difficulty do you have obtaining the food that you need because of the COVID-19 pandemic or social distancing rules?	

### Statistical Analysis

Overall, path model analysis shows the goodness of fit average path coefficient (APC)=0.20,  $P<.001$  and adjusted average

R-squared (AARS)=0.08,  $P=.04$ , average variance inflation factor (AVIF)=1.014, which shows a good average block variance inflation factor (VIF). The proposed hypotheses testing and the results of the path model are available in [Figure 2](#).

**Figure 2.** Analyzed path model. \* $P < .50$ , \*\* $P < .10$ . CL: construal level; URS: uncertainty reduction strategy.



Social media usage increases URS usage (H3) and the hypothetical distance of construal level (H1). Both H1 and H3 are supported. The increased URS results in more preventive behaviors (H4A was supported), but it does not show an association with emotional reactions (H4B was not supported). In contrast, the psychological proximity on COVID-19 could not predict their preventive behaviors (H2A was not supported), but it predicted the emotional reactions (H2B was supported). The preventive behaviors positively associated with symptoms of mental health: depression and sleep disorder (H5A and H5B were supported). The participants' greater affective reactions predicted the increased mental health symptoms: depression and sleep disorder (H6A and H6B were supported).

## Discussion

### Principal Findings

The principal objectives of this study were to examine the effects of social media usage on CLT and URS usage; while higher URS usage promoted the preventive behaviors, which reduced the self-reported mental health symptoms during the devastating COVID-19 outbreak situations, the CLT did not. Contrary to those with higher URS usage, those with low URS usage and emotional retraction showed increasing mental health symptoms, including depression and sleep disorders. Findings related to the underlying mechanism of mental health problems indicated several points regarding social media usage.

First, with increased social media usage, we predicted lower construal levels on COVID-19 (H1 was supported). By leveraging the CLT, we extended Lin et al's [40] uncertainty reduction action from the health communication domain to the context of COVID-19 outbreaks with "infodemic." Prior research on CLT used market research to predict the consumer behavior. However, we attempted to have a fresh perspective on CLT and extend its application area, such as the pandemic situation with preventive behaviors and evoking negative emotions. In doing so, hypothetical thoughts actually lead them to react emotionally; however, an increased probability of displaying preventive behavior was not observed. The lower

construal level is known to be focused on the thought of "how" and specifics, but the social media usage and lower construal level could not consider aerosol transmission for COVID - 19, and it also fails to predict preventive behaviors; that is, wearing gloves, wearing masks, and washing hands. A possible explanation of this is that because the lower construal level narrows down the thoughts to the specifics, the participants focus on the specific incident and risks of the pandemic and not on transmission mechanism including behaviors to prevention. With higher construal, they have a broad perspective about the constructional perspective and its prevention. The preventive behaviors could be a target. In a target- or goal-oriented situation, higher construal results in an intervention being viewed in terms of a higher construal and thus increased goal commitment [50]. Therefore, the lower construal level did not show an association with preventive behaviors. Per our hypothesis (H2B), the participants indicated a lower construal level and showed negative emotional reactions owing to shortening of the hypothetical distance. The overwhelming information with their emotional response may deprive them of the chance to think about the situation objectively or cognitively. Thus, the emotional reaction leads to higher self-reported depression and sleep problems, resulting in a vicious circle. Both URS and CLT usage were predicted to help people maintain their mental health and take the necessary precautions. As a result, only URS usage has a positive impact, while the CLT increases anxiety regarding the COVID-19 pandemic.

Second, contrary to the hypothetical concept on COVID-19, increased URS usage with increased social media usage were positively related to preventive behaviors and were not associated with emotional reactions. The increased preventive behaviors indicated lower mental health symptoms, such as depression and sleep disorder, which implies a reduction in mental health problems with increased preventive behaviors. This finding implies that those with URS usage obtain proper information from social media, including the general internet, to maintain their healthy life rather than focusing on the negative emotional reactions—even in devastating situations. Higher

social media usage and news recommendations, including popular UGC usage suggested in social media, are highly related to each other, which provide targeted information. Therefore, the users are hard to ignore. In this “infodemic” situation, the URS is more desirable to detect appropriate behaviors and maintain their mental symptoms.

### Limitations and Future Studies

Though our results are legitimate, their interpretation requires caution for the following reasons. First, the study sample showed a gender imbalance; 64.2% of the participants were female and 36.7% were male. To control the gender imbalance, the path analyses were controlled by the effects of gender imbalance. Second, though the participants displayed divergent racial and age distributions, the sample was collected only in the United States; hence, the generalizability of the results may be threatened. The sample and generalizability issues are common in academic studies. Future studies will expand our sampling context to a larger and diverse cross-section of the population; that is, other countries and nationalities. Furthermore, the sample bias on AmTurk was raised by Almaatouq et al [47]. In this study, though we used the AmTurk, convenience sampling may jeopardize the study’s reliability, this study attempts to reach a diverse group of social media users. AmTurk users have a greater proclivity for social media use. As a result, sampling bias is lesser than that of the overall school population. Moreover, the quality of data was relatively well-managed compared to that of other methods [48].

