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Patients’ Experiences of Using a Self-help App for Posttraumatic Stress Disorder: Qualitative Study

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Abstract

Background: Posttraumatic stress disorder (PTSD) is a common disorder that requires more treatment options. Mobile health (mHealth) app interventions are promising for patients with PTSD, as they can provide easily accessible support, strategies, and information. However, knowledge about mHealth interventions is sparse and primarily based on quantitative studies.

Objective: The aim of this study is to qualitatively explore the experiences of patients with PTSD with regard to using an mHealth app as a stand-alone intervention before commencing psychotherapeutic treatment.

Methods: We conducted semistructured interviews with 14 participants 6 weeks after they received the app. The participants were all referred to PTSD treatment and were waiting to commence psychotherapeutic treatment. During this waiting time, the participants had no contact with the health staff. Interviews were transcribed and were analyzed using thematic analysis.

Results: A total of 3 themes were identified—the use of app, being a patient, and the overall evaluation of the app. The use of the app was described with the subtheme of habits, and the theme of being a patient included the subthemes of having negative experiences with the app and being a part of a research project. The use of the app encompassed how psychological factors and technical problems could interfere with the use of the app. The theme of being a patient depicted that the waiting time before starting treatment was long, and a subgroup of patients experienced feeling worse during this time, which they partly attributed to using the app. Several suggestions for change have been described in the overall evaluation of the app.

Conclusions: The findings in this study revealed that emotional arousal influenced the use of the app and that it was difficult for participants to establish a habit of using the app, thus reflecting the importance of supporting habit formation when implementing an mHealth app in mental health care services. This study makes an important contribution to the field of mHealth research, as it revealed that some participants had negative experiences resulting from using the app, thus reflecting the potential harm of having an mHealth app without the support of a clinician. It is therefore recommended to use a blended care treatment or an approach in which mental health care professionals prescribe an mHealth app for relevant patients to avoid increased suicidal risk.

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KEYWORDS

app; PTSD; mHealth; qualitative analysis; patient experience; posttraumatic stress disorder; thematic analysis; smartphone; intervention; mobile phone

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Background

Posttraumatic stress disorder (PTSD) is a common disorder, with a prevalence of approximately 2% in European countries [1]. There are serious personal and societal consequences associated with PTSD, such as poor quality of life, high comorbidity, and increased use of health services [1,2]. Furthermore, PTSD is recognized as a risk factor for suicidal thoughts and behaviors and completed suicide [3,4]. Although the costs of PTSD are widely recognized, logistical and individual barriers, such as a lack of available mental health care services and negative beliefs about help-seeking, are common [5,6].

In Denmark, patients are referred to the public mental health services (MHS) by their general practitioner if a complex mental disorder is suspected. Patients are entitled to have a diagnostic interview within 30 days, but psychotherapeutic treatment may start substantially later depending on the available resources in the given clinic. As such, patients often experience waiting list periods exceeding 6 weeks before commencing treatment. During this time, the patient has minimal support from the MHS and, therefore, there is considerable interest in developing technological treatment alternatives.

Smartphones are owned by 79% of adults in European countries [7] and offer a platform with the potential to reach populations with otherwise limited access to health care [8]. Mobile health (mHealth) apps provide easy access to cost-effective treatment tools that can potentially increase treatment engagement and well-being [5,9]. There is great potential to effectively integrate apps into mental health care, as they can offer interventions, provide psychoeducation, promote self-awareness, and help overcome the self-stigmatization associated with receiving mental health care [10-12]. A systematic review and meta-analysis of the effects of self-management apps for patients with PTSD revealed that no significant difference was found between self-management app–based treatment groups and the control group on waiting list [8]. However, only 6 studies were included, leaving the quality of the evidence base low.

Although there is a growing body of quantitative research on mHealth apps as a supplement or stand-alone treatment [6,13-16], qualitative studies are surprisingly absent. To our knowledge, only 2 studies have used a qualitative approach to investigate patients’ experiences using an mHealth app for PTSD. A study on attitudes toward mHealth in a sample of veterans with either PTSD, depression, and/or an alcohol abuse disorder revealed a marked difference in the openness toward using mHealth apps depending on rurality, where rural veterans expressed more negative views than urban veterans [17]. Another study investigating the PTSD Coach app showed that participants found some coping strategies and self-assessment tools useful [18]. Consequently, it is still unclear how patients with PTSD perceive and experience using mHealth apps [8]. There is a need for future research to explore these experiences, as they can provide unique insights into compliance, engagement, adherence, as well as positive and adverse effects.

With this exploratory qualitative study, we seek to fill this research gap.

Objectives

To investigate the potential of using mHealth apps for patients with PTSD in MHS, an mHealth app named PTSD Help was developed for use as a stand-alone treatment and as a supplement to psychotherapeutic treatment. This study explores the following research question: how do patients diagnosed with PTSD experience the use of an app, PTSD Help, as a stand-alone treatment before psychotherapeutic treatment?

By exploring this aspect qualitatively, we aim to uncover both the experienced benefits and limitations of using the app, which can be used in the process of development and implementation of mHealth apps for PTSD in MHS.

Methods

Context

The study was conducted within the context of the study “The PTSD help app in a Danish PTSD population: A randomized controlled feasibility trial,” which investigated the feasibility of implementing the PTSD Help app in the Danish MHS [13]. The participants in the larger study were randomized to either a waiting list control group or a PTSD Help app treatment group. All participants received treatment for their PTSD diagnosis after 6 weeks [13]. The randomized controlled feasibility trial of the PTSD Help app study will be published in the near future. This study used a qualitative study design to explore the patients’ experiences using the app as a stand-alone treatment in the waiting period before the commencement of treatment in the MHS.

Intervention: PTSD Help

PTSD Help is an mHealth app that includes functionalities such as psychoeducation, emotion regulation tools, a note function, and a crisis plan (Figure 1). Emotion regulation tools offer a range of different interventions, including distraction exercises, grounding exercises, simple body exercises, and calming images accompanied by music. As sleep problems are common in the PTSD population, the app contains two functions to alleviate sleep problems: guided sleep meditation, in which the individual can choose between a male or female voice, and general sleep hygiene advice. Two self-assessment tools are provided in the app: the PTSD checklist for DSM-5 [19] to monitor PTSD symptoms, which is available with an interval of at least 2 weeks to be as close to the clinical use as possible. The second assessment tool aimed to monitor sleep quality (sleep condition indicator) [20], which is available daily (Figure 2). An overall favorite function is provided, giving the patient the opportunity to choose which functions are the most meaningful and bringing these functions to the front page.

To ensure that PTSD Help can be used across treatment modalities, it is designed as a generic intervention and does not include theory-specific elements. This design was chosen as the Danish MHS, which provides a range of different treatment types for patients with PTSD.
Ethical Considerations
Participants provided both verbal and written informed consent before participating in the study and were informed that they could withdraw their consent at any time. Participants were informed that the interviews were being recorded and subsequently anonymized and transcribed verbatim. To ensure anonymity, participants were given a project ID, and audio recordings of the interviews were stored in a secure database administered by the Capital Region of Denmark. The participants’ psychotherapeutic treatment commenced shortly after the interview was conducted, thus ensuring minimal treatment gap.

Participants
The study was conducted within the MHS of the Capital Region of Denmark (MHS-CRD), where 14 participants were recruited. Participants included in the study were aged ≥18 years, diagnosed with PTSD in accordance with the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-5), were accepted for PTSD treatment, had access to a smartphone with iOS (version 10 or higher) or Android (version 5.0.1. or higher), and provided informed consent. The reasons for exclusion were increased suicidal risk, current episodes of bipolar disorder or psychotic disorder, current substance abuse, inability to understand and/or read Danish, and concurrent psychiatric or psychological treatment of PTSD outside the MHS-CRD [13].
**Procedure**

Participants gained access to the PTSD Help app after the assessment interview and were given brief verbal general instructions on how to use the different functions in the app. This verbal introduction was based on a manuscript to ensure that all participants received the same information and took approximately 5 minutes. Furthermore, 3 days after gaining access to the app, the participants were contacted by telephone to ensure that there were no technical issues in using the app. There was no further assistance in using the app following the telephone call. Finally, the participants were contacted by telephone 6 weeks after having gained access to the app, and they were invited to participate in semistructured interviews (full description of the recruitment procedure has been provided in the study by Scharff et al [13]). The participants were not prohibited from having contact with health staff while waiting to commence psychotherapeutic treatment; however, this was rarely seen in the MHS-CRD and was therefore not monitored. Interviews were conducted in 2019. The sample was randomly selected because of its strict time schedule.

**Materials**

The semistructured interview guide aimed at exploring the participants’ experiences using the PTSD Help app (see Textbox 1 for concepts covered). The interviews lasted approximately 30 minutes and were conducted over the telephone. The interviews were transcribed verbatim by a graduate psychology student.

Assessments were conducted as part of a larger study. The Mini-International Neuropsychiatric Interview 7.02. [21] was used to establish PTSD diagnosis in accordance with the DSM-5. PTSD symptoms were measured using the PTSD checklist for DSM-5 [19], which is a self-report questionnaire that assesses the presence of the four core DSM-5 PTSD symptom clusters during the past month with a cut-off score between 31 and 33, thus providing knowledge on the severity of symptoms.

**Table 1** shows the demographic and clinical characteristics of the total sample of participants. Participants were aged between 20 and 59 years, and the majority were female (8/14, 57%). All participants fulfilled the diagnostic criteria for PTSD according to the International Classification of Diseases, Tenth Revision and had at least one comorbid psychiatric disorder. The most frequently reported comorbid disorder was panic disorder (6/14, 42%), followed by a major depressive episode (3/14, 21%) and agoraphobia (3/14, 21%), thus reflecting a population sample with complex mental health problems.

**Textbox 1. Concepts covered in the interviews.**

<table>
<thead>
<tr>
<th>Concepts</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Use of apps in general</td>
</tr>
<tr>
<td>• PTSD Help app utility value</td>
</tr>
<tr>
<td>• PTSD Help usefulness</td>
</tr>
<tr>
<td>• Design</td>
</tr>
<tr>
<td>• Suggestions for change</td>
</tr>
<tr>
<td>• Disadvantages or negative experiences with using the app</td>
</tr>
</tbody>
</table>
Table 1. Demographic and clinical characteristics of all participants (N=14).

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years), mean (SD; range)</td>
<td>39 (13.5; 20-59)</td>
</tr>
<tr>
<td><strong>Gender, n (%)</strong></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>8 (57)</td>
</tr>
<tr>
<td>Male</td>
<td>6 (43)</td>
</tr>
<tr>
<td><strong>Diagnosis MINI (ICD-10)(^b), n (%)</strong></td>
<td></td>
</tr>
<tr>
<td>PTSD(^c) (F43.1 in ICD-10)</td>
<td>14 (100)</td>
</tr>
<tr>
<td>PCL-5(^d) score, mean (SD)</td>
<td>46.6 (9.3)</td>
</tr>
<tr>
<td><strong>Comorbidity using MINI (ICD-10), n (%)</strong></td>
<td></td>
</tr>
<tr>
<td>Major depressive episode (F32.2 in ICD-10)</td>
<td>3 (21)</td>
</tr>
<tr>
<td>Major depressive disorder, recurrent (F33.2 in ICD-10)</td>
<td>1 (7)</td>
</tr>
<tr>
<td>Agoraphobia (F40.0 in ICD-10)</td>
<td>3 (21)</td>
</tr>
<tr>
<td>Social anxiety disorder (F40.1 in ICD-10)</td>
<td>2 (14)</td>
</tr>
<tr>
<td>Panic disorder (F41.0 in ICD-10)</td>
<td>6 (42)</td>
</tr>
</tbody>
</table>

\(^a\)MINI: the Mini-International Neuropsychiatric Interview.  
\(^b\)ICD-10: International Classification of Diseases, Tenth Revision.  
\(^c\)PTSD: posttraumatic stress disorder.  
\(^d\)PCL-5: The Posttraumatic Stress Disorder Checklist for the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition.

Data Analysis

Semistructured interviews were conducted by 2 members of the research team (MEL and IMTPA) and a graduate student of psychology. Data were analyzed by first author LHGR and researcher II using thematic analysis under the supervision of an experienced qualitative researcher. Thematic analysis is a qualitative method that allows for the organization, interpretation, and reporting of data [22,23]. The analysis was conducted through 6 phases that adhered to Braun and Clarke’s thematic analysis approach [22]. The researchers LHGR and II separately coded the interviews and conducted the thematic analysis. The Lincoln and Guba [24] criteria for trustworthiness were addressed in each phase to ensure the high quality of the analysis. Through researcher triangulation, overlaps were discovered and discussed, and 3 themes were chosen. Themes were chosen according to their relationship to the overall research question.

Results

Overview

Table 2 summarizes the most frequently used functions in the app and the least used functions. The data indicated that all the participants except one (13/14, 92.9%) had used the app and that the mean use was 16.8 (SD 12.3) times during the study period. The total app use ranged from 0 to 39 times, indicating that some participants frequently engaged in the app, whereas one participant never used it during the study period. The most frequently used function in the app was the “Symptoms and strategies” function with a mean of 5.9 (SD 4.4). The least used function was the “Sleep Condition Indicator” with 57.1% (8/14) participants using it with a mean of 1.0 (SD 1.1), followed by the function “Positive activites” with 64.3% (9/14) participants using it with a mean of 1.1 (SD 1.1).

The following themes emerged in the thematic analysis: (1) use of app, (2) being a patient, and (3) overall evaluation of the app. An overview of themes and subthemes is provided in Textbox 2 and presented using verbatim quotes from the participants in the following text.
Table 2. Total app use and the most and least frequently used functions.

<table>
<thead>
<tr>
<th>App use</th>
<th>Number of times that functions were used, mean (SD; range)</th>
<th>Endorsed, n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total app use</td>
<td>16.8 (12.3; 0-39)</td>
<td>13 (92.9)</td>
</tr>
<tr>
<td><strong>Most used functions</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Symptoms and strategies</td>
<td>5.9 (4.4; 0-15)</td>
<td>12 (85.7)</td>
</tr>
<tr>
<td>Crisis plan</td>
<td>5.7 (3.1; 0-13)</td>
<td>13 (92.9)</td>
</tr>
<tr>
<td>Help falling asleep</td>
<td>4.1 (5.6; 0-19)</td>
<td>10 (71.4)</td>
</tr>
<tr>
<td><strong>Least used functions</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Body exercises</td>
<td>1.2 (0.9; 0-3)</td>
<td>11 (78.6)</td>
</tr>
<tr>
<td>Positive activities</td>
<td>1.1 (1.1; 0-3)</td>
<td>9 (64.3)</td>
</tr>
<tr>
<td>Sleep condition indicator</td>
<td>1.0 (1.1; 0-3)</td>
<td>8 (57.1)</td>
</tr>
</tbody>
</table>

Textbox 2. Themes and subthemes.

Themes and subthemes
- Use of App
  - Subtheme 1: Habits
- Being a Patient
  - Subtheme 2: Negative experiences with the app
  - Subtheme 3: Being a part of a research project
- Overall Evaluation of the App

Theme 1: Use of the App

Overview

The use of the app concerns psychological factors related to app use (such as anxiety, stress, and habits) and technical problems. The psychological factors had a dual function, as they could both motivate as well as disrupt the use of the app. For example, some participants reported using the app during panic attacks, whereas others reported that a high level of anxiety prevented them from using the app:

But when you are completely panic-struck, it's not like you think "now I'm going to use it," it's often like it's too late, so it is more when you are about to calm down that it is actually a help, right. [Participant ID24]

Some participants reported using the app to prevent stress, whereas others referred to using the app overall as a distraction tool, which was seen as a positive and useful function. A subgroup of participants experienced technical difficulties, such as missing sound on the sleep meditation or that the mobile phone automatically went to screensaver mode when they used meditation exercises, which caused some participants to stop using the app altogether.

Subtheme 1: Habits

The subtheme of habits emerged as participants described their use of the app to explain a low level of app use. One participant described how a high level of anxiety prevented the habitual use of the app, as high arousal interrupted regular use.

