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Original Paper

A Persuasive mHealth Behavioral Change Intervention for Promoting Physical Activity in the Workplace: Feasibility Randomized Controlled Trial

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Abstract

Background: Employees in an office setting are more likely to remain physically inactive. Physical inactivity has become one of the major barriers to overcoming the risk factors for anxiety, depression, coronary heart disease, certain cancers, and type 2 diabetes. Currently, there is a gap in mobile health (mHealth) apps to promote physical activity (PA) for workers in the workplace. Studies on behavior change theories have concluded that health apps generally lack the use of theoretical constructs.

Objective: The objective of this study was to study the feasibility of a persuasive app aimed at encouraging PA among employees and to understand the motivational aspects behind the implementation of mHealth apps among office workers.

Methods: A 4-week study using a mixed methods (quantitative and qualitative) design was conducted with office-based employees in cities in 4 countries: Oulu, Finland; Carlow, Ireland; London, United Kingdom; and Dhaka, Bangladesh. Of the 220 invited participants (experimental group, n=115; control group, n=105), 84 participated (experimental group, n=56; control group, n=28), consisting of working-age volunteers working in an office setting. Participants used 2 different interventions: The experimental group used an mHealth app for PA motivation, and the control group used a paper diary. The purpose was to motivate employees to engage in healthier behavior regarding the promotion of PA in the workplace. A user-centered design process was followed to design, develop, and evaluate the mHealth app, incorporating self-determination theory (SDT) and using game elements. The paper diary had no specific theory-driven approach, design technique, nor game elements.

Results: Compliance with app usage remained relatively low, with 27 participants (experimental group, n=20; control group, n=7) completing the study. The results support the original hypothesis that the mHealth app would help increase PA (ie, promoting daily walking in the workplace) in comparison to a paper diary (P=.033). The mHealth app supported 2 of the basic SDT psychological needs, namely autonomy (P=.004) and competence (P=.014), but not the needs of relatedness (P=.535).

Conclusions: The SDT-based mHealth application motivated employees to increase their PA in the workplace. However, compliance with app usage remained low. Future research should further develop the app based on user feedback and test it in a larger sample.

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KEYWORDS

mHealth behavioral change intervention; persuasive app; UCD; game elements; physical activity; SDT

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Introduction

Lack of physical activity (PA) affects normal physiological processes in the human body, which may destabilize the body's energy balance, cause muscle atrophy, and diminish exercise capability [1]. Physical inactivity has become one of the major barriers to overcoming the risk factors for obesity, stroke, type 2 diabetes, and mental health issues. These risk factors can cause long-term disease that lead to death [2]. Several factors may discourage participation in PA (eg, a lack of parks, paved areas, and sports or recreation facilities), and the World Health Organization member states have set a target to reduce physical inactivity up to 10% by 2025 [3]. Despite this, some individuals remain persistently physically inactive, thus leading to a high risk of medical complications and causing significant health care expense [4,5]. The consequences may be compounded by physical inactivity in the workplace. Interventions that are designed and developed for the workplace environment are encouraged and may result in progress in PA [6].

Technology-enhanced solutions are a promising approach to motivating people and promoting PA. Mobile health (mHealth), using smartphones for health-oriented applications, has emerged as a vital tool for health-oriented behavioral change interventions [7] and to reduce health problems [8].

Persuasive health apps have been proposed as a technique to foster behavioral change [9-11]. State-of-the-art behavioral change efforts are essential for increasing PA promotion [12]. However, mHealth apps are not generally grounded in behavior change theories [13-15].

According to the self-determination theory (SDT), people can be intrinsically and extrinsically motivated to perform an action [16,17]. An intrinsic level of motivation is completed through the fulfillment of the 3 psychological needs: autonomy, competence, and relatedness. Autonomy shows a sense of having the option to measure the social environment and distributing selections that conform to carrying out a daily task [18]. Competence indicates a sense of completing the task in a social environment. Relatedness specifies the feeling of working to connect with others [18]. Hence, SDT is a promising method for overcoming the challenges of physical inactivity in the work environment and a lack of social interaction among employees. Workers can be motivated intrinsically (ie, they feel gratified in performing their daily walking routine). Then, they are extrinsically more motivated to complete their PA task, since they want to finish the job (eg, they can track their progress by scoring points and earning badges based on a leaderboard during their daily walk). However, employees who are amotivated may not demonstrate an awareness to perform any level of their daily PA task. Thus, intervention strategies that are purported to satisfy the 3 needs of SDT might encourage positive behavioral change [19].

Gamification is the use of game elements in non-gaming contexts [20] and motivating individuals by making their experience more fun and playful [21]. Human behavior is motivated by extrinsic aspects such as incentives or rewards that have been utilized to encourage motivation among employees [22,23]. Virtual points and badges are ways of representing rewards [24]. Furthermore, competition is a persuasive technique derived from the Theory of Competition [25], referring to “the act of seeking or endeavoring to gain what another is endeavoring to gain at the same time” [26]. A leaderboard is a way to represent competition in which users’ activities are demonstrated [27]. The implementation of rewards is a practical way to foster users’ behaviors in non-gaming contexts [28]. In PA research, points, badges [29-35], and leaderboards [29-31,34,35] (PBL) can persuade individuals to complete a specific activity.

As a potential solution to increase PA in the workplace, this study designed and developed a persuasive mHealth app called iGO that incorporates SDT. SDT was selected for its acknowledgment in PA research [36] and its capability to support an individual’s behavior by offering reinforcement of the 3 basic psychological needs: autonomy, competence, and relatedness. The design followed the user-centered design (UCD) process [37]. The iGO mHealth app allowed users to set goals for PA after breakfast and lunch sessions and enabled them to track their walking performance. The purpose was to motivate employees to increase their daily PA and social interaction among colleagues and others. This study aimed to answer the following research questions:

1. What is the feasibility that the persuasive iGO app will motivate employees to increase their daily walking in the workplace?
2. What is the employees’ view of the persuasive iGO app regarding the needs of autonomy, competence, and relatedness for promoting daily walking?

To answer the research questions, we evaluated the iGO mHealth app during a 4-week study with a mixed methods (quantitative and qualitative) design. We hypothesized that iGO would motivate employees to increase their daily walking and increase their autonomy (confidence level and ability to choose regular walking to reach their goal), competence, and relatedness.

Methods

Study Design

An experimental study was conducted with a group of office-based employees for 4 weeks. Participants were randomly assigned to 1 of 2 groups. The experimental group used the iGO mHealth app, and the control group used a paper diary on weekdays for 4 consecutive weeks.

App Design

iGO was iteratively developed in previous studies, and the app design has been presented elsewhere [38,39]. Briefly, we designed and developed the gamified, persuasive mHealth app iGO [39] to encourage employees to walk more often and to break up long sitting periods during working hours. iGO is based on the SDT-driven system model [38]. This model is a combination of the SDT theory, game elements, and motivating outcomes (exercise, walking, and weight control). The SDT theory model of health behavioral change defined by Ryan et al [40] was adopted. The iGO app utilizes the 3 basic SDT psychological needs and aims to motivate users to increase their

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daily PA by increasing their levels of autonomy (ability to choose a daily walking task to reach a 10-minute goal after breakfast and lunch breaks), competence (feeling effective in their ongoing interactions with the social environment and to reach the daily walking goals), and relatedness (feeling connected with colleagues for the purpose of PA).

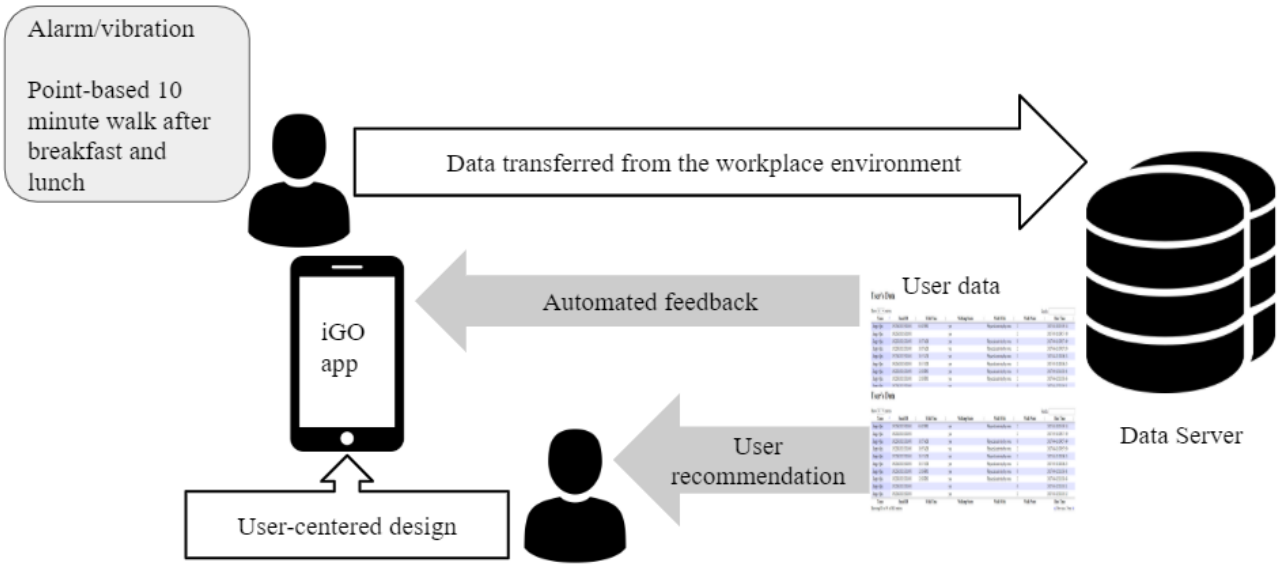
User-Centered Design (UCD)

Our proposed gamified system model was used to design and develop a low-fidelity prototype (paper prototype) of iGO applying the UCD process, consisting of 5 steps: empathize, define, ideate, prototype, and test. The details have been published elsewhere [38]. The prototype allowed users to enter their information, such as name, age, and weight. By logging into the app, the user had the option to participate in PA with others or alone [38]. Every 5 minutes of PA resulted in 1 point; therefore, a 5-minute walk was awarded 1 point, and a 10-minute walk was awarded 2 points. The users could monitor their activities on the leaderboard. The iGO app prototype [38] was tested by 5 volunteers. Based on the users' recommendations, a high-fidelity prototype of the iGO mHealth app was designed and evaluated during a 1-week study [39] and further upgraded to a newer version of the iGO mHealth app, as presented in the following sections.

Working Version of the iGO mHealth App

The overall concept of the iGO app is shown in Figure 1. Users' key characteristics (comprising intrinsic motivation and levels of autonomy, competence, and relatedness with regard to their PA participation) and responses were collected from the system. In addition, their daily walking activity was logged automatically by the system. Users received notifications and their progress-related rewards are displayed on the leaderboard.

Figure 1. Overall concept of the mobile health app iGO, developed using the user-centered design process.



The flow within the iGO mHealth app is shown in Figure 2.

The iGO app (Multimedia Appendix 1) provides a choice in the main menu to select "yes" or "no" regarding the user's breakfast or lunch status. If the user selects "no" to indicate he or she did not have breakfast, the alarm reappears after 10 minutes and asks the user to select an option to proceed. Selecting "yes" will ask the user for a preference — either "physical activity with others" or "physical activity alone" — and the activity is timed for 10 minutes. Users have the choice to accept or skip the app function by pressing the "yes" or "no" button when they are asked whether they had breakfast or lunch. Users express their views and are able to select their choices through the app. Thus, the iGO provides autonomous support. Moreover, the autonomous choice of "physical activity alone" allows users to walk up to 10 minutes or more if they wish (their walking data are stored in the data server). We included rewards such as PBL game elements in the system to motivate participants to walk for 10 minutes and add points to meet their goal.

The accelerometer sensor in the smartphone tracks the footsteps of the users, targeting 1000 steps in 10 minutes, based on the recommendation of 3000 steps in 30 minutes [41]. Here, 500 steps are counted as 1 reward point. Reminders are sent via an alarm/vibration during breakfast and lunch. The leaderboard appears as an interactive social display when the users select "View points" from the main menu. The leaderboard shows the ranked list of users, their names, photos, and earned points. Users can customize their picture and name visibility settings when signing into their iGO account. Additional details of the user interface of the functionality pages of the iGO mHealth app have been published elsewhere [42]. Walking data are gathered on the web server (Figure 3).

An 8-week usability evaluation of the final iGO mHealth app was conducted earlier, utilizing the unified theory of acceptance and technology model. The details have been published elsewhere [42]. Briefly, the usability was evaluated based on performance expectancy, effort expectancy, social influence, facilitating conditions, behavioral intention, and use behavior. The results showed success in motivating the users to participate in PA.

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Figure 2. Flow within the iGO mobile health app.

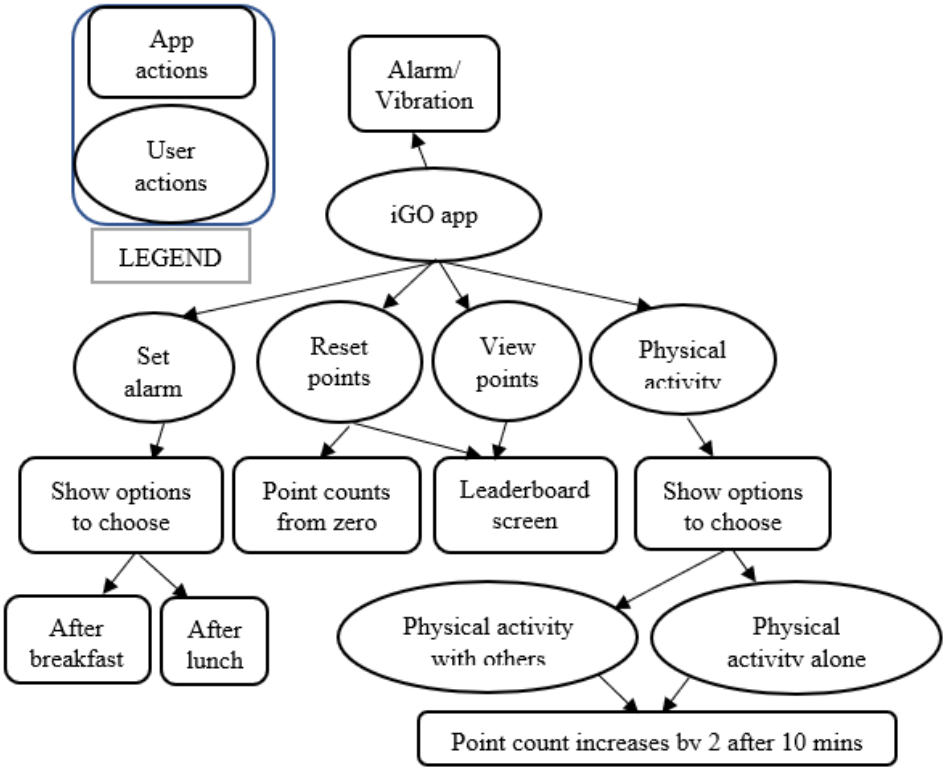

Figure 3. A user's walk and step count after the lunch recess are tracked, and the data are gathered in the web server.

User's Data

Show 10 entries Search:

Name	Email ID	Walk Time	Walking Status	Walk With	Walk Point	Date Time
[redacted]	1922682021301050	04:02 PM	yes	Physical activity by own	2	2017-04-10 15:03:14
[redacted]	1922682021301050		yes		2	2017-04-11 09:57:40
[redacted]	1922682021301050	10:57 AM	yes	Physical activity by own	0	2017-04-11 09:57:49
[redacted]	1922682021301050	10:57 AM	yes	Physical activity by own	2	2017-04-11 09:57:50
[redacted]	1922682021301050	10:57 AM	yes	Physical activity by own	1	2017-04-11 10:06:24
[redacted]	1922682021301050	10:57 AM	yes	Physical activity by own	2	2017-04-11 10:06:25
[redacted]	1922682021301050	12:03 PM	yes	Physical activity by own	0	2017-04-12 11:03:41
[redacted]	1922682021301050	12:03 PM	yes	Physical activity by own	2	2017-04-12 11:03:43
[redacted]	1922682021301050		yes		0	2017-04-12 11:05:11
[redacted]	1922682021301050		yes		2	2017-04-12 11:05:12
Name	Email ID	Walk Time	Walking Status	Walk With	Walk Point	Date Time

Showing 81 to 90 of 862 entries Previous Next

Participants

The 4-week experimental study was conducted at 4 sites in 4 countries: the city of Oulu, Northern Finland (population, ~199,000); Carlow, South Leinster, Ireland (population, ~26,000); the megacity of London, United Kingdom (population, ~8,136,000); and the megacity of Dhaka, Bangladesh (population, ~1,984,000). The 4 countries were selected due to practical reasons owing to existing collaborations. To recruit the participants, we selected 10 multinational information and communications technology companies (2 in the United Kingdom, 2 in Ireland, 3 in Finland, and 3 in Bangladesh), 1 research institute from each country (University of Oulu, Finland; Queen Mary University of London, United Kingdom; Institute of Technology, Carlow, Ireland; and Bangladesh University of Professionals, Bangladesh), and people in startup companies (Finland, United Kingdom, Ireland, Bangladesh). The list of the companies was collected, and we personally communicated with university researchers and professors. People working in the information technology sector were invited to participate, owing to the relationship between information technology skills and technology acceptance. We contacted each site by email and asked for an invitation email to be forwarded to their employees. The first author of the study contacted the people at the startup companies directly. A total of 220 people was invited. The people were randomized to the experimental (n=115) and control (n=105) groups before sending the invitations (Figure 4). Participants were randomized to the groups manually in a blindfolded randomly mixed order. They were contacted to confirm their willingness to participate in a 4-week trial. We obtained informed consent (Multimedia Appendix 2) from all participants before conducting the study. The consent form was in English in all countries. The participants were able to withdraw from the study in any phase. Based on the study design, a review by an ethical committee was not required.

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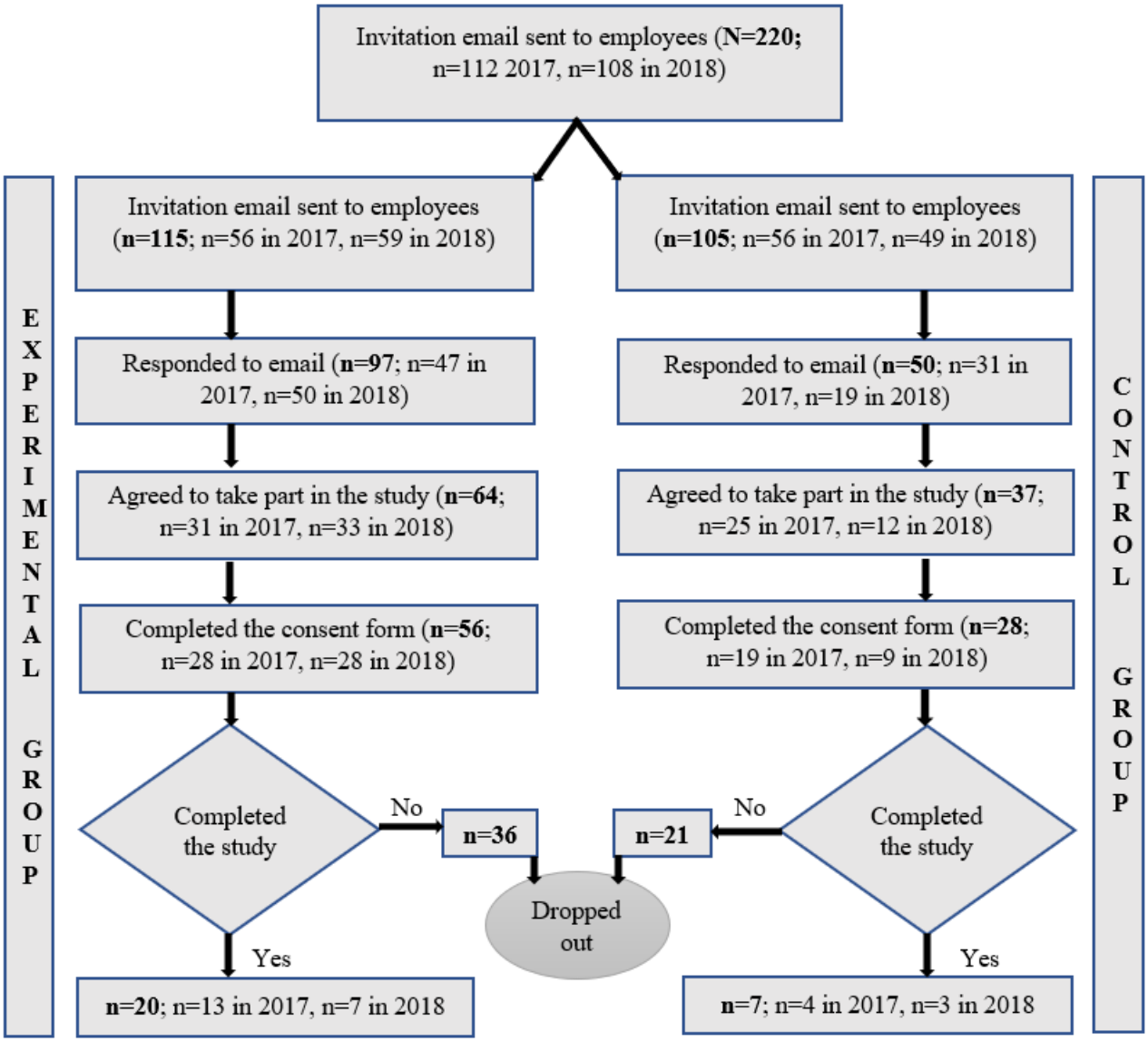
Figure 4. Flow chart of the study participants.



The flow chart of the study participants is shown in Figure 4. The final study population consisted of 84 working-age volunteers working in an office setting who completed the consent form. The characteristics of the participants are given in Tables 1 and 2. A participant was considered to have completed the study if he or she used the app or paper diary for 4 weeks and returned the final questionnaire.

In the experimental group, 115 people were asked to participate in the 4-week trial using the iGO app. Of these participants, 56 completed the consent procedure (mean age 39 years, range 24-49 years), and 20 participants completed the study (12 men and 8 women; mean weight 72.2 kg; mean BMI 24.8 kg/m²). The reasons given for dropping out of the trial (n=36) were a lack of time, holidays, laziness, or personal issues (16/36, 44%); unwillingness to use the mHealth app because they disliked its appearance or were already using an mHealth app (6/36, 17%); did not feel a need for this type of service or were already taking care of themselves (3/36, 8%); and other reasons (7/36, 20%). A further 11% (4/36) did not give a reason for declining.

The control group (n=105) was asked to participate in the 4-week trial using a paper diary. Of these 105 people, 28 completed the consent procedure (mean age, 39 years; range 26-49 years), and 7 participants completed the study (5 men and 2 women; mean weight 71.4 kg; mean BMI 24.5 kg/m²). The reasons given for dropping out (n=21) were a lack of time, holidays, laziness, or personal issues (6/21, 28%); unwillingness to use the paper diary because they disliked it, since it was only paper, with no alarm (7/21, 35%); did not feel a need for this type of service or they were already taking care of themselves (3/21, 13%); and other reasons (6/21, 26%).

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Table 1. Baseline characteristics of the participants.

Variable	Invited, N=220		Consented, n=84		Completed, n=27	
	E[a], n=115	C[b], n=105	E, n=56	C, n=28	E, n=20	C, n=7
Gender, n (%)						
Female	44 (38.3)	42 (40.0)	23 (41.0)	12 (42.9)	10 (50.0)	4 (57.1)
Male	71 (61.7)	63 (60.0)	33 (59.0)	16 (57.1)	10 (50.0)	3 (42.9)
Work situation, n (%)						
University	62 (53.9)	50 (47.6)	—[c]	—	—	—
IT[d] industry	36 (31.3)	41 (39.0)	—	—	—	—
Startup company	17 (14.8)	14 (13.4)	—	—	—	—
Country, n (%)						
United Kingdom	32 (27.8)	30 (28.5)	18 (32.1)	9 (32.1)	6 (30.0)	2 (28.6)
Ireland	22 (19.1)	19 (18.1)	12 (21.4)	5 (17.9)	6 (30.0)	1 (14.3)
Finland	26 (22.6)	24 (22.9)	15 (26.8)	8 (28.6)	5 (25.0)	3 (42.9)
Bangladesh	35 (30.4)	32 (30.5)	11 (19.6)	6 (21.4)	3 (25.0)	1 (14.3)

[a]E: experimental group.

[b]C: control group.

[c]Data were not available.

[d]IT: information technology.

Table 2. Baseline characteristics of the participants by country.

Variable	Invited, N=220		Consented, n=84		Completed, n=27	
	E[a], n=115	C[b], n=105	E, n=56	C, n=28	E, n=20	C, n=7
United Kingdom, n (%)						
Female	11 (34.4)	13 (43.3)	7 (38.9)	3 (33.3)	2 (33.3)	1 (50.0)
Male	21 (65.6)	17 (56.7)	11 (61.1)	6 (66.7)	4 (66.7)	1 (50.0)
Ireland, n (%)						
Female	10 (45.5)	7 (36.8)	5 (41.7)	1 (20.0)	3 (50.0)	0 (0)
Male	12 (54.5)	12 (63.2)	7 (58.3)	4 (80.0)	3 (50.0)	1 (100)
Finland, n (%)						
Female	11 (42.3)	9 (37.5)	6 (40.0)	4 (50.0)	3 (60.0)	2 (66.7)
Male	15 (57.7)	15 (62.5)	9 (60.0)	4 (50.0)	2 (40.0)	1 (33.3)
Bangladesh, n (%)						
Female	12 (34.3)	13 (40.6)	5 (45.5)	4 (66.7)	2 (66.7)	1 (100)
Male	23 (65.7)	19 (59.4)	6 (54.5)	2 (33.3)	1 (33.3)	0 (0)

[a]E: experimental group.

[b]C: control group.

Paper Diary

The paper diary had a simple chart to record walking after breakfast and lunch. The diary did not incorporate SDT needs and PBL elements. Users entered their data manually. Participants were instructed to complete their walking record on the paper diary during their breakfast and lunch breaks every weekday for 4 weeks. An alarm/vibration as a reminder was not included with the paper diary (Multimedia Appendix 3).

Questionnaire

Based on the users' feedback in the previous study [38], a quantitative questionnaire (Multimedia Appendix 4) was initially designed, validated, and tested. The validation was conducted by 4 experts with similar research backgrounds. The questionnaire was co-designed by 6 end users living in Finland and Ireland. The questionnaire used a 7-point Likert scale, with answers ranging from "Much worse" to "Much better" (for increasing PA) and "Completely disagree" to "Completely

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agree" (for autonomy, competence, and relatedness). Similarly, a set of qualitative questions (Multimedia Appendix 4) was designed and tested to determine how the mHealth app or paper diary helped users improve their PA, any personal approaches used in the app or paper diary to help with their PA, any ways in which the iGO mHealth app or paper diary failed to help users or made their PA worse, and how the app could be improved.

Interview

Semistructured 20-minute interviews [43] were conducted and audio recorded with all participants in the experimental group who completed the study. They were asked about the external contexts as well as their opinions and feelings on the usage of the iGO app. To evaluate the responses to open questions, conventional content analyses were performed by the first author. Microsoft Excel (Microsoft Corp, Redmond, WA) was used to store and organize the data collected during the interviews. Analysis was carried out in three steps: (1) the data were repeatedly read for familiarity, (2) words or phrases corresponding to the key themes were highlighted and coded, and (3) the context and frequency of theme-related sentences were recorded.

Procedure

The iGO app was first installed on the participant's smart device. Samsung (Seoul, South Korea) Android phones were lent to any participants who did not have a compatible phone. Participants were instructed to use the mHealth app or paper diary for 4 weeks. Participants in the experimental group were asked to use the mHealth app daily for at least 10 minutes after breakfast and 10 minutes after lunch, while walking during their break time. The participants customized the breakfast and lunch times to their preferred times. Based on the set time, the phone initiated a vibration/alarm as a reminder for participants to start walking. After walking for 10 minutes, the participants were notified by the iGO app that they completed their goal. The participants filled in the quantitative questionnaires at the end of the study.

Statistical Analysis

The statistical tool SPSS 25.0 (IBM Corp, Armonk, NY) was used to analyze the quantitative data. Differences between the experimental group and control group were compared using *t* tests. The *P* value for each of the psychological needs of autonomy, relatedness, and competence was calculated separately. $P<.05$ was considered statistically significant.

Results

Quantitative Results

An overview of the quantitative questionnaire results is shown in Table 3. The answers were rated using a 7-point Likert scale, with scores of 1 to 7 corresponding to responses ranging from "Much worse" to "Much better" (for increasing physical inactivity) and to responses ranging from "Completely disagree" to "Completely agree" (for autonomy, competence, and relatedness).

Table 3. User ratings of whether the iGO app (experimental group) or paper diary (control group) increased physical activity, autonomy, competence, and relatedness, rated using a 7-point Likert scale.

Condition	Experimental group (n=20), mean	Control group (n=7), mean	*P* value
Increasing physical activity	6.15	4.30	.033
Autonomy	5.05	3.30	.004
Competence	4.86	2.00	.014
Relatedness	3.15	3.43	.535

The score for increasing physical activity was significantly higher for participants in the experimental group than for those in the control group ($P=.033$). Also, participants in the experimental group were significantly more likely to consider that the mHealth app increased their motivation to participate in PA alone, compared with the control group ($P=.004$).

Participants in the experimental group were significantly more likely to consider that the mHealth app increased their feeling of competence to view themselves in a social environment (ie, on the leaderboard), compared with the control group ($P=.014$). There was no difference between the experimental and control groups in their reported motivation to participate in PA with others.

Participants inputted their weight when installing the iGO app on the smartphone and transferred this information to the postexperimental questionnaires. A trend for weight loss was found when using iGO, with borderline statistical significance (pre-intervention mean weight, 72.2 kg vs post-intervention mean weight, 71.4 kg, $P=.054$).

Open Questions

Autonomy

Based on the interview, most experimental group participants (14/20, 70%) were motivated, set their daily goal of 10-minute walking after breakfast and lunch, and tracked their daily walking when using the iGO app, which indicated autonomy.