In addition, the results obtained in the context of COVID-19 are not directly similar to those obtained in the context of posttraumatic stress disorder (PTSD) or the effects of tragic events. However, in terms of experiencing sudden loss and isolation from others and financial problems, this is a novel situation akin to war and tragic, violent events that may cause PTSD [51-53]. Furthermore, the second effect of PTSD on the person’s family members may result from the person’s mental health problems [54]. As the self-isolation period gets prolonged, a higher rate of domestic violence has been reported [51,52,55]. Consequently, mental health issues may extend the secondary effects on their family, community, and society [56,57]. Therefore, future studies are required to investigate the effect of mental health problems due to the COVID-19 pandemic on family, community, and society.

### Conclusions

Considering the importance of preventing severe diseases and stopping contagion, psychological and mental issues are treated as secondary problems. However, our results imply that URS usage is associated with prevention behaviors and consequently, mental health problems tend to be managed. However, UGC on social media provides a chance to encourage people to live in a tragic situation by shortening the proximity with COVID-19, and it heightened the affective reactions reinforced mental health problems. The implications of this study are that while using social media, media literacy—that is, information-seeking behavior in the URS—is essential to maintain mental health during the self-isolation period and the pandemic situation to retain their psychological responses.

### Conflicts of Interest

None declared.

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## Abbreviations

**AmTurk:** Amazon Mechanical Turk

**CES-D:** Center for Epidemiology Scale for Depression



**CLT:** Psychological Distance and Level of Construal theory

**NPI:** nonpharmaceutical intervention

**PSQI:** Pittsburgh Sleep Quality Index

**PTSD:** posttraumatic stress disorder

**RQ:** research question

**UGC:** user-generated content

**URS:** uncertainty reduction strategy

**URT:** uncertainty reduction theory

**WHO:** World Health Organization

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Corrigenda and Addenda

# Correction: Toward Designs of Workplace Stress Management Mobile Apps for Frontline Health Workers During the COVID-19 Pandemic and Beyond: Mixed Methods Qualitative Study

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In “Toward Designs of Workplace Stress Management Mobile Apps for Frontline Health Workers During the COVID-19 Pandemic and Beyond: Mixed Methods Qualitative Study” (*JMIR Form Res* 2022;6(1):e30640) the authors noted one error.

In the originally published manuscript, the title was incorrectly set as:

*Toward Designs of Workplace Stress Management Mobile Apps for Frontline Health Workers During the COVID-19 Pandemic and Beyond: Design Implications for a Mixed Methods Qualitative Study*

The title has been corrected to:

*Toward Designs of Workplace Stress Management Mobile Apps for Frontline Health Workers During the COVID-19 Pandemic and Beyond: Mixed Methods Qualitative Study*

The correction will appear in the online version of the paper on the JMIR Publications website on January 25, 2022, together with the publication of this correction notice. Because this was made after submission to PubMed, PubMed Central, and other full-text repositories, the corrected article has also been resubmitted to those repositories.

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Corrigenda and Addenda

# Correction: Medication Adherence Reminder System for Virtual Home Assistants: Mixed Methods Evaluation Study

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In "Medication Adherence Reminder System for Virtual Home Assistants: Mixed Methods Evaluation Study" (*JMIR Form Res* 2021;5(7):e27327), three errors were noted.

Due to a system error, the name of one author, Cynthia F Corbett, was replaced with the name of another author on the paper, Elizabeth M Combs. In the originally published paper, the order of authors was listed as follows:

*Elizabeth M Combs, Elizabeth M Combs, Peyton S Chandarana, Isabel Stringfellow, Karen Worthy, Thien Nguyen, Pamela J Wright, Jason M O'Kane*

This has been corrected to:

*Cynthia F Corbett, Elizabeth M Combs, Peyton S Chandarana, Isabel Stringfellow, Karen Worthy, Thien Nguyen, Pamela J Wright, Jason M O'Kane*

In the originally published paper, the ORCID of author Cynthia F Corbett was incorrectly published as follows:

0000-0002-2254-6958

This has been corrected to:

0000-0003-2706-2116

In the originally published paper, the email of the Corresponding Author was incorrectly published as follows:

*combsel@email.sc.edu*

This has been corrected to:

*corbett@sc.edu*

The correction will appear in the online version of the paper on the JMIR Publications website on January 27, 2022, together with the publication of this correction notice. Because this was made after submission to PubMed, PubMed Central, and other full-text repositories, the corrected article has also been resubmitted to those repositories.

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