Well, of course in the beginning I used it to get to know it. And also customize it like in case of emergency, and I have also chosen my favourite functions. And I used it in the beginning, and actually got a little habit of using it a couple of times a day, but then it unfortunately went down the drain. [Participant ID14]
Several participants reported either forgetting that they had the app or forgetting to use the app in relevant situations. A participant explained how he, in the beginning, tried to use the app as a distraction tool when he had a panic attack but that he quickly forgot he had the app:

You forget that you have it on your phone. Because it’s not something you think about in everyday life, like “now I have the app” and then I get these feelings where I can feel all this anxiety, it’s not that I go to my phone and use it, I think I just forget. That I have this tool available. [Participant ID16]

Theme 2: Being a Patient

Overview

The theme refers to how the patient experienced having the PTSD Help app during the waiting time until psychotherapeutic treatment started. Within this theme, the subthemes, negative experiences with the app and being a part of a research project, emerged.

For some participants, the waiting time from when the diagnostic interviews were conducted to when the psychotherapeutic treatment started felt long. One participant stated that the waiting time was too long, and he used the app as a way to not feel completely lost while waiting. Thus, the app was experienced as a supportive tool for some participants during the waiting time.

The participants also discussed their experience of participating in the initial diagnostic interview in the MHS-CRD. For example, one participant explained how there was no time in the initial diagnostic interview to explain the diagnosis, which led the patient to seek this information in the app:

...but there has not really been a time when someone has sat down with me and explained what the symptoms are, what I should expect, how the process will be, and here I think the app has been good. Because I can google everything on the internet, but here I know that it comes from a source created by doctors and psychologists. So, it’s not just something that’s just lying around on the internet. [Participant ID39]

On the other hand, some participants reported being overwhelmed by the status of being a patient. Having to use the app added to the stress. A participant explained how facing PTSD-related problems would make things worse, and that she did not feel able to engage in the app unsupported:

So, from the very first interview, it took almost a month before I had the next two appointments. And during that time, I shut down everything, and didn’t want to relate to anything, or think about anything, and I pushed everything away, and when there were four-five days until I had to start, everything got worse up to the maximum again. I only slept two-three hours a night and woke up with anxiety and palpitation and...yes. So, the bottom line is that when I’m forced to deal with it, it gets worse. [Participant ID29]

The participants who addressed the theme of being a patient all highlighted the waiting time as problematic and that information (either from the app or from a professional) about their diagnosis and the overall treatment process were helpful.

Subtheme 2: Negative Experiences With the App

Although there was an overall positive attitude toward the app in that participants reported becoming more aware of symptoms and sensations that increased their understanding of the disorder, negative experiences from using the app were also reported. Although participants generally saw becoming more aware of their symptoms as clinically beneficial, some experienced it as a worsening of symptoms and exposing vulnerability in a situation of minimal support. One example of a participant reporting using the app regularly reported feeling worse from the increased self-awareness that followed using the intervention tools in the app:

So, you may have become more aware of yourself if you can put it that way? [Interviewer]

Yes exactly, and what to look for to why you have these symptoms, and what these symptoms mean and that it is not, you know, your own fault, if you can say so. [Participant]

Have you noticed if any of your symptoms have changed since you got the app? [Interviewer]

I do not think changed, I just think they have become...all in all, worse. [Participant ID39]

The participants who reported negative experiences all agreed that focusing on their PTSD symptoms without support from a professional caused increased distress.

Subtheme 3: Being a Part of a Research Project

Some participants reported how being a part of a research project was stressful:

But what I would also like to say is that I have been to a psychologist before, and now I go to the psychiatric clinic in Hilleroed to find out what treatment I should have, and then at the same time, I should also use the app, and at the same time you get calls, and I get asked a lot of things about the app, so I just think...I’m well aware that you have some of these things, but it might be a little...too much, then I have to use the app, then I go to a psychologist, so it might also take up a little too much time in everyday life, I think...That you are constantly made aware that you have this problem. [Participant ID16]

Another participant felt almost the opposite, as he explained how contact with the research team helped him relax as he knew he could reach out to the research team if he needed help.

Theme 3: Overall Evaluation of the App

This theme covers how the participants experienced using the app, the design of the app, and its specific functionalities. Within this theme, participants provided several suggestions for changes to the app.

Overall, most participants reported using the app regularly and were generally positive toward it. The design of the app was
reported to be accessible and easy to use, although some participants reported that a few of the functionalities, such as the location of the questionnaires, were not placed intuitively and were therefore confusing. The participants had several suggestions for improvements, such as implementing notifications as reminders, providing psychoeducation for relatives, and personalizing the app.

...you’re able to personalise the app, where you can put some pictures in it that make you happy, or something like that, right. Because I have learned that on my computer, when it’s in sleep mode, it shows some pictures, and for me it has actually been really relaxing to be able to sit there and watch these pictures and think “okay.” So, something like that, I don’t know...you just relax when seeing something of your own that you have chosen in advance, and maybe also some music that you might like or something like that. [Participant ID24]

In particular, the suggestion to implement notifications in the app as a reminder for using the exercises, self-assessment, and other features was mentioned several times. There was a broad consensus across participants that the key advantages of the app were that it was a reliable source of information on PTSD and that it worked well as a distraction tool. A small number of participants reported being surprised at how effective some of the emotion regulation tools were (eg, the soothing images).

**Discussion**

**Principal Findings**

This qualitative study explored patients’ experiences with using the PTSD Help app as a stand-alone treatment before commencing psychotherapeutic treatment. All the interviewed participants except one (13/14, 92.9%) had used at least some functions in the app with the range of use among the participants from 0 to 39 times during the study period. Thus, nearly all participants had experience from engaging with the app to report. The data also indicated a broad range of use among participants. A total of 3 themes were identified in the analysis— the use of the app, being a patient, and the overall evaluation of the app. Overall, the participants felt comfortable using the app and experienced several functions in the app as helpful. However, the analysis found that a subgroup of participants reported negative experiences with the app. Finally, the wish for a more personalized app emerged.

Our findings showed that some participants reported that increased emotional arousal (eg, anxiety) could lead to both an increase and a decrease in app use depending on the situation. Thus, an optimal level of distress seemed to promote the use of the app and increase individuals’ ability to use emotional regulation strategies when needed. One could speculate that to remember to use the app efficiently, at least some distress is necessary. This issue is important to note, as it raises the question of the existence of an optimal load of symptoms when using an app as a stand-alone treatment. Previous studies on the effectiveness of mobile apps have focused on symptom improvement rather than patterns of use [6]. Our study suggests that it is possible that patients who are less impaired by their symptoms will benefit the most and be the most engaged users of the app, whereas patients with more severe symptoms will, to a higher degree, refrain from using the app.

What is new is our finding that a subgroup of participants reported negative experiences with the app. Although this applies only to a limited number of participants, it must be taken seriously, as increased symptom severity in PTSD has been associated with increased suicidal risk [3,4]. This finding emphasizes the potential general challenge of app interventions as a stand-alone treatment. In contrast to psychotherapy, where the clinician’s continuous evaluation of the patient, including risks, benefits, and goals, guides which intervention is used, mHealth apps offer the same functions to all patients, potentially leaving vulnerable patients unassisted in choosing and applying interventions [25]. Although the PTSD Help app offers a crisis management plan and strategies for coping with suicide risk, the use of these functions is dependent on the patient, who may have limited insight and, as such, risk not using the functions when needed or not being able to use the functions unassisted. Consequently, it could be argued that to be able to support this vulnerable subgroup of patients, a blended care intervention, including clinician support, is crucial.

Habits were raised as a subtitle in the way the participants used the app. As using the app is a prerequisite to obtain an effect, it is relevant to understand patterns of use and factors involved in the participants’ use of the app. One perspective on patterns of use comes from research on habits and habit formation [26]. Developing habits is a dynamic process in which behavioral control is initially goal dependent but shifts to context dependence as the behavior is repeated [27]. In our study, the participants were responsible for defining their goal on their own and received limited contextual instructions in using the app, and the instructions were somewhat vague (eg, ‘when you are feeling distressed’). The analysis found that participants reported how forgetfulness and the use of the app not becoming habitual caused unintentional nonadherence. Accordingly, a recent systematic review focusing on medication adherence across chronic medical conditions found that habit strength was strongly correlated with medication adherence [28]. Focusing on psychotherapy, a study on a guided self-help intervention using cognitive bias modification training found a significant treatment effect in patients with depression who reported having created a habitual use of the practiced self-help response [29]. These findings suggest that supporting habit formation through clinician-supported interventions on goal definition and contextual instructions appears to be important when implementing an mHealth app and could have had an impact on the frequency of use of the PTSD Help app.

In relation to the previous suggestion to use a blended care approach to support patients with potential suicidal thoughts in using the app, a blended care approach could also strengthen habit formation and thus potentially be of more help. This would also apply to vulnerable patients with an increased risk of suicide. If using the app successfully becomes a habitual behavior, it will automatically be activated in the relevant context and, therefore, not be dependent on available mental
resources, which may be limited in situations with high emotional arousal.

This study also revealed how the waiting time until treatment starts could feel long and stressful for the patient and result in the patient not engaging in the app, and clinician support could alleviate this. Previous studies have shown that including clinician support in internet-based treatments increases the effect size and patient adherence [30,31]. A study on a clinician-supported version of the PTSD Coach app found promising results in terms of acceptability and feasibility among patients and clinicians [32]. The procedure in the present study did not include clinician support, but it included a technical support call after 3 days, which some participants perceived as a clinical support call, which in turn might have encouraged participants to be more engaged in using the app after this call.

Our findings suggest that providing participants with more contextual instructions and at least some clinician support on a regular basis may be important to make the use of the app habitual, which could prove pivotal in optimizing the effect of an app.

The participants’ evaluation of the app was closely related to suggestions for change, in which a wish to be able to personalize the app was prominent. This request is consistent with previous qualitative studies on the internet and mobile-based interventions [33,34]. Although the app offers personalization of the content to some extent, this finding echoes the need for more personalized material and interventions. With the PTSD Help app, this could mean changing the focus from the individual choosing his or her own preferred functions in the app to the app recommending relevant interventions based on a data collection of the individual’s specific distribution of symptoms. As the app already contains self-monitoring tools, in line with recommendations [9], it seems plausible to use this collected data in an automated tailoring algorithm. A variety of functions should be offered in the app to ensure that it holds content of relevance to every participant with a variety of individual needs and preferences.

Regarding age, all the participants were aged ≤60 years, making it difficult to generalize the results past that age. However, the majority of patients treated in MHS in Denmark are aged ≤60 years, as demonstrated in demographic data from a large sample of 2473 patients without a diagnosis of psychosis in MHS-CRD, where the average age was 33.0 years [35]. Thus, our results cannot be generalized to older adults but can mirror the average age seen in MHS in Denmark.

Limitations
Some limitations influence the strength of the conclusions drawn from the results of this study. The sample was based on a convenience sampling principle, because of a strict time limit for recruitment. The most optimal sampling strategy would have been a selected sample, which would have allowed the information from this study to be applied beyond its settings [36]. Furthermore, no participant in the study was older than 59 years, making it difficult to generalize our findings to older adults.

There is a possibility that there was a positive sampling bias, as those participants who agreed to participate generally had a positive attitude toward the app. Two participants were asked to participate but declined because of a reported negative attitude toward the app. One could speculate that this positive attitude is not necessarily the general attitude of all participants using the app. This could also explain how the data on the total app use showed that one participant did not engage in the app at all during the study period, but this was not revealed in the interviews.

The study covered participants’ experiences of using the app and acknowledged that there are multiple factors, such as technological, psychological, and social factors, which affect the experience. These factors may not be fully covered by the semistructured interview in this study, as they are not always apparent to the participant or the participant may not wish to reveal them to a member of the research team.

Future Implications
In light of the current COVID-19 pandemic and the urgent need for developing internet-based treatment services that ensure treatment commitment and adherence, it is important to cover the patient’s experience of using mHealth apps, as this will provide the research field with essential information about usability, acceptability, and possible negative effects. This qualitative study makes an important contribution to the field of mHealth research, showing that providing an mHealth app to patients with PTSD without clinician support should be done with caution. Our findings stress that personalization and active interactions could be beneficial to integrate in future mHealth apps to ensure continuous engagement and positive experiences with the treatment. On the basis of these findings, we provide two suggestions when implementing an mHealth app in an MHS with a PTSD population: (1) using a blended care treatment with clinician support to provide assistance and regular psychiatric assessment as well as to stimulate habitual use and (2) using an approach where mental health care professionals prescribe an mHealth app for relevant patients. Using one of these suggestions when implementing an mHealth app for patients with PTSD in MHS will enable clinicians to identify patients who are at risk of experiencing worsening symptoms from using the app unassisted. Future studies could investigate the association between use and outcome to determine if a dose-response mechanism exists and which functions patients seem to engage the most with signaling, which might be more important than others.

Conclusions
This qualitative study examined how patients with PTSD experienced the mHealth app PTSD Help as a stand-alone treatment before commencing psychotherapeutic treatment. The overall findings were that the majority of participants expressed that they had a positive experience using the app, but that a subgroup of participants reported negative experiences using the app. The lack of habitual use of the app was also raised to explain a low level of use and not using the app in relevant situations.
There are undoubtedly many advantages in implementing mHealth apps in MHS. Our findings demonstrate the need for research on which patients can benefit and which patients are at risk of experiencing worsening of symptoms from having an mHealth app as a stand-alone treatment. We hope that this study will serve as a springboard for future mHealth studies to form hypotheses about which patients in particular can benefit from using an mHealth app (either as a stand-alone treatment or as a supplement to treatment) and explore this in a mixed methods approach to provide new fine-grained insights into the research field. As a consequence of the participants’ wish for a more personalized app, we also encourage further investigation of the possibility of developing such an app using a tailoring algorithm to recommend interventions to the user.

Acknowledgments
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Authors’ Contributions
LHGR, FBS, and MEL designed the study. MEL, IMTPA, and the graduate student conducted the interviews. LHGR and II performed the thematic analysis under the supervision of ABC. LHGR drafted the paper under the supervision of SBM, all authors read the final version of the manuscript and contributed to its revision.

Conflicts of Interest
MEL and FBS were involved in the development of the app.

References


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Abbreviations

DSM-5: The Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition
mHealth: mobile health
MHS: mental health services
MHS-CRD: Mental Health Services of the Capital Region of Denmark
PTSD: posttraumatic stress disorder

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Physiologic Response to the Pfizer-BioNTech COVID-19 Vaccine Measured Using Wearable Devices: Prospective Observational Study

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Abstract

Background: The Pfizer-BioNTech COVID-19 vaccine uses a novel messenger RNA technology to elicit a protective immune response. Short-term physiologic responses to the vaccine have not been studied using wearable devices.

Objective: We aim to characterize physiologic changes in response to COVID-19 vaccination in a small cohort of participants using a wearable device (WHOOP Strap 3.0). This is a proof of concept for using consumer-grade wearable devices to monitor response to COVID-19 vaccines.

Methods: In this prospective observational study, physiologic data from 19 internal medicine residents at a single institution that received both doses of the Pfizer-BioNTech COVID-19 vaccine was collected using the WHOOP Strap 3.0. The primary outcomes were percent change from baseline in heart rate variability (HRV), resting heart rate (RHR), and respiratory rate (RR). Secondary outcomes were percent change from baseline in total, rapid eye movement, and deep sleep. Exploratory outcomes included local and systemic reactogenicity following each dose and prophylactic analgesic use.

Results: In 19 individuals (mean age 28.8, SD 2.2 years; n=10, 53% female), HRV was decreased on day 1 following administration of the first vaccine dose (mean –13.44%, SD 13.62%) and second vaccine dose (mean –9.25%, SD 22.6%). RHR and RR showed no change from baseline after either vaccine dose. Sleep duration was increased up to 4 days post vaccination, after an initial decrease on day 1. Increased sleep duration prior to vaccination was associated with a greater change in HRV. Local and systemic reactogenicity was more severe after dose two.