> *I sort of liked the way how it influenced me to go for a walk and became my daily routine, liked it.*
>
> *I felt like using the app has changed my habit of sitting idle in the office after breakfast/lunch.*

Competence

Participants (13/20, 65%) felt competent when using the iGO app to view themselves in a social environment to walk daily.

> *[It] assisted me to interact with the phone and to walk with others*

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> *[It] became a habit, but I wanted to see more in the apps like more connection [among] people who are using it!*

They felt competent using the mHealth app, which indicates fulfillment of the psychological need of competence.

Relatedness

Only few participants (5/20, 25%) were motivated to participate in PA (eg, walking with others) when using iGO. One participant felt connected with their colleagues and noted: "[I] walked with colleagues and friends and made me mix with others while walking; a social platform." Perhaps iGO allowed the participant to walk daily with colleagues from the same office and track their progress from the data server. In this way, they might feel connected with colleagues. However, one participant stated: "I cannot feel any betterment to walk with others." The sense of being connected to others using the gamified prototype is not valid in this case. Therefore, we cannot agree that the last psychological need, relatedness, was fulfilled.

Game Elements

One participant ranked in the leaderboard reported: "I liked the way … it influenced me to go … walking and [it] became my daily routine, liked it."

However, the social, fun part of the game elements was not apparent among the participants who reported:

> *Maybe add a way to create events to [attend].*
>
> *Should add more socializing features.*
>
> *Maybe more social fun activities options.*

Participants wanted to see different points for the 2 walking conditions. One participant mentioned, "Some difference in the points for walking alone and walking with others."

Other Comments

The log data showed that some regular users did not upload their name and photo so they were visible on the leaderboard, even though users preferred a leaderboard that included their details when prototyping the iGO app. Within the control group, most participants suggested that some sort of reminder should be added in the paper diary.

> *I wish there were a kind of alarm type feature or image that [could] draw … attention towards the paper.*
>
> *[A] paper diary can be easily ignored in the busy schedule, so it should be more attractive.*

Of the participants who completed the study using the iGO app, 8 (8/20, 40%) participants used a provisioned Samsung phone, whereas the remaining participants used their own smartphones. The log data showed that those who used their own phone had more points and ranked higher on the leaderboard. Moreover, the data from the participants who completed the study in Ireland showed that those who ranked highly on the leaderboard (4/6, 66%) were colleagues from the same offices and building.

Discussion

Principal Findings

This study presents the feasibility of an mHealth app designed for promoting walking in the workplace during breaks. Based on the examination, the iGO app helped to overcome physical inactivity by increasing walking. The data supported compliance with 2 of the basic psychological needs, namely autonomy and competence, but not for the needs of relatedness. However, compliance in using the app remained low.

Satisfaction with the SDT basic needs for autonomy, competence, and relatedness is essential for establishing intrinsically motivated and sustained PA behavior [44]. In this study, most participants were motivated and set their daily goal of 10-minute walking after breakfast and lunch. Participants felt competent using iGO to view themselves in a social environment to walk daily.

Discontinuation is a central problem in technology-enhanced intervention studies [45], and participant age, gender, education level, and employment status can influence the risk of dropping out during the study [46]. In this study, the number of consented participants who did not continue the study was comparatively high. Participants were busy in their work life. They were young developers or programmers working in technology-based industries. This may indicate that the reasons for discontinuation were their young age and employment status.

Studies have shown that interventions targeting PA promotion can be designed to focus on setting-specific issues that are open to change within demographic settings differentiated by gender, age, social disadvantage, and geographic location [47]. Our users were from 4 different countries. Apart from those in the United Kingdom and Ireland who were native English speakers, participants from Finland and Bangladesh had their own native language (Finnish and Bengali, respectively). However, they all spoke English due to their international working environment. Thus, participants were not affected by the language factor when the app was in English. Instead, cultural differences may have a significant effect on the use of behavior change apps and need to be studied in more detail in future.

On the other hand, weather conditions may affect outdoor PA, as demonstrated for older adults [48]. The United Kingdom, Ireland, and Finland have varying day lengths and seasonal outdoor temperatures, in contrast to Bangladesh. Extremely cold temperatures and slippery conditions may reduce participation in outdoor activities during the winter period (eg, in Finland) but may not affect indoor behaviors. Similarly, extreme heat levels have a negative impact on human health and productivity [49], which may have limited walking outside of the office buildings in Bangladesh. The office interiors were well-equipped with air conditioning systems but may have had comparatively limited space to even walk in the office corridors. However, because the mHealth app was designed to encourage workers to walk during their breakfast or break, which they were able to do in the office area, they were not much affected by weather factors.

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We did not examine the users' recommendations, age, and gender based on the specific geographic location but averaged all users' preferences from the 4 different countries when designing the app. The SDT needs of relatedness were absent in this study (ie, the participants did not connect with others while walking). Previous research has suggested that being connected to more people may help with PA promotion [50,51] and users tend to do more PA if they are socially connected with others for the same purpose. In this study, the environment appeared to not fully support regular PA by the participants, perhaps due to the lack of actual daily interaction with colleagues. The low levels of relatedness may be explained by the fact that few colleagues were using the iGO app at the same time. The social features of an mHealth tool have been shown to initiate positive changes in social interaction among colleagues and signing up for the tool [52]. In this study, the leaderboard included participants from the 4 countries. However, this may have demotivated participants, since it may be more motivating to compete against participants that people know personally.

Cognitive, emotional, and social benefits are credited to gamification [53]. Building positive social relationships and fostering a sense of integration are the core social benefits noted for gamification [54]. In the present study, the game elements may not have provided enough social benefits for the users. Additional features could have been added for scoring. For instance, walking with others might have scored additional points. Competition allows users to identify their situation and compare their activities to others [55]. Although a leaderboard is a way to represent competition based on users' activity [27], competition was not noticed among the users in this study. Participants who focused more on PA than points may have earned more points than those who focused on earning points. To facilitate PA promotion, strengthening of motivation and changes in self-awareness are two essential mechanisms [56]. This suggests that participants may have been motivated intrinsically by using the mHealth app and that their self-awareness of PA in the workplace was increased through the use of the mHealth app.

Using mobile reminders is a conventional approach in health research [57-59]. The use of digital triggers (eg, alarm or vibration) can be automated in smartphones so that the users recognize the meaning of the alert. Triggers such as an adaptive control mechanism are framed to meet the needs and goals for short-term actions and longer-term behavioral change [60]. The reminders programmed in our mHealth app helped the users react for a near-term response (eg, a reminder to walk). Researchers have highlighted that mHealth solutions are still methodological and need to resolve privacy issues [61], such as security features that include secure encryption and two-factor authentication [62]. Some participants might have chosen to omit their name or photo on the leaderboard because of their preference to not disclose their daily PA-based track record (eg, total minutes of walking, earned points) to others.

Compliance with the paper diary was comparatively low, compared with that of the mHealth app. Participants forgot to complete the paper diary, it was less attractive, there was no alarm system, and it was difficult to record walking time on paper.

Walking can be beneficial for weight loss [63] and other health outcomes [64,65]. mHealth interventions with theory-based podcasts, social support [66], encouraged self-tracking [66,67], and health coaching [68] have been shown to result in weight loss. During this 4-week study, there was a trend for weight reduction among the experimental group. It is unknown whether the mHealth app influenced weight loss, since the follow-up time was relatively short, the sample size was limited, and only self-reported weight data were used.

Limitations and Future Study

This study has some limitations. First, the final sample size was relatively small. Larger-scale studies are needed to confirm the findings. Many consented participants, who typically were young programmers or developers, discontinued the 4-week study. A next-generation solution should be designed based on the feedback received, in order to increase compliance. Second, participants were randomized before they received their invitations. This may have influenced the difference in the number of participants between the groups.

Another limitation of the study is that the weight was self-reported and collected only at the beginning and end of the study. However, this study targeted an increase in PA, not weight loss, which may reduce the possibility for bias.

The iGO app was still a prototype with somewhat limited graphical design and user interface. Some participants may have failed to connect with others due to the contemporary design of the mHealth app. PA measured by a smartphone can underestimate the number of steps, as people may leave their phone on their office desks. Fewer measured minutes of walking may result in fewer points and therefore an inaccurate leaderboard, which could demotivate participants to follow ranks and points on the leaderboard. Furthermore, the accelerometer sensor was not installed in some smartphones, and users were not able to track their steps. Hence, the actual walking data may be different from the data in the web server. The measured increase in PA was obtained from questionnaire data. We used the accelerometer-based step count to calculate the rewards. However, we did not use the objective PA data for other purposes in this study.

More features and options could be added, such as socializing functions and social, fun activities allowing users to interact with others [69,70]. Adding a gamified social networking platform [71,72] with more user-friendly social features, such as a more specific social game element, might allow users to interact with others via chat messages in the mHealth app. Points could be awarded and redeemed in schemes such as the Tesco Clubcard [73,74] and Carrots Rewards App [75]. The iGO app could have options for users to share each other's points and perhaps exchange points for social voucher cards.

Conclusions

In the research for this paper, we conducted a feasibility study on the mHealth persuasive app for promoting PA in the workplace. This mHealth app was developed by incorporating

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the SDT theory and applying game design elements. The design of the app followed the UCD process. A 4-week study was conducted with a group of office workers. The mHealth app supported users to increase their PA at the workplace, when compared with a paper diary. The iGO app fulfilled the SDT basic needs of autonomy and competence, but not relatedness (ie, it did not support participants in feeling connected with others). This study demonstrates how even a simple mHealth app can help employees increase their PA. The design of the app appeared to be a successful approach that is viable for future persuasive apps. Future research should aim to develop the app further based on users' feedback and test it on a larger scale, enabling the critical components within the mHealth intervention to be studied.

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Conflicts of Interest

None declared.

This randomized study was not registered. The editor granted an exception from ICMJE rules mandating prospective registration of randomized trials because the risk of bias appears low and the study was considered formative. However, readers are advised to carefully assess the validity of any potential explicit or implicit claims related to primary outcomes or effectiveness, as retrospective registration does not prevent authors from changing their outcome measures retrospectively.

Multimedia Appendix 1
User interfaces of the iGO app.
[DOCX File , 2193 KB - formative_v4i5e15083_app1.docx]

Multimedia Appendix 2
Consent form.
[DOCX File , 27 KB - formative_v4i5e15083_app2.docx]

Multimedia Appendix 3
Paper diary.
[DOCX File , 14 KB - formative_v4i5e15083_app3.docx]

Multimedia Appendix 4
Questionnaire.
[DOCX File , 16 KB - formative_v4i5e15083_app4.docx]

Multimedia Appendix 5
CONSORT-EHEALTH Checklist V1.6.
[PDF File (Adobe PDF File), 1802 KB - formative_v4i5e15083_app5.pdf]

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Abbreviations

mHealth: mobile health
PA: physical activity
PBL: points, badges, and leaderboards
SDT: self-determination theory
UCD: user-centered design

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Original Paper

Privacy-Preserving Deep Learning for the Detection of Protected Health Information in Real-World Data: Comparative Evaluation

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Abstract

Background: Collaborative privacy-preserving training methods allow for the integration of locally stored private data sets into machine learning approaches while ensuring confidentiality and nondisclosure.

Objective: In this work we assess the performance of a state-of-the-art neural network approach for the detection of protected health information in texts trained in a collaborative privacy-preserving way.

Methods: The training adopts distributed selective stochastic gradient descent (ie, it works by exchanging local learning results achieved on private data sets). Five networks were trained on separated real-world clinical data sets by using the privacy-protecting protocol. In total, the data sets contain 1304 real longitudinal patient records for 296 patients.

Results: These networks reached a mean F1 value of 0.955. The gold standard centralized training that is based on the union of all sets and does not take data security into consideration reaches a final value of 0.962.

Conclusions: Using real-world clinical data, our study shows that detection of protected health information can be secured by collaborative privacy-preserving training. In general, the approach shows the feasibility of deep learning on distributed and confidential clinical data while ensuring data protection.

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KEYWORDS

privacy-preserving protocols; neural networks; health informatics; distributed machine learning

Introduction

Background

Data protection is a major issue in health care, but clinical research and medical care also rely on high accessibility of patient data. The problem is aggravated in the context of data-driven medicine, where the amount of data needed exceeds the capacity of manual data curation and manual deidentification that would be necessary to protect patient privacy. In the United States, the Health Insurance Portability and Accountability Act of 1996 obliges data curators to remove protected health information (PHI) from medical records before they are shared with researchers. The same holds true for many other countries (see, for instance, §6 GDSG NW [Germany], SI 1438/2002 reg. 7 [England and Wales]). Computer-based data deidentification primarily needs to solve the task of detecting personal information like names, phone numbers, locations, etc. Deidentification systems must meet two opposed interests. To ensure privacy, they must work with high sensitivity (ie, avoid overlooking personal data). Additionally, these systems need to maintain high specificity (ie, avoid removing data unnecessarily). Otherwise, deidentified texts would contain little valuable information compared with the original inputs.

Many approaches to finding protected personal information in health records are based on supervised machine learning [1-3]. Such systems have proven to be very efficient for the

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deidentification task. One presented by Dernoncourt et al [3] even outperformed other state-of-the-art approaches in 2016. The general shortcoming of such approaches in this context is that they depend heavily on labeled training data. These training data usually consist of original health records containing personal information. Thus, these data cannot be shared among researchers for distributed training due to the above-mentioned problem. Consequently, there are many small training data sets at medical research institutes which can only be used locally. An additional challenge arises from the fact that even trained neural networks (NNs) can be abused to recover PHI that has been used for training [4,5]. Hence, a trained network for deidentification cannot be shared with other researchers or the public without causing a threat to patient privacy.

Related Work

Several systems for the deidentification of PHI have been presented in the last 20 years. Meystre et al [6] state that most of the systems introduced before 2010 are rule-based or rely on pattern matching. The underlying patterns and rules are typically hand-crafted. Thus, domain experts are needed for the costly generation of such systems resulting in limited generalizability [6]. More recent approaches are mainly based on machine learning or, more precisely, conditional random fields and support vector machines [7]. For these systems, only features of the input data must be specified by hand. Several such tools, however, use additional rules for identifying certain classes of PHI or postprocessing [1,2,8]. The method proposed by Dernoncourt et al [3] is one of the first that solely makes use of NNs and thus is independent of manual feature selection. Liu et al [9] compare several rule-based and NN-based approaches to the deidentification task. Moreover, they introduce an ensemble method that combines these systems.

Collaborative privacy-preserving machine learning has already been studied by several authors. Many systems introduced in this field homomorphically encrypt local data and share the ciphered information for centralized training [10-12]. Thus, these systems need an authority trusted by all parties to start encrypted communication. Another issue of cryptographic centralized training is the cost for encryption and decryption which can become untenable for high-dimensional data in practical applications [10]. By using a decentralized training which obviates the need for sharing individually identifiable health information, these problems vanish. Chang et al [13] experimented with several nonparallel distributed training heuristics. In their proposed framework, local workers conceal their training data but share full sets of learned network parameters. According to Shokri and Shmatikov [4], this transfer of local parameters might still lead to indirect leakage of personal information. Moreover, Fredrikson et al [5] investigated model inversion attacks that infer sensitive information included in the training data from a given trained model. The authors distinguish between black- versus white-box attacks: black-box attacks exploit prediction/classification queries via functional access to a model without knowing its internal details, while white-box attacks additionally use details of the model (eg, network topology and weight matrices). Fredrikson et al [5] demonstrated the feasibility of model inversion attacks especially in the case of white-box approaches using real-world data and publicly available trained classifiers. Their experiments included NNs used for facial recognition. A model inversion attack was able to reconstruct faces of the training set after entering the corresponding names, which can well be considered a relevant violation of privacy.

Hence, we decided to use the collaborative and parallel training method introduced by Shokri and Shmatikov [4]. It reduces the risk of indirect leakage and allows the cooperation of institutes with different computational capacities. For this training scheme, no encryption or any other data protection is needed except the local data and computations must be secured. Like most other collaborative privacy-preserving learning approaches, it only protects from honest-but-curious adversaries. That means malicious participants can hamper the learning or even render it unusable, but they cannot gain information not meant for them. A similar training approach was used by Liu et al [14]. In contrast to our study, they trained feedforward NNs and investigated the effect of using mobile devices to conduct the local training.

Aim of the Study

Our study is aimed at showing the feasibility of a collaborative privacy-preserving learning approach for deep NNs trained to detect personal information in real-world clinical data. We adopted the network topology of the mentioned deidentification approach described by Dernoncourt et al [3]. To overcome the problem of small data sets and privacy issues, we used collaborative privacy-preserving learning suggested by Shokri and Shmatikov [4]. This technique allows the integration of many local data sets into the training while minimizing the risk of leaking protected information. It restricts the training to the local site of each data provider (ie, own data stay with each provider) and only relies on the sharing of small fractions of the local improvements.

We evaluated the performance of the deidentification network trained in a collaborative and privacy-preserving manner. For this purpose, we used an existing set of longitudinal clinical narratives published in the course of the Informatics for Integrating Biology and the Bedside (i2b2) 2014 deidentification challenge hosted by the National Center for Biomedical Computing [7,15] (deidentified clinical records used in this research were provided by the i2b2 National Center for Biomedical Computing funded by U54LM008748 and were originally prepared for the Shared Tasks for Challenges in Natural Language Processing for Clinical Data organized by Dr. Özlem Uzuner, i2b2, and the State University of New York).

Methods

Recurrent Neural Network for Deidentification

General Topology and Training Goal

The recurrent neural network (RNN) presented by Dernoncourt et al [3] is constructed to work on fragments of medical notes. The computed output is a sequence of labels with each label corresponding to one term (also called a token) of the input text. In our adapted version, a label can either be non-PHI or one of 28 PHI classes or subclasses adopted from the definitions of

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the i2b2 deidentification challenge (Table 1). If there is at least one subclass, the general class is not used as a label.

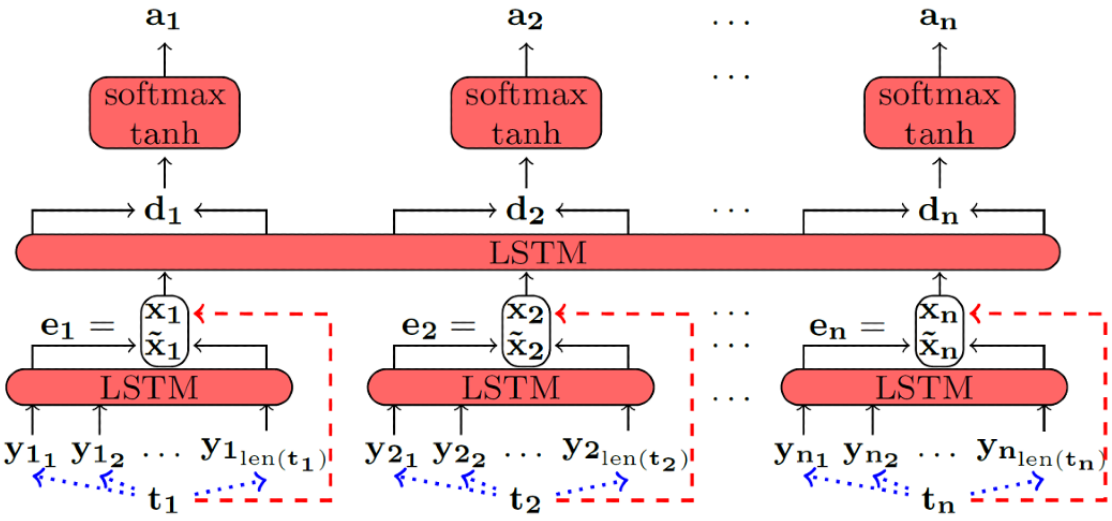
The network topology shows two different layers. The first layer consists of long short-term memory (LSTM) RNNs and is called the character-enhanced token embedding layer. The actual label assignment is conducted in the label prediction layer seen in Figure 1.

Table 1. Possible protected health information classes of terms.

Class	Subclasses
Name	Patient, clinician, username
Profession	—
Location	Hospital, organization, street, city, state, country, zip, other
Age	—
Date	—
Contact	Phone, fax, email, URL, Internet Protocol address[a]
Identification	Social security number[a], medical record number, health plan number, account number[a], license number[a], vehicle identification[a], device identification, biometric identification, identification number

[a]Classes that are not present in the published data set [7].

Figure 1. Network topology of the recurrent neural network used for deidentification [3].



Preprocessing

During preprocessing, the input text is subdivided into terms $\mathbf{t_i}$ which are then transformed into their vector representations $\mathbf{x_i} \in \mathbb{R}^{300}$. For the transformation we use the Word2Vec approach which can map words into a low-dimensional vector space while keeping some semantic and syntactic information [16]. This transformation from word to vector is depicted by the red-dashed arrows (Figure 1). As a result of the preprocessing, the input text $T = (\mathbf{t_1}, \ldots, \mathbf{t_n})$ is available as a sequence of Word2Vec vectors $X = (\mathbf{x_1}, \ldots, \mathbf{x_n})$.

In the second preprocessing step, every term $\mathbf{t_i}$ is further divided into its individual characters $(t_{i\_1}, \ldots, t_{i\_len(ti)})$. Again, every character is translated into a vector $\mathbf{y_{i\_j}} \in \{0,1\}^{128}$ of low dimensionality. The translation is represented by blue-dotted arrows (Figure 1). In contrast to the word embedding, characters are encoded by a simple one-hot method (ie, by vectors with exactly one nonzero component). The dimension being nonzero is obtained by taking the Unicode representation of the corresponding character if it is smaller than 127. For all other characters, the last dimension is set to 1. In this way, all ASCII punctuations and symbols as well as the basic Latin alphabet can be encoded. All letters are mapped to corresponding one-hot vectors without taking any syntactic information into account.

To sum up, at the end of the preprocessing there are vectors $\mathbf{x_i}$ (word embeddings) representing every input term and vectors $\mathbf{y_{i\_j}}$ (character embeddings) each representing one occurrence of a character.

Character-Enhanced Token Embedding Layer

For every word, the first layer contains an independent instance of a bidirectional LSTM. Hence, the number of RNNs changes for every input text.

LSTMs integrate new parts of an input sequence into their computation in every step. Furthermore, they keep some information of the already processed prefix of the sequence. This makes them capable of learning long-term dependencies

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between vectors whose positions in the input are far apart [17]. Mathematically, a general unidirectional LSTM can be described as follows.

Let W_i, W_c, W_o be three weight matrices and $\mathbf{b_i}$, $\mathbf{b_c}$, $\mathbf{b_o}$ be three bias vectors. These parameters are learned during the training. If the input sequence equals (z_1, ... , z_m), the LSTM conducts m steps. In the $\mathbf{t}^{th}$ iteration, the hidden state $\mathbf{h_t}$ and the memory state $\mathbf{c_t}$ are computed using $\mathbf{z_t}$, $\mathbf{h_{t-1}}$, and $\mathbf{c_{t-1}}$ as inputs and the following formulas:

$\mathbf{i_t} = \sigma(W_i \cdot \text{concat}(\mathbf{z_t}, \mathbf{h_{t-1}}) + \mathbf{b_i} + \mathbf{1})$

$\mathbf{c_t} = \mathbf{i_t} \odot \mathbf{c_{t-1}} + (1 - \mathbf{i_t}) \odot \tanh(W_c \cdot \text{concat}(\mathbf{z_t}, \mathbf{h_{t-1}}) + \mathbf{b_c})$

$\mathbf{o_t} = \sigma(W_o \cdot \text{concat}(\mathbf{z_t}, \mathbf{h_{t-1}}) + \mathbf{b_o})$

$\mathbf{h_t} = \mathbf{o_t} \odot \tanh(\mathbf{c_t})$

where $\odot$ denotes the element-wise multiplication, σ the element-wise logistic sigmoid function, and tanh the element-wise hyperbolic tangent function. For the first iteration the hidden state $\mathbf{h_0}$ and the cell state $\mathbf{c_0}$ must be initialized arbitrarily. Sometimes the full sequence of hidden states ($\mathbf{h_1}$, ... , $\mathbf{h_m}$) is considered the output of the LSTM and sometimes just the last hidden state $\mathbf{h_m}$ is seen as the output.

A bidirectional LSTM consists of two independent unidirectional LSTMs. The first one works on the original input sequence ($\mathbf{z_1}$, ... , $\mathbf{z_m}$), whereas the second one computes the output for the reversed sequence ($\mathbf{z_m}$, … , $\mathbf{z_1}$).

By combining the two output sequences ($\mathbf{h_1}^{for}$, ... , $\mathbf{hm}^{for}$) and ($\mathbf{h_1}^{back}$, ... , $\mathbf{hm}^{back}$) one gets the overall output (concat($\mathbf{h_1}^{for}$, ... , $\mathbf{h_1}^{back}$),..., concat($\mathbf{hm}^{for}$, ... , $\mathbf{hm}^{back}$)) or concat($\mathbf{h_m}^{for}$, ... , $\mathbf{h_m}^{back}$), respectively.

The token embedding layer contains one bidirectional LSTM per term $\mathbf{t_i}$ of the input text. Every such LSTM works on the corresponding sequence of character embeddings ($\mathbf{y_{i\_1}}$,...,$\mathbf{y_{i\_len(ti)}}$). At this stage no information are exchanged between LSTMs working on different tokens. However, they all share the same weight matrices and bias vectors. The output of the $\mathbf{i}^{th}$ RNN can be written as $\square_i$ =concat($\mathbf{h_{i\_len(t\_i)}}^{for}$, $\mathbf{h_{i\_len(t\_i)}}^{back}$).

This vector is used as an additional word embedding to overcome shortcomings of Word2Vec [3]. The presented computation always leads to a reproducible vector representation of a token, whereas Word2Vec cannot handle vocabulary that was not used during training. Moreover, this strategy keeps more semantic information than pure Word2Vec combined with a preceding lemmatization step. However, in comparison to the Word2Vec embedding, those LSTMs compute vectors that do not contain any information of interword dependencies.

To keep the advantages of both strategies, the two word embeddings of every token are combined in one vector $\mathbf{e_i}$ = concat($\mathbf{x_i}$, $\square_i$). In summary, it can be stated that for the input sequence ($\mathbf{t_1}$, ... , $\mathbf{t_n}$) the character-enhanced token embedding layer computes the output ($\mathbf{e_1}$, ... , $\mathbf{e_n}$).

Label Prediction Layer

The subsequent layer evaluates the dependencies between different words of the input text. Again, a bidirectional LSTM is used for the task. In contrast to the previous layer, only one LSTM is used independent of the number of tokens. This RNN uses the output sequence ($\mathbf{e_1}$, ... , $\mathbf{e_n}$) of the previous layer as its input. The output consists of the full sequence ($\mathbf{d_1}$, ... , $\mathbf{d_n}$) where $\mathbf{d_i}$ = concat($\mathbf{h_1}^{for}$, ... , $\mathbf{h_1}^{back}$).

Every $\mathbf{d_i}$ is further processed by a two-layer, fully connected feedforward network. The parameters are the same for every input $\mathbf{d_i}$ and are trained jointly for every sequence ($\mathbf{d_1}$, ... , $\mathbf{d_n}$). The network works as follows:

$\mathbf{l_i} = \tanh(W_1 \cdot \mathbf{d_1} + \mathbf{b_1})$ hidden layer

$\mathbf{a_i} = \text{softmax}(W_2 \cdot \mathbf{l_i} + \mathbf{b_2})$ output layer

Thus, the results $\mathbf{a_i} \in [0,1]^{29}$ can be interpreted as conditional posterior probabilities of the possible labels given the input token $\mathbf{t_i}$. By choosing label($\mathbf{t_i}$) = $\text{argmax}_{j \in \{1,...,29\}} \mathbf{a_{i\_j}}$, every word is uniquely assigned one of the 28 PHI classes (Table 1) or the non-PHI label. The loss is defined pursuant to the cross-entropy and minimized during training.

Collaborative Training

Aim

The aim of collaborative learning is the integration of many (private) training sets into the learning process. Note that this goal is different from the one of distributed training that solely aims at faster training through the use of several computation nodes. The following sections summarize three alternative collaborative approaches: the nonprotective standard method, a round robin technique, and the privacy-preserving distributed selective stochastic gradient descent (DSSGD).

Nonprotective Training

The nonconfidential training (Figure 2) relies on central data processing. The dashed arrows denote the disclosure of the local training data, which leads to a large central data set. Usually only one entity controls the training by distributing tasks and data to workers of a large computing cluster [18]. The jagged arrow marks the distributed training supervised by the central server. The server has full control over all data and over the training procedure. Hence, this method is not suitable for protecting local data but enables fast training with full information integration.

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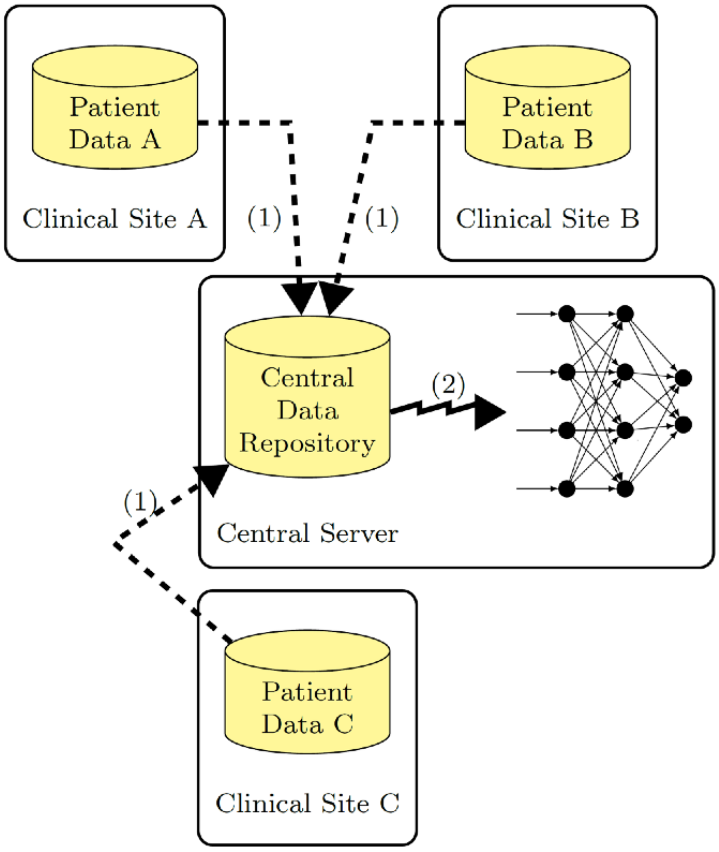
Figure 2. Nonprotected training with shared data.



Semiprotective Round Robin Training

An initial step toward privacy protecting training is to keep local training data secret and just share the NN that is trained by applying a round robin algorithm (Figure 3). In a first step, worker A trains the network using only its local data (jagged arrow [1]). After it is finished, the trained network is handed to the second worker (solid arrow [2]) who improves the network further by training with its local data (jagged arrow [3]). The other workers contribute analogously until the first training epoch is finished. Afterward the next round can be conducted in the same way. This training is similar to the cyclical weight transfer presented by Chang et al [13].

Although this protocol allows the workers to initially keep the local data secret, it does not prevent leakage of personal information through the passing on of the trained network. The parameters might still reveal parts of confidential information that have been used for training.

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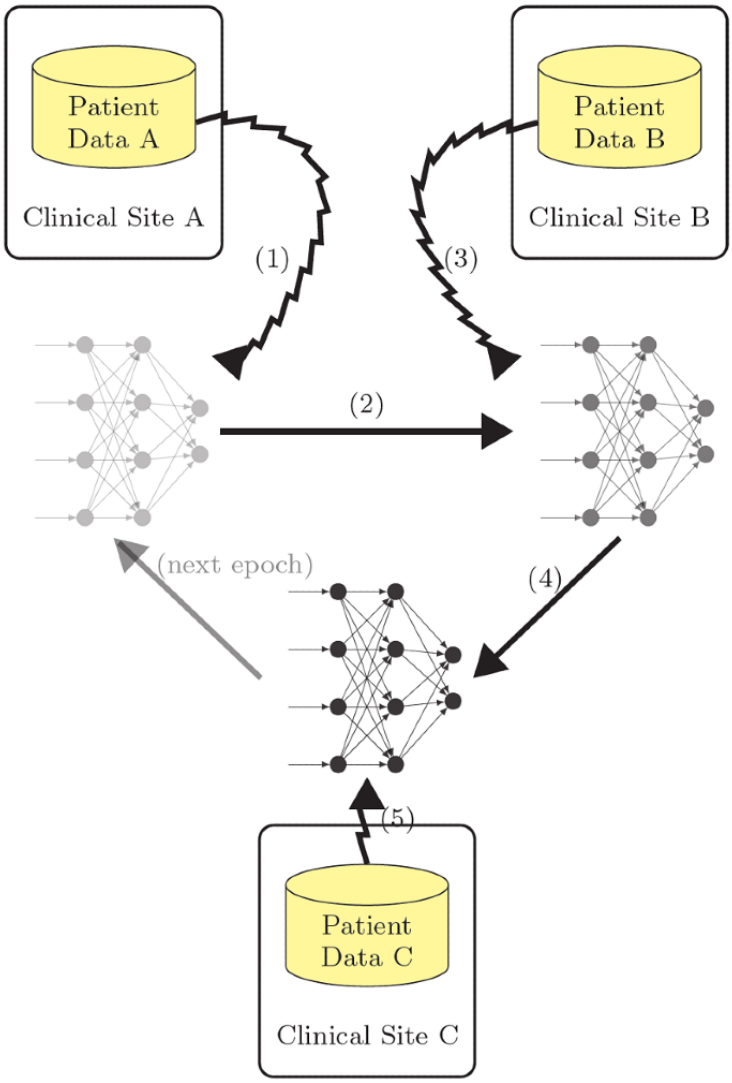
Figure 3. Semiprotective round robin training with local data.



Distributed Selective Stochastic Gradient Descent

DSSGD enables an exclusively local training and additionally allows every participant to decide how much information about local parameters is shared (Figure 4). The following description of DSSGD solely corresponds to the version used for our experiments. We would like to point out that there are several other options suggested by Shokri and Shmatikov [4].

The basic idea of gradient descent in general is to find a (local) minimum of the loss function by adapting the weights along their negative gradients. In the fully stochastic version, every gradient is computed over only one sample at a time. Hereafter, the phrase stochastic gradient descent refers to this kind of gradient computation.

Let $\mathbf{p}$ be the flattened vector representing all parameters of the network (ie, W_i, W_c, W_o, $\mathbf{b_i}$, $\mathbf{b_c}$, $\mathbf{b_o}$ of both LSTM types and W_1, W_2, $\mathbf{b_1}$, $\mathbf{b_2}$ of the feedforward layers). The cross-entropy error of the weights with respect to one training text T is defined as

$$E(\mathbf{p}) = -\sum_{i=1,\ldots,n} (\text{class}(\mathbf{t_i}) \cdot \ln(\mathbf{a_i}))$$

where $\text{class}(\mathbf{t_i}) \in \{0,1\}^{29}$ is the one-hot representation of the correct class of token $\mathbf{t_i}$.

After the error has been computed in the forward pass, the gradient of $E(\mathbf{p})$ can be determined in the backward pass using backpropagation. The individual parameters are then updated in the following way:

$$\mathbf{p}_j = \mathbf{p}_j - \eta \cdot \partial E / \partial \mathbf{p}_j (\mathbf{p})$$

where η denotes a fixed learning rate.

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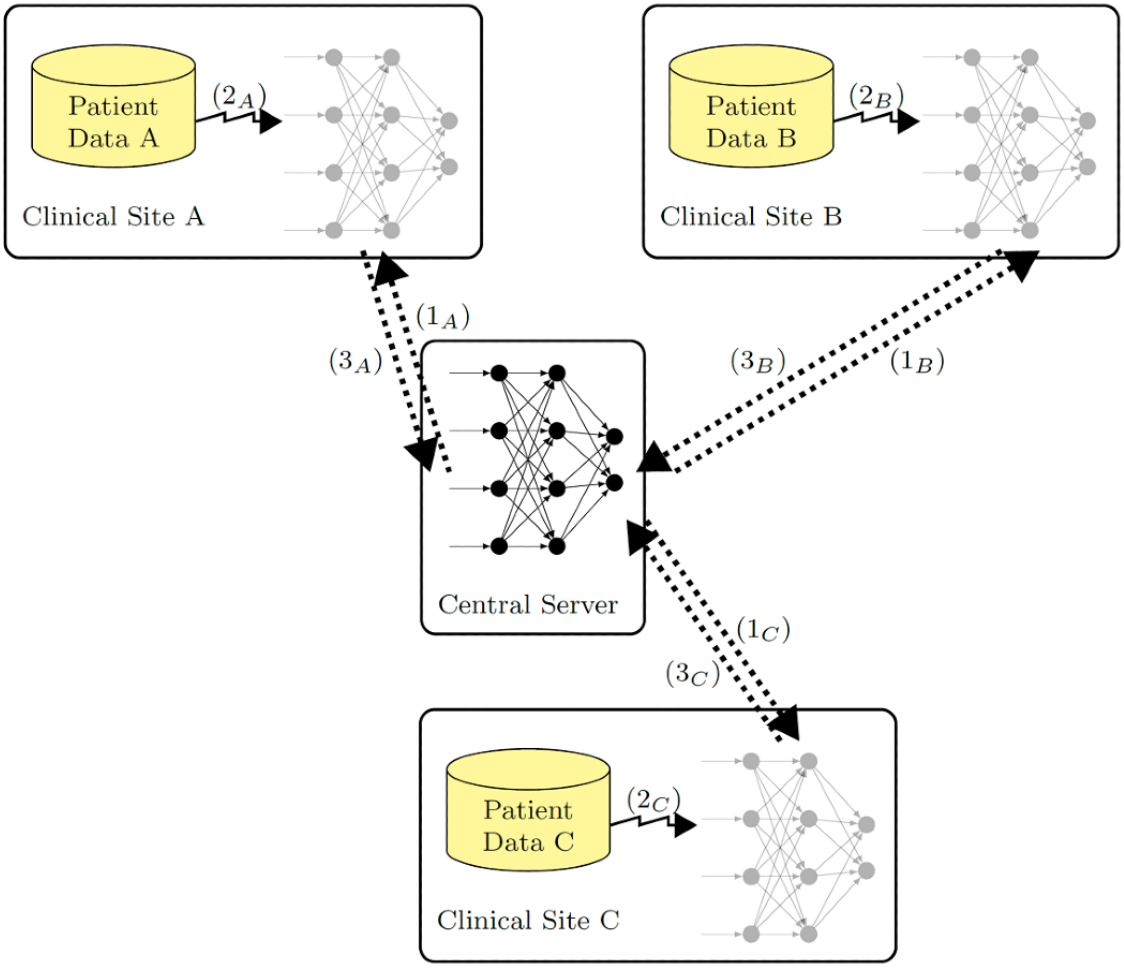
Figure 4. Distributed selective stochastic gradient descent with local data.



The peculiarity of DSSGD is that the learning is conducted in a collaborative fashion but without a central manager (Figure 4). Every participating worker computes error gradients by using only its local data (jagged arrows). A certain number of local partial derivatives is shared with the other workers (dotted arrows) via the central server after every epoch. This fraction of shared derivatives θ can be set by local data curators. In order to prevent unwanted divulgation of private information, the absolute values of shared scalars can be clipped to an individually defined minimum/maximum γ. Moreover, some lower bound τ can be chosen to omit sharing updates with information that is too small. All those additional settings are unknown to other workers.

The central server is solely used to upload and download subsets of local derivatives asynchronously. It does not manage the local workers like a central manager and does not have access to the local training data.

In the following text, the local training as well as the parameter exchange is described in more detail. In the beginning, different parties agree upon a topology of the network and a learning rate. On this basis, the global weights $\mathbf{p}_{glo}$ are initialized at the server. Beside the single set of weights, the server maintains a statistic for every weight indicating how often it has been updated by workers.

Figure 5 summarizes the work conducted by one single worker where *D* denotes the local training set. In the beginning, a worker builds a local copy of the network collectively agreed upon. Additionally, the local learning rate is set to the globally fixed value. A single epoch of the local training begins with the download of a subset of the global weights. The size of this set is specified by the local hyperparameter θ_d. The $\theta_d \cdot \text{len}(\mathbf{p}_{glo})$ parameters with the highest global update statistics are chosen for the download. By adjusting θ_d, the worker can decide how much other workers can influence its final result. In the subsequent step, simple stochastic gradient descent is used to improve local weights. After one epoch, the weight updates that are sent to the server are chosen. For this purpose, the first step is to check for every update whether its absolute value exceeds the threshold τ determined in the beginning. If this is not the case, this single update value is not communicated. Second, the remaining updates are clamped to the interval $[-\gamma,+\gamma]$. The third and last part of the selection process is based on randomness. To meet the upload rate θ_u, the set of possible updates is sampled uniformly at random. The training is ended when a minimum or any other stopping criterion is reached. A comprehensive assessment of the passive protection assured by the presented method can be found in the original paper [4].

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Figure 5. Local training procedure [4].

Require: $\theta_d, \theta_u, \gamma, \tau$
  Initialize local network
  repeat
    Download $\theta_d \cdot \text{len}(\mathbf{p_{glo}})$ parameters
    update = 0
    for all $T \in D$ **do**
      $\mathbf{d} = -\eta \cdot \nabla E(\mathbf{p_{loc}})$
      $\mathbf{p_{loc}} = \mathbf{p_{loc}} + \mathbf{d}$
      update = ***update*** + **d**
    for all $update_j$ **do**
      if $|update_j| < \tau$ **then**
        $update_j = 0$
      else
        $update_j = \text{clamp}\ (update_j, (-\gamma, +\gamma))$
    Sample $\theta_d \cdot \text{len}(\mathbf{p_{glo}})$ nonzero parameters from ***update***
    Update global parameters by adding chosen updates
  until local minimum is reached

Experiments

To evaluate the performance of the network for deidentification and the different training methods, we used a data set also used by Dernoncourt et al [3] for training the noncollaborative version. The basis of this data set is 1304 real longitudinal patient records for 296 diabetic patients provided by Partners Healthcare and adapted by Stubbs and Uzuner [15] for the 2014 i2b2 deidentification challenge. These notes were collected at different hospitals and are written in natural language (English) by caregivers to document or communicate patients' medical history, physical and mental state, prescriptions, and other events. During the generation of this gold standard set, several human annotators marked critical PHI in the notes, which was later replaced by realistic surrogate data. Names, for example, have been replaced by imaginary names. See Stubbs and Uzuner [15] for a detailed description of the data set and the replacement methods.

The full training subset contains around 598,000 tokens with approximately 17,000 instances of PHI, while the subset used for testing consists of approximately 387,000 tokens including more than 11,000 instances of PHI. Records of patients represented in the training set are not contained in the test set. Due to the class imbalance, the F1 measure was used to quantify performances during experiments.

For the tokenization of the data sets, we made use of the tokenize package published as part of the Natural Language Toolkit. The Word2Vec embedding was generated with the help of the Gensim library and was trained on all English Wikipedia articles available in the beginning of November 2018. All networks were implemented with the help of the open source software library TensorFlow. We used graphics processing unit support based on the CUDA platform to accelerate training.

The first experiment (A) was conducted to get baseline results. We trained one RNN as described in section Recurrent Neural Network for deidentification using the full training data set. This training corresponds to the nonprotective case outlined in section Nonprotective Training. Plain stochastic gradient descent with a learning rate of 0.9 was used for the optimization. After every epoch, the performance was determined with respect to the test set. The hidden states, the cell states, and the biases of LSTMs used in the token embedding layer were of size 128. Thus, the weight matrices were in space $\mathbb{R}^{128\times256}$ and $\mathbf{e_i} \in \mathbb{R}^{556}$. During training, dropout with probability 0.5 was applied to the sequence ($\mathbf{e_1}$,..., $\mathbf{e_n}$) to counteract overfitting that might have been introduced by the large number of training epochs. The single LSTM of the label prediction layer held parameter vectors that were all of size 100 and hence output the sequence ($\mathbf{d_1}$,..., $\mathbf{d_n}$) with $d_i \in \mathbb{R}^{200}$. For the final two feedforward layers, the weights were $W_1 \in \mathbb{R}^{100\times200}$ and $W_1 \in \mathbb{R}^{29\times100}$.

Experiment B was performed according to the description in section Semiprotective Round Robin Training. The full training set was subdivided into 5 disjoint private sets of similar size. All records of one patient were kept in the same subset. The training was performed in a round robin fashion using stochastic gradient descent with a learning rate of 0.9 at each worker. The test set was, as in all experiments, left untouched and tested against after every full epoch (ie, after 5 local epochs).

In a third experiment (C_0.1), the collaborative privacy-preserving training (Distributed Selective Stochastic Gradient Descent section) was tested. For this purpose, the global network topology was chosen, as in the previous experiments. We trained 5 RNNs collaboratively that asynchronously shared some of their weight updates. The training data were distributed as in experiment B. In contrast to the previous experiment, the nets were tested against the global test set after every local epoch, since there is no global epoch in this setup.

Thus, there are 5 results for every epoch. The training hyperparameters for all nets were θ_d=0.1, θ_u=0.5, γ=10, τ=0.0001, while the global learning rate of DSSGD was set to

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0.9. Afterward we conducted a similar experiment with the only difference being that θ_d was set to 0.5 (experiment C_0.5).

Experiment D was run in the same way as experiment C_0.1 except for the fact that this time the 5 networks did not communicate at all and just trained on their local sets. Again, we made use of simple stochastic gradient descent with a learning rate of 0.9. A summary of all experiments can be found in Table 2.

Table 2. Summary of the experiments.

Name	Learning strategy
A	Centralized training using stochastic gradient descent (learning rate: 0.9)
B	Collaborative training of 5 workers using the round robin method (learning rate: 0.9)
C_0.1	Collaborative privacy preserving training of 5 workers with DSSGD[a] (θ_d = 0.1, θ_u = 0.5, γ = 10, τ = 0.0001; learning rate: 0.9)
C_0.5	Collaborative privacy preserving training of 5 workers with DSSGD (θ_d = 0.5, θ_u = 0.5, γ = 10, τ = 0.0001; learning rate: 0.9)
D	Local training without collaboration of 5 workers using stochastic gradient descent

[a]DSSGD: distributed selective stochastic gradient descent.

Results

To obtain results that can be compared to the outcomes achieved by Dernoncourt et al [3], we adopted their scoring. Thus, every token labeled as PHI by the network was considered a true positive result if and only if this token was actually some PHI. The scoring, therefore, does not consider the PHI classes but only the decision PHI versus non-PHI.

In all experiments the nets underwent 200 epochs of training. The illustration on the left in Figure 6 depicts the development of F1 scores achieved on the test set. The black line corresponds to experiment A and the magenta one to experiment B. Note that both lines are very similar and partially overlap. For the other experiments, there are 5 results per time point. The solid green line depicts the mean F1 values achieved in experiment C_0.1, while the area colored in green indicates the full range in which the values fell. Similarly, the results of experiment D are represented. For these measurements, the color red was used. For reasons of clarity, the results of experiment C_0.5 are depicted in the image on the right. Again, these results are shown in green. The remaining lines are the same as in the illustration on the left. The final scores are given in Table 3.

Figure 6. Performances achieved on the test set during the experiments including C_0.1 (left) or C_0.5 (right).

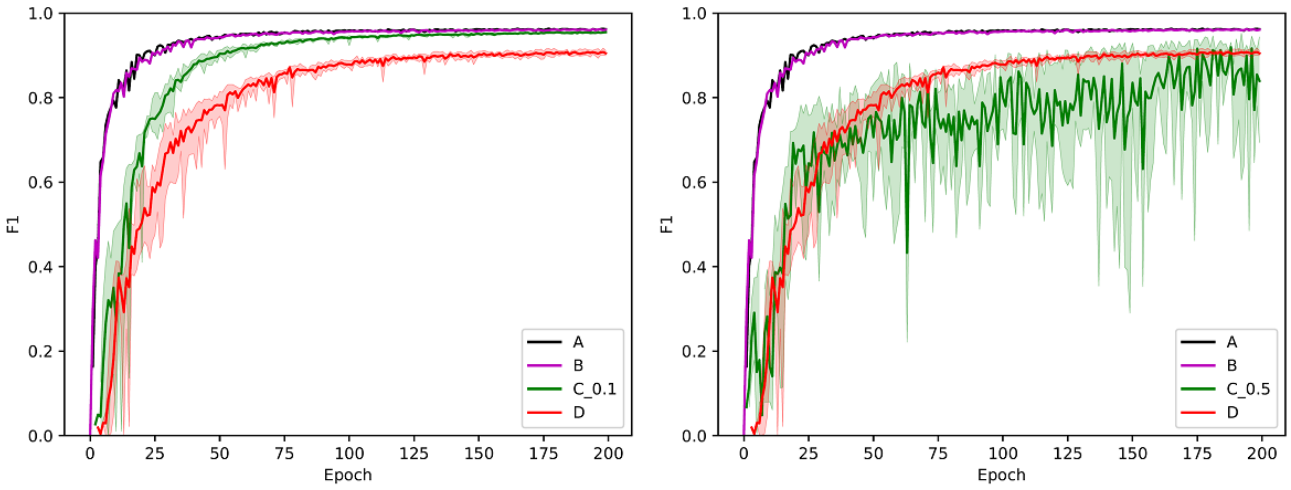

Table 3. Scores after 200 training epochs.

Experiment	F1		
	Minimum	Mean	Maximum
A	—	0.962	—
B	—	0.961	—
C_0.1	0.955	0.955	0.956
C_0.5	0.694	0.840	0.944
D	0.900	0.905	0.911

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Discussion

Using real-world clinical data, our study shows that collaborative privacy-preserving training enables a NN-based detection of PHI in clinical free-text records. The approach, thus, solves the dilemma of requiring machine learning techniques for easily adapting a PHI detection system to heterogeneous clinical documentation while avoiding disclosure of locally stored patient data.

Comparisons of the results achieved by the networks trained with plain stochastic gradient descent (A and D) underline the intuitive assumption that larger training data sets lead to better performances.

The similarity between the results of experiments A and B originates from the fact that both training methods are equivalent except for the kind of shuffling of samples during training. If the only aim is to keep the exact local data private and not to protect as much private information as possible, the round robin technique (or cyclic weight transfer) is the best choice. If, however, a real privacy-preserving collaborative learning mechanism is need as in the presented medical domain, DSSGD is the correct training algorithm. It offers both privacy preservation and good performance. The results of experiments C_0.1 and D show that a lack of sufficiently large local training data sets can be compensated by applying collaborative privacy-preserving training based on DSSGD. This finding is in line with the observations made by Shokri and Shmatikov [4] and the results obtained by Liu et al [14] who tested the protocol with some smaller nonrecurrent neural networks. By applying the collaborative training, all workers reach similar outcomes rapidly. After 25 epochs, all nets perform better than the ones trained with the corresponding noncollaborative version (D). The local F1 values all tend to the results achieved in the centralized version (A). During all experiments, a rather high learning rate was used that might have led to nonoptimal solutions. However, since it was kept constant throughout all 5 experiments, the insights gained by comparison are still valid. Another shortcoming of our experiments is that the γ value was set without using a calibrating data set as is suggested by Shokri and Shmatikov [4].

During experiments C_0.1 and C_0.5, the importance of well-chosen communication parameters θ_u, θ_d became apparent. If the download rate is set to high, the global results interfere too much with local training sessions. This leads to high fluctuations and prevents the local weights from converging.

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SF and CS were affiliated with the Department of Medical Informatics, Medical Faculty at RWTH Aachen University at the time of writing and are currently affiliated with the Institute of Medical Statistics, Computer and Data Sciences at Jena University Hospital.

Conflicts of Interest

None declared.

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Abbreviations

DSSGD: distributed selective stochastic gradient descent
i2b2: Informatics for Integrating Biology and the Bedside
LSTM: long short-term memory
NN: neural network
PHI: protected health information
RNN: recurrent neural network

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Original Paper

Mental Health Therapy Protocols and eHealth Design: Focus Group Study

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Abstract

Background: Electronic health (eHealth) programs are often based on protocols developed for the original face-to-face therapies. However, in practice, therapists and patients may not always follow the original therapy protocols. This form of personalization may also interfere with the intended implementation and effects of eHealth interventions if designers do not take these practices into account.

Objective: The aim of this explorative study was to gain insights into the personalization practices of therapists and patients using cognitive behavioral therapy, one of the most commonly applied types of psychotherapy, in a youth addiction care center as a case context.

Methods: Focus group discussions were conducted asking therapists and patients to estimate the extent to which a therapy protocol was followed and about the type and reasons for personalization of a given therapy protocol. A total of 7 focus group sessions were organized involving therapists and patients. We used a commonly applied protocol for cognitive behavioral therapy as a therapy protocol example in youth mental health care. The first focus group discussions aimed at assessing the extent to which patients (N=5) or therapists (N=6) adapted the protocol. The second focus group discussions aimed at estimating the extent to which the therapy protocol is applied and personalized based on findings from the first focus groups to gain further qualitative insight into the reasons for personalization with groups of therapists and patients together (N=7). Qualitative data were analyzed using thematic analysis.

Results: Therapists used the protocol as a "toolbox" comprising different therapy tools, and personalized the protocol to enhance the therapeutic alliance and based on their therapy-provision experiences. Therapists estimated that they strictly follow 48% of the protocol, adapt 30%, and replace 22% by other nonprotocol therapeutic components. Patients personalized their own therapy to conform the assignments to their daily lives and routines, and to reduce their levels of stress and worry. Patients estimated that 29% of the provided therapy had been strictly followed by the therapist, 48% had been adjusted, and 23% had been replaced by other nonprotocol therapeutic components.

Conclusions: A standard cognitive behavioral therapy protocol is not strictly and fully applied but is mainly personalized. Based on these results, the following recommendations for eHealth designers are proposed to enhance alignment of eHealth to therapeutic practice and implementation: (1) study and copy at least the applied parts of a protocol, (2) co-design eHealth with therapists and patients so they can allocate the components that should be open for user customization, and (3) investigate if components of the therapy protocol that are not applied should remain part of the eHealth applied. To best generate this information, we suggest that eHealth designers should collaborate with therapists, patients, protocol developers, and mental health care managers during the development process.

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KEYWORDS

eHealth design; mental health care; personalization; protocol; youth addiction care

Introduction

Adequate treatment is needed to reduce the risk of adolescents developing adverse consequences due to mental health disorders (eg, [1,2]). Therapy protocols contribute to the implementation of evidence-based therapeutic practice and help therapists to structure their face-to-face therapy sessions [3]. Although psychosocial therapies are effective in reducing psychiatric symptoms in adolescents with mental disorders, the available therapies show only modest effects and not all adolescents benefit [4,5]. The use of information and communication technologies in therapeutic practice, including electronic health (eHealth) interventions, in the delivery of (mental) health care [6] is a promising means to improve patient engagement and therapeutic effectiveness (eg, [7-9]).

The therapy protocols that form the basis for face-to-face therapies are typically used as a basis for the design of eHealth strategies [10]. Therapy protocols play a large role in the success of evidence-based therapies [11], and therefore their implementation is recommended as much as possible. However, both therapists and patients can personalize or only partly apply a therapy protocol in therapeutic practice (eg, [12-17]). For example, therapists might consider that following therapy protocols can be a hindrance to forming a strong therapeutic alliance [18]. Moreover, strict adherence to protocols may be perceived to come at the expense of building trust between a patient and therapist, which is an indicator for positive therapy outcomes by allowing them to work together in an effective way [19].

The gap between therapy protocols and their implementation in therapeutic practice has serious consequences for eHealth design. If the possibilities of personalization in therapeutic practices are not taken into account during the design stage, eHealth may not suit current therapy practice, thereby severely limiting its implementation. This can occur when eHealth does not suit how therapists use the therapy protocol or if therapists have negative expectations about the benefits of eHealth compared to face-to-face therapy [20-22]. Indeed, many eHealth interventions have failed to integrate personalization to the individual user in the design [23].

To align eHealth to the reality of therapeutic practice, it is important to understand the content of the existing therapy protocols and how they are applied in practice by both therapists and patients. Designers of eHealth can then use this information to ensure that eHealth matches the needs of therapeutic practice, consequently improving the quality and enhancing the implementation potential of the intervention. Toward this goal, the aim of this explorative study was to gain insight into personalization practices in a mental health care context and provide recommendations to eHealth designers on how they can best access and involve the need for protocol personalization in eHealth design. To achieve this, we examined therapists' and patients' perceptions of protocol application in a youth addiction treatment facility as a case study by generating both quantitative and qualitative data. First, we conducted focus groups to assess the extent to which therapists and patients personalized and applied a common therapeutic protocol in therapeutic practice. Second, we conducted focus groups with patients and therapists together to assess the degree to which they applied and personalized the therapy using the quantitative data generated from the first focus group as input for discussion.

Methods

Therapy Protocol

The commonly applied protocol for cognitive behavioral therapy (CBT) in adolescent addiction care was used as a case protocol [24]. The protocol consists of 9 sessions, followed by 4 "sessions of choice" (selected from 7 optional sessions in consensus with patients). In each session, patients set specific short-term goals with regard to the therapeutic homework. Part of the therapy protocol is a therapy workbook that patients can bring home and to therapy sessions. The activities described in the workbook correspond to the content of therapy sessions.

Procedure

We conducted semistructured focus group sessions in two phases at two locations of one large outpatient treatment facility center for adolescent addiction care in the Netherlands (see Table 1). The aim of the first phase was to investigate therapists' and patients' estimations of the amount and type of protocol personalization.

Therapists estimated how much of their therapy consisted of a strictly followed and adapted therapy protocol and patients indicated how much of the therapy provided by their therapist they strictly followed and adapted. Of note, the patient could be receiving a personalized therapy protocol in practice. Both the therapists and patients also indicated how much other (nonprotocol) therapeutic components were added in practice, which were represented by percentages for a total of 100% (ie, the whole therapy). The second phase involved an independent group of therapists and patients who did not participate in the first phase, in which the results of the first phase were applied to the discussion to gain insight into the reasons for personalization. Participants were brought together with a moderator (the first author MvD) for a discussion lasting 1 hour. Before starting the group discussions, the participants provided informed consent and the concept of personalization was explained (ie, changing a designed end product such as a therapy protocol to match the needs and capacities of the end user and enhance effectivity of the product [25]).

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Table 1. Setup of the focus group sessions with therapists and patients on protocol application and personalization.

Goal	Phase	Participants
Generate information with separate groups of either therapists or patients about how much of their therapy consisted of a strictly followed therapy protocol, adapted therapy protocol, and added therapeutic parts.	1	Group discussion with therapists (location A N=3, location B N=3), group discussion with patients (location A N=2, location B N=2), and interview with a patient (N=1, location B).
Joint evaluation of the results from Phase 1 with combined groups of both patients and therapists.	2	One mixed group discussion with a therapist and two patients at location A and one mixed group discussion with two therapists and two patients at location B.

Participants

We invited experienced therapists who received training in the CBT protocol to participate in focus group sessions. Patients, who were at least 18 years old and receiving CBT, were recruited by their therapists to participate in the study. Therapists received an information leaflet to inform their patients about the study. A therapist informed us if a patient wanted to participate. In turn, we contacted the patient to schedule an appointment for the focus group discussion. In the first phase, 6 therapists (3 women, 3 men) and 5 patients (1 woman, 4 men) participated. In the second phase, 3 therapists (1 man, 2 women) and 4 patients (1 woman, 3 men) participated. All interviews took place at the youth mental health care facility.

Data Analysis

The data are presented according to the standards of reporting qualitative research proposed by O'Brien et al [26]. We used thematic analysis instead of grounded theory to analyze the data. With grounded theory, the goal is to generate an exploratory and overarching framework or theory [27], which was not the goal of this study. Alternatively, with thematic analysis, the themes are derived from the data [28-30], which can offer direct guidance for eHealth designers. We focused on the phases described by Braun and Clarke [28] for data analysis. The interviewer (MvD) is a PhD candidate with two masters degrees in clinical and health psychology. She is therefore qualified in conducting qualitative interviews, and did not have any assumptions or prior relationships with the participants before the discussions. All interviews took place at the youth mental health care facilities of the therapists and patients. Experienced therapists were invited to participate in the study. They had to be trained in the new CBT protocol that was the focus of the study. Patients who had received CBT were informed about and invited to participate in the focus group discussions by their therapists. In this way, more patients were informed about the study, which enhanced the chance that more patients would be willing to participate. After the patients provided consent to participate, the researcher contacted the patient by phone to ensure that they clearly understood the study and to make an appointment for the focus group discussion.