Conclusions: This is the first observational study of the physiologic response to any of the novel COVID-19 vaccines as measured using wearable devices. Using this relatively small healthy cohort, we provide evidence that HRV decreases in response to both vaccine doses, with no significant changes in RHR or RR. Sleep duration initially decreased following each dose with a subsequent increase thereafter. Future studies with a larger sample size and comparison to other inflammatory and immune biomarkers such as antibody response will be needed to determine the true utility of this type of continuous wearable monitoring in regards to vaccine responses. Our data raises the possibility that increased sleep prior to vaccination may impact physiologic
responses and may be a modifiable way to increase vaccine response. These results may inform future studies using wearables for monitoring vaccine responses.

**Trial Registration:** ClinicalTrials.gov NCT04304703; https://www.clinicaltrials.gov/ct2/show/NCT04304703

**(JMIR Form Res 2021;5(8):e28568)** doi:10.2196/28568

**KEYWORDS**
COVID-19; wearable devices; remote physiologic monitoring; heart rate; heart rate variability; respiratory rate; sleep; REM sleep; deep sleep; wearable; vaccine; monitoring; respiratory; physiological; cohort

**Introduction**

The COVID-19 pandemic has had a substantial global impact resulting in over 165 million infections and nearly 3.5 million deaths worldwide [1,2]. Vaccines are required to end the pandemic. The first vaccine to receive emergency use authorization for prevention of COVID-19 infection by the United States Food and Drug Administration was the BNT162b2 messenger RNA (mRNA) COVID-19 vaccine (Pfizer-BioNTech COVID vaccine) that encodes the spike protein of the SARS-CoV-2 virus [3,4]. Following preliminary studies with this mRNA vaccine showing neutralizing antibody response, a phase 3 randomized clinical trial demonstrated that the Pfizer-BioNTech vaccine was safe and had an efficacy of 95% in reducing risk of contracting COVID-19 compared to placebo [4-6].

An estimated 21% of US adults report using wearable devices that objectively measure physiologic parameters [7]. Although marketed for personal use, the widespread nature and convenience of these devices allows health care professionals to monitor physiologic changes in real time [8]. The WHOOP Strap 3.0 has been externally validated for tracking of heart rate variability (HRV), resting heart rate (RHR), respiratory rate (RR), and sleep stage duration [9]. HRV is determined by the subtle variation in the time between successive heart beats, thus HRV is a measure of the balance between the sympathetic and parasympathetic nervous system and their composite effects on heart rate [10].

A recent study using the WHOOP device was able to track physiologic changes, specifically an increase in nocturnal RR and decrease in HRV, in individuals who reported COVID-19 infection. These changes were noted 2 days before symptom onset in 20% of individuals and in 80% of the cohort after symptom onset [11]. Other studies have used HRV and RR measured by wearable devices to prospectively and retrospectively predict and identify COVID-19 infection (confirmed by positive testing) [12-14]. Therefore, we postulated that it would be possible to track an array of physiologic responses following COVID-19 vaccination. This wearable remote monitoring strategy could serve as a proof of concept and guide design of future studies of the physiologic and immune responses to vaccines.

**Methods**

**Study Population**

Internal medicine residents at Penn State Hershey Medical Center previously enrolled in a clinical trial (NCT04304703) using the WHOOP Strap 3.0 to measure physiologic parameters were used for this analysis (Multimedia Appendix 1, Figure 1) [15].

**Figure 1.** A total of 19 participants, 53% female, who were vaccinated with two doses of the Pfizer-BioNTech COVID-19 vaccine (mean time between doses 19.6, SD 2.8 days), transmitted continuous physiologic data via the WHOOP device. Changes from baseline were observed in HRV and were most pronounced on day 1 and 2 for dose 1 and only day 1 for dose 2. RR and RHR were unaffected following vaccination. Sleep duration initially decreased on day 1 post vaccine dose 1 and dose 2, with a compensatory increase from days 2 to 4, prior to return to baseline. Sleep deprivation was associated with a blunted HRV response, and premedication was associated with less change in RR and increases in REM and deep sleep percentages. HRV: heart rate variability; REM: rapid eye movement; RHR: resting heart rate; RR: respiratory rate.
Study Design
The primary objective of this prospective observational study was to determine the physiologic changes following the first and second doses of the Pfizer-BioNTech COVID-19 vaccine. Primary outcomes were percent change from baseline in HRV, RR, and RHR for days 1 to 6 following each vaccine dose. Secondary outcomes were percent change from baseline duration of total, rapid eye movement (REM), and deep sleep. Exploratory outcomes included analysis of local and systemic reactogenicity (type and duration) associated with vaccination and prophylactic analgesic use.

Study Procedures
Internal medicine residents were given a WHOOP Strap 3.0 to wear to measure physiologic parameters and sleep [15] (for full details, see Multimedia Appendix 2 [9,16-19]). Eligible participants were surveyed to disclose their vaccination dates for the novel Pfizer-BioNTech COVID-19 vaccine along with local and systemic reactogenicity and analgesic use following each vaccine dose.

Inclusion criteria for this analysis were patients concurrently enrolled in a clinical trial (NCT04304703) using the WHOOP device and who transmitted at least 80% of physiologic data during the study period including at least 24 of 45 days prior to dose one (to establish baseline metrics) and all data for the 6 days following vaccine dose one, dose two, or both. These data cutoffs were chosen based on published data using the WHOOP device for establishing a change from baseline in RR [11]. Local and systemic reactogenicity was graded as mild, moderate, or severe based on guidelines from the Centers for Disease Control and Prevention [1,20]. Patients were excluded if they did not or were unable to disclose the dates of vaccination (Multimedia Appendix 3). Data were blinded to study investigators for analysis. Recorded demographics included age, gender, comorbidities, and year of residency training.

Data collection was approved by the Institutional Board Review at Penn State Hershey Medical Center (STUDY14522). Statistical Analysis
We defined a significant change from baseline to be greater than 5% a priori. This cutoff was set based on recent findings in two studies: (1) changes in RR and other physiologic parameters in COVID-19–positive individuals, which were used to develop a predictive algorithm for COVID-19 infection risk stratification [11], and (2) precision measurements of heart rate, RR, HRV, and REM sleep stage duration using the WHOOP device were found to have less than 10% error [9].

The percent change of each metric for each participant in the data set was averaged together for the overall percent change of that metric for each day (d; equation 1). In equation 1, \( b_n \) is given as the average of the metric from the baseline period for participant \( n \), and \( x_n \) is the value of the metric on the day (d) being calculated post vaccine dose.

\[
\text{percent change} = \left( \frac{x_n - b_n}{b_n} \right) \times 100
\]

To determine the effect of sleep for the week leading up to the vaccine on the physiological effects of the vaccine, we computed Pearson correlations between hours of sleep in the 7 days prior to vaccine dose 1 and the percent changes of the physiological measurements post vaccine dose 1 [21].

Symptoms were aggregated and the density of the self-reported duration of symptoms was calculated [22]. Postvaccination reaction severity was compared to changes in physiologic parameters by Pearson correlations.

Results
Baseline Characteristics
A total of 19 participants met inclusion and exclusion criteria for this analysis; 18 individuals for dose 1 and 13 for dose 2 (Multimedia Appendix 3). Participants were 53% (n=10) female, with an age range of 26 to 35 years and a mean and median age of 28.8 (SD 2.2) and 29 years, respectively. No comorbidities were reported in 74% (n=14) of participants (Multimedia Appendix 1).

Baseline metrics were collected for all participants up to 45 days prior to vaccination dose 1 (Table 1). Mean baselines were as follows: RHR 63.09 (SD 6.36) bpm, HRV 52.09 (SD 21.58) ms, and RR 16.27 (SD 1.23) respirations per minute (rpm). Although interindividual variability in metrics had a wider range, intraindividual variability was much lower, most notably in nocturnal RR, with an intraindividual SD of mean 0.37 (SD 0.12) rpm.

Table 1. Baseline physiological and sleep metrics intraindividual mean and SD.

<table>
<thead>
<tr>
<th>Metric</th>
<th>Intraindividual mean, mean (SD)</th>
<th>Intraindividual SD, mean (SD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Heart rate variability (ms)</td>
<td>52.09 (21.58)</td>
<td>13.16 (6.94)</td>
</tr>
<tr>
<td>Resting heart rate (bpm)</td>
<td>63.09 (6.36)</td>
<td>4.95 (1.50)</td>
</tr>
<tr>
<td>Respiratory rate (rpm)</td>
<td>16.27 (1.23)</td>
<td>0.37 (0.12)</td>
</tr>
<tr>
<td>Sleep (hours)</td>
<td>6.71 (0.58)</td>
<td>1.48 (0.39)</td>
</tr>
<tr>
<td>REM sleep (%)</td>
<td>21.99 (6.71)</td>
<td>6.49 (1.23)</td>
</tr>
<tr>
<td>Deep sleep (%)</td>
<td>19.10 (2.15)</td>
<td>3.81 (0.66)</td>
</tr>
</tbody>
</table>

\( \text{REM} \): rapid eye movement.
Physiologic Response to COVID-19 Vaccination by Dose

For dose 1 (n=18), there was a reduction in HRV on day 1 (mean percent change –13.44%, SD 13.62%). HRV returned to baseline by day 3 and remained at baseline thereafter (Figure 2A, blue; Table 2). There was no significant change in RHR and RR compared to baseline in the 6 days following vaccination (Figure 2B, C, blue; Table 2).

For dose 2 (n=13), HRV decreased on day 1 (mean percent change –9.25%, SD 22.69%) but quickly normalized to baseline by day 2 (Figure 2A, magenta; Table 3). Similar to dose 1, there was no significant change in RHR and RR in response to dose 2, with both metrics remaining at baseline from day 1 to day 6 (Table 3).

Figure 2. Percent change from baseline in (A) heart rate variability, (B) respiratory rate, and (C) resting heart rate, measured 6 days following COVID-19 vaccine dose 1 (blue) and 2 (magenta). Data is reported as mean (SD).
Table 2. Percent changes from baseline in physiological and sleep metrics for 6 days postvaccine dose 1 (n=18).

<table>
<thead>
<tr>
<th>Metrics</th>
<th>Day 1, mean percent change (SD)</th>
<th>Day 2, mean percent change (SD)</th>
<th>Day 3, mean percent change (SD)</th>
<th>Day 4, mean percent change (SD)</th>
<th>Day 5, mean percent change (SD)</th>
<th>Day 6, mean percent change (SD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Heart rate variability</td>
<td>–13.44 (13.62)</td>
<td>–2.74 (15.63)</td>
<td>2.19 (27.93)</td>
<td>–1.32 (30.39)</td>
<td>–4.35 (26.79)</td>
<td>–2.80 (27.46)</td>
</tr>
<tr>
<td>Resting heart rate</td>
<td>2.73 (5.50)</td>
<td>1.10 (6.93)</td>
<td>–2.23 (7.31)</td>
<td>0.72 (8.80)</td>
<td>0.26 (8.68)</td>
<td>2.02 (11.48)</td>
</tr>
<tr>
<td>Respiratory rate</td>
<td>0.16 (1.95)</td>
<td>1.34 (1.98)</td>
<td>–0.23 (2.70)</td>
<td>0.02 (3.81)</td>
<td>–1.73 (2.56)</td>
<td>–1.04 (2.29)</td>
</tr>
<tr>
<td>Hours of sleep</td>
<td>–8.41 (22.96)</td>
<td>5.00 (18.27)</td>
<td>9.41 (21.60)</td>
<td>7.74 (17.81)</td>
<td>3.21 (24.38)</td>
<td>3.21 (27.54)</td>
</tr>
<tr>
<td>Percent of REM* sleep</td>
<td>–4.94 (37.65)</td>
<td>–6.53 (30.06)</td>
<td>–5.13 (33.34)</td>
<td>–6.70 (19.62)</td>
<td>–2.70 (31.10)</td>
<td>–16.98 (29.41)</td>
</tr>
<tr>
<td>Percent of deep sleep</td>
<td>9.64 (26.30)</td>
<td>3.08 (23.00)</td>
<td>4.11 (12.66)</td>
<td>4.58 (15.28)</td>
<td>–6.05 (19.58)</td>
<td>–2.38 (17.53)</td>
</tr>
</tbody>
</table>

*REM: rapid eye movement.

Table 3. Percent changes from baseline in physiological and sleep metrics for 6 days postvaccine dose 2 (n=13).

<table>
<thead>
<tr>
<th>Metrics</th>
<th>Day 1, mean percent change (SD)</th>
<th>Day 2, mean percent change (SD)</th>
<th>Day 3, mean percent change (SD)</th>
<th>Day 4, mean percent change (SD)</th>
<th>Day 5, mean percent change (SD)</th>
<th>Day 6, mean percent change (SD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Heart rate variability</td>
<td>–9.25 (22.69)</td>
<td>7.48 (32.44)</td>
<td>–1.30 (19.44)</td>
<td>–5.56 (13.70)</td>
<td>–7.76 (13.12)</td>
<td>2.19 (30.22)</td>
</tr>
<tr>
<td>Resting heart rate</td>
<td>4.20 (9.42)</td>
<td>0.82 (8.27)</td>
<td>–0.15 (5.15)</td>
<td>1.37 (6.17)</td>
<td>4.63 (10.38)</td>
<td>1.70 (12.83)</td>
</tr>
<tr>
<td>Respiratory rate</td>
<td>0.19 (4.10)</td>
<td>1.07 (6.44)</td>
<td>–0.26 (4.00)</td>
<td>0.15 (3.22)</td>
<td>–0.54 (3.63)</td>
<td>0.13 (3.06)</td>
</tr>
<tr>
<td>Hours of sleep</td>
<td>–2.10 (26.18)</td>
<td>5.33 (17.71)</td>
<td>6.06 (23.84)</td>
<td>9.22 (28.37)</td>
<td>–4.58 (20.45)</td>
<td>0.49 (12.30)</td>
</tr>
<tr>
<td>Percent of REM* sleep</td>
<td>13.79 (45.88)</td>
<td>–8.73 (39.57)</td>
<td>12.67 (36.41)</td>
<td>0.64 (37.99)</td>
<td>6.12 (32.02)</td>
<td>–8.35 (43.06)</td>
</tr>
<tr>
<td>Percent of deep sleep</td>
<td>4.00 (25.02)</td>
<td>–1.70 (19.21)</td>
<td>3.56 (20.31)</td>
<td>–6.01 (22.09)</td>
<td>3.42 (21.31)</td>
<td>–11.37 (24.40)</td>
</tr>
</tbody>
</table>

*REM: rapid eye movement.

Postvaccination Changes in Sleep

Total sleep duration, REM, and deep sleep duration (in hours) were measured for all participants for 6 days following vaccine administration. Total sleep duration followed a similar overall pattern for both vaccine doses: an initial decrease was observed on day 1 (dose 1: mean –8.41%, SD 22.96%; dose 2: mean –2.1%, SD 26.8%) followed by an increase above baseline on days 2, 3, and 4, with subsequent return to baseline on days 5 to 6 (Figure 3A; Tables 2 and 3). The change in sleep duration peaked on day 3 following dose 1 and day 4 following dose 2. Total sleep duration was proportional to time in bed and thus showed similar trends in response to vaccine dose 1 and dose 2.

Patterns of change in REM and deep sleep did not follow the same pattern as total sleep duration but showed greater variability overall (Figure 3B, C; Tables 2 and 3). Total sleep cycles and sleep disturbances had no correlation with changes in physiologic metrics following either vaccine dose.
Figure 3. Percent change from baseline in (A) total sleep duration, (B) REM sleep duration, and (C) deep sleep duration, measured 6 days following COVID-19 vaccine dose 1 (blue) and 2 (magenta). Data is reported as mean (SD). REM: rapid eye movement.

Sleep Impact on HRV Changes
Sleep duration was evaluated 7 days preceding vaccine administration to establish an individualized baseline. During the baseline assessment period, participants slept, on average, 6 hours and 43 (SD 35) minutes per night, of which 21.99% (1 hour and 28 minutes) was REM sleep and 19.1% (1 hour and 17 minutes) was deep sleep. A greater amount of sleep in the 7 days prior to receiving the first dose of the vaccine was moderately correlated with a higher percent change in HRV the 2 days following vaccine dose 1 (Pearson R=0.570 day 1; R=0.494 day 2).