We received formal ethics approval from the Human Research Ethics Committee of the Delft University of Technology in the Netherlands. All discussions were recorded with an audio recording device after receiving verbal consent from participants. Quantitative data were saved with only a link to the type of participant (ie, therapist or patient). All focus group sessions took 1 hour each and were audio recorded and transcribed by one author (MvD). Interview guides were used during the discussions, and field notes were taken both during and after the discussions.

After transcribing the data, all recordings were checked again to ensure the accuracy of the transcripts in line with the recommendations of O'Brien et al [26]. All of the transcripts were then reviewed multiple times before coding the data by the same author (MvD). This ensured that the themes generated from the codes were not based on only a few examples. Similar themes were grouped together into higher-level themes. When analyzing the data, the themes were linked to each other, ensuring a coherent story. Sufficient time was allocated to analyze the data adequately.

The fourth topic of O'Brien et al [26] focuses on the results (topics 16 and 17) that are described in the following section. Supportive quotes were chosen to substantiate analytic findings. This was followed by the fifth topic that describes the discussion section (topics 18 and 19) and the "other" topic that deals with conflicts of interests and funding (topics 20 and 21).

Results

Phase 1: Focus Group Sessions With Therapists

Therapists indicated that they strictly applied 30%-75% (mean 48%) of the therapy protocol and adapted between 10% and 50% (mean 30%) of the therapy protocol. They further reported adding 10%–33% (mean 22%) nonprotocol-related therapeutic components. The percentages of one therapist were excluded because the percentages of strict application and personalization overlapped.

We first scrutinized the quotes several times and generated codes from the quotes that focused on reasons for therapists choosing to personalize the therapy protocol. These codes referred to therapists who personalized the protocol based on a patient's needs ("Tweaking works the best, adapting [the therapy] to where the patient is": Therapist 1A); what they thought would be more beneficial for the patient ("It is more related to whether they have stopped [using substances] than focusing on cravings. Also, if they already went to therapy before, elements considered to be repetitive are removed": Therapist 2A); and because therapists were aware of other therapy protocols that could help patients with different problems at the same time ("I also give group therapy, and some elements that I notice work [during group therapy] I also use during individual therapy": Therapist 1B). In addition, the codes reflected that therapists personalized the protocol to enhance the therapeutic alliance ("Much is related to the connection, the

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therapeutic alliance is important so I invest a lot of time in building one": Therapist 1B). Further analysis of the codes resulted in higher-level themes.

The main theme derived from the codes of the therapists was that they used the protocol as a "toolbox" (ie, a bundle of therapy tools that they could choose from). The code that did not fit this main theme focused on adding elements from other therapy protocols. However, all therapists mentioned that they did not apply the order of the therapy protocol in a strict manner. The protocol was not considered as a step-by-step manual but rather as a manual comprising all possible interventions: "I do not use the CBT toolbox as a step-by-step manual but I can choose interventions from the toolbox that I find relevant" (Therapist 1B). Three subthemes were derived: therapists who personalized based on what they thought their patient needed, on their own therapy-provision experiences, or because they thought it enhanced the therapeutic alliance.

The first subtheme under the grand toolbox theme consisted of therapists who personalized the therapy protocol based on what they thought their patient needed. They considered that by adapting the therapy, their patients would be better prepared to handle specific situations. This was influenced by the (possibly difficult) situations that patients experienced prior to the therapy session (eg, had an argument with their parents), how the motivation of patients could change their behavior, and if patients understood all elements of the therapy protocol. For example, therapists tried to enhance the trust of patients by ensuring them that they could achieve the goals they set or by mainly focusing on the homework that a patient did well instead of focusing on the homework that a patient did not do well:

> *What is important for patients, such as dealing with social pressure. In general, I follow the therapy protocol but if you notice that patients have difficulties with it [social pressure] you focus on that.* [Therapist 3A]

The second subtheme to the grand toolbox theme consisted of therapists who personalized the therapy protocol based on their own therapy-providing experiences. During the discussions, they commented that they might not apply or only partly apply the workbook to prevent their patients from experiencing feelings of failure, since patients generally forget to bring it to therapy or fill in the homework assignments. Therapists thought that not applying the workbook prevented their patients from experiencing feelings of failure:

> *I always estimate if they [the patient] are the type of person that can do homework at home, if they [the patient] are someone who will really do it [the homework], you want to prevent experiences of failure.* [Therapist 3B]

In addition, more experienced therapists have more knowledge of and experience with other types of therapy protocols. Therefore, more experienced therapists tend to apply elements from other therapy protocols during therapy more often compared to less experienced therapists.

The third subtheme to the grand toolbox theme consisted of therapists who personalized the therapy protocol because they thought it would enhance the therapeutic alliance:

> *It depends on the connection [between me and the patient]. The therapeutic alliance is important, on which I spend a lot of time.* [Therapist 1B]

They would try to work on the bond with a patient by focusing more on the positive steps a patient made rather than focusing on what a patient did not do. In addition, this was expected to enhance the motivation of patients to continue with therapy and try to achieve the tasks they agreed on.

Phase 1: Focus Group Sessions With Patients

Patients indicated that they strictly applied 12%-65% (mean 29%) of the therapy provided by their therapist, adapted between 9%-64% (mean 48%), and added between 18%-26% (mean 23%). The percentages of one patient were excluded, because the percentages of strict application and personalization overlapped.

After scrutinizing the quotes several times, we generated codes that focused on reasons for patients choosing to personalize their therapy. These codes referred to patients who personalized how they achieved their homework because they preferred to personalize the tasks, "Actually I try to think of some rules for myself" (Patient 1B), and because they were somewhat careless and forgot to complete their homework, "It is quite hard to keep up with it and it is not really in my routine, like brushing my teeth" (Patient 2A). In addition, the personalization of patients was influenced by the connection they had with their therapist: "The connection you have with your therapist influences how well therapy works" (Patient 2A). We went through the codes again, resulting in higher-level themes.

The main theme that was derived from the codes of the patients was that they personalized the therapy based on their own situation. The code that did not match the main theme focused on personalization of therapy by the therapists. Even though therapists and patients decided on the homework the patient would work on together, all patients mentioned that they personalized their homework. Two subthemes were derived: personalization to better match therapy with the daily life of the patient, and personalization that was influenced by the varying motivation of patients.

The first subtheme to the grand own situation theme focused on patients who mentioned that they personalized their therapy to better match the therapy with their daily lives. That is, they personalized the therapy to achieve a better match with their own situation, personality, and preferences. This helped to reduce their feelings of stress and worry:

> *I always change it [doing the homework assignments] a little bit so that it is in line with my personality and how I want to be seen by others.* [Patient 2A]

> *…It is the intention [to do the workbook assignments], but I don't do it. I would rather talk about it [cravings] than write these experiences down.* [Patient 1B]

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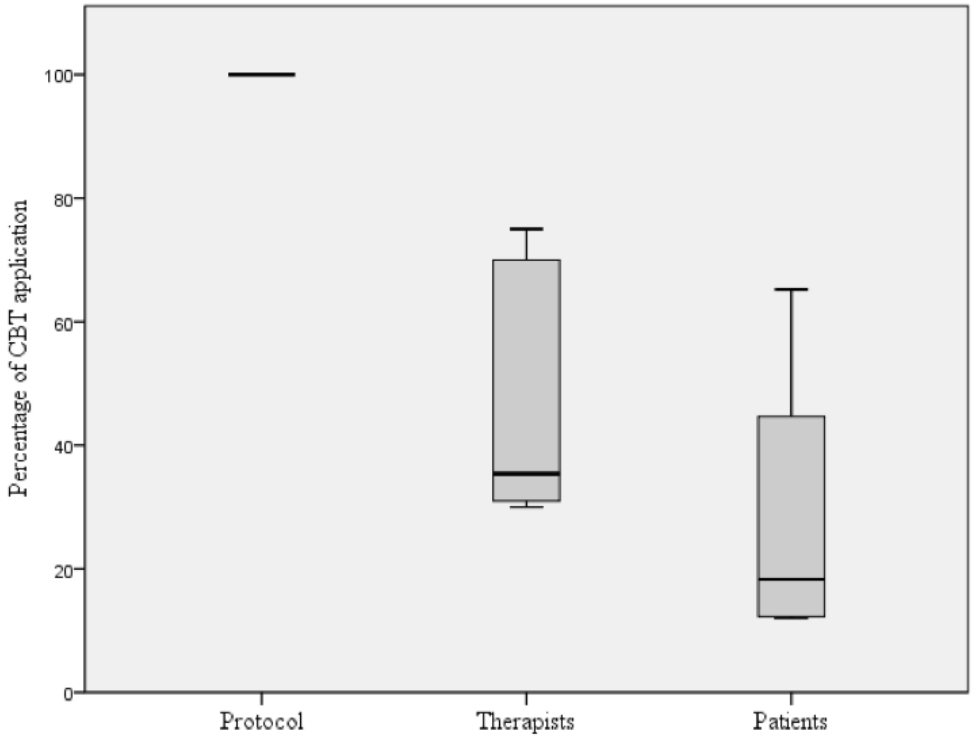
The second subtheme to the grand own situation theme consisted of patients who mentioned that the extent of their personalization was influenced by their varying motivation. In some cases, they simply did not want to or forgot to do the homework assignments. In addition, a relapse could influence the motivation to continue therapy in either a positive or a negative way: “Sometimes, I just do not feel like doing it [workbook assignments] and I just do not do it” (Patient 1A). One patient said that doing the workbook assignments for a longer period of time helped him to generate insights into his triggers for cravings. The therapeutic alliance influenced their motivation, mainly because a therapist would put things into perspective (including when a patient had a relapse).

Along with the thematic analysis, we analyzed the quantitative data of the patients and therapists. All of the percentages related to therapy protocol application and personalization by therapist and patients are combined in Figure 1, and these data were used in the second phase of the focus group discussions with a separate group of patients and therapists together.

Figure 1. Range and median percentage of cognitive behavioral therapy application by therapists and patients.



Phase 2: Focus Group Sessions With Both Patients and Therapists

We first analyzed the quotes that focused on reasons for patients and therapists to personalize the therapy protocol and generated codes from these quotes. The codes of the therapists referred to personalization aimed at maintaining or enhancing the motivation of patients, to work on a connection of trust with their patient, and to align the therapy to the problem of the patient. The codes of the patients referred to personalization by discussing what was happening in their life during a therapy session, and personalization of homework based on how they felt during therapy and at home. Further analysis of the codes resulted in higher-level themes.

Since therapists reported that they always personalize the therapy to some extent, most therapists and some patients had expected more personalization. One therapist thought that therapists could also have interpreted a strict therapy protocol application from the guideline, meaning that therapists did not apply the detailed and precise content of the therapy protocol sessions but rather used the content to assist them in making decisions about which elements of the therapy protocol sessions would be most appropriate for a given case: “I think that the therapists do follow the therapy protocol as a guideline, but that they noted this [strict application] down as applying it in an unchanged way” (Therapist 5B). Other themes derived from the codes in the second phase focused on enhancing the therapeutic alliance and on personalization based on the experience of therapists.

The first main theme of therapists derived from the quotes focused on enhancing the therapeutic alliance: “Aligning to the need of the other [the patient] and small talk [with the patient] contributes to the personal connection with a therapist, which contributes to a more personal relationship that is needed to create openness and allowing a patient to accept help from a therapist” (Therapist 4B). Fostering an alliance was seen as crucial in order for a patient to trust the therapist and work together to solve the problem of the patient. Two subthemes were derived: personalization based on the individual situation of a patient and keeping or enhancing the motivation of a patient.

The first subtheme to the grand therapeutic alliance theme focused on the individual situation of a patient. In general, therapists first focus on the individual situation of a patient, followed by the relevant therapy protocol session that best suits the situation. They could also apply elements from different

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therapy protocols when a patient had other psychological problems. In this way, patients were helped with all of their problems at the same time: "The patients often have multiple problems, so you have anxiety and mood protocols, or other ones" (Therapist 4B).

The second subtheme to the grand therapeutic alliance theme focused on keeping or enhancing the motivation of patients. They either did or did not apply the therapy workbook, mainly to prevent experiences of failure and maintain motivation to adhere to therapy if a patient forgets the workbook: "You also have to prevent that it [filling in the workbook] becomes a failing experience…they can think, well if I can't even do that well…" (Therapist 4B). In addition, therapists applied motivational interviewing to enhance the motivation of patients: "It is part of the attitude as a therapist that you are empathetic, you listen and align" (Therapist 4B).

The therapy protocol helped therapists to structure the therapy, but therapists differed in their opinion regarding protocol application. One therapist from location A followed the therapy protocol as strictly as possible, whereas another therapist from location B only used the therapy protocol to guide the therapy sessions. The therapist from location A mentioned that the therapy protocols helped to provide guidance to the therapy sessions, whereas the therapist from location B found it more important to focus on the situation of a patient.

The second grand theme of the therapists focused on the experience of therapists that influenced the amount of personalization. More experienced therapists often have experience with different therapy protocols, since therapy protocols often change or improve over time. This increased their knowledge, preferences, and possibilities to personalize therapy protocols compared to less experienced therapists. Therefore, two therapists mentioned that the experience of therapists could also influence therapy protocol application and personalization.

Based on the quotes of the patients, we derived two main themes. The first grand theme focused on personalization based on their own personal situation. They personalized their homework based on possible relapses and how they felt:

> *I had to do exposure exercises once a day. But if I do not feel well, it does not work and I'm not going to let myself feel worse by doing another exercise.* [Patient 4B]

The second grand theme focused on personalization based on the personal preferences of patients. The strategies applied to work on their therapy and prepare for a therapy session differed among patients based on their personal preferences, such as by shutting down the mobile phone when starting therapy or working on assignments on a computer instead of in the workbook. The main themes and subthemes emerging from both phases of the discussion groups are summarized in Table 2.

Table 2. Themes and subthemes of the focus group discussions with therapists and patients.

Participant	Main theme	Subthemes
Therapists: Phase 1	Use protocol as a toolbox	Personalization based on patient needs; personalization based on own therapy-provision experiences; personalization to enhance therapeutic alliance
Patients: Phase 1	Personalization based on own situation	Personalization to better match therapy with daily lives; personalization influenced by varying motivation
Therapists: Phase 2	Personalization to enhance therapeutic alliance; personalization based on experience	Personalization based on the individual situation of a patient; personalization to maintain or enhance the motivation of patient
Patients: Phase 2	Personalization based on personal situation; personalization based on personal preferences	None

Discussion

Principal Findings

Existing research focusing on the effect of eHealth in mental health care suggests overall small to medium effect sizes [7,8,31-33]. Moreover, research suggests that combining eHealth with therapist contact (ie, blended eHealth) is more effective compared to fully online eHealth without therapist contact [9,34]. One main contributor to the effectiveness of eHealth is that it can extend the reach of psychological therapy beyond the clinical setting, as the technologies can be used anytime and anywhere [35,36]. eHealth designers typically use the therapy protocols of evidence-based face-to-face therapies as a basis for the design of eHealth. However, not all parts of therapy protocols are always applied in therapeutic practice [16,37]. If eHealth designers do not take this into account, the designed eHealth might not optimally fit the existing therapeutic practice, which will consequently impede implementation and motivation to adopt the eHealth by both therapists and patients. In the present study, we analyzed the proportion, type, and reasons for personalization of a given therapy protocol by therapists and patients in focus group studies.

The results showed that the therapy protocol is not fully applied in clinical practice but is also personalized (see Table 2), which is in line with previous studies [13,38]. The available therapy protocol is thus only one factor considered in a therapeutic process. Other factors that influence the therapeutic process are the personalization practices of therapists based on the needs of a patient, motivation of a patient, therapy-provision experiences of therapists, and the therapeutic alliance between the therapist and patient. Therapists estimated that they only strictly followed 48% of the protocol, adapted 30% of the

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protocol, and replaced 22% of the protocol by other nonprotocol therapeutic components such as other therapy protocol elements. Other personalization practices that influence the amount of therapy protocol application is personalization of patients to better match the therapy with their daily lives, personal situations, and preferences, which was also influenced by their varying motivation. Patients estimated that they strictly followed 29% of the therapy assigned, 48% of which was adapted, and they estimated that they replaced 23% of the therapy by other nontherapeutic elements.

It is important to mention the clear difference in personalization between therapists and patients. The estimations of patients and therapists regarding their amount of personalization are not only different because they may personalize less or more but also because of their own share in the personalization process. Therapists already personalize a therapy protocol, and their patients further personalize the elements provided according to their daily lives. Moreover, therapists are aware of the entire content of the therapy protocol, whereas patients are not. Since therapists provide the patient with a partly personalized therapy, patients can never fully know the entire possible content of a therapy protocol and have less personalization options of the standard therapy protocol. For example, therapists often mentioned that they did not use the therapy workbook to avoid patients from experiencing feelings of failure if they either did not do the homework assignments or forgot to bring the workbook to therapy. However, by doing so, they also prevented patients from trying to execute the homework assignments in their workbook. Moreover, personalization by therapists can have both positive, neutral, and negative effects [39-42]. For example, the elements that are personalized by a therapist or how a therapist personalizes specific protocol elements may not match with the preferences of a patient. This may influence the alignment of the therapy to a patient and may possibly lower motivation of a patient to adhere to the therapy. In general, most therapists in the second phase had expected that therapists would personalize more than suggested by the estimated percentages of protocol application from therapists in the first phase. A previous study that only focused on personalization by therapists found that therapists personalize more than our results suggest [43]. A possible explanation for this difference is that the previous study aimed at assessing all types of activities in the general psychotherapeutic practice of eating disorders, whereas we focused specifically on the personalization practices of both patients and therapists using a CBT protocol in youth addiction care as a case protocol.

Implications and Recommendations

The results of our study have important implications for eHealth clients and eHealth developers by providing insight into the protocol elements in eHealth that should and should not be open for personalization to facilitate implementation and patient engagement. Designers can implement the personalization practices by focusing on the function that personalization has in therapeutic practice (ie, enhancing the motivation of patients to adhere to the therapy). However, since personalization may have both positive and negative therapeutic effects, it is important to know what elements are crucial to apply in practice to enhance therapeutic effects. This is particularly relevant since design can influence and enhance motivation to adhere to or execute specific behaviors. One such example is the application of motivating elements from entertainment games (also called "gamification"). Gamification design has shown potential in health care, and in mental health care in particular [44-46], such as by improving healthy behaviors [46-57]. Based on the results of this study, it is recommended that eHealth designers: (1) study and copy at least the actual applied parts of a therapy protocol in eHealth, (2) co-design eHealth with therapists and patients so they can allocate the components that should be open for user customization, and (3) investigate if components of the therapy protocol that are not actually applied by therapists or patients should remain part of the eHealth. Without such considerations, implementation would be negatively impacted owing to a mismatch from the habits of therapists [20] or the complexity of mental problems that patients experience [58]. In addition, validation studies of therapy protocols should focus on the actual application of these protocols in therapeutic practice, which can be considered to be generally overestimated [18,59,60]. This may in turn overestimate the benefit of therapy protocols to therapeutic effects. Below, we elaborate on these three recommendations.

With regard to the first recommendation, our study showed that therapists and patients do not fully apply the therapy protocol. This information should be generated and implemented in the second product design phase of a personalized design process [25]. In this phase, stakeholders such as therapists, patients, and protocol developers can be involved to ensure that the design of the product is suitable to support the user during therapy, that it is technically possible to use during therapy, and that the eHealth design suits the therapeutic practice of a treatment center. In this phase, the information of the applied therapy protocol elements by therapists and patients is generated so that eHealth designers can at least copy these components in the eHealth. One method of generating this information is to record therapy sessions of patients with therapists. Therapy protocol developers can then listen to these recordings and rate the parts of a therapy protocol that are applied in therapeutic practice.

As a second recommendation, the results of our study showed that therapists and patients personalized the therapy protocol by adjusting specific protocol components and adding other (nonprotocol) therapeutic components. Understanding why and how therapists and patients personalize a therapeutic protocol is important information for eHealth designers to select the components of eHealth that should be open to personalization for therapists and patients. This information can be generated and implemented in the last tailoring phase of a personalized design process [25] with patients and for more and less experienced therapists. In this phase, the designed product is tailored to the individual user using two main types of tailoring: user-controlled customization and use-dependent adaptation. With user-controlled customization, a user can tailor a product themselves according to their own preferences and needs. Patients noted that they personalized the therapy based on their own personal situation and personal preferences; thus, it is also important to give them the opportunity to do so when using an eHealth product. Therapists mentioned that they personalize a therapy protocol based on the patient situation or their

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therapeutic experiences. By providing therapists the possibility to tailor the elements in eHealth, they can choose whether or not to use these elements during therapy with a specific patient, while not being forced to use all elements of the eHealth app. With use-dependent adaptation, a product automatically adapts itself to the user, for example by not showing specific parts of a therapy protocol if the therapist always skips these in therapeutic practice or by tailoring the moment reminder popups to a patient who typically experiences cravings after dinner.

As a third recommendation, eHealth designers should investigate if there are components of the therapy protocol that are not actually applied by therapists or patients but should be part of the eHealth since they are crucial for the effect of therapy. The eHealth designer can generate this information by interviewing therapy protocol developers about the crucial therapy protocol components. This information can be generated by involving stakeholders in the second product design phase of a personalized design process [25]. One approach would be to allow the therapist to use the eHealth app as a toolbox, which can ensure that crucial elements are not too easily personalized or skipped.

Limitations

Our study has two main limitations. The first concerns asking therapists and patients to quantify their own behavior, which may be challenging. Previous research also found that therapists overestimated the extent of therapy protocol application [61] or that self-reporting had very poor reliability [62]. For example, not all respondents understood the assignment, as the indicated percentages of strict therapy protocol application of a patient and therapist overlapped with their other percentages. This overlapping is impossible, as one cannot both strictly follow and change a therapy protocol at the same time. However, asking therapists and patients to quantify their own behavior may still be a suitable technique when asking them only to estimate the amount of therapy protocol application and personalization they adopt. Accordingly, this approach is considered suitable to generate first insights, but results cannot be solely based on this technique. A second limitation is that we did not take the therapeutic experience of the therapists and severity of the patients' conditions into account [63]. Compared to less experienced therapists, more experienced therapists generally have more experience with other therapy protocols, which may influence their personalization practices. In addition, it is possible that the severity of a patient's condition could have influenced recruitment and results. Another limitation is that this study was conducted with a limited number of participants, which might have enhanced the possible influence of individual preferences regarding protocol application and personalization on the results [64]. Future research should take this into account, such as by conducting the study with a larger sample size while taking into account these background variables. In addition, future designs of a toolkit should consider involving actual eHealth designers, eHealth design employers, and researchers. This is important since the toolkit may otherwise not correspond with current practices of target groups, which would negatively influence its implementation.

Conclusions

To optimize eHealth implementation, our study indicates that eHealth designers should have information as to which therapeutic components should be duplicated, which components should be open to personalization possibilities, and which components that are not applied in practice should remain part of the eHealth design. To generate this information, we suggest that eHealth designers collaborate with therapists, patients, protocol developers, and mental health care managers during the design process of eHealth [25]. Not involving all of these stakeholders increases the risk that the designed eHealth might not optimally fit the therapeutic practice, which would impede implementation. For example, therapy protocol designers typically know what protocol components are crucial for the therapeutic effect but do not know how the protocols are applied and personalized in therapeutic practice. Personalization practices can be implemented by actively co-designing with patients and therapists with different levels of experience to ensure that the eHealth is aligned to their preferences and capacities. Based on the present research, we expect that the implementation of eHealth can be facilitated when stakeholder representatives (eg, patients, therapists, protocol developers, and mental health care managers) are collectively involved in the design process by providing the eHealth developer with their needs and demands of therapy protocol application and personalization.

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Conflicts of Interest

None declared.

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Abbreviations

CBT: cognitive behavioral therapy
eHealth: electronic health

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Original Paper

Using the Preparation Phase of the Multiphase Optimization Strategy to Develop a Messaging Component for Weight Loss: Formative and Pilot Research

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Abstract

Background: Mobile messaging is often used in behavioral weight loss interventions, yet little is known as to the extent to which they contribute to weight loss when part of a multicomponent treatment package. The multiphase optimization strategy (MOST) is a framework that researchers can use to systematically investigate interventions that achieve desirable outcomes given specified constraints.

Objective: This study describes the use of MOST to develop a messaging intervention as a component to test as part of a weight loss treatment package in a subsequent optimization trial.

Methods: On the basis of our conceptual model, a text message intervention was created to support self-regulation of weight-related behaviors. We tested the messages in the ENLIGHTEN feasibility pilot study. Adults with overweight and obesity were recruited to participate in an 8-week weight loss program. Participants received a commercially available self-monitoring smartphone app, coaching calls, and text messages. The number and frequency of text messages sent were determined by individual preferences, and weight was assessed at 8 weeks.

Results: Participants (n=9) in the feasibility pilot study lost 3.2% of their initial body weight over the 8-week intervention and preferred to receive 1.8 texts per day for 4.3 days per week. Researcher burden in manually sending messages was high, and the cost of receiving text messages was a concern. Therefore, a fully automated push notification system was developed to facilitate sending tailored daily messages to participants to support weight loss.

Conclusions: Following the completion of specifying the conceptual model and the feasibility pilot study, the message intervention went through a final iteration. Theory and feasibility pilot study results during the preparation phase informed critical decisions about automation, frequency, triggers, and content before inclusion as a treatment component in a factorial optimization trial.

Trial Registration: ClinicalTrials.gov NCT01814072; https://clinicaltrials.gov/ct2/show/NCT01814072

(JMIR Form Res 2020;4(5):e16297) doi:10.2196/16297

KEYWORDS

weight loss; body weight; text messaging; optimization; automation

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Introduction

Background

Mobile device use is ubiquitous in the United States: in 2018, 95% of adults owned a cell phone and 77% owned a smartphone [1,2]. Text messaging, or SMS, is a common feature of many users' plans, with 81% of users indicating that they send or receive text messages as a part of regular phone use [3]. More than half of Americans look for health information on their mobile phone [4]. Thus, research on effectively using mobile systems to deliver health interventions has proliferated in recent years.

Messaging (also referred to as *texting*, *sending messages*, or *text messaging system*) affords many attractive features for mobile health interventions. Messaging systems can have broad reach using few resources compared with intervention components requiring consistent human labor or in-person delivery. Furthermore, message delivery can be systematically automated per predetermined decision rules, reducing the personnel costs associated with requiring an interventionist to monitor and trigger messages in real time. Text messages can be sent to the most basic of mobile phones at little cost, or the same content can be sent through a native smartphone app as a push notification at no cost to the recipient. Hence, mobile messaging can be implemented cost-efficiently on mobile devices in a variety of ways to fit the needs of the target population.

Although the first randomized controlled trial examining messaging as a health intervention was only conducted in 2005 [5,6], messaging has now been used in a variety of health interventions. Messages delivered by phones have shown positive effects on multiple health behaviors [6-9]. Yet, many questions about what content and at what frequency remain regarding the effective use of messaging to promote weight loss specifically [10]. These questions have become more compelling now that new technological innovations (such as real-time monitoring of continuous data from mobile sensors) make it possible to perform real-time data analytics as a basis for delivering just-in-time adaptive messaging interventions.

One common functionality of messaging is merely to deliver prompts or reminders about behaviors that need to be performed daily or multiple times per day. The complexity of reminders can vary from a once daily prompt (eg, to take medication [11]) to multiple daily prompts to take medications at particular times or to perform other behaviors (eg, physical activity [12]) multiple times daily. For more complex health targets such as weight loss that involve multiple behaviors that typically occur many times a day, thought needs to be invested in message timing and frequency [13]. If messages are not experienced as more helpful than burdensome, users may fail to attend to messages altogether. Customizing a messaging program to deliver messages flexibly, in a manner responsive to the needs of the user, could provide new opportunities to optimize positive effects of message interventions for more complex multiple behavioral demands.

Message Tailoring

Personalized and tailored messages are established to be more effective than generic messages [6,8] in part because a message is perceived to be more relevant or actionable if tailored to be targeting the individual, some specific aspect of their behavior, or goal attainment. The question then becomes: What level of tailoring is necessary and on what variables should messages be tailored to garner a positive behavioral effect? Message tailoring for most behavioral interventions to date has been restricted to surface level features: for example, personalizing with name, gender, or another baseline variable that does not change over time [6,8,14]. For health behaviors that require recurrent messages over long periods of time, lightly tailored messages could become repetitive and ineffective. One strategy that is now possible involves tailoring messages in real time to respond to the user's current state [15], thereby increasing the receptivity of the person to the message and its intended effect. Consistent with evaluations of other tailored interventions and learning theory, giving participants real-time feedback can improve engagement with the intervention, thereby producing improvement in desired health behaviors [16,17]. At this time, it is technically possible to create a messaging system for weight loss that could pull known data regarding self-monitoring consumption, physical activity, and weight to facilitate the participant's performance of positive health behaviors over time. Therefore, we sought to leverage new technology capabilities of messaging to support weight loss as a potential component of a weight loss program, first by using the preparation phase of the multiphase optimization strategy (MOST).

The Multiphase Optimization Strategy: Preparation Phase

MOST comprises several phases as depicted in Figure 1 [18] that support the design, assembly, and evaluation of a treatment package that meets optimization criteria, guided by some need as determined by an investigator. MOST provides a framework to systematically and efficiently improve interventions and thereby move intervention science forward. One use of the first phase, the preparation phase, of MOST is to engage in formative work and feasibility or pilot testing of treatment aspects, levels, or components before moving on to the optimization phase. The purpose of this paper is to describe the preparation phase of our project, when we engaged in a review of the literature and behavioral theory, conducted a pre-post feasibility pilot, and elicited user feedback and preferences to develop an automated, responsive, tailored messaging program to support weight loss as one component of a treatment package. By doing so, we ensure that the messaging component is based on sound behavioral theory, is feasible to deliver, and meets the needs of participants before implementing the component in a larger factorial trial (Optimization of Remotely Delivered INtensive Lifestyle Treatment for Obesity Study [Opt-IN]; ClinicalTrials.gov NCT01814072). Opt-IN, described in detail elsewhere [19,20], is a 6-month behavioral weight loss study comprising 32 experimental conditions.