Postvaccination Symptoms
An array of local and systemic reactions to vaccination were reported by participants, ranging from arm soreness to fatigue and body aches. A greater frequency and duration of symptoms were reported following dose 2 (Figure 4A, B). Arm soreness was reported in more than 60% of participants for both doses. The majority of symptoms subsided by hour 60 post vaccination (Figure 4A). The mean symptom duration following dose 1 was 49.7 (SD 49.2) hours, which decreased to 34.1 (SD 13.3) hours for dose 2. The most frequent symptom duration after dose 1 and dose 2 was 24 hours. Overall, postvaccination reactogenicity would be classified as mild to moderate, as no severe adverse reactions such as angioedema or other allergic reactions requiring urgent treatment were reported [1,20]. Presence of postvaccination reactogenicity did not show a strong correlation with changes in sleep or other physiologic parameters.
Analgesic Effects on HRV, Sleep, and Postvaccination Symptoms

None of the 19 participants premedicated with analgesic medications (ibuprofen or acetaminophen) prior to dose 1; however, 7 of the 13 (54%) participants premedicated prior to dose 2 (Multimedia Appendices 4 and 5). Overall changes in HRV were the same in both groups (premedication vs no premedication; Multimedia Appendix 5). Those who did not premedicate had a greater response (increase) in RR on day 1 and day 2, but overall RR was unaffected when both groups were analyzed together (Multimedia Appendix 4). RHR had a slightly greater increase on day 1 for those who did premedicate (Multimedia Appendix 4). The group that premedicated had both a greater initial decrease and compensatory increase in total sleep duration (Multimedia Appendix 5). This group also had higher percentage of REM and deep sleep in the days after receiving dose 2, which were most prominent on day 1 (Multimedia Appendix 5).

The duration of all reported symptoms between the groups were similar: participants without medication experienced symptoms for a mean of 30.0 (SD 13.4) hours, and participants who self-medicated prior to dose 2 experienced symptoms for 37.7 (SD 10.0) hours. There was no significant difference in symptom severity among the two groups [1,20].

Discussion

Principal Findings

In this small observational study in a relatively young and healthy cohort of participants, we provide evidence that consumer-grade wearable devices can be used to measure physiologic response to COVID-19 vaccination (Figure 1). HRV change from baseline was the most prominent signal in our
study population, while RHR and RR were unaffected (Figure 2).

Decreases in HRV, a surrogate of autonomic tone, have been shown to predict negative clinical outcomes following severe infections [23-25]. HRV decreases have also been correlated with an increased C-reactive protein (CRP) within the first 2 days following administration of the influenza A vaccine [26]. Lower magnitude CRP elevations have been associated with increased risk of infection, suggesting that greater HRV decreases and CRP increases would equate to a protective inflammatory or immunologic response [26,27]. Thus, we propose that a higher percent change in HRV may equate to a more robust immune response to COVID-19 vaccination [14,26,28-30]. The directionality of HRV change (decrease) is significant, as this is suggestive of increased parasympathetic tone due to generation of an immune response to the vaccine [14,28]. Further investigation of HRV response to vaccination could provide a useful surrogate marker for immune system activation (Figure 5) [31]. This could be accomplished in a randomized controlled trial (RCT) of vaccination versus placebo with wearable tracking of HRV in comparison to CRP levels, antibody titers, and protection against infection.

There was relatively no change in both RR and RHR in response to vaccination (Figure 2B, C). This is of particular interest given that spikes in RR are clinically relevant in prediction of COVID-19 infection and progression of disease [1,11-13]. Although we did not directly collect data on oxygen saturation or hypoxia, it is likely that changes in RR are specific to COVID-19 infection, which has a predilection for pulmonary pathology. Thus, this change would not be expected with vaccination as, unlike natural disease, it does not impact pulmonary function.

Interestingly, there was a moderate correlation between change in HRV and amount of sleep prior to vaccination (greater sleep was associated with a greater decrease in HRV). Sleep deprivation is known to have a significant impact on viral susceptibility and blunted adaptive immune response in the presence of viral vaccines [32-38]. Decreased antibody titers and overall immune response have been observed in vaccinated participants that are sleep deprived, most notably in response to the influenza and hepatitis A vaccine [34-39]. A recent study of 2884 health care workers showed that 1-hour longer sleep duration was associated with 12% lower odds of COVID-19 infection [40]. Our data demonstrate that sleep duration impacts physiologic response to COVID-19 vaccination and, if correlated with immune response in further studies, could be leveraged to potentiate the effectiveness of vaccination in general.

Limitations and Future Studies
This is a small observational study in a specific cohort of participants with no control arm. A larger powered study is needed for formal statistical analysis of physiologic changes and to control for baseline demographics. The lack of a control group institutes bias; an RCT with a placebo arm (no vaccine) would allow for comparison of physiologic metrics to a control group. However, our use of percent change from baseline in our outcomes would help overcome intrindividual variability confounding of results (ie, individuals may have a greater magnitude change in parameters simply because they have a higher baseline, which is accounted for by using percent change.
from established baseline). Last, this population is known to have a greater degree of sleep deprivation secondary to duty hours and clinical demands, which may be a confounder and reduce the generalizability of the results [41].

Incorporation of biomarkers such as CRP is needed to corroborate association with physiologic changes (Figure 5) as previously observed in other vaccine studies [26,29,42,43]. Despite only exploring the response to the Pfizer-BioNTech COVID-19 vaccine, this study further confirms the feasibility of using wearable remote physiologic data to monitor responses to vaccines. This simple method to track vaccine responses would be useful for future novel vaccines. The key will be to determine how well remotely monitored physiologic metrics can predict inflammatory response, vaccination antibody titers, and ultimately protection from infection. This may provide a noninvasive method for individualized prediction of vaccine efficacy.

**Conclusion**

Wearable devices are now widely available to everyday consumers, and as technology has advanced, they are being more widely used to capture medical data [7,8,12,13,44]. This study is a proof of concept for this remote monitoring strategy to capture physiologic response to COVID-19 vaccines. If correlated with immune response and vaccine efficacy in future studies, this approach could be leveraged in the general population to predict response to vaccines. Our data also raises the possibility that increased sleep prior to vaccination may impact physiologic responses. This warrants further study and is a potentially modifiable factor to optimize vaccine response.

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**Acknowledgments**

This study was supported by the 2020-2021 Penn State Hershey Department of Medicine House Staff Award granted to AGH and the 2020 Penn State Hershey Health Systems Science Innovation Grant awarded to AGH.

**Authors’ Contributions**

AGH and KMD contributed equally to this study. AGH, KMD, and BB designed the research study and refined the data collection plan; BB analyzed the data with input from AGH and KMD; AGH, KMD, and BB wrote the manuscript; AKT, JBM, SB, SAM, JJC, CIP, and AT edited the manuscript.

**Conflicts of Interest**

CIP is a consultant for Axle Informatics for work not related to this manuscript. CIP is also the site PI for the Adaptive COVID-19 Treatment Trial (ACTT) and the ACTIV-5 / Big Effect Trial (BET-B) for the Treatment of COVID-19 which receive funding from the National Institutes of Health. This work is not related to the submitted manuscript.

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**Multimedia Appendix 1**

Baseline characteristics of study participants.
[DOCX File, 13 KB - formative_v5i8e28568_app1.docx]

**Multimedia Appendix 2**

Description of physiologic metrics.
[DOCX File, 112 KB - formative_v5i8e28568_app2.docx]

**Multimedia Appendix 3**

Study flowchart. A total of 38 participants were initially enrolled in the study; 33 were screened for inclusion and exclusion criteria, yielding 19 participants that were included for final analysis (18 participants for dose 1 and 13 participants for dose 2).
[PNG File, 102 KB - formative_v5i8e28568_app3.png]

**Multimedia Appendix 4**

Premedication subgroup analysis. Percent change from baseline in (A) heart rate variability, (B) respiratory rate, and (C) resting heart rate, measured 6 days following COVID-19 vaccine dose 2 is reported for participants who premedicated prior to vaccination (purple) and participants who did not premedicate (green). Data is reported as mean (SD).
[PNG File, 133 KB - formative_v5i8e28568_app4.png]

**Multimedia Appendix 5**

Premedication subgroup analysis. Percent change from baseline in (A) total sleep duration, (B) rapid eye movement sleep duration, and (C) deep sleep duration, measured 6 days following COVID-19 vaccine dose 2 is reported for participants who premedicated prior to vaccination (purple) and participants who did not premedicate (green). Data is reported as mean and SD.
[PNG File, 133 KB - formative_v5i8e28568_app5.png]
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Early Report

Electronic Paper Displays in Hospital Operations: Proposal for Deployment and Implementation

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Abstract

Background: Display signage is ubiquitous and essential in hospitals to serve several clerical, operational, and clinical functions, including displaying notices, providing directions, and presenting clinical information. These functions improve efficiency and patient engagement, reduce errors, and enhance the continuity of care. Over time, signage has evolved from analog approaches such as whiteboards and handwritten notices to digital displays such as liquid crystal displays, light emitting diodes, and, now, electronic ink displays. Electronic ink displays are paper-like displays that are not backlit and show content by aligning microencapsulated color beads in response to an applied electric current. Power is only required to generate content and not to retain it. These displays are very readable, with low eye strain; minimize the emission of blue light; require minimal power; and can be driven by several data sources, ranging from virtual servers to electronic health record systems. These attributes make adapting electronic ink displays to hospitals an ideal use case.

Objective: In this paper, we aimed to outline the use of signage and displays in hospitals with a focus on electronic ink displays. We aimed to assess the advantages and limitations of using these displays in hospitals and outline the various public-facing and patient-facing applications of electronic ink displays. Finally, we aimed to discuss the technological considerations and an implementation framework that must be followed when adopting and deploying electronic ink displays.

Methods: The public-facing applications of electronic ink displays include signage and way-finders, timetables for shared workspaces, and noticeboards and bulletin boards. The clinical display applications may be smaller form factors such as door signs or bedside cards. The larger, ≥40-inch form factors may be used within patient rooms or at clinical command centers as a digital whiteboard to display general information, patient and clinician information, and care plans. In all these applications, such displays could replace analog whiteboards, noticeboards, and even other digital screens.

Results: We are conducting pilot research projects to delineate best use cases and practices in adopting electronic ink displays in clinical settings. This will entail liaising with key stakeholders, gathering objective logistical and feasibility data, and, ultimately, quantifying and describing the effect on clinical care and patient satisfaction.
Conclusions: There are several use cases in a clinical setting that may lend themselves perfectly to electronic ink display use. The main considerations to be studied in this adoption are network connectivity, content management, privacy and security robustness, and detailed comparison with existing modalities. Electronic ink displays offer a superior opportunity to future-proof existing practices. There is a need for theoretical considerations and real-world testing to determine if the advantages outweigh the limitations of electronic ink displays.

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KEYWORDS

electronic ink; patient satisfaction; display systems; whiteboards; hospital; deployment; proposal; implementation; communication; engagement; efficiency; usage

Introduction

Background on Hospital-Based Signage

Display signage is ubiquitous in hospitals and is important for daily hospital operations and clinical care [1]. Signage serves a range of clerical, operational, and clinical functions, including waypoint finding; displaying directions, notices, and bulletins; and presenting and organizing clinical schedules. The use of signs in clinical care became standard practice after a 2001 report by the Institute of Medicine emphasized patient-centered care [2]. Clinicians demonstrated that whiteboards increased patient engagement, thereby increasing satisfaction, mitigating common medical errors, and enhancing continuity of care [3-5].

Over the past decade, plasma and liquid crystal display (LCD) televisions have replaced analog surfaces to convey information. These dynamic digital alternatives enable both public-facing and clinical display systems to refresh and display data longitudinally or continuously. Public-facing displays serve general needs, including providing directions and maps, bulletins, notices, and general information. These may require intermittent or continuous changes, depending on the purpose they serve. Displays serving as bulletin boards may require the ability to display multiple messages, either requiring significant space when presented as analog or requiring continuous refreshes when digitally presented. Clinical display systems present individualized patient data to clinicians or patients. These require more ad hoc changes when analog, creating a risk of inaccurate information due to lapses in manual updates. Alternatively, digital clinical displays lend themselves to a more automated approach through electronic health record (EHR) linkage. As the cost of digitizing display systems has decreased, there is renewed interest in replacing physical signage in hospital systems with a host of digital display options.

Electronic display screens have garnered attention as an effective alternative to traditional paper or printed signage. With increasing network integration, LCD and light emitting diode (LED) screens have demonstrated value despite their cost [6]. As part of a data network (ie, “internet of things”), electronic display screens are more autonomous, allowing hospitals to provide accurate real-time information without much, if any, human manipulation. Electronic display screens can be remotely updated from a central hub, reducing the time and manpower needed for maintenance. They may be more environmentally sustainable by reducing paper and chemical waste [6]. There has already been traction in adopting electronic displays for public-facing information such as hospital waypoint finding, announcements, event postings, public health messaging, and cafeteria menus. These screens also have the potential to replace standard dry-erase boards as an individualized clinical display, standardizing information that patients receive daily or, in some settings such as the clinic or emergency department, multiple times each day. Each hospital will face its own unique challenges regarding the cost of physical devices, energy use concerns, integration difficulties, and privacy concerns for displays of patient information. This can make adoption of patient-facing electronic displays difficult [7].

One potential alternative to traditional signage is the use of electronic ink displays. Electronic ink is made of microcapsules of black pigments and white pigments suspended in a clear fluid. When a positive or negative electric field is applied, corresponding particles move to the top of the microcapsule where they become visible to the viewer. These systems are low power, easy to read, and can be manufactured at scale. Commercially used in eReaders and store placards and, thus, already known to many consumers, the adoption of electronic ink displays may serve as a viable platform to deliver information in the hospital setting. In this paper, we described the use of electronic ink, a low-power, high-resolution display screen that can be adapted to multiple hospital uses. We presented several use cases for electronic ink displays and described an implementation schema for hospital systems seeking to explore the use of these displays both for public and clinical functions.

Electronic Ink

A formative development of paper-like electrophoretic surfaces was initiated at Xerox Palo Alto Research Center in 1974, under the pseudonym “Gyricon” [8,9]. A thin layer of transparent plastics with millions of small charged beads, akin to the dry powdery substances found in toner, rotates to present one colored side to the viewer when voltage is applied (Figure 1). The image, once set, does not change shape until new voltage patterns are applied.
In the mid-1990s, a professor at the Massachusetts Institute of Technology Media Lab tasked 2 of his students to take the early work of Gyricon and create a variant of electrophoretic ink that would allow for more precise image rendering and the ability to scale up to mass production. That project was commercialized in 1997 as E Ink [8]. Unlike Gyricon’s bichromal electrophoretic inks, E Ink instead uses microcapsules containing black and white pigments suspended in a clear fluid. These microcapsules are 50 microns in size and impart a more precise method of manipulating ink particles to create high-resolution, crisp displays. A core benefit of all electrophoretic inks is that they only need power to change an image, not to maintain it. This results in low-power displays in comparison with standard LCD panels (ie, 25-50 mW vs 100-200 mW for 1.5-2.5–inch displays) [10].

The end result is a readable, “paper-like” display that does not require backlighting and consumes significantly less power than typical LCD or LED screens. For the display of information that is static and does not require constant refreshes, electronic ink displays provide a potential alternative to more heavily powered LCD screens. This enables electronic ink technology to be used in places where a power source may not be available or constant backlighting is not required. Advances in both flexible screens and coloration enabled paper-like electronic ink screens to be applied to a variety of consumer-facing signage such as grocery store signs, advertisements, and identification badges [11,12].