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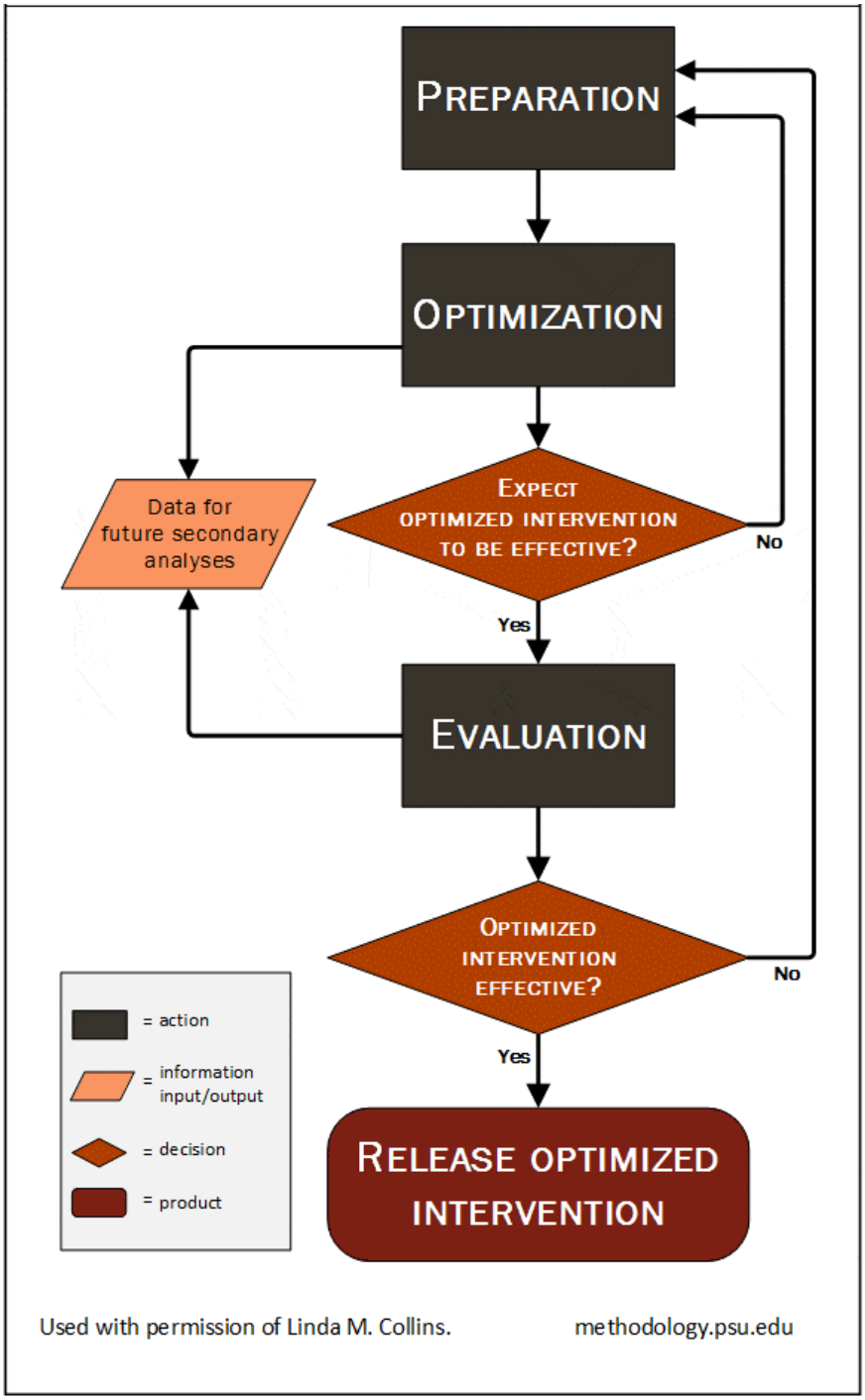
Figure 1. The multiphase optimization strategy (MOST).



Methods

Objectives

The first objective in the preparation phase of this work was to define a conceptual model to guide the message component development and testing. We did so in alignment with social cognitive theory. The second objective was to determine the feasibility of constructing and delivering messages to participants and the acceptability and preferences regarding the messages to inform implementation of the message component in the future optimization trial. Finally, we structured the logic and fully programmed the component to be tailored and automatically delivered with fidelity.

Preparation Phase Part 1: Specifying a Conceptual Model

Social cognitive theory is one model for behavioral change that can be helpful in describing how a messaging intervention could contribute to weight loss [21]. Specifically, the provision of behavioral facilitation and supportive accountability via messaging could build self-efficacy, and the confidence about being able to perform a specific behavior despite the presence of challenges and barriers.

Behavioral facilitation, or the provision of instrumental and informational support, refers to supporting the individual with knowledge, skills, resources, or adjustments to the environment that can make unhealthy behaviors easier to change [22]. When

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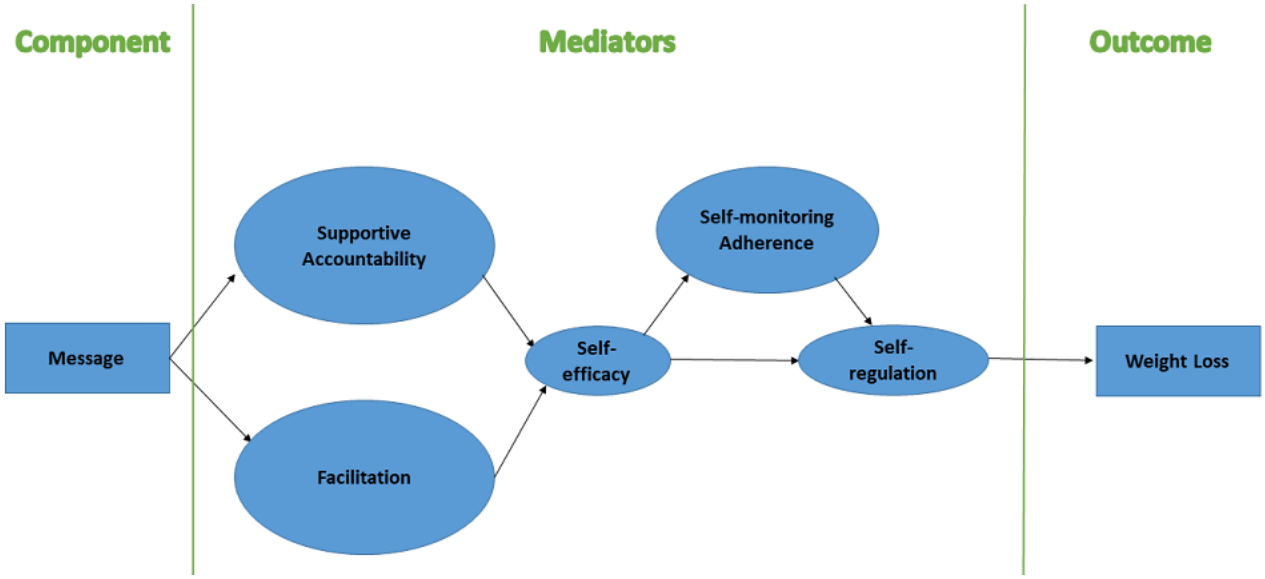
an individual receives tips, directions, or aids in problem solving, they may perceive navigating difficult behavior changes as less overwhelming and vicariously learn how to perform self-regulatory behaviors [23]. Building the ability to do the behavior is an essential ingredient of self-efficacy.

Supportive accountability refers to a relationship of encouragement and accountability that is established between two individuals, such as participant and coach, and that has been demonstrated to enhance adherence to positive behavior change [24-26]. The supportive accountability model postulates that adherence is strengthened when participants and coaches maintain a therapeutic bond, wherein the expectations of being cared about and monitored throughout the intervention are clearly stated. The provision of verbal persuasion and performance feedback can enhance a sense of mastery and further build self-efficacy.

The proposed conceptual model (Figure 2) postulates that providing both behavioral facilitation and facilitation guide individuals toward experience with behavioral changes that increase self-efficacy. We hypothesize in our theoretical model that these two domains, facilitated by messages we send, will both produce increases in self-efficacy, thereby increasing self-regulation. Self-regulation, an internal process, involves the use of self-control, internal monitoring of behaviors in relation to a goal or value in the face of temptation, and is a well-established and important capacity that is strongly tied to success in weight loss [27]. When an individual gains self-efficacy for the health behaviors, the social cognitive model posits that self-regulation, or the internal capacity to independently regulate desires in favor of healthy behaviors, is strengthened.

Figure 2. Optimization of Remotely Delivered INtensive Lifestyle Treatment for Obesity Study (Opt-IN) messaging conceptual model.



Preparation Phase Part 2: The ENLIGHTEN Feasibility Pilot Study

To test feasibility and acceptability of messaging and preliminary efficacy for producing weight loss, an 8-week weight loss pre-post feasibility pilot study was conducted using a commercially available smartphone app (ie, Lose It!), coaching calls, and text messaging. The purpose of this feasibility pilot study was to determine whether the messaging strategy was acceptable to participants and to determine the feasibility of messages. As such, the feasibility pilot study was not powered. The ENLIGHTEN study was approved by Northwestern University's Institutional Review Board (STU00078810).

Participants

Participants were recruited from a large Chicago area employer. Enrollees had to be between 18 and 60 years of age, have a BMI between 25 and 40 kg/m^2, weight <300 lb, be weight stable, and own an Android (Google Mobile Services) or iPhone (Apple) smartphone. Participants were excluded if they had unstable medical conditions, high risk for cardiovascular symptoms with physical activity, diabetes requiring insulin, Crohn's disease, obstructive sleep apnea, active binge eating, substance abuse or dependence, or active suicidal ideation. Participants were also excluded if they took medication known to cause significant weight gain or loss, used an assistive device for mobility (eg, wheelchair, walker, cane), had been hospitalized for a psychiatric disorder within the past 5 years or could not read the study questionnaires. Female participants could not be pregnant, trying to get pregnant, or lactating. Each participant completed an informed consent process and selected the timing and frequency of text messages (up to 3× per day, including weekends) that were manually sent to them by a coach throughout the week. Text messages addressed the topics of diet, physical activity, and weight change. Each message either targeted the construct of supportive accountability (eg, "Way to get that exercise in this week!") or facilitation (eg, "It's a beautiful day, get out, and enjoy an after dinner walk!").

Results

Results of Preparation Phase 2

The ENLIGHTEN feasibility pilot study enrolled 9 participants (6/9, 67% female; 5/9, 56% black; mean age 42.4 years, mean

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weight 197.2 lb, mean BMI 31.8 kg/m^2). Participants who completed the intervention (n=8) lost an average of 3% of their initial body weight (range: +0.75 lb to −14.75 lb) and preferred to be sent an average of 1.8 texts per day, on 4.3 days of the week, with a range of 2 to 7 texts per week.

Preparation Phase Part 3: Final Development of Message Treatment Component

The final stage of our preparation phase was to fully develop the message treatment component such that it could be implemented in the next phase, the optimization trial. To reduce the burden on staff and ensure fidelity of the treatment, we automated message sending by specifying programming logic for frequency and timing, content sent, and tailoring in response to user status.

Automation of Messaging

One limitation of the feasibility trial to note was the significant staff burden required to manually send text messages to participants. As such, automation of sending messages was of paramount importance during further message program development. Automating, via a push notification protocol, not only reduces staff time but also enables the interventionist to maintain treatment fidelity due to the lack of human error that can produce untimely, missed, or poorly constructed text messages. Text messages are typically sent via SMS, which utilizes a 160-character restricted protocol. In contrast, we use Apple's push notification service for iOS and Google Cloud Messaging service for Android. In style, length, and prominence, push notification messages are intended to be similar to SMS text messages. The advantages of the technology structure or architecture are 2-fold. First, neither participants nor study staff pays text message charges through their phone plan. Second, messages are integrated within the smartphone app to be used for self-monitoring in the optimization trial. Participants are alerted when a message arrives through content that pops up on either the iPhone's lock screen or the Android's notification bar. Clicking on the message opens the smartphone app and guides the participant to the message, providing an opportunity for the participant to continue engaging with the app after opening the message.

Message Frequency and Triggers

Specific timing of the messages was structured to balance the message value with the burden that notifications place on the participant [28]. The feasibility pilot study revealed a frequency preference of 1 or 2 messages per day on average, but the number preferred varied widely. Due to the wide variability in preference, and given the Enlighten feasibility pilot study average of 1.8 texts per day on 4.3 days of the week (corresponding to approximately 7.7 texts per week), participants in the optimization trial chose what times were most convenient and least burdensome to receive a minimum *dose* of 7 text messages each week (Table 1). Timing choices included receiving a text at random times between 8 AM and 5 PM, only in the AM between 8 AM and noon, only in the PM between 12 PM and 5 PM, or a rotation where texts were alternately sent in the AM or PM. Participants could also choose whether to receive 2 bonus messages per week that were sent on their own varied schedule.

Table 1. Message preference schedules for participant selection.

Preference option[a]	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday
A	T1[b]	T2	T3	T4	T5	T6	T7
B	T1/T2	N/A[c]	T3/T4	N/A	T5/T6	N/A	T7
C	N/A	T1/T2	N/A	T3/T4	N/A	T5/T6	T7

[a]Schedule of text messages to be sent across a week.

[b]T: Text.

[c]N/A: not applicable.

The message trigger acted as the beginning of a logic structure that we hypothesize to increase likelihood of seeing the message (Figure 3), which supports fidelity of treatment receipt of our message component. If the participant opens the app during one of their preferred day and time windows, we infer that they are ready to receive a message, and thus a message will be sent (Figure 3). A slight delay is in place to avoid bombardment, giving the user time after they first open the app to complete a self-monitoring entry (eg, weight, food intake) before compiling and sending any pending messages. However, not all participants will interact with the app during their preference windows. To account for this, a message was automatically sent at the end of the preference period if no interaction with the smartphone app occurred. For example, if a participant's preference is to receive one message every day in the morning (between 8 AM and 12 PM) and they have not opened the app at all during that window, a message is sent at midnight.

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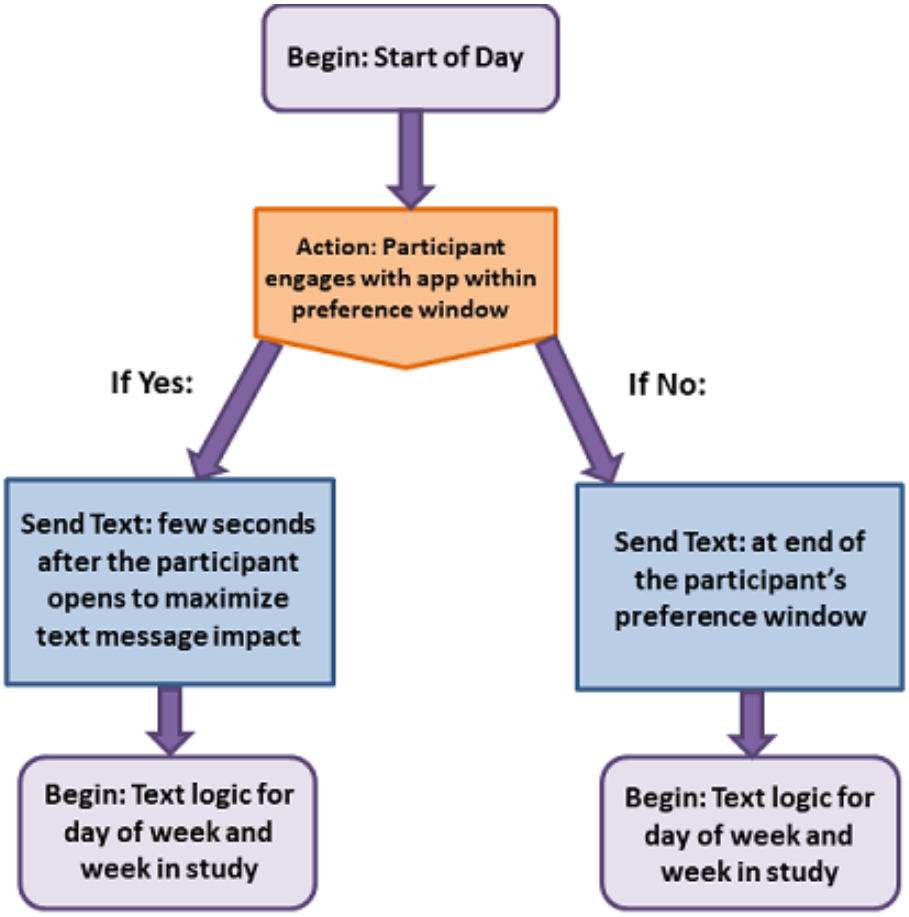
Figure 3. Logic structure for Optimization of Remotely Delivered INtensive Lifestyle Treatment for Obesity Study (Opt-IN) text message triggers.



Message Content

The content of all messages relates to behavioral facilitation or supportive accountability from the conceptual model in Figure 2. To make all messages relevant and engaging, a schedule of messages was created to target all aspects of weight loss and associated behaviors without becoming monotonous. Thus, participants received at least 7 messages per week, each with content from one of 7 behavioral categories: weight, physical activity, behavioral activation, adherence, physical activity goal attainment, calorie consumption goal attainment, or fat gram consumption goal attainment. The first message each week is from the weight category, which updates the participant on weight change over the previous week. The order of the remaining topics is different but predetermined each week for consistency across participants (Table 2). For example, a participant in week 2 of the study would receive a behavior activation message as their second text of the week, but someone in week 11 would receive a calorie consumption goal attainment text as their second text.

Table 2. Sample weekly text schedule with example content.

Weekly example	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday
Topic	Weight	MVPA[a] goal attainment	Adherence	Behavioral activation	MVPA	Fat goal attainment	Calorie goal attainment
Message	You have lost X pounds in the past week! Way to go—remember to maintain these behavior changes as you continue with your weight loss!	Try to schedule in your activity! Make it a priority so you can meet those goals!	Focus on getting back on track with food entry on your phone in order to help you know your caloric and fat intake!	Adding in a small breakfast like a yogurt or an apple can make a big impact on your weight loss success!	Nice work exercising this week! Keep it up for the rest of the week.	If you're having trouble adding the right kinds of fat into your diet or recording your foods, don't be afraid to ask for suggestions on your next call.	It looks like you went over your calorie goal yesterday. Don't worry, slips are normal! Get back on track today.

[a]MVPA: moderate-vigorous physical activity.

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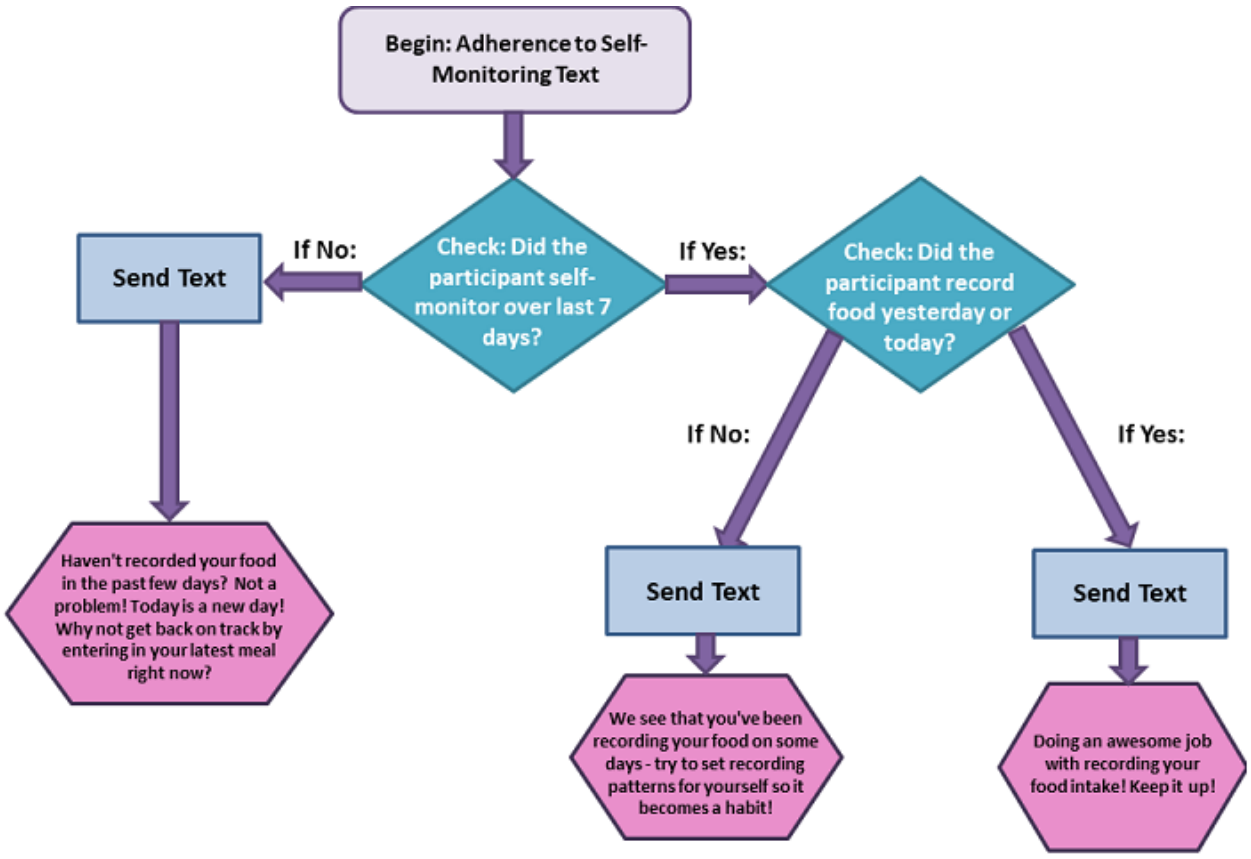
Tailoring in Response to User Status

To increase relevance and engagement, the text content is tailored to the individual's personal progression toward study goal attainment (ie, weight loss, daily calorie intake, daily fat gram intake, and physical activity). As such, most messages delivered are based on what the participant has (or has not) self-monitored within the smartphone app. The texts are designed to encourage and reinforce positive participant behaviors, not to be negatively critical or discouraging. Hence, content was written to reinforce not only achieving goals, but also coming close to goal attainment, much like a human health coach might. For example, if a participant with a 1200 daily calorie goal enters 1220 calories, a calorie goal attainment text message would still reflect that they did well staying in the calorie range, rather than telling them they exceeded their daily calorie goal. Similarly, if a participant had not self-monitored food in the app on the day an adherence to self-monitoring text was to be sent, but had self-monitored food the prior day, the adherence to self-monitoring text would reinforce their recording on some days, while encouraging them to continue setting patterns (Figure 4).

Figure 4. Optimization of Remotely Delivered INtensive Lifestyle Treatment for Obesity Study (Opt-IN) message tailoring: adherence to self-monitoring example.



Tailoring messages to make them feel both personalized and as if they are coming directly from the health coach was also considered an important factor in maintaining a strong therapeutic alliance between participant and their coach. Based on the assumption of this kind of social presence, we posit that the simulated human connection through messages created with this structure will be more efficacious than a *robot* or automated machine [6,24,29].

Discussion

Summary of Findings

As part of the MOST framework, critical preparation work was completed to develop a messaging protocol that was theoretically grounded, responsive to user feedback, easy to scale in a remotely delivered intervention, tailored to the individual's current state, and feasible to deliver with fidelity in a factorial trial. Despite widespread use of messaging as a component of health behavior change interventions, information about the derivation of message content is often absent, leaving it unclear how and why the messages were developed and implemented in a particular way [6]. Furthermore, message interventions are often delivered as part of a treatment package and may not be able to be compartmentalized to test unique effects on outcomes due to overlapping function with other treatment components. Therefore, before embarking on an attempt to use a factorial design to optimize a treatment package for obesity, it was critical to spend time in the preparation phase to fully develop the messaging treatment component we wanted to test for effect on weight loss.

The development of our messaging component included designing messages based on theory, testing the feasibility and acceptability of the messages, and identifying participant preferences regarding message receipt. The resulting messages

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are personalized, timely, and relevant to the participant, which may increase the likelihood that the participant will respond in a desirable manner by maintaining or improving a targeted behavior. The preparation work also allowed us to create a component with potential for high treatment fidelity, a critical need in intervention trials and especially for factorial trials with a high number of randomized conditions. The resulting technology has the unique ability to deploy messages either in response to interaction with the smartphone app or based on the participant's preferred schedule. This capitalizes on participant receptivity: when the individual is actively using the app, a time they are most likely thinking about their health behaviors. If an individual is not interacting with the study app, sending messages based on their preferred schedule may provide a real time-time helpful reminder to re-engage with target health behaviors to prevent a lapse.

Artificial Intelligence

The features of our message component may very well be perceived as an artificially intelligent system. Messages are sent at times of high receptivity, with content that uses current participant status, and that responds in a way to support the self-efficacy of an individual much in the way a live health coach might. Human staff have availability constraints, cost a significant amount, and are prone to make errors in intervention delivery. Therefore, using human staff to coach individuals in a weight loss program has many barriers to scalability. The message program design described, if effective, may well be a first foray into artificial intelligent coaching that can provide just-in-time adaptive interventions. In sum, these essential preparatory activities supported the development of a theoretically sound, scalable, and low-cost treatment component that was feasible to deliver in our optimization trial design.

Critiques and Strengths

One possible critique of our work is that it had a significant upfront cost to design and program sufficient to meet our requirements and confer a realistic and human feel. The overall cost might be worth time and effort downstream if it relieves staff time across enough participants over enough time. One benefit is that once programmed, as we have done, it can be scaled up and distributed widely with a relatively low maintenance cost, an important requirement set during our preparation phase. Comparatively, many intervention components are developed as part of multicomponent treatment packages, sometimes without critical preparatory work, and tested as such in a randomized controlled trial, the results of which are unable to reveal whether the component has any important or significant effect on the outcome. We believe the upfront cost of preparation in the context of MOST is warranted to develop rigorous, robust, and testable components.

Future Work

Although weight loss programs that include a text messaging component have been effective [8,30-32], current evidence is not clear if it is an essential active component of a treatment package. In the next phase of this research, the optimization phase, the Opt-IN study will include messages as a factor that participants will be randomized to receive or not receive in a factorial research design. By using a factorial design, we will answer whether this type of messaging program provides a meaningful effect in a weight loss intervention package. It is critical to test the messaging component in this way because it provides significant advantages to investigators in that they are low-cost, easy-to-use, and can be delivered in real-time. This is an appealing alternative to costly human coaches who may not be able to deliver interventions at a time when the person needs it in everyday life [10,33-36].

Although our preparation phase work and the subsequent Opt-IN trial will make progress in optimizing a cost-contained treatment package for obesity, its limitation relevant to mobile messaging is that it will inform the utility of including messaging in a one-size fits all treatment package. One could also optimize weight loss by testing the use of message systems in stepped sequences as in a sequential multiple assignment randomized trial [37,38] or in specific just in time contexts as in a microrandomized trial [39]. The current lack of optimization is not limited to obesity treatment but has rather been unaddressed across various health interventions [7,15,40,41]. Thus, future research is needed to optimize all aspects of mobile messaging as a treatment component to fully realize its potential.

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Conflicts of Interest

BS serves on the scientific advisory boards of Arrivale and Actigraph. The remaining authors declare no conflicts of interest.

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Abbreviations

MOST: multiphase optimization strategy
NIDDK: National Institute of Diabetes and Digestive and Kidney Diseases
Opt-IN: Optimization of Remotely Delivered INtensive Lifestyle Treatment for Obesity Study

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Original Paper

Identifying Women at Risk for Polycystic Ovary Syndrome Using a Mobile Health App: Virtual Tool Functionality Assessment

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Abstract

Background: Polycystic ovary syndrome (PCOS) is an endocrine disrupting disorder affecting about 10% of reproductive-aged women. PCOS diagnosis may be delayed several years and may require multiple physicians, resulting in lost time for risk-reducing interventions. Menstrual tracking apps are a potential tool to alert women of their risk while also prompting evaluation from a medical professional.

Objective: The primary objective of this study was to develop and pilot test the irregular cycle feature, a predictive model that generated a PCOS risk score, in the menstrual tracking app, Clue. The secondary objectives were to run the model using virtual test subjects, create a quantitative risk score, compare the feature's risk score with that of a physician, and determine the sensitivity and specificity of the model before empirical testing on human subjects.

Methods: A literature review was conducted to generate a list of signs and symptoms of PCOS, termed variables. Variables were then assigned a probability and built into a Bayesian network. Questions were created based on these variables. A total of 9 virtual test subjects were identified using self-reported menstrual cycles and answers to the feature's questions. Upon completion of the questionnaire, a Result Screen and Doctor's Report summarizing the probability of having PCOS was displayed. This provided information about PCOS and data to facilitate diagnosis by a medical professional. To assess the accuracy of the feature, the same set of 9 virtual test subjects was assigned probabilities by the feature and the physician, who served as the gold standard. The feature recommended individuals with a score greater than or equal to 25% to follow-up with a physician. Differences between the feature and physician scores were evaluated using a t test and a Pearson correlation coefficient in 8 of the 9 virtual test subjects. A second iteration was conducted to assess the feature's probability capabilities.

Results: The irregular cycle feature's first iteration produced 1 false-positive compared with the physician score and had an absolute mean difference of 15.5% (SD 15.1%) among the virtual test subjects. The second iteration had 2 false positives compared with the physician score and had an absolute mean difference of 18.8% (SD 13.6%). The feature overpredicted the virtual test subjects' risk of PCOS compared with the physician. However, a significant positive correlation existed between the feature and physician score (Pearson correlation coefficient=0.82; *P*=.01). The second iteration performed worse, with a Pearson correlation coefficient of 0.73 (*P*=.03).

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Conclusions: The first iteration of the feature outperformed the second and better predicted the probability of PCOS. Although further research is needed with a more robust sample size, this pilot study indicates the potential value for developing a screening tool to prompt high-risk subjects to seek evaluation by a medical professional.