Advantages of Electronic Ink Displays

There are several advantages to electronic ink displays compared with conventional LED or LCD screens. Because of the paper-like quality of electronic ink displays, they simulate analog paper surfaces and do not require backlighting, unlike conventional screens. This may make reading electronic ink displays easier by eliminating glare. Given the lack of backlighting, electronic ink displays emit no heat, decreasing the need for cooling systems or vents; this is a distinct advantage for display screens that are integrated into wall alcoves. Electronic ink displays are also lightweight and robust. Because they lack a liquid polymer or crystal layer and light source, the thickness and weight of electronic ink displays are markedly reduced. These features render them convenient to carry, transport, and install, and they are generally less susceptible to damage when dropped. This also allows electronic ink displays to be placed in locations where the weight and structural requirements of LCD panels may have been prohibitive.

Once the electronic ink has been set with the use of charges, it remains static until a refresh is triggered. This enables electronic ink displays to minimize power consumption, compared with other screen types [10]. Displays can, therefore, be powered over long periods of time using minimal power, even with conventional direct current batteries rather than requiring alternating-current wall plugs. Given the minimal power required to refresh a screen or display new information, electronic ink displays can be powered using power over ethernet. This allows for data to flow to the electronic ink display from a central controller while eliminating the need to use additional power infrastructures in existing hospital spaces. The end result for hospital groups is that, depending on the application, electronic ink displays may require less infrastructure support (eg, power over ethernet instead of requiring new electrical outlets), consume less energy, and emit little to no heat. These advantages may result in significant cost savings over the course of the device’s lifetime. Finally, each electronic ink display can be loaded with an integrated operating system. This provides flexibility to the platform and can eliminate the need to mirror the display of a tethered computer. By operating as standalone devices, electronic ink screens can be installed in a variety of locations and operational settings.

Disadvantages of Electronic Ink Displays

There are several important limitations of electronic ink screens to consider before implementation in a clinical setting. First, due to a lower screen refresh rate compared with LED or LCD screens, electronic ink displays are not ideal for displaying video, animations, or rapidly changing information. Because of a set number of ink pigments suspended in electronic ink, colors are also limited, compared with the wide palette of colors available in LCD and LED displays. However, recent advances in microencapsulation have enabled combinations of colors
with white pigment to enable color electronic ink displays. With continued development, future iterations of these systems may produce different colors that advance the available color palette for electronic ink displays, such as the four-pigment system, Advanced Color ePaper, that is in development at E Ink [13].

### Methods

#### Potential Applications in Hospital Operations

Numerous potential applications for electronic ink displays exist in a hospital setting. We classify applications into 2 categories: public-facing displays and clinical display systems (Table 1).

<table>
<thead>
<tr>
<th>Criteria</th>
<th>Type of display</th>
<th>Clinical displays</th>
</tr>
</thead>
<tbody>
<tr>
<td>Potential applications</td>
<td>Public-facing displays</td>
<td>Clinical displays</td>
</tr>
<tr>
<td>• Door signs and bedside cards</td>
<td>Notices and bulletins for employees, patients, and caregivers</td>
<td></td>
</tr>
<tr>
<td>• Way-finders and maps</td>
<td>Way-finders and maps</td>
<td></td>
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<tr>
<td>• Location tags and placards</td>
<td>Location tags and placards</td>
<td></td>
</tr>
<tr>
<td>• Guidelines and regulations</td>
<td>Guidelines and regulations</td>
<td></td>
</tr>
<tr>
<td>• Public education and awareness messages</td>
<td>Public education and awareness messages</td>
<td></td>
</tr>
</tbody>
</table>

### Public-Facing Applications

Signage can be used to provide wayfinding and information to visitors in the hospital setting. Hospital settings are often complex and growing and can encompass several buildings built in different eras, creating wayfinding challenges. Easy-to-follow signage and legible directions are key to reducing stress and improving satisfaction for patients when navigating these campuses. Shared clinical spaces, offices, and conference rooms may be used for different purposes at different times and require frequent updates to avoid confusion. Electronic ink displays offer the opportunity to replace some of these screens, providing easily understandable signage that can be updated from a central location on demand.

Portable, lightweight electronic ink displays can also be used instead of noticeboards. Often pinboards and television screens are used to display bulletins and general information to visitors. If linked to a centralized location on the local network, updating electronic ink displays require less manual work than these traditional signage methods. They are potentially lower in total ownership cost and more energy efficient than LED and LCD screens for this purpose, and installation may be easier, especially, for locations that do not require intensive refreshing of screens. Since they are able to be attached to mobile carts, they are more portable, making it less challenging to transport them across different indoor or outdoor locations around the hospital. During the COVID-19 pandemic, signage has been used to provide reminders to hospital staff and visitors of important public health measures such as social distancing, hand hygiene, and mask wearing. The rapid pace at which guidelines continue to change around public health measures, testing requirements, and other COVID-19–related interventions suggests that the use of electronic ink displays could be an effective, low-energy method to provide up-to-date information to hospital visitors.

### Patient-Facing Applications

Electronic ink also has utility for clinical displays. In their simplest form, electronic ink displays can be used as a door sign or bedside card, available in several sizes and resolutions (Figure 2). They are easily installed with standard wall anchors, or they can be hung on a hospital bed; they are powered for several months with AA, AAA, or rechargeable batteries. These small electronic ink displays can contain information about patients, including their location or next steps in their plan (eg, travel to radiology department for an x-ray or a cardiac stress test). When integrated with radiofrequency identification or low-energy Bluetooth beacons, electronic ink displays can also function as a wayfinding application. These applications may improve efficiency, help provide on-demand data about a patient’s itinerary, and relocate on-demand changes in scheduling or clinical information to the bedside. Digital door signs and bedside cards can be programmed to display as little or as much information as desired and can also be used to display patient safety elements such as precautions, allergies, and alerts.
Dry-erase boards have been used in the hospital to orient patients to the date, provide information regarding their care team members, and even communicate pain scores [14-16]. In addition, paper and laminated signs have been used outside of patient rooms to convey information regarding isolation status, fall risk, and need for personal protective equipment [4]. In some instances, hospitals display daily plans to inpatients and their families, and, for acutely ill patients in the emergency department, whiteboards can be used by the teams to coordinate care. A significant drawback to the use of paper or traditional whiteboards is the need to manually and consistently update them at set intervals. In busy hospital settings, this can result in outdated or inaccurate information, creating new safety risks that the tool was originally intended to mitigate. As an alternative to either a whiteboard or a backlit screen such as a television screen, electronic ink screens can be used to display patient information (Figure 3). Since electronic ink screens do not emit light, they are less distracting to patients who are trying to sleep or rest during their stay. This may be instrumental in preventing delirium caused by persistent light stimuli from LCD screens. By providing an indirect stimulus concerning the course of their clinical care, it is possible that electronic ink displays can help provide orientation to patients with prolonged stays in the hospital, thereby addressing disorientation and delirium [17,18]. Patients are becoming increasingly more comfortable with the use of technology to enhance their care. In a 2012 survey study of an urban emergency department, approximately 90% of patients preferred technology-based behavioral interventions [19]. Communication boards can be configured to display data customized for each unique clinical environment. Basic functions include displaying information to orient patients, such as date, time, and names and roles of the current clinical team. Information on diagnostic tests and imaging, as well as final disposition, may help guide patients and their families to understand their clinical course and anticipate potential events that may happen in the hospital. For patient-facing screens, additional functionality may include displaying local weather, transit schedules, cafeteria menus, and important hospital notices, thereby providing on-demand information to patients and their families. Strong communication and efficient information delivery have been associated with improved patient satisfaction, which may, ultimately, influence hospital choice and improve quality of care [20,21].

The success of electronic ink displays in hospitals is contingent on their integration with existing information systems. Legislative and regulatory changes have promoted significant advances in interoperability. These advances have created standard methods for connecting applications to exposed application programing interfaces (APIs) in EHRs, allowing for seamless data exchange. Using this exchange, electronic ink devices may be configured to display real-time information directly from EHRs. Additional discussion on protocols to directly exchange information can be found under the subheading “Technological Considerations” in the Discussion section of this paper.
Results

We are planning several pilot studies to evaluate the use of electronic ink screens in various hospital settings. We hope to use these pilot studies to help delineate the best practices and use cases for electronic ink screens in clinical care and hospital operations. These pilot studies will also help develop the information security infrastructure and support needed to manage multiple electronic ink screens at the same time. This programming architecture also permits custom displays of different data on various screens. At this time, electronic ink displays are deployed in our emergency department to display information about a patient’s emergency stay, and we are investigating their effect on patient satisfaction. Other use cases will include wayfinding through smaller display screens affixed to hospital beds, two-way asynchronous communication between patients and clinicians through the electronic ink screens, and patient identification in the operating room.

Discussion

Technological Considerations

Connectivity

Ensuring secure and reliable network connectivity is an important consideration in electronic ink display deployments. Electronic ink displays can be deployed in several different manners. The simplest manner is with limited network connectivity, requiring manual entry of information to be displayed. One way to deploy this is to create a virtual environment—a server-based command control for network displays—on the hospital network, which is directly connected to the display. Eventually, the most sustainable and future-proof method will be to connect these displays to data sources that are configured to update specified information such as EHRs automatically and as close to real time as possible. This would add the most value to the efficiency and accuracy of clinical displays inside and outside patient rooms.

Deploying a large number of electronic ink displays in a hospital environment has different considerations compared with the implementation of LCD display screens. Unlike LCD screens that require a persistent internet connection to display information, electronic ink screens only require data connection to change the information displays. Depending on the intended information, electronic ink screens may, therefore, require less internet bandwidth compared with LCD screens. The nature of the intermittent data of electronic ink displays may also pose less of a network security risk, as there is no maintained continuous internet connection; instead, the central architecture pings each electronic ink display only when new data are displayed. Until network infrastructure can handle the traffic, the use of dedicated networks in the form of virtual machines may help ensure efficient display performance and also minimize the chance of unintended disruptions to the primary hospital network.
Privacy and Security

When considering the use of electronic ink displays, hospital systems should understand the potential privacy and security risks. Privacy breaches can occur when unencrypted data that contain protected health information (PHI) are intercepted or when the incorrect data are transmitted to an electronic ink display. For example, manual updates of electronic ink displays in patient rooms could inadvertently expose other individuals in the room to PHI, or, if a patient’s information is displayed to the incorrect screen, this could result in a privacy violation. Patient privacy is a prime concern when PHI is transmitted to displays from EHRs. To protect against breaches in patient privacy, data transmission should avoid use of PHI or use the minimum PHI necessary for care delivery. PHI or other sensitive information that needs to be transmitted should use modern encryption protocols. Given that electronic ink displays are visible to anyone in the physical room, masking PHI on the screen could also be considered, such as displaying patient initials instead of full names.

Despite best practices, there remains the possibility that manually entered data in an electronic ink display could inadvertently be erroneous or expose PHI to another patient if an incorrect display is loaded by mistake. These errors are significantly mitigated through the use of automated checks and integrated rules in the electronic medical record that may prevent the display of data in inappropriate locations. Notwithstanding these technical mitigation strategies, we recommend additional physical mitigation, including a physical shut-off button to wipe the screen in case individuals find unauthorized information displayed on the screen.

Network security can be compromised when smart displays are used as an entry point to hospital networks or used as a distributed denial of service attack. Understanding these risks and creating strategies to effectively mitigate them are central to safely deploying these technologies in hospitals (Table 2).

Table 2. Privacy and security considerations for electronic ink displays.

<table>
<thead>
<tr>
<th>Potential concern</th>
<th>Potential solutions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Privacy and data breaches</td>
<td>● Communicate deidentified data where possible</td>
</tr>
<tr>
<td></td>
<td>● Suspend continuous network connection and data transfer when not required</td>
</tr>
<tr>
<td></td>
<td>● Enable electronic ink displays to communicate via independent networks to minimize integration with hospital networks unless necessary</td>
</tr>
<tr>
<td></td>
<td>● Limit network access by only delegating accounts that need access and following institutional password requirements</td>
</tr>
<tr>
<td></td>
<td>● Establish a log system to audit and document evidence of undesired activity</td>
</tr>
<tr>
<td></td>
<td>● Develop a risk-mitigation plan and an incident-response policy that may be implemented in case of emergency</td>
</tr>
<tr>
<td>Distributed denial of service attacks</td>
<td>● Establish a log system to audit and document evidence of undesired activity</td>
</tr>
<tr>
<td></td>
<td>● Displays placed on separate networks with intermittent limited access to hospital servers only as required</td>
</tr>
<tr>
<td></td>
<td>● Ensure server updates and vulnerabilities are addressed</td>
</tr>
<tr>
<td>Failure</td>
<td>● Staggered adoption with careful testing of failure rates</td>
</tr>
<tr>
<td></td>
<td>● Initial use in conjunction with existing standard practices</td>
</tr>
<tr>
<td></td>
<td>● Develop a risk-mitigation plan and an incident-response policy that may be implemented in case of emergency</td>
</tr>
</tbody>
</table>

Open firewall ports, used to deliver data to screens, may provide a portal to enter a hospital network and intercept critical health information or conduct malicious attacks against hospital infrastructure [22]. To alleviate these risks, smart display systems can be programmed to only connect to a hospital network for a brief period, during which refreshes are performed and data are transmitted. As is best practice, smart devices should be isolated from main hospital networks.

In order to transmit sensitive notifications containing protected health information, electronic ink displays should securely connect to encrypted wireless networks using Wi-Fi Protected Access 2 connection. Wi-Fi Protected Access-enterprise encryption systems, which require a user to enter a unique username and password to log into the network, provide an even higher layer of security necessary for networks that transmit confidential information. This way, even if a hacker learns the password of one device, they cannot compromise the entire system. Another option is to use two-factor authentication to validate the administrator who is accessing the configuration of the electronic ink screen. This additional layer of security may help mitigate bot-based hacking attempts.

Malicious users with control over smart devices could also conduct distributed denial of service attacks by sending rapid triggers from the devices, in an attempt to overwhelm the hospital network [23,24]. As noted previously, limiting continuity of network transmission should address this issue. Finally, good stewardship of smart devices is paramount to protecting security, such as limiting access only to highly trained staff and continually encouraging good practices.

Systems Integration

The success of electronic ink devices in the hospital relies heavily on the ability to effectively update the information displayed from a central location. For public-facing signage, this likely requires the establishment of a centralized dashboard for content management. Patient-facing displays, on the other hand, likely require integration of EHR for maximum efficiency.
Improvements in interoperability and a nationwide focus on providing patients access to their entire medical records have made it feasible to propose patient-facing applications that integrate EHRs directly. As a part of the Meaningful Use Act [25], hospitals were incentivized to provide access to health care information to patients. The more recent information-blocking provision of the 21st Century Cures Act [26] removed nearly all barriers to patients’ ability to access their hospital records. Electronic ink displays may act as a vehicle to provide on-demand access to pertinent patient information that could reduce barriers to accessing health records as well as assisting hospitals in satisfying the requirements of the Meaningful Use Act [27]. For example, emergency department patients can obtain their personal laboratory results or understand a status update from a consultant who has been asked to evaluate them.

Exchange of clinical information between electronic ink devices and EHRs should be built around widely accepted standards. Fast Healthcare Interoperability Resources [28] provides an open-source and widely accepted means for packaging and delivering clinical data. Although some form of health information exchange is required as a part of the Meaningful Use Act, each institution’s API may differ. The ideal systems integration uses the APIs health level 7 or Fast Healthcare Interoperability Resources, enabling and automating information exchange on electronic ink screens [29].

A Framework for Electronic Ink Display Deployment

For health care organizations that seek to deploy electronic ink displays, we recommend steps grounded in the plan-do-study-act (PDSA) method (Figure 4) [30]. The PDSA method is often used to accelerate quality improvement initiatives by rapidly testing changes through structured planning, implementation, observation, and iterative improvements based on pilot studies [30]. For successful deployment of a novel technology, it may be helpful to form a centralized committee of network specialists, hospital administration, and clinical experts who understand outcomes surrounding the use of electronic ink displays and information security, to ensure that all stakeholders required to successfully deploy an electronic ink display can assemble and map key tasks prior to implementation. Establishing a central data server that can query and modify displays in a secure manner will be critical to the success of pilot studies, particularly, for electronic ink displays, and should be developed prior to deployment of electronic ink displays in the clinical setting.

Figure 4. A proposed framework to deploy and evaluate the impact of electronic ink displays in a hospital setting.

As part of the “plan” phase, the first step in an electronic ink display implementation is to plan for the infrastructure components. Since the displays will require network connectivity, hospital information security officers should be engaged to perform a risk assessment of the technology and mitigate any high-priority risks identified. It is also important to limit the initial scope of work for any display during the process of deployment. This permits a gradual rollout of electronic ink displays and allows adequate space for implementation issues to be resolved by the study team. Several key stakeholders, including clinical and nonclinical staff, patients, and patient advocates, should discuss and finalize the data elements that make the most sense in a given scenario. Key discussion points should center around important identifying information that may be displayed on the screen.

As part of the “do” phase, the team should select limited, yet important, use cases that would benefit from a brief pilot run. Benchmarks for success of the pilot study and the duration of the study should be established in advance, to provide clear parameters and expectations around deployment. Despite selecting individual pilot studies, a central resource of information technology and device and programming expertise should help govern and manage electronic ink displays. This will ensure that there is continuity around different projects and
that data from projects remain unified in a central location. Additionally, this mechanism will allow for seamless transfer of operating systems and platforms to additional investigations planned by the study team.

As part of the “study” phase, the pilot study should be evaluated to assess feasibility, return on investment, and user experience of the electronic ink displays. Researchers may consider the use of validated measures such as the System Usability Scale or Net Promoter score to understand usability, acceptability, and satisfaction associated with implementation of the system [31-34]. In addition, hardware stability, power consumption and cost, data security and quality, and network load should be monitored during the pilot study.

As part of the “act” phase, lessons learned from the pilot study, including technical, workflow, and other components of the socio-technical model for health information technology, should be carefully reviewed [35]. Based on the pilot studies completed, a use case for widespread implementation should be developed. Messaging with and training of the staff who will operate and interact with electronic ink displays should occur prior to the date when the displays become activated. To prepare for larger rollouts, processes and protocols should be adjusted based on these lessons learned. A dedicated governance process team, including the project team, information technology staff, and institutional leaders, is essential for identifying the appropriateness of employing smart displays for any use case. It is also important to understand the reliability of the technology and the impact it has on technical infrastructures, so it can be safely used for its desired tasks.

Conclusions

Electronic ink displays may be a valuable tool to help optimize hospital operations and communications. They have a variety of use cases for both patients and staff. Key technical considerations for a successful deployment include an appropriate network connectivity, a robust content management process, and a careful configuration that minimizes privacy and security risks. The PDSA framework may guide hospitals, starting with a small pilot study and iteratively refining the process until eventually scaling to the entire organization. Electronic ink displays present a tremendous opportunity to future-proof existing analog processes while overcoming some of the disadvantages of commonly used digital modalities. The promise might outweigh the minor limitations, but there is still a need for testing in real-world health care environments to rigorously evaluate and determine the impacts of electronic ink displays.

Acknowledgments

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Conflicts of Interest

PRC has a financial interest in Biobot Analytics, a company engaged in the collection and analysis of wastewater to develop epidemiological data. PRC’s interests were reviewed and are managed by Brigham and Women’s Hospital and Mass General Brigham in accordance with their conflict of interest policies. ABL was previously a member of the Abbott Medical Device Cybersecurity Council. JS is an employee of E Ink Corporation.

References


Abbreviations

- **API**: application programing interface
- **EHR**: electronic health record
- **LCD**: liquid crystal display
- **LED**: light emitting diode
- **PDSA**: plan-do-study-act
- **PHI**: protected health information
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Abstract

Background: Smoking prevalence during and after pregnancy remains high among socioeconomically disadvantaged women. Mobile health (mHealth) apps with game and social support elements seem promising to support smoking cessation.

Objective: This study aims to describe the user-centered design and usability evaluation of Kindle, an mHealth app with game and social support elements, to support disadvantaged young women during and after pregnancy through the first stages of smoking cessation.

Methods: Disadvantaged women (n=9), members of their social networks (n=4), and nurses supporting these women (n=51) were informants throughout the iterative prototype development of Kindle according to the International Organization for Standardization 9241-11:2018. Specific phases included understanding the context of use through secondary analysis of qualitative interview data (phase 1), establishing the user and organizational requirements (phase 2), production of design solutions (phase 3), and usability inspection of the prototype through a heuristic evaluation (3 experts) along with user testing by a think aloud method (5 disadvantaged women and 5 nurses; phase 4). Usability problems were categorized according to the principles of the Healthcare Information and Management Systems Society.

Results: Phase 1 resulted in an understanding of the VoorZorg program and the needs of VoorZorg nurses and clients (eg, focus on early stages of change and building new supportive networks to aid clients in smoking cessation). In phase 2, we established requirements (n=22; eg, mHealth app, secure communication between nurses and clients, easy-to-use interfaces, inclusion of game elements, and tailoring at early stages of change in smoking cessation). Phase 3 resulted in a prototype of Kindle, combining the interface for nurses and clients, including the following functionalities: personal goal setting with earning points; secured chat function between nurses and other clients; and tips, diary, and profile creation. The heuristic evaluation and thinking aloud method in phase 4 revealed 78 usability problems in the interfaces. Most usability problems concerned simplicity (eg, unclear clickable button) and naturalness (eg, unclear icon).

Conclusions: The user-centered design and usability testing of the mHealth app Kindle yielded useful insights. The involvement of end users, specifically socioeconomically disadvantaged women during and after their pregnancy, resulted in a prototype that met their needs and requirements (eg, mHealth app, secure communication between nurses and clients, easy-to-use interfaces, inclusion of game elements, and tailoring to the early stages of change in smoking cessation) to achieve readiness for smoking cessation. Moreover, the usability evaluation by end users and experts revealed unique usability problems for this population. These insights allow for further optimization of Kindle and encourage future studies to engage disadvantaged populations in all phases of mHealth intervention design and usability testing.
think aloud; heuristic evaluation; usability; mHealth; game elements; smoking prevention; user-centered design; mobile phone

Introduction

Background

Tobacco smoking among pregnant women accounts for a substantial proportion of preventable morbidity and mortality [1]. Smoking cessation among pregnant women not only benefits their own health but also reduces the risks of miscarriage, preterm birth, and low birth weight [2]. Moreover, cessation of smoking after pregnancy prevents their offspring from secondhand smoke exposure and, consequently, from diseases linked to secondhand smoke exposure, such as sudden infant death syndrome and respiratory diseases [2]. Strong predictors of smoking prevalence among women in Europe and the United States are low levels of educational attainment, health literacy, and socioeconomic status [3-5].

Mobile health (mHealth) apps appear to have positive effects on smoking cessation [6,7], and the inclusion of multiple game elements seems particularly promising [8]. In general, pregnant women have been found to frequently use eHealth and mHealth [9] and consider mHealth as a useful and playable tool [10]. In particular, the functionalities to interact with other mothers are useful, yet the quality of these web-based communities has been criticized by women. Moreover, women have indicated that interactive functionalities could be enriched by a direct chat with their health care professionals in addition to face-to-face care [10] and that they prefer easy-to-use interfaces [10]. Women have also signaled that they are more likely to be influenced by pregnancy-related information retrieved from an mHealth pregnancy app than widespread internet use [9]. However, women lack mHealth apps that allow personalization and have concerns about data security [10].

Although smoking during pregnancy is a problem among disadvantaged women (ie, those with a lower educational level, unplanned pregnancies, and additional risk factors [3]), the positive effects of mHealth interventions on smoking cessation are not evident in disadvantaged populations, as these interventions show only few improvements in health outcomes in disadvantaged populations [11]. Another review of disadvantaged patients with diabetes showed that mHealth interventions should be improved in terms of access, design, and usability [12]. As mHealth interventions are typically designed with minimal involvement of end users [13], the effectiveness of mHealth interventions among disadvantaged populations might be improved by a user-centered design approach. In a user-centered design approach, users influence how a design takes shape by providing input at subsequent design phases, typically during requirement gathering and usability testing. The added value of a user-centered approach has been demonstrated by a meta-analysis of randomized controlled trials on serious games for health lifestyle promotion. The effectiveness of participatory design depends on roles (eg, informants and co-design) and game design elements (eg, game levels or challenges) [14]. However, to the best of our knowledge, few studies have followed a user-centered design approach in the design of mHealth apps for disadvantaged populations [15,16].

In the Netherlands, the most disadvantaged pregnant women are offered a preventive care program called VoorZorg, which is supplementary to standard maternal care in the Netherlands [17]. The program resembles the nurse-family partnership developed in the United States [18] and the family-nurse partnership implemented in the United Kingdom [19]. These women are supported on multiple domains (eg, personal development and health promotion) [20] by certified, specialized nurses during home visits lasting 2.5 years.

On enrollment in VoorZorg (at 16-28 weeks of gestation), 43% of the women smoked. This reduced to 33% at 32 weeks of gestation and to 48% at 8 weeks after delivery [20]. VoorZorg nurses find it hard to support these women in smoking cessation due to large part to the use of support methods that do not fit the needs of women. Moreover, women are poorly motivated to stop smoking because of multiple stressors and other challenges they face [21]. Disadvantaged women appear to be in the early stages of change for smoking cessation, and their social networks mainly play a negative role in their smoking cessation efforts [22]. These insights reveal a misalignment between these women’s contexts and traditional action-oriented interventions for smoking cessation. Without planned interventions, these women will remain stuck in the early stages [23]. VoorZorg nurses and their clients are thus in need of an innovative intervention to move women through early stages of change with supportive social networks to stimulate them to quit smoking. As such an intervention is still nonexistent and recognizing the use of mHealth apps seems promising, we developed and evaluated a smartphone prototype with game elements to support disadvantaged young women during and after pregnancy with smoking cessation named Kindle.

Objectives

This paper aims to report the user-centered design process and usability evaluation of Kindle by disadvantaged women and health care professionals and provides insights and recommendations regarding the design of mHealth apps for disadvantaged user populations.

Methods

Design

In this user-centered design study, we included women from the VoorZorg program, members of their social networks, and VoorZorg nurses as informants in the design of Kindle. The study was conducted from June 2017 to May 2018 in the Netherlands. The design team members were designers affiliated with Waag (an organization developing innovative, inclusive technology for society), researchers (MD, PhD student Public Health; MF, PhD Public Health; SS, Master of Science student
Medical Informatics; and MJ, professor Medical Informatics and human factors engineering expert), and a VoorZorg program representative of the Netherlands Centre for Preventive Youth Health. Kindle was inspected for usability by 3 human factors engineering experts under the supervision of MJ and tested by representative end users in June 2018.

Informed consent was obtained from all participants in this study. The Medical Ethics Review Committee of Amsterdam University Medical Centers confirmed that the Medical Research Involving Human Subjects Act does not apply to this study, and therefore, no official approval of the committee was required. We used the Statement on Reporting of Evaluation Studies in the Health Informatics framework to report our study [24].

In the iterative user-centered design process of Kindle, we followed the standards of the International Organization for Standardization 9241-11:2018, which supports the identification and planning of effective human-centered design activities. These design activities entail four phases: (1) understanding and specifying the context of use, (2) specifying the user and organizational requirements, (3) production of design solutions, and (4) evaluating design solutions [25].

The usability of the Kindle was assessed as part of the fourth phase. Usability is generally defined as “the extent to which a system, product, or service can be used by specified users to achieve specified goals with effectiveness, efficiency, and satisfaction in a specified context of use” [25]. As no usability method is effective in all circumstances, a combination of usability methods that complement each other is generally preferred [26]. One expert-based usability inspection method is heuristic evaluation. During heuristic evaluation, a small number of human factors engineering experts evaluate a user interface according to a set of heuristics, which likely results in high-quality results over short periods [26,27]. The Healthcare Information and Management Systems Society (HIMSS) principles are commonly used to categorize usability problems. These principles include simplicity, naturalness, consistency, minimizing cognitive load, efficient interactions, forgiveness and feedback, effective use of language, effective information presentation, and preservation of context [28]. The think aloud method is a low-threshold, user-based usability testing method [29]. Think aloud entails end users performing tasks with the user interface while verbalizing what they are doing and provides insight into the causes of usability problems encountered by end users, thereby providing suggestions for redesign [26].

Phase 2: Specify User and Organizational Requirements

Overview

For the specification of user and organizational requirements, we used the same secondary analysis of our qualitative interviews in phase 1. Moreover, we held two intervention design inquiry sessions, one among VoorZorg nurses and one among clients and members of their social networks.

Participant Recruitment

Women who participated in VoorZorg, members of their social networks, and VoorZorg nurses were involved as informants in the user-centered design process of Kindle (ie, phases 2, 3, and 4). Participant recruitment started by informing managers of Youth Health Care Organizations executing the VoorZorg program and asking their permission to contact their nurses. The nurses were then informed about the study during a conference. Subsequently, nurses were asked via email whether they were willing to participate and willing to invite their clients for this study. In general, the target population of VoorZorg consists of women who at enrollment are (1) up to 28 weeks of gestation of their first (live born) child, (2) aged <26 years, (3) lower educated, (4) proficient in Dutch, and (5) have minimally one additional risk factor (eg, alcohol or drug use, financial difficulties, domestic violence, and psychosocial symptoms). Less than 1% of the births per Dutch municipality qualify to enroll in VoorZorg [17]. Most of these women (98%) had four or more risk factors [30]. Next, all participating clients were asked, by the researcher (MD), to invite members of their social networks to design sessions.

Inclusion was based on consecutive sampling. Women (ie, clients) were included when they were registered in the VoorZorg program and were in any of the stages of change in smoking cessation [23]. Members of the social networks of these clients were included when they were related to clients meeting the inclusion criteria. For nurses to be included, they must have worked as a VoorZorg nurse in the Netherlands for a minimum of 6 months.

Response and Characteristics

The mean age of the clients (n=9) was 24 years (SD 4.29). Most clients had a child aged <1 year (n=6) or had a child aged ≥1 year (n=3) and were in the early stages of change in smoking cessation [23], smoking 2.5-20 cigarettes per day. Most pregnancies were unplanned, with one client being pregnant during the study. Clients either had a low educational level (ie, primary education, prevocational secondary education, years 1–3 of higher secondary education, and vocational secondary education level 1) or intermediate level of education (ie, years 4–6 of higher secondary education and no higher vocational or university education) [31]. Participating members of the social networks were partners (n=1), family members or household members (n=1), and friends (n=2). They also had low or intermediate educational levels and were all current smokers, smoking 5–27.5 cigarettes per day. Nurses were all women and, on average, 53 years of age (SD 10.55) with 9 years (SD 2.61) of experience as a VoorZorg nurse, and 37 out of 97 (38%) of their clients were current smokers (Table 1).
Table 1. Sample characteristics of end users.