(JMIR Form Res 2020;4(5):e15094) doi:10.2196/15094

KEYWORDS

polycystic ovary syndrome; mobile health app; Clue; menstrual irregularities; telemedicine; mHealth, mobile phone

Introduction

Background

According to the Rotterdam criteria, polycystic ovary syndrome (PCOS) is clinically diagnosed by the presence of at least two of the following: androgen excess, menstrual irregularity, or presence of polycystic ovary morphology on ultrasound examination [1]. The Androgen Excess and PCOS Society has also proposed guidelines for diagnosis, which include hyperandrogenism, ovarian dysfunction, and exclusion of other androgen excess or related disorders [2]. Women with menstrual irregularities, particularly those with PCOS, have an increased risk of developing comorbidities, such as metabolic syndrome, heart disease, or diabetes [3]. In 2005, the economic burden of evaluating and providing care to women of reproductive age with PCOS was US $4.36 billion, which was equivalent to US $5.65 billion in 2018 [4]. This assessment included the costs of infertility treatments, living and treating metabolic disorders, and addressing hirsutism. The calculated expenses of PCOS are likely an underestimate of the actual cost of providing care because many women will live beyond reproductive age with expensive metabolic disorders such as metabolic syndrome, which adds at least US $2000 more of health care expenses annually [4,5].

In the current era of ubiquitous smartphones, individuals are turning to mobile phone apps for immediate health tracking and care [6,7]. Women, in particular, have reported higher rates of downloading health apps [8]. By having menstrual cycle data collected in real time, women are able to share accurate details with their medical providers [9]. Thus, these apps can have significant implications for women with menstrual irregularities.

For women at high risk of developing PCOS, having a mobile health app that identifies and tracks menstrual cycles may help facilitate symptom tracking and prevent inaccurate reporting of signs and symptoms [10]. However, current menstrual tracking apps are not well equipped to deal with irregular menstrual cycles [11].

Objectives

The primary objective was to develop and pilot test the irregular cycle feature. The irregular cycle feature is a predictive model that generates a PCOS risk score for a user based on responses to an adaptive questionnaire. The secondary objectives were to run the model using 9 virtual subjects, create a quantitative risk score, compare the model's risk score with that of a board-certified reproductive endocrinology and infertility physician-scientist (physician), and determine the sensitivity and specificity of the model before empirical testing on human subjects.

Methods

Creating the Framework

Clue is an app created by BioWink GmbH, which allows users to track menstrual cycles and related health information [12]. Data collected include, but are not limited to, menstrual cycle length, duration of flow, menstruation-related pain symptoms, and method of birth control. To create a user profile, the app also prompts individuals to input age, height, and weight. Personally identifiable information is collected by Clue and stored in a secure backend system where it is encrypted [13].

An adaptive questionnaire, or a question set modified based on answers to previous questions, was developed. To create the framework for the adaptive questionnaire, the physician from Boston University and researchers at Clue compiled signs and symptoms (variables) associated with PCOS based on the Rotterdam criteria and common diseases that display similar variables based on the physician's clinical experience. For the purpose of developing this tool, other common diseases accounted for in the Bayesian network created with overlapping signs and symptoms included Cushing syndrome, hypothyroidism, hyperprolactinemia, and functional amenorrhea. The physician developed a list of common variables for these disorders based on clinical experience and the Rotterdam diagnostic criteria [1]. These variables included irregular menstrual cycles, hirsutism, alopecia, and acne. A literature review was then conducted to determine the prevalence of these variables specifically in women with PCOS. The literature review consisted of searches in UpToDate (Wolters Kluwer Health's) for the prevalence of each included variable. When a search yielded no prevalence, an additional search was conducted on PubMed to determine the appropriate prevalence. For example, the team's PubMed search using the MeSH term *hyperandrogenism* for clinical hyperandrogenism yielded a 10% prevalence in women of reproductive age [14]. Each variable and associated prevalence were then incorporated into a Bayesian network to generate joint probabilities (Figure 1). A total for 40 unique articles were used to determine the prevalence for the 4 variables

A Bayesian network is a modeling tool that integrates independent and dependent probabilities to calculate an overall probability based on each variable [15]. The Bayesian network was created manually using Netica. For each variable, the prevalence of symptoms, given the presence or absence of a disease, was manually encoded in the Bayesian network. The prevalence of each symptom determined in the literature review was then inserted as the probability for each variable. The physician was consulted when published values were widely variable. For nodes in the network with many parents, such as

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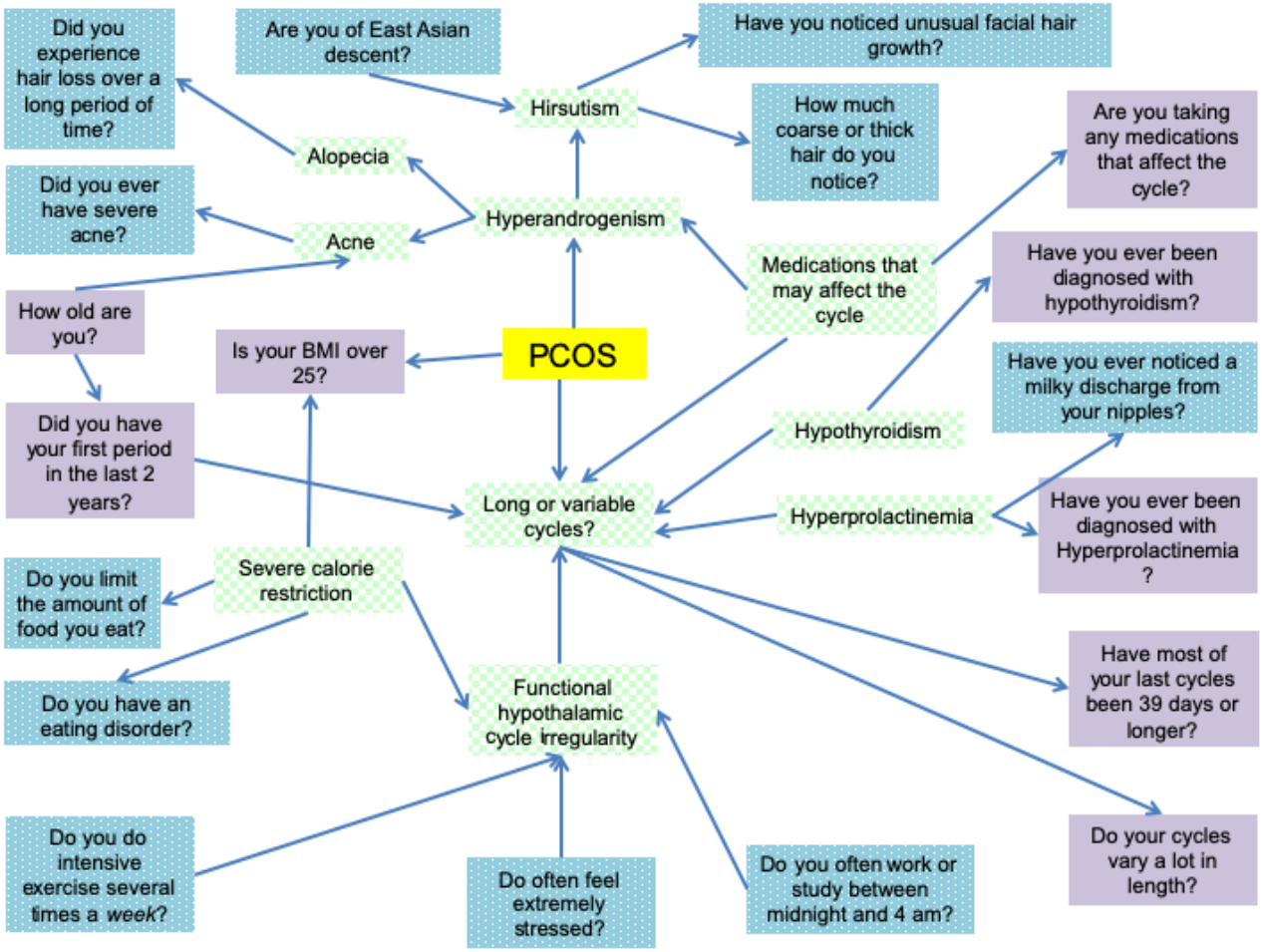
long or variable cycles, there were many possible combinations of dependencies. For simplicity, they were assumed to be uncorrelated. The software tool then constructed the Bayesian network. Figure 1 is reflective of the Bayesian network that was generated using the Netica software with probabilities omitted. Specific parameters for each variable are proprietary to Clue.

Figure 1. Green, checkered boxes indicate major diagnostic concerns for polycystic ovary syndrome. Purple, solid boxes are representative of the questions that are on the screen. The blue, dotted boxes are additional questions asked by the irregular cycle feature. PCOS: polycystic ovary syndrome.



Phase 1: Development of Question Sets

Virtual Test Subjects

A virtual test subject is an algorithmic model representative of how an individual or a group of individuals may appear or behave in the real world [16]. These computer models have proven useful in creating predictive models for epidemics, such as the spread of influenza or serving as educational materials for physicians [17,18]. Virtual test subjects have also previously been used to train physicians on the administration of glucose clamp procedures [16]. To conduct the pilot testing of this feature, a set of virtual test subjects was created. Each virtual test subject was generated by a designated team member and had a unique set of answers to preformulated questions that were built into the irregular cycle feature. For example, 1 virtual test subject would be asked whether or not they experienced excess hair growth and would respond yes, whereas a different virtual test subject would respond no. These slight changes in responses allowed the team to run an analysis to understand the validity of the network. The scores of the irregular cycle feature generated for each of these virtual subjects were then compared with the score provided by a physician. The answers to each question for all virtual test subjects remained consistent between the irregular cycle feature and physician scoring. Only 14 virtual test subjects were created for ease of testing the feature.

Eligibility Requirements

The inclusion criteria, which were based on the definitions of abnormal uterine bleeding from the International Federation of Gynecology and Obstetrics, for prompting with the irregular cycle feature included logging irregular cycles for at least 6 months or have not logged a period in 90 days, cycles longer than 38 days, or a cycle length variation that is higher than average for their age group. For individuals aged between 16 and 26 years, the cycle length variation threshold is >9 days cycle to cycle. For users aged >27 years, the cycle length variation should be >7 days [19]. A virtual test subject would be excluded from the study if these criteria were not met.

Screener Questions

Once the network was established, questions were written to assess signs and symptoms deemed relevant by the literature review. Questions were separated into a screener and the adaptive questionnaire, within the irregular cycle feature. The screener consisted of 7 questions used to collect information

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regarding height, weight, age, birth control use, medical conditions, life stage, and age at menarche. The specific questions and abbreviated answers are shown in Multimedia Appendix 1.

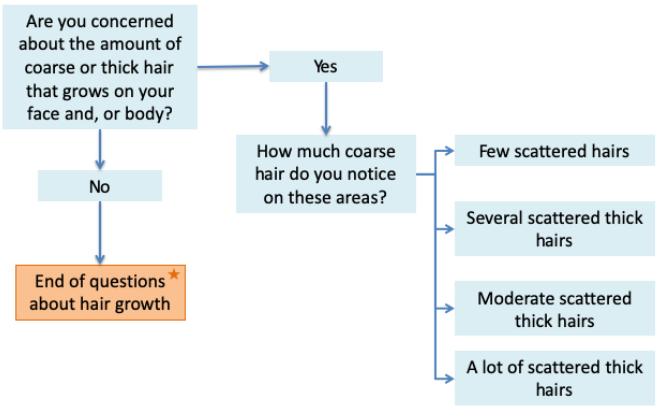
Adaptive Questionnaire

After the screener, the subject was presented with the adaptive questionnaire, which features questions aimed at completing the picture of risk factors for PCOS. These questions were based on the Ovulation and Menstruation Health Study conducted at Boston University [20], which measures androgen excess, levels of stress, and eating patterns. Questions in the adaptive survey portion of the irregular cycle feature included measures of body hair, medications that can affect the menstrual cycle, hair loss, acne, irregular sleep, stress, strenuous physical work, and eating habits. Although this was not an exhaustive medical history, these variables were deemed useful for preliminary identification of PCOS based on the current literature. A complete list of additional questions assessed by the feature is shown in Multimedia Appendix 2. As some symptoms vary by racial and ethnic groups, virtual test subjects were also able to report their background. In total, 14 virtual test subjects were created to assess the functionality of the Bayesian network. Each of the virtual test subjects had unique answers to the irregular cycle feature screener and the adaptive questionnaire to test the ability of the network to produce an accurate PCOS probability. Each virtual test subject had a different combination of questions left blank. Leaving questions blank allowed the team to determine how accurate the irregular cycle feature could score virtual test subjects compared with the physician in the setting of missing data. The questions left blank were selected based on the relative missing data that currently exist in the user-entered data in the Clue app. The 14 virtual test subjects created were generated to be comparable with aggregated, deidentified Clue user data. Nine virtual test subjects were considered representative of cycles, birth control usage reporting, and symptom tracking available from the Clue user base and were included in the analysis.

Phase 2: Question Flow

As the irregular cycle feature is adaptive, not every question is asked to every subject. For instance, Figure 2 shows that if a virtual test subject reported that they were not concerned about excess hair growth, the tool would not ask about how much hair was present on their body. In this manner, the model streamlined the data collection and reduced the time it took a subject to complete the module. Compiling this information, the network then calculated whether menstrual cycle irregularities were an indicator of PCOS or if the menstrual irregularities were possibly because of a different condition.

Figure 2. This figure highlights the adaptive nature of irregular cycle feature by modeling with questions assessing hair growth. The orange, starred box indicates the end of the question set.



Phase 3: Assignment of Thresholds for Risk

The physician on the team assigned 4 categories of risk: low, indeterminate, moderate, or high to each virtual test subject based on her assessment of the virtual test subject's symptoms compared with the Rotterdam diagnostic criteria for PCOS. According to the Rotterdam criteria, PCOS is clinically diagnosed by the presence of at least two of the following: androgen excess, menstrual irregularity, or presence of polycystic ovary morphology on ultrasound examination [1]. TThe physician was shown the responses from each of the virtual test subjects that were run through the irregular cycle feature. She then determined a category of risk based on the Rotterdam diagnostic criteria excluding hypothalamic and thyroid causes based on responses to questions. For example, if a virtual test subject presented with increased body hair but also reported a history of disordered eating, the body hair was more likely to be associated with anorexia than with PCOS. The physician would then assign a low risk category. To compare this with the quantitative values generated by the irregular cycle feature, the team determined a set of numerical ranges for the categories based on proposed definitions for converting qualitative and quantitative classifications by Hillson [21].

Virtual test subjects that were determined to have a low risk of PCOS were assigned a value within the range of 0% to 9%. The numerical range for indeterminate risk was assigned as 10% to 29%. These values were selected based on the *unlikely* and *possible* qualitative terms in the proposal by Hillson [21]. Virtual test subjects with moderate individual risk were assigned percentages within the range of 30% to 59%. These values encompassed the categories of *probable* and *good chance* as defined by Hillson [21]. Virtual test subjects with high individual risk were assigned a value within the range of 60% to 100%. These values were selected based on the Hillson's

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interpretation of *highly probable* to *definite* terms [21]. These probability scales are summarized in Figure 3.

During the evaluation of the virtual test subjects, the physician determined that 2 virtual test subjects were confounded by additional variables and could not be accurately assessed because of lack of data. These 2 cases were assigned a probability of 10%, as they fell into the indeterminate category. A total of 10% was arbitrarily chosen for this study because it is reflective of a low but possible risk of developing PCOS.

Results Screens were created to provide feedback at the end of the assessment based on each of these thresholds. Distinct and direct recommendations were given based on the calculated probability of PCOS yielded by the irregular cycle feature. There were 3 possible screens, including a Positive Result Screen, a Neutral Result Screen, and an Inconclusive Result Screen. All screens include a brief description of how the result was reached and a disclaimer that the result was not a diagnosis.

Users calculated as having a probability of PCOS that was greater than or equal to 25% by the irregular cycle feature were prompted with a Positive Result Screen (Multimedia Appendix 3). This screen displays a description of PCOS, related health risks, and a call to action encouraging the user to seek medical attention. In addition, it described the steps a physician may take to diagnose the individual with PCOS or another related disorder affecting menstrual cycle regularity.

The Neutral Result Screen (Multimedia Appendix 4) was presented to users with an irregular cycle feature probability of less than 25%. It stated that a prediction could not be made regarding what was causing the irregularities. It included other potential causes such as lifestyle factors, hypothyroidism, and Cushing syndrome. The user was also prompted to seek advice from a medical professional. The text described that the physician would likely perform a detailed history regarding symptoms, a simple physical examination, and blood tests if necessary.

The Inconclusive Screen (Multimedia Appendix 5) was presented to users who have reported confounding variables or too much missing data. These variables included, but were not limited to, the use or recent discontinuation of hormonal birth control, age outside applicable range, recent pregnancy, and breastfeeding. The potential use of medications, particularly those with hormones, in individuals creates too many confounding variables and is beyond the capabilities of the network's calculations. Thus, when an individual reported a confounding variable that also causes hormonal dysregulation, the screen prompted them with a suggestion to visit a medical professional who can perform additional testing to determine the reason behind their menstrual irregularity. Of the 14 virtual test subjects, 6 were ultimately prompted with an Inconclusive Screen because of their answers.

The Doctor's Report was a shareable document that was generated at the end of each assessment for presentation to a medical professional (Multimedia Appendices 6 and 7). It included details regarding the virtual test subject's menstrual cycle characteristics and history as well as the signs and symptoms reported via the irregular cycle feature questionnaire. The medical board at Clue and the physician from Boston University were consulted in its design to ensure that it appropriately highlighted a user's health data. The Doctor's Report was generated to determine whether the individual was expected to have PCOS or not. This ensured that the individual was able to provide important medical information to their provider regardless of the output so long as their cycles were irregular.

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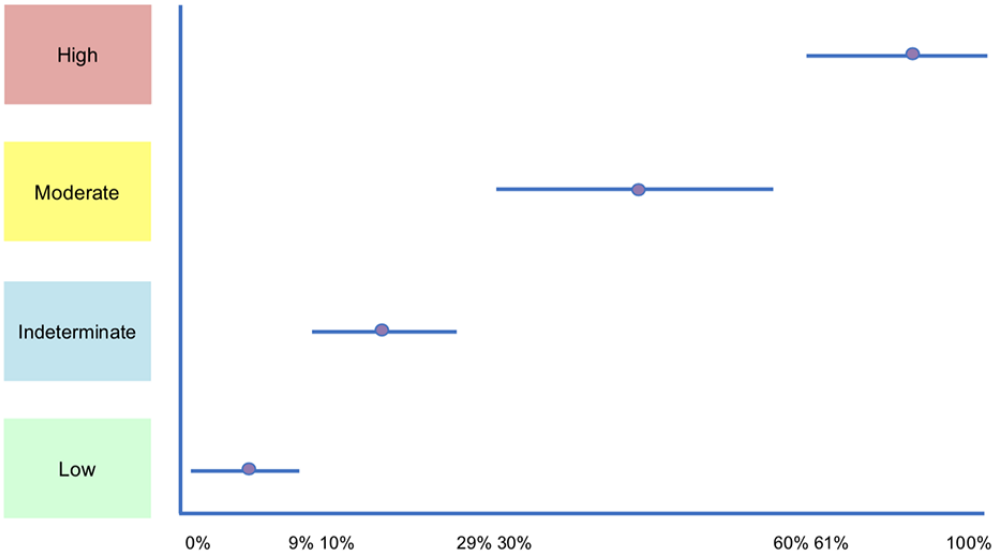
Figure 3. Sliding scale percent probability ranges. The blue bar indicates the range of percentages that fall into the high, moderate, indeterminate, and low categories. The purple circle illustrates the percentage typically used in the assignment of percent probability.



Phase 4: Validation of the Tool

To validate the usability and accuracy of the network, the physician-generated probabilities from phase 3 were compared with those predicted by the irregular cycle feature. This helped determine whether the feature could make assessments similar to those performed in a clinical setting. A summary of the probability assignments by both the irregular cycle feature and the physician is shown in Table 1.

Table 1. Probability assignments[a]

Virtual test subject #	Physician's assessment	Physician's assigned probability, %	Irregular cycle feature's assigned probability, %
Subject 1	High	80	91
Subject 2	High	80	93
Subject 8	PCOS[b]: 30%; hypothalamic pituitary: 70%	30	66
Subject 12	Currently taking hormones: this is a special case—indication of irregular cycles means the feature should direct them to talk to their physician	10	10
Subject 14	Low PCOS	5	34
Subject 17	Moderate to high PCOS	70	37
Subject 5	Indeterminable	10	9
Subject 7	High	80	14
Subject 15	None	0	1

[a]Summary of the physician's assessments (categorical probabilities), physician's assigned probabilities, and the irregular cycle feature calculated probability for all test subjects that went through the irregular cycle feature questionnaire during the first iteration.

[b]PCOS: polycystic ovary syndrome.

Statistical Analysis

Microsoft Excel version 16.16 was used to conduct all statistical analyses. The utility of the irregular cycle feature was assessed by (1) comparing the sensitivity (false-negatives) and specificity (false-positives) with the assessment made by the physician, (2) mean difference among virtual test subject scores, and (3) the Pearson correlation coefficient. Normality was assessed by plotting the data points. The correlation between the irregular cycle feature and physician, a *P* value from the correlation, and

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a Pearson correlation coefficient were calculated using the 9 eligible virtual test subjects. Multimedia Appendix 8 illustrates the sensitivity, specificity, and mean difference for the 9 virtual test subjects. A second analysis was then conducted, excluding 1 virtual test subject. When the outlier data point was removed, there was a normal distribution in the scores. As this data point significantly skewed the values, the data resulted in a final set of 8 virtual test subjects that were used to assess the sensitivity and specificity, mean difference, and Pearson correlation coefficient.

An additional iteration of the irregular cycle feature's Bayesian network was also completed to determine the effect of hirsutism on the accuracy of scoring for PCOS in the virtual test subjects. To assess whether the prevalence previously selected for hirsutism was reflective of current literature, a second literature review was conducted. This review yielded a slightly lower prevalence of hirsutism in PCOS. As such, this new prevalence was integrated into the irregular cycle feature's Bayesian network. The virtual test subjects were run through the feature again. A summary of the statistical tests and outcomes for the old and new prevalence can be seen in Tables 2-5.

Table 2. Summary of statistical calculations for 9 virtual test subjects.[a]

Statistical test	Value
Pearson correlation coefficient	0.62
P value	.08

[a]Statistics for all virtual test subjects that were created by the team, including subject 7, who was ultimately excluded because it was a statistical outlier.

Table 3. Summary of statistical calculations for 8 virtual test subjects.[a]

Statistical test	Value
Pearson correlation coefficient	0.82
P value	.01

[a]Statistics for 8 test subjects created by the team. It excludes subject 7, who was suspected to be an outlier based on the mean difference.

Table 4. Summary of statistical calculations for 8 virtual test subjects on the second iteration of the irregular cycle feature.[a]

Statistical test	Value
Pearson correlation coefficient	0.73
P value	.03

[a]Statistics calculated with lowered probabilities of hirsutism in polycystic ovary syndrome for all test cases excluding subject 7 (the suspected outlier).

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Table 5. Sensitivity, specificity, and mean difference of irregular cycle feature and physician scores by iteration.

Virtual test subject	Feature (%)	Physician (%)	Specificity	Sensitivity	Difference (%)
Iteration number 1[a]					
1	91	80	0	0	11
2	93	80	0	0	13
8	66	30	0	0	36
12	10	10	0	0	0
14	34	5	1	0	29
17	37	70	0	0	−33
5	9	10	0	0	−1
15	1	0	0	0	1
Iteration number 2[b]					
1	88	80	0	0	8
2	92	80	0	0	12
8	56	30	0	0	26
12	10	10	0	0	0
14	26	5	1	0	19
17	29	70	0	0	−31
5	22	10	0	0	12
15	42	0	1	0	42

[a]Absolute mean difference for iteration 1 was 15.5% (SD 15.1%); mean difference 7%.

[b]Absolute mean difference for iteration 1 was 18.8% (SD 13.6%); mean difference: 11%.

Results

The majority of virtual test subjects had an irregular cycle feature score that overpredicted PCOS when compared with the physician screening score (Table 5). The first iteration of the irregular cycle feature produced only 1 false-positive compared with the physician screening score and had an absolute mean difference of 15.5% (SD 15.1%) among virtual test subjects. The second iteration of the irregular cycle feature had 2 false positives compared with the physician screening score and had an absolute mean difference of 18.8% (SD 13.6%). The first iteration irregular cycle feature score overpredicted the probability of PCOS compared with the physician with a mean absolute difference of 7. The correlation value was calculated to be 0.82 for the 8 virtual test subjects. The same 8 virtual test subjects were also used to generate a linear regression (Figure 4). The *P* value was then determined to be .01 (Table 3). As the *P* value was less than .05, the team determined that the predictive capabilities of the irregular cycle feature were statistically significantly different from the assessments made by the physician, although the risk difference was not considered to be clinically significant. A few sample virtual test subjects are shown in Table 6 to demonstrate the questions, answers, and predictions generated by the irregular cycle feature.

The results generated by the irregular cycle feature compared with those assigned by the physician are shown in Table 1. For virtual test subject 1, the physician assigned an 80% probability, compared with the 91% probability calculated by the feature. In both cases, the virtual test subject would be prompted with a Positive Result Screen and the Doctor's Report stating PCOS as a possible cause for irregular menstrual cycles.

In virtual test subject 8, the physician assigned a 30% probability of PCOS and further suggested a hypothalamic or pituitary cause of the menstrual irregularities. The irregular cycle feature, which predicted a 66% probability, would prompt the individual to seek advice from a medical professional via the Positive Result Screen and also suggest PCOS as a possible cause for signs and symptoms reported.

For virtual test subject 12, the physician assigned a 10% probability of PCOS. The irregular cycle feature also suggested a 10% probability of PCOS. The physician determined that the hormones taken by the individual indicated a special case, and that recommendations could not be made based on the answers provided. The feature's Inconclusive Screen was presented to this virtual test subject.

For virtual test subject 15, both the physician and the irregular cycle feature predicted a 0% to 1% chance of PCOS, and the subject received the Neutral Result Screen and Doctor's Report stating PCOS as an unlikely cause of menstrual irregularities.

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Figure 4. This graph demonstrates the linear regression for 8 test cases, excluding subject 7 (the suspected outlier).

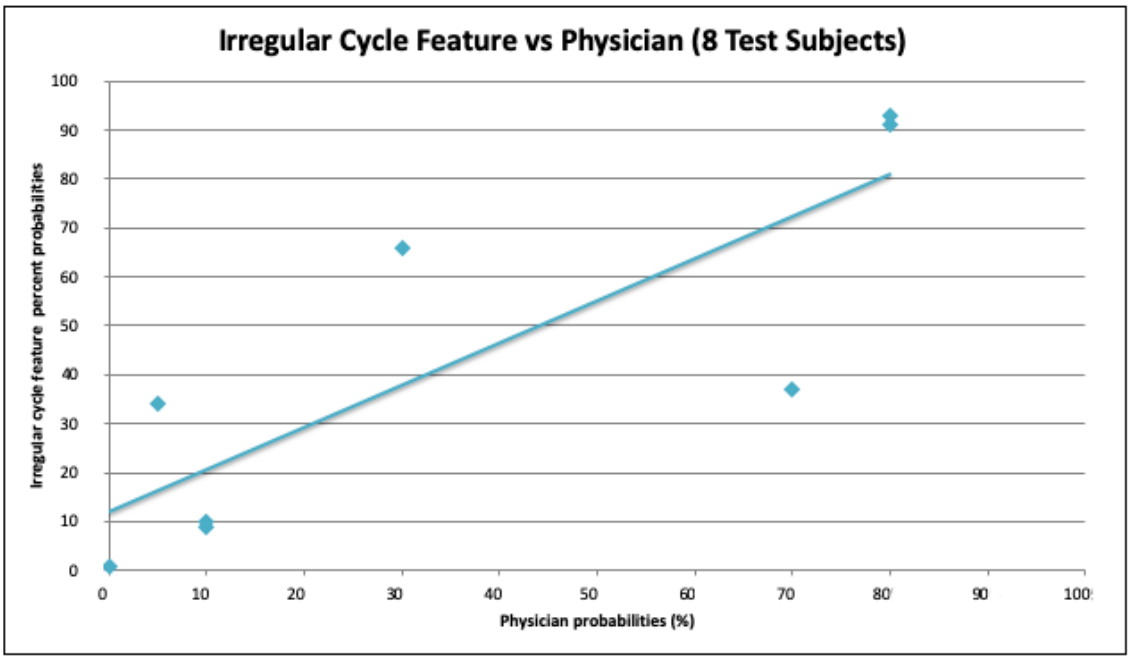

Table 6. Sample questions, answers, and probabilities using irregular cycle feature.[a]

Question	Subject 1	Subject 8	Subject 12	Subject 15
Concerned about hair growth?	Yes	Yes	Yes	No
How much thick hair?	Lots of Hair	Several	Several	__[b]
Majority of cycles ≥38 days?[c]	Yes	Yes	Yes	No
Taking meds that could affect the cycle?	No	No	Yes	—
BMI >25 kg/m^2[c]	No	No	No	—
Cycle variation out of range?[c]	Yes	—	—	No
Eating disorder?[c]	No	Yes	—	—
Hair loss?	No	No	—	—
Acne?	No	No	—	—
Menarche during last 2 years?[c]	No	—	—	—
Age range?[c]	—	19-40	—	—
Of East Asian heritage?[c]	—	—	—	—
Diagnosed with hypothyroidism?[c]	—	—	—	—
Irregular sleep?	—	—	—	—
Stress?	—	—	—	—
Strenuous physical work?	—	—	—	—
Limiting food?	—	—	—	—
Diagnosed with hyperprolactinemia?	—	—	—	—
Polycystic ovary syndrome probability[d]	91%	66%	10%	1%

[a]This table displays the virtual test subject answers to the irregular cycle feature questionnaire

[b]Data not included in a virtual test subject's answer (ie, sections left blank)

[c]Screener questions.

[d]Polycystic ovary syndrome percent probability generated by the irregular cycle feature

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Discussion

Principal Findings

To the best of our knowledge, this is the first app developed by an interdisciplinary team to calculate the probability that an individual may have a risk of PCOS. As seen in virtual test subject 1, the similarly high probabilities assigned by the physician and irregular cycle feature demonstrate that in textbook cases of PCOS, the feature accurately prompts individuals to seek out a medical professional. This will be important for the identification of several risk factors for PCOS. Virtual test subject 8 highlights the overpredictive nature of the irregular cycle feature. Although the irregular cycle feature probability is slightly higher than the physician's prediction, the tool still proves useful, as it advises an individual to seek a health care provider for further testing. In addition, the lack of data input for virtual test subject 8, specifically for menstrual variation and confounding diagnoses, can be improved once data are collected from actual Clue users to make more accurate predictions. Virtual test subject 12, who used hormonal birth control, demonstrates how the feature calculates a probability for individuals inputting the minimum amount of information and confounders while also indicating menstrual irregularities. The irregular cycle feature would prompt similar individuals to seek a medical professional for any issues regarding their menstrual irregularities. Virtual test subject 15 did not report menstrual irregularities nor did they indicate areas of concern, such as those associated with hyperandrogenism: acne, alopecia, or hirsutism. This illustrates that the model can accurately eliminate individuals who are unlikely to have a disorder.