<table>
<thead>
<tr>
<th>End users</th>
<th>Age (years), mean (SD)</th>
<th>Stage of change quitting smoking</th>
<th>Number of cigarettes smoked per day, mean (SD)</th>
<th>Planned pregnancy</th>
<th>Age of child (years)</th>
<th>Educational level</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clients</td>
<td>24 (4.29)</td>
<td></td>
<td>7.33 (6.29)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Client 1</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>No</td>
<td>&lt;1</td>
<td>Low</td>
</tr>
<tr>
<td>Client 2</td>
<td>Contemplation</td>
<td>20</td>
<td>No</td>
<td>&lt;1</td>
<td>Low</td>
<td></td>
</tr>
<tr>
<td>Client 3</td>
<td>Action</td>
<td>—</td>
<td>Yes</td>
<td>&gt;1</td>
<td>Low</td>
<td></td>
</tr>
<tr>
<td>Client 4</td>
<td>Contemplation</td>
<td>5</td>
<td>No</td>
<td>&lt;1</td>
<td>Intermediate</td>
<td></td>
</tr>
<tr>
<td>Client 5</td>
<td>Precontemplation</td>
<td>—</td>
<td>No</td>
<td>&lt;1</td>
<td>Low</td>
<td></td>
</tr>
<tr>
<td>Client 6</td>
<td>Contemplation</td>
<td>2.5</td>
<td>No</td>
<td>&lt;1</td>
<td>Intermediate</td>
<td></td>
</tr>
<tr>
<td>Client 7</td>
<td>Precontemplation</td>
<td>3.5</td>
<td>Yes</td>
<td>&gt;1</td>
<td>Intermediate</td>
<td></td>
</tr>
<tr>
<td>Client 8</td>
<td>Preparation</td>
<td>6.5</td>
<td>No</td>
<td>&lt;1</td>
<td>Intermediate</td>
<td></td>
</tr>
<tr>
<td>Client 9</td>
<td>Preparation</td>
<td>10</td>
<td>Yes</td>
<td>&gt;1; pregnant</td>
<td>Intermediate</td>
<td></td>
</tr>
</tbody>
</table>

Social network 31 (12.42) 19.17 (12.33)

<table>
<thead>
<tr>
<th>Social network</th>
<th>Stage of change quitting smoking</th>
<th>Number of cigarettes smoked per day, mean (SD)</th>
<th>Planned pregnancy</th>
<th>Age of child (years)</th>
<th>Educational level</th>
</tr>
</thead>
<tbody>
<tr>
<td>Member 1</td>
<td>Contemplation</td>
<td>25</td>
<td>N/A</td>
<td>N/A</td>
<td>Low</td>
</tr>
<tr>
<td>Member 2</td>
<td>—</td>
<td>—</td>
<td>N/A</td>
<td>N/A</td>
<td>—</td>
</tr>
<tr>
<td>Member 3</td>
<td>Precontemplation</td>
<td>27.5</td>
<td>N/A</td>
<td>N/A</td>
<td>Low</td>
</tr>
<tr>
<td>Member 4</td>
<td>Preparation</td>
<td>5</td>
<td>N/A</td>
<td>N/A</td>
<td>Intermediate</td>
</tr>
<tr>
<td>Nurses</td>
<td>53 (10.55)</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
</tr>
</tbody>
</table>

*Missing data.

*N/A: not applicable.

We intended to recruit 8 clients and members of their social networks in design rounds 2, 4, and 5. Approximately half of the recruited participants (n=9) did not show up at these design rounds (phases 2 and 3). On the basis of the standards in the field of usability end user testing [32,33], we intended and recruited 5 end users to evaluate the usability of each interface of Kindle (participation rate 100%; phase 4). Owing to the geographical disparity of end users, some design rounds entailed multiple sessions at different locations. Approximately half of the participants took part in multiple phases, of which 2 nurses participated in two rounds of phase 3 (Table 2).
**Table 2.** Sample participation of end users per design phase and round.

<table>
<thead>
<tr>
<th>End users</th>
<th>Phase 2</th>
<th>Phase 3</th>
<th>Phase 4</th>
<th>Phase 5</th>
<th>Usability</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Round 1</td>
<td>Round 2</td>
<td>Round 3</td>
<td>Round 4</td>
<td>Round 5</td>
</tr>
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<td>Clients</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Client 1</td>
<td></td>
<td>✓</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Client 2</td>
<td>✓</td>
<td></td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Client 3</td>
<td>✓</td>
<td>✓</td>
<td></td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Client 4</td>
<td>✓</td>
<td></td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Client 5</td>
<td>✓</td>
<td></td>
<td></td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Client 6</td>
<td>✓</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Client 7</td>
<td></td>
<td></td>
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<tr>
<td>Client 8</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Client 9</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Social network</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Member 1</td>
<td>✓</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Member 2</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Member 3</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Member 4</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nurses</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nurse 1</td>
<td>✓</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nurse 2</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nurse 3</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nurse 4</td>
<td></td>
<td></td>
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<td></td>
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<tr>
<td>Nurse 5</td>
<td></td>
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<tr>
<td>Nurse 6</td>
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<tr>
<td>Nurse 7</td>
<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td>Nurse 8</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Procedure Design Sessions**

All design sessions of Kindle (ie, phases 2, 3, and 4) with end users took place at easily accessible locations (ie, at Waag, at Youth Health Care Organizations, and at the clients’ home). Each session was prepared and guided by 1 or 2 designers, whereas 1 or 2 researchers observed sessions but did not actively participate in it. After each round, designers, researchers, and the VoorZorg program representative discussed the output of the sessions in a project group. Researchers advised on how to proceed to the next sessions, assimilating the output of the sessions with evidence-based behavior change techniques. The VoorZorg program representative advised on, in conformance with output of the sessions, VoorZorg organizational requirements and opportunities. Thereafter, the designers prepared the next session with end users.

Clients and members of their social environment received a €10 (US $11.8) gift card for their participation in each session; clients received an extra €5 (US $5.9) for every member of their social environment they brought to the session. Organizations were compensated for their nurses’ time participating in the design sessions (€25 [US $29.6] per participating nurse per session). Except for the first design session, this session was part of the nurses’ biennial training.

**Specification of User Requirements**

User requirements were specified in the first two rounds of design inquiry sessions (next to the secondary analysis of our qualitative interviews; phase 1). The first round consisted of nurses (n=51) divided into five user groups. In these sessions, nurse’s perspectives on the requirements of the intervention to be developed were gathered. The session started with brainstorming why their clients quit smoking and relapse. Next, nurses were introduced to game elements and were encouraged to think of game elements that might aid their clients’ smoking cessation or prevent relapse. Finally, nurses were asked to give their perspectives on user requirements other than the inclusion of specific game elements of the intervention to be developed.

The second round was held with clients (n=5) and members of their social networks (n=3). Participants shared their reasons for smoking and alternative activities they could undertake and were encouraged to translate these activities into an app.
Phase 3: Produce Design Solutions to Meet User Requirements

Preliminary design solutions were created and assessed by end users, starting with an exploration by nurses (n=5; round 3). Next, clients (n=5) and members of their social networks (n=2) assessed the paper mock-up of Kindle (round 4). Finally, an improved paper mock-up was assessed by both nurses (n=3) and clients (n=3; round 5).

Phase 4: Evaluate Against Requirements

Heuristic Evaluation

A total of 3 human factors engineering experts received a guideline containing background information about VoorZorg, why Kindle was developed, its end users, and aims. Moreover, the guideline explained how to install and open the app on smartphones and entailed instructions on performing the usability inspection. No training was given to the experts on how to use the Kindle before the heuristic evaluation. We instructed the experts to systematically evaluate both the nurse and client interfaces of Kindle by freely exploring the functionalities. Experts were asked to describe usability flaws in detail and classify them according to the HIMSS principles [28]. Experts were instructed to rate the severity of the problems they encountered according to the Nielsen five-point Likert severity rating (0 indicating no usability problem to 4 indicating a usability catastrophe) [34]. Experts were encouraged to write comments to further explain the rationale for their ratings.

The results of the usability inspections by all 3 experts were merged according to functionality and HIMSS principles [28]. The average severity score was calculated when multiple experts identified the same usability problem.

Think Aloud Method

All end users (ie, nurses and clients) had prior experience with smartphone apps and were informants during the design phase of Kindle. However, none of the participants had prior experience with the prototype. Data collection lasted 20-50 minutes and took place at clients’ homes and at the nurses’ workplace at Youth Health Care Organizations. Participants used the smartphones of the evaluators to perform the usability test of Kindle, which was video recorded via a third-party smartphone app (ie, AZ Screen Recorder [by Hecorat Global Technology], downloaded from the Google Play Store that recorded the smartphone screen, audio, and user inputs). We explained to participants that they would use the app by performing specific tasks provided by an evaluator (MD or SS). Participants were instructed to verbalize their thoughts while performing the tasks. Before the actual usability test, participants were given a warm-up task to practice thinking aloud. The warm-up task was to add a specific contact and contact details to the contacts list while thinking aloud. None of the participants had difficulty verbalizing their thoughts during the warm-up task.

The tasks of the usability test were based on real-life scenarios in which testing of all the main functions of the app was covered. The series of tasks were always conducted in a fixed order across participants (Textbox 1). The evaluator reminded participants to continue thinking aloud when they stopped doing so. If a participant was not able to complete a task after three attempts, the evaluator provided a clue.

Textbox 1. Think aloud usability tasks.

<table>
<thead>
<tr>
<th>Nurse Interface</th>
</tr>
</thead>
<tbody>
<tr>
<td>Create profile</td>
</tr>
<tr>
<td>Create group</td>
</tr>
<tr>
<td>Manage group</td>
</tr>
<tr>
<td>Manage personal goals of clients</td>
</tr>
<tr>
<td>Use chat functionalities</td>
</tr>
<tr>
<td>Read and add tips (ie, advice)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Client Interface</th>
</tr>
</thead>
<tbody>
<tr>
<td>Create profile</td>
</tr>
<tr>
<td>Create personal goals</td>
</tr>
<tr>
<td>Use chat functionalities</td>
</tr>
<tr>
<td>Read and add tips (ie, advice)</td>
</tr>
<tr>
<td>Use personal diary</td>
</tr>
</tbody>
</table>

To reveal and describe usability issues in detail, one of the think aloud evaluators (SS) analyzed the videos by coding participants’ utterances and user input per task (ie, functionality). A usability issue was reported when a participant was not able to complete the instructed task in her first attempt. The reported usability problems were then categorized according to the HIMSS usability principles by a think aloud evaluator (SS) [28]. Next, the think aloud protocols were merged by the end user group to provide an overview of usability problems per functionality. These were then merged with the findings from the heuristic evaluation, after which all usability problems from the heuristic evaluation and think aloud method were discussed.
and recommendations were made to resolve each usability problem (SS, MD, and MJ).

**Results**

**Outcomes Phase 1: Understanding and Specification of the User Context**

A secondary analysis of qualitative interview data revealed that clients generally indicated good relationships with their VoorZorg nurse. During home visits, clients and nurses kept in touch via WhatsApp, with varied intensity (e.g., some clients and nurses only communicated concerning appointments and others would regularly ask personal and medical questions via WhatsApp). Most clients interviewed did not have a job nor were they currently enrolled in education. A number of clients did not live on their own but, for example, lived with their parents or in assisted living facilities. Clients had limited social networks and were normally not in contact with other VoorZorg clients. All interviewed clients had a smartphone and access to the internet. Only a few clients had a tablet, laptop, computer, or game console.

**Outcomes Phase 2: Specification of User and Organizational Requirements**

The user and organizational requirements that we identified during the first two rounds of Kindle’s design sessions with nurses, clients, and clients’ social networks were divided into design requirements and functionality requirements (Textbox 2).

Textbox 2. User and organizational requirements.

<table>
<thead>
<tr>
<th>Design</th>
<th>Functionalities</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Mobile health app</td>
<td>• Enabling secured communication between nurses and clients (i.e., social support)</td>
</tr>
<tr>
<td>• Easy to use, simple use of language, little use of texts, and visualizing content due to lower health literacy of clients</td>
<td>• Enabling anonymous communication between clients (i.e., peer contact)</td>
</tr>
<tr>
<td>• Social media–like design</td>
<td>• Tailored at early stages of change in smoking cessation (i.e., precontemplation, contemplation, and preparation [23])</td>
</tr>
<tr>
<td>• Not necessarily be presented as smoking cessation intervention</td>
<td>• Focus on gaining control over life</td>
</tr>
<tr>
<td>• Harmonizing VoorZorg values (i.e., no advising, judging, patronizing, pedantic tone, and yet following and endorsing clients)</td>
<td>• Providing a way of dealing with stressors and boredom</td>
</tr>
<tr>
<td>• App with multiple functionalities to digitalize aspects of the VoorZorg program</td>
<td>• Arousing intrinsic motivation for smoking cessation</td>
</tr>
<tr>
<td>• Usable for both nurses and clients</td>
<td>• Providing clients with self-understanding and building self-efficacy in clients (i.e., social support)</td>
</tr>
<tr>
<td>• Nonaddictive or time consuming</td>
<td>• Rewarding and acknowledging clients’ efforts (i.e., social support and game element)</td>
</tr>
<tr>
<td>• No costs for clients</td>
<td>• Challenging (game element)</td>
</tr>
<tr>
<td>• Not childish</td>
<td>• Earning points or compliments efforts (i.e., social support and game element)</td>
</tr>
<tr>
<td>• Positive focus</td>
<td>• Providing information</td>
</tr>
</tbody>
</table>

**Outcomes Phase 3: Production of Design Solutions to Meet User and Organizational Requirements**

The design sessions resulted in a preliminary prototype, named Kindle (Textbox 3; Figures 1-6), meeting all user and organizational requirements.
Textbox 3. Intervention characteristics of Kindle.

<table>
<thead>
<tr>
<th>Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Kindle</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Type of Intervention</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Mobile health app</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Aim</th>
</tr>
</thead>
<tbody>
<tr>
<td>• To support women through the first stages of smoking cessation</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Targeted Determinants</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Increasing clients’ readiness for smoking cessation</td>
</tr>
<tr>
<td>• Creating a supportive social network for clients</td>
</tr>
<tr>
<td>• Increasing clients’ self-efficacy in obtaining personal goals</td>
</tr>
<tr>
<td>• Increasing clients’ knowledge and self-efficacy (eg, tips)</td>
</tr>
<tr>
<td>• Improving communication with nurse (eg, secured chatting)</td>
</tr>
<tr>
<td>• Processing difficulties in life (eg, diary)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Setting</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Developed for use in a care setting and at clients’ home</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Nurse Interface Functionalities</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Set up a profile by entering their name and choosing an avatar representing themselves and choosing from taking a picture with their smartphone camera or an image from their smartphone gallery (Figure 1).</td>
</tr>
<tr>
<td>• Manage clients from the admin panel. Nurses can add and delete clients to and from Kindle. Moreover, nurses can block clients from participating in the group chat (Figure 2).</td>
</tr>
<tr>
<td>• Endorse and reward clients for their progress in obtaining their goals by assigning hearts (ie, heart-shaped points).</td>
</tr>
<tr>
<td>• Communicate with clients via secured private chat and group chat (Figure 3; ie, secured server). All messages in the chat functionality could be loved by tapping a heart-shaped button (ie, similar to the “like” functionality on social media), by which clients were empowered in their contributions to the chat.</td>
</tr>
<tr>
<td>• Create tips or moderate tips shared by clients (Figure 4).</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Client Interface Functionalities</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Set up a profile by entering their name and choosing an avatar representing themselves and choosing from taking a picture with their smartphone camera or an image from their smartphone gallery (Figure 1).</td>
</tr>
<tr>
<td>• Formulate personal goals (ie, “heart desires”), by which they could work on resolving barriers for smoking cessation and build self-efficacy in obtaining personal goals. Women can select a category (ie, being a mother, healthy lifestyle, my child, work and leisure, safety, finances, talking and listening, family and friends, and help) and then enter their personal goal (Figure 5). Clients could enter three active personal goals to work on at the same time.</td>
</tr>
<tr>
<td>• View their personal goal attainment progress (ie, 50 hearts represent an obtained goal).</td>
</tr>
<tr>
<td>• Communicate with nurse via secured private chat and group chat. All messages in the chat functionality could be “loved.”</td>
</tr>
<tr>
<td>• Read and create tips by and for other clients.</td>
</tr>
<tr>
<td>• Write private posts in their digital diary; clients could also add images to their posts (Figure 6).</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Game Elements [35]</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Avatar creation (ie, setting up profile)</td>
</tr>
<tr>
<td>• Player management features (ie, personal goals and progress)</td>
</tr>
<tr>
<td>• Intermittent rewards (ie, earning hearts with progress in personal goals)</td>
</tr>
<tr>
<td>• Social utility (ie, tips)</td>
</tr>
<tr>
<td>• Support network (ie, chat)</td>
</tr>
<tr>
<td>• User input (ie, tips and diary)</td>
</tr>
</tbody>
</table>
## Development Stage

- Early—the prototype had limited functionality, being a series of screenshots that were linked together via clickable buttons

**Figure 1.** Example screenshot of the profile creation section where the user can choose an avatar (identical in both interfaces).
Figure 2. Example screenshot of the admin panel in the nurse interface of Kindle.

Figure 3. Example screenshot of the group chat functionality in the nurse interface of Kindle.
Figure 4. Example screenshot of the tip functionality of the nurse interface of Kindle.

Figure 5. Example screenshot of the goal setting functionality in the client interface of Kindle.
Outcomes Phase 4: Evaluation Against Requirements

Usability Problems Within the Nurse Interface of Kindle

We found 37 usability problems within the nurse interface of Kindle (Figure 7). We identified the general problems and problems related to functionalities. Most usability problems (n=12) were found in the admin functionality (eg, issues of consistency—using the same icon or button with different meanings), followed by the chat function (n=9; eg, issues for efficient interactions—it is unclear when messages are sent). Most usability issues revealed by both evaluation methods concerned violation of the simplicity of the HIMSS principles (eg, the private chat function is hidden in the admin menu) and naturalness (eg, unclear icons). In total, 24 of 37 (65%) potential usability problems were detected in the heuristic evaluation, 7 of 37 (19%) usability problems were detected in the think aloud method, and 6 of 37 (16%) usability problems were detected by both heuristic evaluation and think aloud. The mean severity of usability problems detected through heuristic evaluation was rated rated as 1.8 (SD 1.00), reflecting that the usability problems found by experts were, on average, minor. We provide a complete overview of the usability problems of the nurse interface of Kindle, per the HIMSS principle found through heuristic evaluation and think aloud and provide a recommendation to solve the issue (Multimedia Appendix 1, Table S1).

Figure 7. The number of usability problems within the nurse interface per functionality and principle.
Usability Problems Within the Client Interface of Kindle

In total, 41 usability problems within the client interface of Kindle were discovered (Figure 8). We identified general problems and problems based on their functionality. Most usability problems (n=11) were found in the chat functionality (eg, issue of consistency—the group chat does not have the heart icon next to the input field, unlike the private chat), followed by the personal goals function (n=9; eg, issue of simplicity—the numbers above the golden heart icons are unclear). Most usability issues by both evaluation methods concerned violation of the HIMSS principles simplicity (eg, it is not clear that the heart is a clickable button to give a like) and naturalness (eg, it is not clear that the lock icon in the navigation bar represents a diary). In total, 31 of 41 (76%) potential usability problems were detected in the heuristic evaluation, 4 of 41 (10%) usability problems were detected in the think aloud method, and 6 of 41 (15%) usability problems were detected by both heuristic evaluation and think aloud. The mean severity of usability problems detected through heuristic evaluation was rated as 1.8 (SD 0.81), reflecting that the usability problems found by experts were minor. A complete overview of the usability problems of the client interface of Kindle, per the HIMSS principle found through heuristic evaluation and thinking aloud, and a recommendation to solve the issue can be found in Multimedia Appendix 1, Table S2.

Figure 8. The number of usability problems within the client interface per functionality and principle.

Recommendations to Improve the Usability of Kindle

For each usability problem, researchers SS and MD and human factors engineering expert MJ made recommendations to improve the usability of the nurses and client interface of the Kindle prototype (Multimedia Appendix 1, Tables S1 and S2). A final iteration round following the recommendations resulted in a final version of Kindle (Textbox 4; Figures 9-11). This final version was evaluated in a pilot study.

Textbox 4. Final version of intervention characteristics.

<table>
<thead>
<tr>
<th>Name</th>
<th>• Kindle</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Intervention Type</strong></td>
<td>• Mobile health app</td>
</tr>
<tr>
<td><strong>Aim</strong></td>
<td>• To support women through the first stages of smoking cessation</td>
</tr>
<tr>
<td><strong>Targeted Determinants</strong></td>
<td>• Increasing clients’ readiness for smoking cessation</td>
</tr>
<tr>
<td></td>
<td>• Creating a supportive social network for clients</td>
</tr>
<tr>
<td></td>
<td>• Increasing clients’ self-efficacy in obtaining personal goals</td>
</tr>
<tr>
<td></td>
<td>• Improving communication with nurse (eg, secured chatting)</td>
</tr>
<tr>
<td><strong>Setting</strong></td>
<td>Developed for use in a care setting and at clients’ home</td>
</tr>
<tr>
<td><strong>Nurse Interface Functionalities</strong></td>
<td>• Manage clients from the admin panel. Nurses can add and delete clients to and from Kindle. Moreover, nurses can block clients from participating in the group.</td>
</tr>
<tr>
<td></td>
<td>• Endorse and reward clients for their progress in obtaining their goals by assigning hearts (ie, heart-shaped points).</td>
</tr>
<tr>
<td></td>
<td>• Communicate with their clients via a secured private chat and group chat (ie, secured server). All messages in the chat functionality could be “loved” by tapping a heart-shaped button (ie, similar to the “like” functionality on social media), by which clients were empowered in their contributions to the chat.</td>
</tr>
<tr>
<td><strong>Client Interface Functionalities</strong></td>
<td>• Formulate personal goals (ie, “heart desires”), by which they could work on resolving barriers for smoking cessation and build self-efficacy in obtaining personal goals. Women can select a category (ie, being a mother, healthy lifestyle, my child, work and leisure, safety, finances, talking and listening, family and friends, and help) and then enter their personal goal.</td>
</tr>
<tr>
<td></td>
<td>• View their goal attainment progress (ie, 50 hearts represent an obtained goal).</td>
</tr>
<tr>
<td></td>
<td>• Communicate with their nurses via a secured private chat and in a group chat with peers (ie, other clients). All messages in the chat functionality could be “loved.”</td>
</tr>
<tr>
<td><strong>Game Elements [35]</strong></td>
<td>• Player management features (ie, personal goals)</td>
</tr>
<tr>
<td></td>
<td>• Intermittent rewards (ie, earning hearts with progress in personal goals)</td>
</tr>
<tr>
<td></td>
<td>• Support network (ie, chat)</td>
</tr>
<tr>
<td><strong>Development Stage</strong></td>
<td>• Advanced: fully functional for pilot implementation and evaluation.</td>
</tr>
</tbody>
</table>
Figure 9. Example screenshot of the goal setting functionality in the client interface of Kindle.

Choose a category, then add a description.

- Being a mother
  - Live healthy
  - Quitting smoking

My goal is...
Figure 10. Example screenshot of the goal setting functionality in the nurse interface of Kindle.

Figure 11. Example screenshot of the group chat functionality in the client interface of Kindle.
Discussion

Principal Findings

In this paper, we describe the user-centered design and usability evaluation of an mHealth app (Kindle) that supports disadvantaged young women during and after pregnancy by moving through the first stages of smoking cessation. Disadvantaged women, members of their social networks, and nurses were informants throughout the phases of the iterative prototype design. In the first phase of the intervention design, secondary analysis of qualitative interview data revealed that nurses and clients keep in touch through WhatsApp during home visits and that all interviewed clients had smartphones and internet access but usually possessed no other devices. The clients were not in contact with other clients. In phase 2, we established user and organizational requirements from the secondary interview data and design sessions with end users. The main requirement was that the intervention should be an mHealth app, offering secure communication between nurses and clients. Moreover, the intervention should be tailored to the early stages of change in smoking cessation, include game and social support elements, and have easy-to-use interfaces. In phase 3, the Kindle prototype with game elements was developed technically. Kindle combines a nurse and client interface and includes the following functionalities: personal goal setting with earning points, chat function with a nurse and other clients, tips, and admin function or diary and profile creation. Prototype usability (phase 4) was evaluated by a combination of heuristic evaluation among experts and think aloud sessions among end users (ie, nurses and disadvantaged women). We found 78 usability problems for both interfaces. Most usability problems concerned violation of the principles of simplicity and naturalness and were found in the chat (both interfaces), admin (nurse interface), and goal setting (client interface) functionalities. Following the recommendations from the usability evaluation, a final iteration round resulted in a final version of Kindle.

Comparison With Prior Work

The first phase of our user-centered design was devoted to understanding and specifying the user context, resulting in a specific focus on the early stages of smoking behavior change [23]. This is in contrast to action stage–oriented smoking cessation apps, which are widely available or being developed [7,36,37]. The use of the transtheoretical model in interventions is associated with positive effects on health behavior [38]. According to an inventory by Paige et al [37], processes of change that aid people in moving through stages of behavioral change are widely applied in mHealth apps for smoking cessation, including Kindle. Moreover, in accordance with other research [8,39-42], the first phase highlighted the importance of supportive social networks for smoking cessation.

By involving both end user groups (clients and nurses), we were able to identify key user and organizational requirements (ie, phase 2) and to incorporate them into Kindle’s design solution (ie, phase 3). This coherence of the mHealth app with user objectives or requirements has been identified as one of the critical factors for smoking cessation mHealth apps [43]. Moreover, we involved end users as informants in our design process, which has been found to be more effective in changing behavioral determinants [14]. The involvement of socioeconomically disadvantaged populations thus appears to be a feasible and effective strategy in mHealth design.

One of the user requirements of Kindle that we identified was the use of game elements and social interactions. Previous research has also suggested the potential of social features in serious games for smoking cessation [8]. Moreover, pregnant women in other studies also highlighted the usefulness and playfulness of social interaction functionalities within mHealth [10]. Yet, among smoking cessation mHealth apps, few have a game or social nature similar to that of Kindle [37,44,45]. Kindle further comprises a unique, secured chat functionality, whereas only 16% of mHealth smoking cessation apps integrated web-based communication exclusive to the app [37]. This is striking because peer-to-peer communication and communication with an advisor (eg, health care professional) is associated with more effective eHealth interventions [38,46] and is generally preferred among pregnant women in web-based apps [10].

Goal setting and rewards were included as game elements in Kindle. These functionalities are also regularly found in smoking cessation mHealth apps [44,47] and appear to have a significant positive impact on health behavior [38]. However, only 15% of mHealth apps for smoking cessation have a progress tracking feature similar to that of Kindle [44]. As we did not find evidence on the effectiveness of functionalities, game elements concerning sharing or creating tips and keeping a digital diary, these elements were not incorporated in the final version of Kindle.

Aligning interventions to the low health literacy levels of clients was another user and organization requirement. Similar to Kindle, most mHealth apps for smoking cessation incorporated plain usage of language as part of health literacy considerations [37]. Finally, it was also a user and organizational requirement that the app be free of charge for end users. Kindle will be freely available, similar to many other smoking cessation mHealth apps [37,44,45,47].

In our usability evaluation, human factors engineering experts inspected and end users tested for each interface (ie, clients and nurses) of Kindle through heuristic evaluation and think aloud, respectively, which has now become a general practice in usability evaluations [48]. The types of problems detected in our study differed according to each evaluation method. The think aloud method with end users disclosed more critical usability problems, concerning being able to actually use the app as intended, whereas the heuristic evaluation among experts mainly resulted in the disclosure of less severe, noncritical problems, concerning the ease of use of the app or a less optimal user experience. These findings are in accordance with earlier research [49,50] and demonstrate that the combination of expert and user usability methods was truly complementary, and result in surplus value in the design of a usable app [26,49].
Most usability problems were found in the chat functionality of both interfaces, the admin function in the nurse interface, and goal setting in the client interface and concerned simplicity and naturalness issues. We formulated recommendations to resolve these issues, so that Kindle, similar to other smoking cessation mHealth apps, obtains good scores on functionality and esthetics [45]. According to participants in co-designing a self-management mHealth intervention, an app’s usability and intuitiveness might be negatively affected by the inclusion of numerous functionalities [51]. Consequently, in the final iteration round, Kindle is expected to benefit from fewer functionalities, whereas the remaining ones (ie, goal setting and chat) should follow usability standards.

Usability evaluations among disadvantaged populations are scarce [12]. However, disadvantaged populations may reveal unique usability problems in terms of the content and functionalities of interventions [32]. This was also reflected in our study, where disadvantaged women revealed approximately 10% (4/41) of the usability problems with the client interface. Nurses detected more usability problems (approximately 7/37, 19%), yet these were mainly found in the admin function, which was not a functionality of the client interface. This relatively low number of problems might be a positive side effect of our user-centered approach to the design of Kindle, which is expected to resolve potential usability issues in early stage versions of the intervention.

Strengths and Limitations

A strength of our study was the involvement of end users throughout all phases of the user-centered design and usability evaluation of Kindle. The involvement and input of disadvantaged women in the design sessions were highly valuable. In this way, we were able to meet their (and organizational) requirements. This will likely result in higher acceptance of the implementation of Kindle as an intervention and, consequently, is expected to support its effectiveness. Another strength of our study was the triangulation of methods in the fourth phase of Kindle’s design. We used two types of usability evaluation methods to detect usability problems in our prototype, which provided us with a more complete overview of usability problems, as only approximately 15% (6/37 and 6/41) of the usability problems found by think aloud and heuristic evaluation overlapped.

Our study also had limitations. First, the design sessions were attended by fewer clients than intended and recruited. The clients often did not show up to a session they had confirmed to attend. Involving disadvantaged populations in research is challenging [5,53]. Moreover, with less than 1% of the births per Dutch municipality qualifying to enroll in VoorZorg, our target population is very small. Nonetheless, we succeeded in fulfilling multiple rounds of design with mixed compositions of participants. In qualitative health research and usability end user tests, smaller sample sizes are acceptable, as they provide higher information power [32,33,54].

Another limitation was the involvement of a limited number of members of women’s social networks in most rounds of intervention design. Identical to clients’ no shows, we were not able to recruit as many members of social networks as intended. However, during Kindle’s design process, we found that existing social networks mainly had a negative role in clients’ smoking cessation efforts [22], and clients wanted support from peers.

Moreover, we evaluated the usability of a prototype with limited functionality. The think aloud method was based on certain real-life tasks that covered all the functionalities. This may have highlighted other usability problems that would have occurred during free use of the app. The limited functionality of the prototype may also have resulted in an incomplete insight into usability problems. However, conducting a usability evaluation using heuristic evaluation and think aloud is common in early system design phases, as insights can be used to redesign the system [26].

Practical and Research Implications

Our study adds to the limited existing research following and reporting on all phases of user-centered design of mHealth interventions aimed at disadvantaged populations and a small fraction of studies that report the results of their usability evaluation [48]. Our study indicates that disadvantaged women are capable of participating in all phases of the intervention design. Their input has been valuable in detecting their needs and important usability problems while performing tasks to evaluate Kindle’s usability. However, the attendance of disadvantaged women in the design sessions was less than intended and recruited. This implies that more research is needed to gain insight into how disadvantaged populations can be involved in all user-centered design processes and usability evaluations of mHealth interventions aimed at these populations. This may help achieve improved intervention reach, adoption, and implementation among disadvantaged populations.

Another research implication stems from the attendance of multiple clients in the design sessions. This showed the added value of connecting clients with other clients (ie, peers), rather than involving existing social networks of women in the intervention design. The social interactions were positive, supported clients, and inspired both end users and designers to incorporate aspects of these interactions in the design solutions. More research is needed on the effectiveness of such social components of digital interventions on health behavior change.

Practically, we will use the results of this study to pilot test Kindle in the VoorZorg context. Finally, we aim to implement Kindle in the nationwide VoorZorg program and other Dutch care settings that encompass intensive support from health care professionals with disadvantaged clients.

Conclusions

The user-centered design and usability evaluation of Kindle provided valuable insights for improving its first design. By involving health care professionals and socioeconomically disadvantaged, young women during and after their pregnancy (ie, end users), we were able to gain insight into their context, needs, and requirements. Consequently, together with the end users, we were able to meet their requirements to achieve readiness for smoking cessation in our first design solution. We evaluated the usability of the prototype through experts and end users, which revealed unique usability problems for this population. These insights allow for further optimization of
Kindle, and we encourage future studies to engage usability testing. disadvantaged populations in mHealth intervention design and

Acknowledgments

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Authors' Contributions

MD contributed to conceptualization, data curation, methodology, formal analysis, investigation, software, validation, visualization, and writing of original draft preparation. MJ contributed to conceptualization; methodology; resources; supervision; validation; and writing, reviewing, and editing the manuscript. SS contributed to formal analysis; investigation; data curation; and writing, reviewing, and editing the manuscript. MF contributed to conceptualization, methodology, resources, funding acquisition, project administration, supervision, validation, and reviewing and editing the manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Overview of usability problems per user interface.

References


Abbreviations

**HIMSS**: Healthcare Information and Management Systems Society

**mHealth**: mobile health