Strengths and Limitations

The team was composed of data and health scientists, software engineers, and a medical expert. Together we constructed a mobile health tool to facilitate identification of possible indicators of PCOS in an app-using population. Furthermore, the irregular cycle feature allows users to self-report menstrual information to facilitate discussion with their physicians. Since a summary generated based on the answers to the interactive survey is specific to each individual, more control is in the hands of the user. In addition, by providing the user with an outline of what the next steps are in terms of testing and visiting a medical professional's office, on rollout to Clue users, this novel tool could shorten the time for a PCOS diagnosis.

The limitations of this study include (1) the use of only a small number of virtual test subjects, (2) the lack of a clinical validation, and (3) the limited applicability of the feature to other disorders that alter menstrual cycle regularity. The small number of virtual test subjects eligible for the irregular cycle feature assessment allowed for modeling how predictive the tool could be with a significant number of missing data points. In a setting where all data points are captured, the feature may have better predictability. Furthermore, because of the nature of this pilot project, the tool has not yet been clinically validated in a human population, and thus, the probability generated by the tool is not a diagnosis. At present, the model cannot make predictions for individuals who report the use of hormone-based medications or facilitate risk prediction for other syndromes that lead to menstrual irregularity, such as Cushing syndrome or hypothyroidism. Further limitations of this study include assigning a single quantitative value to the physician's qualitative assignment of risk (low, indeterminate, medium, and high). Since there is currently no way to assign a range of probabilities to the physician's qualitative score, the team was limited to assigning a single, estimated probability value. Finally, the irregular cycle feature is currently modeled to have a high sensitivity and low specificity, erring on the side of sending more individuals to the physician's office as an attempt to capture the majority of individuals at risk for PCOS. It remains to be seen whether the predictive model will be adaptable to actual human users.

Under appropriate institutional review board approval, a future validation study of the irregular cycle feature will be necessary to assess the utility of the tool between physicians by following up with users at variable time intervals to determine if a medical professional diagnosed PCOS or another condition. Future iterations of this study will use real Clue users to assess the validity of the irregular cycle feature. In addition, other sources of data will be considered to train the network to establish improved conditional dependencies and make additional adjustments to the Bayesian network.

Conclusions

Despite the limitations of the study, the irregular cycle feature is an example of how mobile technology may help users manage their own health and promote subject self-advocacy. By providing more information about PCOS and giving users feedback based on information they have collected, the research team predicts that this feature will provide important information to those at high risk of the disease and potentially shorten the time for diagnosis [22,23]. The creation of the irregular cycle feature may reduce the time to PCOS diagnosis and facilitate conversations between users and physicians through the Results Screens and Doctor's Report.

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Authors' Contributions

ER drafted the manuscript and contributed to the analysis. DT contributed to the design of the tool and created the Bayesian network. AD contributed to the design of the tool. MW contributed to the design of the tool. KL contributed to data analysis. SM participated in study design, oversaw execution of the entire project, and contributed to analysis and writing.

Conflicts of Interest

DT, AD, and MW were all employees of the menstrual tracking app Clue at the time this project was initiated. ER, KL, and SM received no funding from Clue to conduct this research. This work was conducted at Boston University Medical Campus.

Multimedia Appendix 1
Illustrates the questions in the irregular cycle feature screener and the associated abbreviated answer choices.
[PNG File , 58 KB - formative_v4i5e15094_app1.png]

Multimedia Appendix 2
Categories to assess menstrual irregularities. Three different categories for assessing risk of PCOS were established based on the Ovulation and Menstruation Health Study. Each of the questions in the ICF questionnaire (excluding the Screener) is included in the table.
[PNG File , 79 KB - formative_v4i5e15094_app2.png]

Multimedia Appendix 3
Supplemental Figure 1. The Positive Result Screen that would appear for users with a risk score of 25% or higher in the Clue app.
[PNG File , 68 KB - formative_v4i5e15094_app3.png]

Multimedia Appendix 4
Supplemental Figure 2. The Neutral Result Screen that would appear for users with a risk score of 25% or lower in the Clue app.
[PNG File , 62 KB - formative_v4i5e15094_app4.png]

Multimedia Appendix 5
Supplemental Figure 3. The Inconclusive Result Screen that would appear for users with confounding variables or too much missing data in the Clue app.
[PNG File , 69 KB - formative_v4i5e15094_app5.png]

Multimedia Appendix 6
Supplemental Figure 4. The Doctor's Report that would appear for users who had a Positive Result Screen generated in the Clue app.
[PNG File , 101 KB - formative_v4i5e15094_app6.png]

Multimedia Appendix 7
Supplemental Figure 5. The Doctor's Report that would appear for users who had a Neutral or Inconclusive Result Screen generated in the Clue app.
[PNG File , 100 KB - formative_v4i5e15094_app7.png]

Multimedia Appendix 8
Sensitivity, specificity, and mean difference of irregular cycle feature and physician scores for the 9 virtual test subjects.
[PNG File , 189 KB - formative_v4i5e15094_app8.png]

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Abbreviations

PCOS: polycystic ovary syndrome

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Original Paper

Characteristics of Gamblers Who Use the French National Problem Gambling Helpline and Real-Time Chat Facility: Longitudinal Observational Study

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Abstract

Background: Problem gambling is a growing public health issue that is characterized by low rates of face-to-face help seeking. Helplines and real-time chat services could reduce shortfalls in treatment.

Objective: This study aimed to (1) describe the characteristics of gamblers contacting a government-funded help service, (2) study the evolution of their characteristics over time, (3) evaluate the differences between subgroups (ie, gender, media used for gambling, and media used to contact the service), and (4) explore factors influencing referral to care.

Methods: From January 2011 to December 2015, a government-funded gambling helpline and real-time chat website in France received 9474 contacts from gamblers. Counselors filled in a form for each contact, collecting demographics, gambling characteristics, and referrals. Time-series analyses were performed. Univariate logistic models were used to assess differences across subgroups. A multivariate analysis was conducted to determine the variables related to an actual referral.

Results: Gamblers were predominantly men (7017/9474, 74.07%); the average age was 41 years (SD 14). Compared with the men, the women were older (mean 50.7 years, SD 14.0 vs mean 37.9 years, SD 13.0, respectively; *P*<.001), were more often solely offline gamblers (1922/2457, 78.23% vs 4386/7017, 62.51%, respectively; *P*<.001), and had different gambling patterns. Compared with helpline contacts, real-time chat contacts were more often men (124/150, 82.7% vs 3643/4881, 74.64%, respectively; *P*=.04), younger (mean 32.8 years, SD 12.9 vs mean 41.3 years, SD 14.3, respectively; *P*<.001), more often poker gamblers (41/150, 27.3% vs 592/4881, 12.13%, respectively; *P*<.001), and more often web-based gamblers (83/150, 55.3% vs 1462/4881, 29.95%, respectively; *P*<.001). Referral was positively associated with betting (adjusted odds ratio [aOR] 1.46, 95% CI 1.27-1.67; *P*<.001), casino gambling (aOR 1.38, 95% CI 1.21-1.57; *P*<.001), scratch cards (aOR 1.83, 95% CI 1.58-2.12; *P*<.001), poker gambling (aOR 1.35, 95% CI 1.14-1.61; *P*<.001), lottery (aOR 1.27, 95% CI 1.03-1.56; *P*=.03), weekly gambling (aOR 1.73, 95% CI 1.40-2.15; *P*<.001), request for referral (aOR 17.76, 95% CI 14.92-21.13; *P*<.001), and a history of suicide attempts (aOR 2.13, 95% CI 1.51-3.02; *P*<.001), and it was negatively associated with web-based gambling (aOR 0.86, 95% CI 0.75-0.98; *P*=.030) and refusal to be referred (aOR 0.35, 95% CI 0.26-0.49; *P*<.001).

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Conclusions: The governmental helpline and chat contacts included a broad range of sociodemographic profiles. Compared with the helpline, real-time chat exchanges reached a younger population of web-based gamblers, which was the target population. The development of the gambling helpline and help online website is a considerable challenge for the future.

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KEYWORDS

gambling; helpline; chat; counseling; gender; time-series analysis

Introduction

Background

Problem gambling is a growing public health issue. A recent meta-analysis showed that the prevalence rate of problem gambling in the past year in the general population ranged from 0.12% to 5.8% worldwide and from 0.12% to 3.4% in Europe [1]. In France, the prevalence rate of problem gambling increased from 1.3% in 2010 to 1.9% in 2014 [2,3]. Problem gambling is characterized by low levels of help seeking, estimated at 7% to 29% depending on the country [3-9]. The barriers identified to help seeking are (1) intention to handle gambling problems on one's own, (2) stigma and minimization of problems, (3) concerns about treatment content and quality, (4) lack of knowledge about treatment availability, and (5) practical issues of attending treatment [10]. One study provided evidence that help seeking occurred most often when gambling-related harm had become significant, especially financial problems, relationship issues, and negative emotions [11]. Problem gamblers often seek help after they have run out of other options [12].

Helplines have been used for many years in different settings, such as suicidal crisis [13], cancer [14], chronic rheumatic diseases [15], eating disorders [16], or substance use disorders [17]. Helplines and real-time chat for problem gambling have been implemented and assessed in several countries [18-25]. The severity of problem gambling has often been found to be considerable, with high rates of suicidal thoughts observed among helpline contacts [21-23]. Helpline callers have been consistently reported to be heterogeneous groups, with gender differences [19,20,22,25-27]. Most studies on gambling helplines users have reported characteristics close to those known in the broader population of problem gamblers, with more men [19,20,24-26], and gambling types following the commercial offer at the time of the study [18,24,28]. Contacts with helplines have been shown to concern mostly first-time treatment seekers [19,23]. Contacts could thus belong to a population with serious problems [22,23,26] and uncertain demands, and to motivate them and provide them with the most appropriate help could therefore be particularly important. In 2011, more than three-fourths of the contacts to the Problem Gamblers Help Network of West Virginia, who were offered guidance, agreed to be referred [23]. Active referral could be particularly worthwhile in this otherwise untreated population.

In France, in May 1990, on proposal by the *Mission interministérielle de lutte contre les drogues et les conduites addictives*, the government adopted a plan to establish a national telephone information and prevention service on drugs and drug addiction under the supervision of *Addictions Drogues Alcool Info Service* (ADALIS). Since 2010, the Web-based gambling market has been open to competition and is being regulated by the law of May 12, 2010. In June 2010, the telephone helpline for problem gambling *Joueurs Info Service* (JIS) was implemented, followed by the real-time chat website in May 2013. Throughout this study, the term "contact" refers to any contact with the JIS and does not distinguish between phone calls to the helpline and the use of real-time chat. The medium is specified whenever necessary.

Objectives

The purpose of this study was to describe the characteristics of gamblers who contacted the service over the study period and to compare them in subgroups according to gender, the media used for gambling (solely offline or Web-based gamblers), and the channel used to contact the service (helpline callers or real-time chat users). It seemed important to study the evolution of characteristics of the population over time just after the opening of the Web-based gambling market to competition. We also explored factors associated with referral to care. As a result of the opening of the Web-based gambling market to competition, we were expecting an increase in calls concerning Web-based gambling, from younger gamblers, and more men [29,30]. In reference to the international literature on problem gambling helplines and recent gambling prevalence studies in France, we hypothesized that men and women, as well as helpline and real-time chat users, would present different characteristics and gambling patterns. Specifically, we expected men to be younger than women [19,20,22,25], men to be more frequently engaged in poker gambling and bets [3,19,25,31], and women to gamble more frequently in a casino [18,19,25]. The target population of real-time chat was young and Web-based gamblers, so we expected real-time chat users to be younger and to use Web-based gambling more frequently than helpline callers. In addition, we expected that barriers [10] and motivators [11] for help seeking would appear as variables influencing the actual referral of the contacts.

Methods

Description of the Helpline

Since June 2010, under the supervision of the Ministry of Health, JIS has been a free, national, remote support service for problem gambling. JIS is based on the rules of anonymity, confidentiality, neutrality, and absence of moral judgment. Its missions are to inform, advise, support, and guide contacts. All the helpline and website staff are salaried and have received initial training, the aim of which was to develop listening skills and availability and to acquire the necessary knowledge. The helpline is accessible from 7:00 AM to 2:00 AM. Since May

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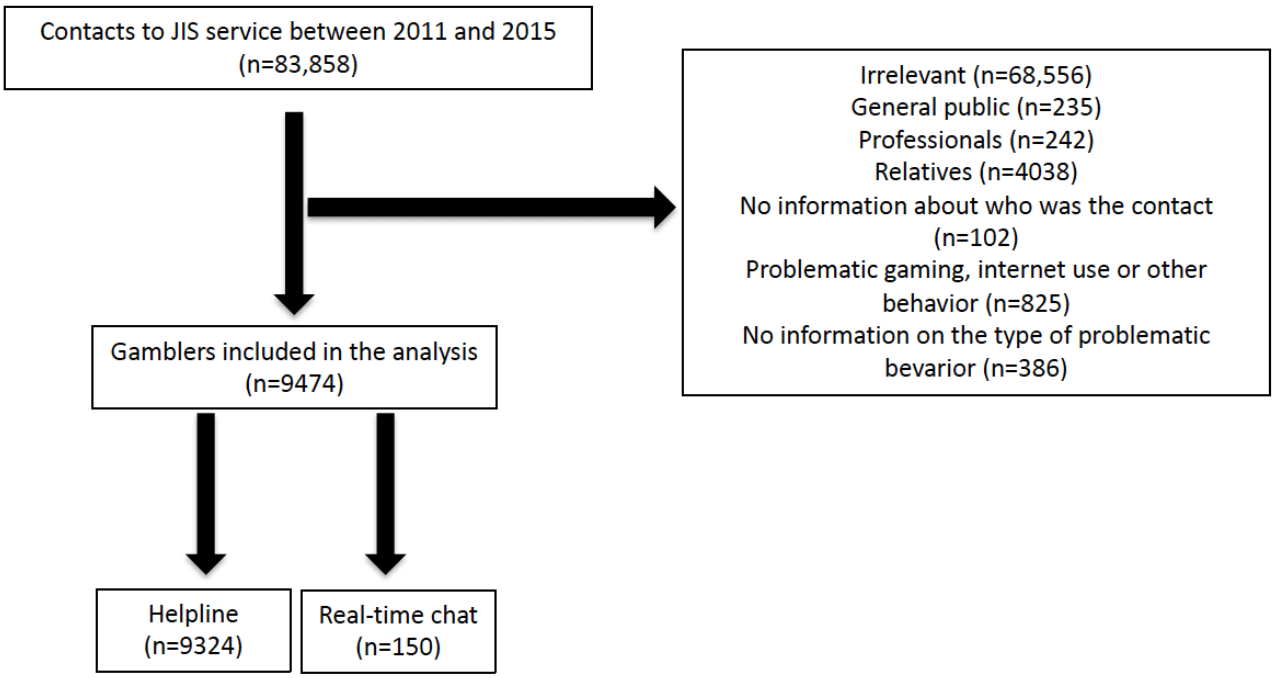
2013, the JIS has also offered real-time chat enabling online individual interviews. No follow-up is offered following the contact. Referral is offered at the discretion of the counselors.

Population

Ethical approval (N°2018-031) was obtained from the institutional review board of Paris Diderot University Hospitals (IRB 00006477). From the JIS database, several inclusion criteria were defined for contacts: (1) all contacts between 2011 and 2015, (2) contacts considered to be relevant to the purpose of JIS, (3) contacts from gamblers and not from gamblers' relatives, and (4) contacts concerned gambling and not any other problem behavior. Between January 2011 and December 2015, the helpline received 83,858 contacts, of which 68,556 (81.75%) were considered irrelevant, ie, errors or jokes. From the remaining 15,302 contacts related to the purpose of JIS, 4038 (26.4%) contacts from gamblers' relatives were excluded, and we included 9474 (61.9%) contacts who were gamblers (Figure 1).

Figure 1. A flow diagram. JIS: Joueurs Info Service.



Data Collection

For each contact, the counselors systematically collected the following data: (1) medium used to contact JIS (helpline or real-time chat); (2) characteristics of the contacts: age and gender, gambler or relative, and first contact with the platform; (3) gambling types: bets (included gambling on sports and horse racing, without distinction), casino, scratch cards, poker, lottery, and other games; (4) media used for gambling (ie, solely offline, Web-based, or both); (5) proxies for the severity of problem gambling: gambling frequency (less than weekly vs weekly or more), time since gambling initiation, and history of suicide attempts; (6) contacts' attitudes to referral (request for referral or refusal to be referred); (7) actual referral (we considered that the contact led to an actual referral when he or she was encouraged to resume a follow-up that already started or to consult a known or a new address). We considered that the contact was not referred when he/she was redirected to websites or helplines related to ADALIS or when he/she was not offered a referral; (8) self-exclusion. In France, self-exclusions related to casino venues and Web-based gambling run for 3 years. Self-excluded gamblers are not accompanied by any type of medical or social counseling.

Missing Data

Two variables—medium used and duration of the contact—were automatically collected and, therefore, presented no missing data. Age, media used for gambling, gambling frequency, and time since gambling initiation had high rates of missing data (32.4%, 34.0%, 50.2%, and 59.3%, respectively), while gender was collected in almost all cases (0.3% missing data). Contact referral was systematically reported and presented no missing data. The main reason for missing data was when the counselor failed to ask the question, which can be considered missing at random (MAR) [32]. Multiple imputation is a general approach to the problem of missing data, which aims to allow for the uncertainty generated by the missing data by creating several different plausible imputed datasets—using existing values from other variables—and appropriately combining results obtained from each of them. Multiple imputation should be used for MAR data, but multiple imputation can produce more accurate estimates than a complete case analysis even when MAR assumptions are not met [33]. Missing data were imputed by multiple imputation using chained equations, and the package "mice" version 3.3.0 [34] under R, version 3.4.4, was used for the imputation.

Data Analysis

For the time-series analyses, univariate linear regressions—based on multiple imputed data—were calculated to assess the relationship between the different variables and

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time. Univariate logistic regression analyses based on multiple imputed data were completed for each of the categories of independent variables to determine relationships with each dichotomous dependent variable (male vs female gender, solely offline vs Web-based or both, and helpline vs real-time chat users). A multivariate logistic model was constructed from the univariate model using the stepwise method with backward elimination to analyze the actual referral of contacts. Independent variables were examined for collinearity using correlation matrices before the completion of the multiple regression analysis. All statistical tests were 2-sided, with a significance threshold of 0.05. The data were analyzed using R 3.4.4. software.

Results

Description of Contacts

The description of contacts is shown in Table 1. Gamblers were predominantly men (7017/9474, 74.07%), the mean age was 41.2 years (SD 14.4; IQR 30.0-51.0), with less than 3% of contacts younger than 20 years and approximately one-quarter older than 50 years. The average duration of the contact was 14.4 min, but variability was large (SD=24.6). Less than a quarter (2131/9474, 22.49%) mentioned having contacted the service previously. The main types of gambling were bets, casino, scratch cards, and poker. The majority of gamblers used solely offline gambling (6308/9474, 66.58%), just over a quarter used only Web-based gambling (2676/9474, 28.25%), and 5.17% (490/9474) used both. The average time since gambling initiation was 16 years (SD 10.2). Approximately one-quarter asked for a referral (2279/9474, 24.06%), whereas 2.30% (218/9474) refused to be referred. More than half the contacts led to a referral. Very few gamblers reported having a history of suicide attempts (193/9474, 2.04%), and 5.03% (477/9474) reported self-exclusion.

Evolution Over Time

We observed stability over the study period for the average age of the gamblers and the average duration of the contact and for the proportions of women and weekly or more than weekly gamblers (see Multimedia Appendix 1). There was an increase in the proportion of contacts for solely offline gambling (beta=3.02; 95% CI 1.76-4.27; $P<.001$) and for certain types of gambling: casino (beta=2.20; 95% CI 1.24-3.16; $P<.001$) and scratch cards (beta=1.23; 95% CI 0.55-1.91; $P<.001$). In contrast, the proportion of contacts for bets and lottery games was stable over the period, and there was a decrease in the proportion of contacts for poker (beta=−2.35; 95% CI −2.89 to −1.82; $P<.001$) and other games (beta=−0.75; 95% CI −1.10 to −0.40; $P<.001$). Between May 2013 and December 2015, we observed an increase in the number of real-time chat users (beta=3.02; 95% CI 1.76-4.27; $P=.005$).

Gender Differences

As shown in Table 1, men outnumbered women (7017/9474, 74.07% vs 2457/9474, 25.93%, respectively). The men were younger than the women (mean 37.9 years, SD 13.0 vs mean 50.7 years, SD 14.0, respectively; $P<.001$) and were mainly younger than 40 years (4143/7017, 59.04%), whereas the majority of women were aged ≥50 years (1387/2457, 56.45%). Contact durations were the same. There were significant differences in gambling types between men and women. Although men betted more than women (3405/7017, 48.52% vs 409/2457, 16.65%, respectively; $P<.001$) and were more frequently engaged in poker gambling (1321/7017, 18.83% vs 134/2457, 5.45%, respectively; $P<.001$), women compared with men more frequently gambled in casino games (1144/2457, 46.56% vs 1812/7017, 25.82%, respectively; $P<.001$), on scratch cards (696/2457, 28.33% vs 1170/7017, 16.67%, respectively; $P<.001$), and on lotteries (302/2457, 12.29% vs 718/7017, 10.23%, respectively; $P=.005$). Men gambled weekly more often than women (6359/7017, 90.62% vs 2125/2457, 86.49%, respectively; $P=.001$). Compared with men, women were more often solely offline gamblers (1922/2457, 78.23% vs 4386/7017, 62.51%, respectively; $P<.001$). There was no difference for history of suicide attempts. Women were more often self-excluded than men (157/2457, 6.39% vs 320/7017, 4.56%, respectively; $P<.001$). Compared with women, men more often expressed an attitude toward referral, whether in the form of a request (1798/7017, 25.62% vs 481/2457, 19.58%, respectively; $P<.001$) or refusal (176/7017, 2.51% vs 42/2457, 1.71%, respectively; $P=.02$). Men were more likely to be referred than women (3974/7017, 56.63% vs 1247/2457, 50.75%, respectively; $P<.001$).

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Table 1. Characteristics of contacts by gender (N=9474). Univariate logistic regression analysis; the significance code lies on the side where the proportion, or the mean, is the highest.

Demographics	Total	Male	Female
Population, n (%)	9474 (100.00)	7017 (74.07)	2457 (25.93)
Age (years), mean (SD)	41.2 (14.4)	37.9 (13.0)	50.7 (14.0)[a]
<20	256 (2.70)	243 (3.46)[a]	13 (0.53)
20-29	1995 (21.06)	1838 (26.19)[a]	157 (6.39)
30-39	2413 (25.47)	2062 (29.39)[a]	351 (14.29)
40-49	2093 (22.09)	1544 (22.00)	549 (22.34)[b]
50-59	1562 (16.49)	837 (11.93)	725 (29.51)[a]
≥60	1155 (12.19)	493 (7.03)	662 (26.94)[a]
Duration of contact (min), mean (SD)	14.4 (24.6)	14.5 (27.4)[b]	14.1 (13.8)
Gambling type, n (%)			
Bets	3814 (40.26)	3405 (48.52)[a]	409 (16.65)
Casino	2956 (31.20)	1812 (25.82)	1144 (46.56)[a]
Scratch cards	1866 (19.70)	1170 (16.67)	696 (28.33)[a]
Poker	1455 (15.36)	1321 (18.83)[a]	134 (5.45)
Lottery	1020 (10.77)	718 (10.23)	302 (12.29)[c]
Others	466 (4.92)	350 (4.99)[b]	116 (4.72)
Media used for gambling, n (%)			
Solely offline	6308 (66.58)	4386 (62.51)	1922 (78.23)[a]
Web-based or both	3166 (33.42)	2631 (37.49)[a]	535 (21.77)
Proxies for severity of gambling			
Gambling frequency weekly or more, n (%)	8484 (89.55)	6359 (90.62)[c]	2125 (86.49)
Time since gambling initiation (years), mean (SD)	16.0 (10.2)	15.7 (10.2)[b]	16.6 (10.0)
History of suicide attempt, n (%)	193 (2.04)	135 (1.92)	58 (2.36)[b]
Contact demand, n (%)			
Referral requested	2279 (24.06)	1798 (25.62)[a]	481 (19.58)
Refusal to be referred	218 (2.30)	176 (2.51)[d]	42 (1.71)
Actual referral, n (%)			
Referred	5221 (55.11)	3974 (56.63)[a]	1247 (50.75)
Nonreferred	4253 (44.89)	3043 (43.37)	1210 (49.25)[a]
Self-exclusion, n (%)	477 (5.03)	320 (4.46)	157 (6.39)[a]

[a]*P*<.001.

[b]Not significant.

[c]*P*<.01.

[d]*P*<.05.

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Differences Between Solely Offline and Other Gamblers

As shown in Table 2, solely offline gamblers were more likely to be women than Web-based gamblers (1922/6308, 30.5% vs 535/3166, 16.9%, respectively; *P*<.001). Solely offline gamblers were older than Web-based gamblers (mean 43.7 years, SD 14.5 vs mean 36.2 years, SD 12.8, respectively; *P*<.001); the majority were aged ≥40 years (3697/6308, 58.61%), whereas Web-based gamblers were mainly aged younger than 40 years (2053/3166, 64.85%). There were significant differences in gambling type between solely offline and Web-based gamblers. Although solely offline gamblers, compared with Web-based gamblers, were more often engaged in casino gambling (2367/6308, 37.52% vs 589/3166, 18.60%, respectively; *P*<.001), scratch cards (1678/6308, 26.60% vs 188/3166, 5.94%, respectively; *P*<.001), and lotteries (745/6308, 11.81% vs 275/3166, 8.69%, respectively; *P*<.001). Web-based gamblers, compared with solely offline gamblers, were more often engaged in betting (1556/3166, 49.15% vs 2258/6308, 35.80%, respectively; *P*<.001), poker gambling (1138/3166, 35.94% vs 317/6308, 5.03%, respectively; *P*<.001), and other gambling games (280/3166, 8.84% vs 186/6308, 2.95%, respectively; *P*<.001). There was no between-group difference in the proxy measures used to assess severity of gambling or for the self-exclusion rates. Solely offline gamblers, compared with Web-based gamblers, more frequently requested to be referred (1625/6308, 25.76% vs 654/3166, 20.66%, respectively; *P*<.001) and were more often actually referred (3615/6308, 57.31% vs 1606/3166, 50.73%, respectively; *P*<.001). Web-based gamblers, compared with solely offline gamblers, more often refused to be referred (93/3166, 2.94% vs 125/6308, 1.98%, respectively; *P*=.04).

Differences Between Helpline Calls and Real-Time Chats

Between May 2013 and December 2015, chat contacts were very few (150/5031, 3.00%). As shown in Table 3, chat contacts, compared with helpline contacts, were more likely to be men (124/150, 82.7% vs 3643/4881, 74.64%, respectively; *P*=.04) and younger (mean 32.8 years, SD 12.9 vs mean 41.3 years, SD 14.3, respectively; *P*<.001). Chat contacts lasted longer than helpline contacts (mean 28.6, SD 20.3 vs mean 14.2, SD 13.9, respectively; *P*<.001). There was no between-group difference on the proxy measures of severity of gambling or for self-exclusion rates. Compared with helpline contacts, chat contacts were more often engaged in Web-based gambling (83/150, 55.3% vs 1462/4881, 29.95%, respectively; *P*<.001), poker gambling (41/150, 27.3% vs 592/4881, 12.13%, respectively; *P*<.001), and other games (16/150, 10.7% vs 182/4881, 3.73%, respectively; *P*<.001) and less often engaged in scratch card gambling (11/150, 7.3% vs 1043/4881, 21.37%, respectively; *P*<.001). Chat contacts, compared with helpline contacts, less often asked to be referred (24/150, 16.0% vs 1258/4881, 25.77%, respectively; *P*=.008), but there was no significant difference for actual referrals.

Differences Between Referred and Nonreferred Gamblers

The multivariate logistic analysis (Table 4) enabled us to identify the following factors positively and independently associated with actual referral: betting (adjusted odds ratio, aOR 1.46, 95% CI 1.27-1.67; *P*<.001), casino gambling (aOR 1.38, 95% CI 1.21-1.57; *P*<.001), scratch cards (aOR 1.83, 95% CI 1.58-2.12; *P*<.001), poker gambling (aOR 1.35, 95% CI 1.14-1.61; *P*<.001), lottery (aOR 1.27, 95% CI 1.03-1.56; *P*=.03), gambling weekly (aOR 1.73, 95% CI 1.40-2.15; *P*<.001), referral requested (aOR 17.76, 95% CI 14.92-21.13; *P*<.001), and having a history of suicide attempts (aOR 2.13, 95% CI 1.51-3.02; *P*<.001). The following factors were negatively and independently associated with actual referral: Web-based gambling (aOR 0.86, 95% CI 0.75-0.98; *P*=.03) and refusal to be referred (aOR 0.35, 95% CI 0.26-0.49; *P*<.001).

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Table 2. Characteristics of contacts by media used for gambling (N=9474). Univariate logistic regression analysis; the significance code lies on the side where the proportion, or the mean, is the highest.

Demographics	Solely offline	Web-based or both
Population, n (%)	6308 (66.58)	3166 (33.42)
Gender, n (%)		
Male	4386 (69.53)	2631 (83.10)[a]
Female	1922 (30.47)[a]	535 (16.90)
Age (years), mean (SD)	43.7 (14.5)[a]	36.2 (12.8)
<20	113 (1.79)	143 (4.52)[a]
20-29	1030 (16.33)	965 (30.48)[a]
30-39	1468 (23.27)	945 (29.85)[a]
40-49	1482 (23.49)[a]	611 (19.30)
50-59	1248 (19.78)[a]	314 (9.92)
≥60	967 (15.33)[a]	188 (5.94)
Duration of contact (min), mean (SD)	14.2 (22.5)	14.8 (28.5)[b]
Gambling type		
Bets	2258 (35.80)	1556 (49.15)[a]
Casino	2367 (37.52)[a]	589 (18.60)
Scratch cards	1678 (26.60)[a]	188 (5.94)
Poker	317 (5.03)	1138 (35.94)[a]
Lottery	745 (11.81)[a]	275 (8.69)
Others	186 (2.95)	280 (8.84)[a]
Proxies for severity of gambling		
Gambling frequency weekly or more, n (%)	5630 (89.25)	2854 (90.15)[b]
Time since gambling initiation (years), mean (SD)	16.7 (10.3)[b]	14.5 (9.6)
History of suicide attempt, n (%)	131 (2.08)[b]	62 (1.96)
Contact demand, n (%)		
Referral requested	1625 (25.76)[a]	654 (20.66)
Refusal to be referred	125 (1.98)	93 (2.94)[c]
Actual referral, n (%)		
Referred	3615 (57.31)[a]	1606 (50.73)
Nonreferred	2692 (42.68)	1560 (49.27)[a]
Self-exclusion, n (%)	316 (5.01)	161 (5.09)[b]

[a]*P*<.001.

[b]Not significant.

[c]*P*<.05.

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Table 3. Characteristics of contact who accessed the helpline and real-time chat (N=5031). Univariate logistic regression analysis; the significance code lies on the side where the proportion, or the mean, is the highest.

Demographics	Helpline	Real-time chat
Population, n (%)	4881 (97.02)	150 (2.98)
Gender, n (%)		
Male	3643 (74.64)	124 (82.7)[a]
Female	1238 (25.36)[a]	26 (17.3)
Age (years), mean (SD)	41.3 (14.3)[b]	32.8 (12.9)
<20	122 (2.50)	14 (9.3)[b]
20-29	1012 (20.73)	65 (43.3)[b]
30-39	1283 (26.29)[c]	35 (23.3)
40-49	1082 (22.17)[a]	17 (11.3)
50-59	787 (16.12)[a]	12 (8.0)
≥60 or older	595 (12.19)[a]	7 (4.7)
Duration of contact (min), mean (SD)	14.2 (13.9)	28.6 (20.3)[b]
Gambling type, n (%)		
Bets	2006 (41.10)	69 (46.0)[c]
Casino	1650 (33.80)[c]	43 (28.7)
Scratch cards	1043 (21.37)[b]	11 (7.3)
Poker	592 (12.13)	41 (27.3)[b]
Lottery	515 (10.55)[c]	10 (6.7)
Others	182 (3.73)	16 (10.7)[b]
Media for gambling, n (%)		
Solely offline	3419 (70.05)[b]	67 (44.7)
Web-based or both	1462 (29.95)	83 (55.3)[b]
Proxies for severity of gambling		
Gambling frequency weekly or more, n (%)	4418 (90.51)[c]	130 (86.7)
Time since gambling initiation (years), mean (SD)	14.1 (9.2)	20.1 (9.7)[c]
History of suicide attempt, n (%)	110 (2.25)	4 (2.7)[c]
Contact demand, n (%)		
Referral requested	1258 (25.77)[d]	24 (16.0)
Refusal to be referred	101 (2.07)	6 (4.0)[c]
Actual referral, n (%)		
Referred	2879 (58.98)[c]	78 (52.0)
Nonreferred	2002 (41.02)	72 (48.0)[c]
Self-exclusion, n (%)	247 (5.06)	9 (6.0)[c]

[a]*P*<.05.

[b]*P*<.001.

[c]Not significant.

[d]*P*<.01.

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Table 4. Association between the actual referral and the characteristics of the gamblers (a multivariate logistic regression analysis).

Independent variables	Adjusted odds ratio (95% CI)	*P* value
Gender		
Female	Ref[a]	Ref
Male	1.12 (0.99-1.26)	.07
Age (years)		
<20	0.85 (0.60-1.20)	.36
20-29	0.88 (0.75-1.03)	.10
30-39	Ref	Ref
40-49	0.96 (0.82-1.13)	.62
50-59	0.86 (0.72-1.02)	.09
≥60	0.85 (0.69-1.04)	.11
Gambling type		
Bets		<.001
No	Ref	
Yes	1.46 (1.27-1.67)	
Casino		<.001
No	Ref	
Yes	1.38 (1.21-1.57)	
Scratch cards		<.001
No	Ref	
Yes	1.83 (1.58-2.12)	
Poker		<.001
No	Ref	
Yes	1.35 (1.14-1.61)	
Lottery		
No	Ref	Ref
Yes	1.27 (1.03-1.56)	.03
Media used for gambling		
Solely offline	Ref	Ref
Web-based and both	0.86 (0.75-0.98)	.03
Proxies for severity of gambling		
Gambling frequency		
Less than a week	Ref	Ref
Weekly or more	1.73 (1.40-2.15)	<.001
History of suicide attempts		
No	Ref	Ref
Yes	2.13 (1.51-3.02)	<.001
Contact demand		
Referral requested		
No	Ref	Ref
Yes	17.76 (14.92-21.13)	<.001
Refusal to be referred		
No	Ref	Ref

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Independent variables	Adjusted odds ratio (95% CI)	*P* value
Yes	0.35 (0.26-0.49)	<.001

[a]Ref: reference.

Discussion

Principal Findings

We included 9474 contacts from gamblers over 5 years, among whom 55.1% (5221/9474) were referred. Our main findings were that real-time chat contacts differed significantly from helpline contacts, as they were younger and more often Web-based gamblers, and that referral was not only associated with gambling severity variables, such as a history of suicide attempts and gambling frequency, but also with Web-based gambling per se. In addition, referral was associated with a demand for referral, but female contacts less often expressed a demand for referral.

Evolution Over the Study Period

The decrease observed in poker-gambling contacts over the study period could be explained by a decline in the turnover of the legal poker market in France in 2013 [31]. In addition, the decrease in frequency of the other games could correspond to a decrease in gambling not included in the legal offer and thus to a possible regression of illegal gambling. Thus, helplines could be an interesting epidemiological tool for tracking problems related to gambling that follow the commercial offer of gambling activities [28]. On the contrary, the increase in the proportion of contacts engaged solely in offline gambling does not reflect the market, as Web-based gambling is growing fast and seems to cause more problems [29] and to be related to less help seeking [30] than offline gambling. One hypothesis is that the problem gambling prevention campaign, which accompanied the opening of the Web-based gambling market in 2010, may have attracted people who already had a gambling problem and were therefore mostly solely offline gamblers. Communication on the services available for problem gambling was a part of this prevention campaign.

Gender Differences

Our study highlights gender differences among the contacts made by gamblers. Contacts were more often men, which is consistent with several studies [19,20,24,26] and with the latest epidemiological survey in France, which evidenced 70% of men among problem gamblers [3]. Female gamblers were older, as in several other studies [19,20,22,26]. The types of gambling were different between men and women: men were more often engaged in betting and poker gambling, and women were more often engaged in casino gambling, scratch cards, and lotteries. These differences were also found in several previous studies [19,20,26] on problem gambling and support the quality of our data. Male and female gamblers seemed to present the same levels of severity as assessed with the proxy variables used here, ie, gambling frequency, time since gambling initiation, and history of suicide attempts, supporting other findings where severity was assessed on the Problem Gambling Severity Index [26]. Other studies showed even greater severity among women. However, women were less likely to express a demand for referral. This could be a special situation, with women having as severe a gambling problem as men, seeking help, but more reluctant than men to express a demand for formal guidance. This element suggests that the follow-up of female gamblers could involve a taboo, indirectly fueling the treatment gap. However, even if little information is available about gender differences in barriers to seeking help, men might be more vulnerable than women to shame, embarrassment, pride, or stigma [10].

Actual Referral

The referral rate in this study was lower than that found in other studies [23]. According to our hypothesis, contacts' attitudes (ie, referral requested or refusal to be referred) were not the only predictor of being referred. The severity of the pathology as assessed by the two proxies (ie, gambling frequency and history of suicide attempts) was predictor of being referred. We noted that Web-based gamblers were less often referred, although they appear to be the category of gamblers that is increasing most markedly [3,29].

Helpline Versus Real-Time Chat

It should be noted that despite the spectacular increase in the use of the internet in our lives, the telephone proved to be much more popular (97.0% of contacts between May 2013 and December 2015) when seeking help in the context of problem gambling in France. It is our opinion that the very low level of use of real-time chat compared with the helpline could be because of the lack of publicity for the online service. In the advertising strategy, the only general measure consists in the obligation to display a health message with the phone number of JIS in any commercial communication in favor of a gambling operator. In addition, there is little communication about the internet services offered by JIS. The launch of real-time chat in May 2013 was intended to reach a younger population that is more likely to be using the internet, and it seems that this objective was attained, even though the total number of users of real-time chat was relatively small. Even if its use is increasing, the promotion of the real-time chat service could enable faster growth. Owing to the massive increase in the use of the internet in our lives and the fast development of the Web-based gambling market [3,29], reaching gamblers on the internet will clearly be the challenge for the future. We demonstrated that chat interviews could be particularly suited to young Web-based gamblers. However, this type of online contact should not prevent referral, as helpline and chat contacts presented the same levels of severity assessed with the chosen proxies.

Limitations

The JIS does not use a screening tool or diagnostic scale for problem gambling, which could have enabled a better clinical characterization of the population. It is highly probable that most gamblers contacting the helpline or real-time chats were problem gamblers, as demonstrated in other studies in similar

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settings (94% [26], 91% [22], and 82% [23]). By nature, contacts were gamblers who had identified damage related to gambling and felt the need to ask for help. The proxy measures used to assess severity should thus be interpreted with considerable caution.

Contacts were anonymous, but counselors noted that 19.7% of the gamblers mentioned having contacted the service previously (the missing data on this variable were high, at 77.5%, and were not imputed). Thus, there could be a proportion of duplicates among the contacts. This observation should be put into perspective, because each call is anonymous and there is no possible follow-up via JIS, so each contact was considered as a new event. For some patients, the service could be sufficient, as found in one study after a single session, showing improvement in psychological outcomes (ie, increased confidence score and decreased distress) [35], or in another, which observed a decrease in the number of days of gambling and in financial losses [36]. In addition, we have no information of individuals' attendance in care facilities following referral. The gap between referral and actual attendance could be around 20% according to one study [23]. This raises the importance of not targeting a low referral rate, as, later, attendance for face-to-face appointments would probably be even lower. The JIS structure for problem gambling could benefit from improvements through the development of partnerships with care centers offering face-to-face appointments directly and as quickly as possible, as is the case, eg, in Australia [26].

Clinical Implications

In the literature, recourse to gambling helplines is often a first contact. In 2001, the majority of gamblers using the New England helpline were seeking help for the first time [19]. Similarly, in 2011, about 90% of people using the West Virginia Problem Gamblers Help Network had never previously sought help for problem gambling [23]. The use of this kind of service could serve as a catalyst and enable people to access face-to-face care facilities. Thus, 55% of people using the West Virginia Problem Gamblers Help Network attended a face-to-face assessment interview [23]. More than 90% of participants on the Gambling Help Online website between November 2010 and February 2012 accessed further help from formal or nonformal support facilities following a helpline contact [35]. The use of new technologies, such as real-time chats, could help to remove some of the barriers to treatment encountered by gamblers [37] and could be a valuable tool to prevent early complications of gambling addiction, such as spiraling social costs and suicidal tendencies. Reasons reported by participants who had completed an online counseling session for problem gambling on the Gambling Help Online website between November 2010 and February 2012 fell into four categories: confidentiality and anonymity, convenience and accessibility, service system access, and a preference for the therapeutic medium [38]. With the development of internet-based therapy, JIS could be the tool of choice to treat a population that cannot or will not visit a face-to-face specialized care facility.

Conclusions

This is the first study describing contacts to a national helpline and chat service for problem gambling in France. The referral rate was low and linked to gamblers' demands and the severity of problem gambling. It was also lower among Web-based gamblers. Female gamblers less often expressed a demand for referral, and an effort could be made to facilitate communication among female gamblers and to detect their needs to help them more effectively. The real-time chat mode seems to respond to the need to broaden the media offer for help, reaching a younger population of Web-based gamblers. However, it is underused, and its development is a major challenge for the future. Overall, increasing the referral rate after initial non–face-to-face contact is a public health issue, and our study provides avenues for improving the referral rate.

Acknowledgments

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Conflicts of Interest

None declared.

Multimedia Appendix 1
Monthly time series (2011-2015, except for (12) May 2013-December 2015), trends, and regression lines for characteristics of Joueurs Info Service contacts from gamblers: (1) Proportion of women; (2) Mean age of contacts; (3) Mean duration of contacts; (4) Proportion of bets; (5) Proportion of casino games; (6) Proportion of scratch cards; (7) Proportion of poker; (8) Proportion of lottery; (9) Proportion of other games; (10) Proportion of solely offline gamblers; (11) Proportion of weekly gamblers; (12) Proportion of real-time chat users.
[PNG File , 270 KB - formative_v4i5e13388_app1.png]

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Abbreviations

ADALIS: Addictions Drogues Alcool Info Service
aOR: adjusted odds ratio
JIS: Joueurs Info Service
MAR: missing at random

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Original Paper

Toward Gamified Pain Management Apps: Mobile Application Rating Scale–Based Quality Assessment of Pain-Mentor's First Prototype Through an Expert Study

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Abstract

Background: The use of health apps to support the treatment of chronic pain is gaining importance. Most available pain management apps are still lacking in content quality and quantity as their developers neither involve health experts to ensure target group suitability nor use gamification to engage and motivate the user. To close this gap, we aimed to develop a gamified pain management app, Pain-Mentor.

Objective: To determine whether medical professionals would approve of Pain-Mentor's concept and content, this study aimed to evaluate the quality of the app's first prototype with experts from the field of chronic pain management and to discover necessary improvements.

Methods: A total of 11 health professionals with a background in chronic pain treatment and 2 mobile health experts participated in this study. Each expert first received a detailed presentation of the app. Afterward, they tested Pain-Mentor and then rated its quality using the mobile application rating scale (MARS) in a semistructured interview.

Results: The experts found the app to be of excellent general (mean 4.54, SD 0.55) and subjective quality (mean 4.57, SD 0.43). The app-specific section was rated as good (mean 4.38, SD 0.75). Overall, the experts approved of the app's content, namely, pain and stress management techniques, behavior change techniques, and gamification. They believed that the use of gamification in Pain-Mentor positively influences the patients' motivation and engagement and thus has the potential to promote the learning of pain management techniques. Moreover, applying the MARS in a semistructured interview provided in-depth insight into the ratings and concrete suggestions for improvement.

Conclusions: The experts rated Pain-Mentor to be of excellent quality. It can be concluded that experts perceived the use of gamification in this pain management app in a positive manner. This showed that combining pain management with gamification did not negatively affect the app's integrity. This study was therefore a promising first step in the development of Pain-Mentor.

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KEYWORDS

mHealth; chronic pain; stress management; pain management; health app; gamification; health professional

Introduction

Background

Approximately one-third of the American and European population suffers from chronic pain [1,2]. This makes chronic pain a major health care problem that needs to be taken more seriously [2]. With profound negative consequences on psychological, social, physical, and economic aspects for those affected, chronic pain can have a serious negative impact on a person's overall quality of life [3-6].

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Next to medical treatments (eg, medication, surgical rehabilitation, and physical therapy), psychological treatments are an important aspect of pain management [1].

In fact, the combination of 5 theory-based functionalities, namely, pain-related education, self-monitoring, goal setting, social support, and the training of self-care strategies, has been suggested to promote the self-management of chronic pain [7-11]. As patients need to understand and manage the thoughts, emotions, and behaviors that often accompany chronic pain [1], the mediated self-care strategies should include stress-coping skills such as relaxation techniques, problem solving, and communication skills training [12-14]. Multimodal approaches that integrate these aspects can improve the overall quality of life in patients with chronic pain, as compared with treatments that are strictly medication focused [15-17].

However, the integration of multimodal approaches into routine primary and tertiary care has been slow [2]. Major barriers such as poor accessibility because of geographical reasons, limited availability of trained professionals, and high therapy-related costs keep patients from accessing pain-specific education and psychological treatment [18-20]. As a result, most patients never receive the required education or skills training to promote self-management of pain [19-21].

However, the care for chronic pain is no longer strictly limited to medical environments and clinician-guided telehealth because of the rising number of mobile health (mHealth) products [22]. mHealth describes the use of mobile technology to improve health [23] by affecting the user's education, motivation, and adherence [24,25]. It has already been applied to support mental as well as physical health programs [26]. As such, mHealth can enhance the self-management of chronic conditions [27]. Indeed, preliminary evidence suggests that pain management apps have great potential to support chronic pain treatment and are well received by patients [12,28] and health care professionals [29]. In fact, a majority of studies reviewed by Thurnheer et al [29] showed beneficial effects of the use of pain management apps on pain severity. As such apps are available anywhere, anytime [30], they can reduce the frequency and cost of face-to-face interventions [31]. Moreover, they can combine a variety of features (eg, educational content, a diary, personalized recommendations, and communication with health care professionals) within one app [29]. As a result, they have the potential to make health care systems more effective [31].

To ensure their effectiveness, apps for chronic pain management must be based on evidence-based content (ie, pain-related education, self-monitoring, goal setting, social support, and the training of self-care strategies including stress management) [23,32,33]. Even though these aspects are easy enough to implement, app reviews show that existing pain management apps have limited content. Rather than providing evidence-based behavior change programs, the reviewed pain management apps reveal a lack of combination of evidence-based functionalities [34-36]. Indeed, most apps only include 1 of the 5 suggested components [34,36]. Apps mostly focus on supplying information [34-36]. They seldom help to achieve social support and often lack evidence-based self-care skills and tracking of the multidimensional experience of pain. Most apps only allow to track pain intensity (eg, FitBack [12]) [34,35,37,38]. Some apps also allow the user to track other pain-related aspects such as pain location, medication, and pain source (eg, Pain Squat [18]). However, only a small number of apps also allow the assessment of emotional and cognitive aspects. In addition, the educational content that is included is often of poor quality. An exception is the pain diary app, PainTracker, which includes 3 of the 5 suggested functionalities. It allows the tracking of a number of pain-related aspects, allows goal setting, and provides informational content [28]. Notwithstanding this exception, the overall lack of content in available pain management apps leads to a distrust in their effectiveness [39]. As a result, comprehensive, evidence-based, and clinically informed smartphone apps for pain self-management are highly needed [35].

Although important, the use of evidence-based content alone has been considered as insufficient to ensure adequate user engagement and motivation [40], two aspects that have great influence on the usage of an intervention program [41]. In fact, further improvement is needed to make pain management apps more engaging and entertaining [28].

One way to increase user engagement and motivation is through gamification. Gamification, the use of game elements in nongame contexts [42], aims to make interventions, such as health apps, more enjoyable, motivating, and engaging [43]. However, the use of gamification in health apps has been critically discussed as its effects depend on the context and the goal of the app [44]. Although users do not always want the implementation of gamification in health apps [25], it could be shown that its use can have positive effects on both health and wellness [44].

Gamification has already been shown to positively influence user self-management [43], lifestyle [45], health and behavioral outcomes [46], and the retention of desired user behaviors [47]. This confirms that the implementation of gamification can be effective in promoting behavior change through apps [48].

Nevertheless, few pain management apps make use of this concept. Two pain management apps for adolescent patients with cancer have included gamification in the form of a virtual rewards system and ranks that are linked to the users' pain diaries and adherence [18,49]. However, to our knowledge, there is no chronic pain management app with an extensive gamification framework for adults.

Pain-Mentor

As current pain management apps lack in their use of both evidence-based self-management skills [35] and gamification [28], we aimed to develop Pain-Mentor to close this gap in research. Pain management apps have great potential to promote patient self-care in out-clinic settings [29]. Therefore, Pain-Mentor supports the therapy of patients with chronic pain by teaching evidence-based techniques from multi-modal pain therapy and how they can be applied in everyday life. The app is based on the concept of Stress-Mentor [50], a gamified stress management app. Stress-Mentor includes all 5 suggested theory-based functionalities. For example, it realizes self-monitoring through a diary that allows the tracking of up

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to 14 diary categories (ie, sleep duration and quality, sport duration and intensity, daily uplifts and daily hassles, stress level, mood, digestion, consumption of water, fruits and vegetables, coffee and alcohol, and step count). In addition, the app teaches different self-help skills through daily and weekly tasks. In these tasks, the user can choose 1 of 3 suggested skills that he or she wants to practice. The techniques offered by the app depend on the user's entries into a stress checklist. In the stress checklist, the user can enter stress-related aspects (ie, fears and worries, sadness, anger, stress at work, stress in private life, muscle tension, and head, neck, and back grievances caused by tension, digestive problems, and sleep problems) on a scale of 0 to 10 on a weekly basis. This concept of personalized tasks encourages the user to set daily and weekly goals and supports the repetition of exercises. The mediated skills include relaxation exercises (ie, abdominal breathing, meditation, mindfulness, progressive muscle relaxation, guided imagery, stretching exercises, and self-massage), problem solving (ie, time management, goal setting, planning of social support and social change, and barrier identification), cognitive aspects (ie, assertiveness training, refuting irrational ideas, appraisal of stress and stressful situations, and avoiding perfectionism), and the transfer of educational information about stress. Moreover, the app provides tips on stress based on the user's documented stress level.

In addition to self-monitoring, stress management skills, and educational information, Stress-Mentor includes several other behavior change techniques (see the study by Christmann et al [50] for a detailed list) to support long-term behavior change. The included behavior change techniques are linked to an extensive gamification concept aimed at motivating and engaging the user [50]. As such, the app includes an avatar (a bird-like cartoon animal) that provides feedback by reflecting both the user's diary entries (vicarious reinforcement) [51,52] and progress. Another aspect is the app's agent (a wise owl), who is a mentor that entrusts the care of the avatar to the user via a behavioral contract and provides instructions on app functions, general encouragement, and educational tips on stress. The user can collect *woodland coins* that can later be exchanged for items for the user's avatar. Moreover, the app provides feedback on the user's performance through progress bars, a diary overview diagram [53], badges, and the visual development of the avatar and its surroundings. A detailed description of the implemented behavior change techniques and how they were linked with gamification was previously published [50].

As stress management and cognitive and behavioral aspects play an important role in the treatment of chronic pain [1], Stress-Mentor's concept was adopted for the first prototype of the pain management app (Pain-Mentor) evaluated in this study. Although all stress-related content remains, additions were made to the existing diary, tips, symptoms checklist, and daily tasks to further adapt Pain-Mentor to the context of chronic pain treatment. We made the following adjustments to better suit Pain-Mentor to its designated usage context. First, the stress checklist was renamed to symptoms checklist. The symptoms checklist was then extended with a numerical rating scale for pain that is commonly used in therapy. It allows the user to enter his or her pain level on a scale of 0 (no pain) to 10 (worst possible pain) [54]. The diary was also extended by this scale. This provides users with the opportunity to track the trend of their pain on a daily basis [55]. A total of 8 pain-specific daily tasks were added to the task pool: 1 each to develop a plan for setbacks, planning social support for pain management, and planning a dropped activity and 5 physical exercises for muscle strengthening and stretching. Moreover, the tips given by the app's mentor were extended with additional information on chronic pain and pain management. A screenshot of the app is displayed in Figure 1.

All in all, Pain-Mentor differs from other pain management apps regarding one important property: it includes all 5 suggested self-management functionalities (ie, educational information on pain and stress, a total of 87 pain-specific and stress-specific self-help skills, goal setting through tasks of the day and tasks of the week, multidimensional self-monitoring, and social support) and combines this content with gamification to motivate and engage the user. This poses great potential for supporting in-person therapy and reducing therapy costs [56].

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Figure 1. Screenshot of Pain-Mentor.

Motivation

In contrast to the general recommendation, most pain management apps are not based on scientific evidence and have not been thoroughly tested [39]. This also means that designers have neither included experts from pain management in the development of their apps [38] nor used expert reviews to assess their quality [34]. Contrary to this, Pain-Mentor's contents were extended in consultation with a physician who specialized in chronic pain treatment. The involvement of health care professionals in the development of health apps, as was done for Pain-Mentor, is important for health apps to contribute value to the delivery of health care and chronic disease management [57]. With many apps promising effective pain treatment, patients face a large array of possible apps to choose from, with little guidance regarding their quality [31]. To ensure quality, functionality, and relevance of the content, health apps need to be tested in scientific trials and must involve health care professionals not only during their development but also in the evaluation process [58].

In general, health apps must be acceptable to both the user who must decide whether the program is usable and can provide benefit in an operational environment and the health professionals who determine whether the app does what it is supposed to do [59]. In contrast to the users' goal, the experts' primary goal is to assess the quality of a health app to identify apps that can be recommended to their patients [60]. They focus on different aspects and provide different feedback than users and developers [61]. Therefore, even though experts have scientifically evaluated few pain management apps [35], testing the quality of health apps through expert evaluations is essential to assess the quality of key app features [62].

This study, therefore, conducted an expert evaluation of the first prototype of the newly developed pain management app, Pain-Mentor, that combines a multimodal approach to pain self-management with an extensive gamification framework. The aim of this study was to gather information on how to further improve Pain-Mentor to create an app that has high value, the potential to positively influence chronic pain patients, and is accepted and recommended by medical professionals. For this purpose, the app's general quality was evaluated from the perspective of health professionals. This approach enabled us to identify areas that need improvement and helped to further adjust Pain-Mentor for the purpose of its application.

Methods

Recruitment

To assess the app's quality per the standards of health professionals, experts with a background in chronic pain management and mHealth development were recruited (Figure 2). For this purpose, based on an internet search, physicians specializing in pain treatment and general psychotherapists in a 100-km radius of the Technische Universität Kaiserslautern (Germany) were contacted via email. Among the 94 experts contacted, 8 were willing to participate in this study. An additional 5 experts learned about the study from one of their

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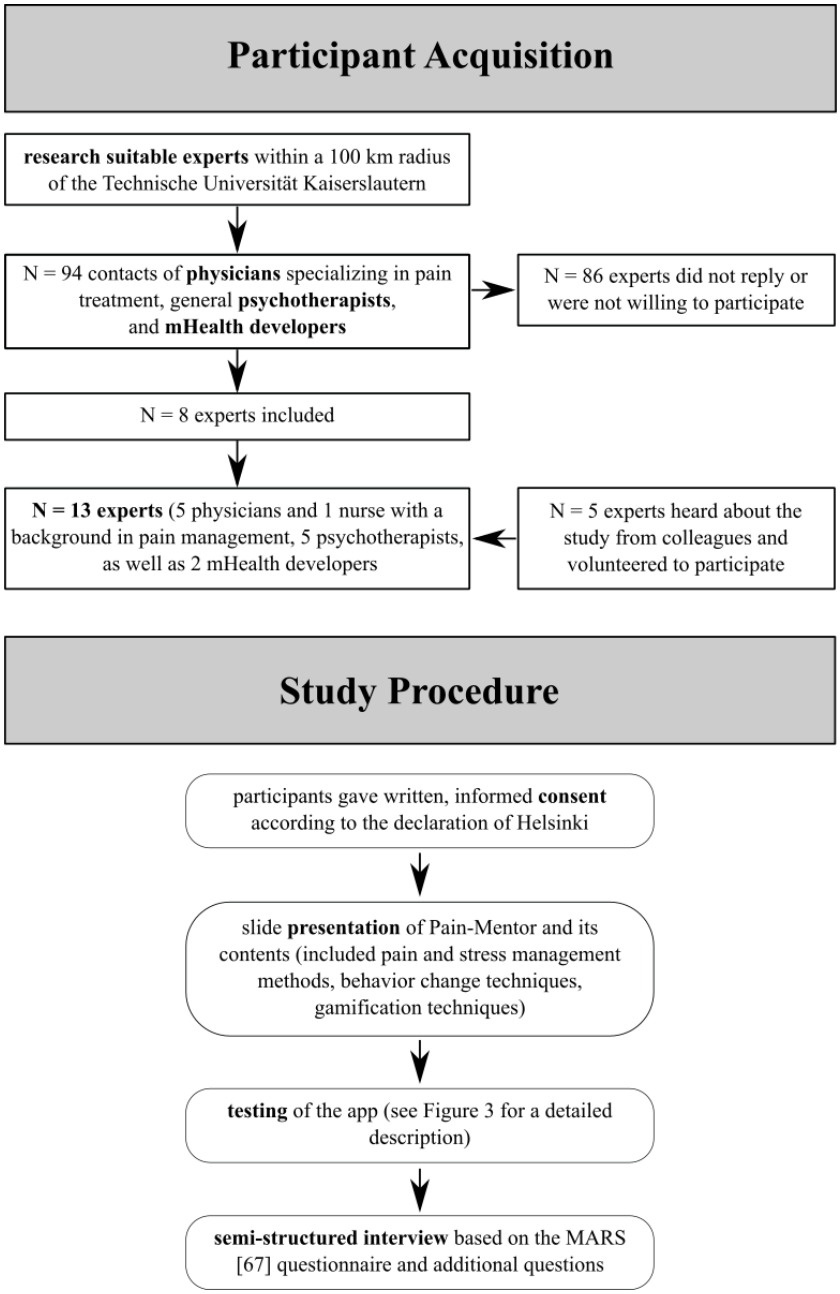
colleagues and volunteered to participate as a result. In the end, 13 experts (5 physicians, 1 nurse with a background in pain management, 5 psychotherapists, and 2 mHealth developers) participated in this study. Previous research suggested the use of at least 2 to 4 experts [63-65], although a larger sample size increases the percentage of identified problems in the apps. As about 95% of all problems can be identified with as many as 9 participants [66], it can be concluded that the sample size of this study provided good insight into the app's quality and enabled to identify most of the concerns arising from experts from chronic pain treatment. All participants had specific experience in the field of pain and pain management.

Figure 2. Depiction of the participant acquisition and study procedure. MARS: mobile application rating scale; mHealth: mobile health.



Procedure

The whole procedure was approved by the local ethics committee from the Department of Social Sciences, Technische Universität Kaiserslautern.

To ensure a standardized approach, the following study procedure was predefined. At the beginning, the health professional was informed about the procedure, aim, and data collected in the study. Each participant gave written consent according to the Declaration of Helsinki. Afterward, Pain-Mentor and its contents were presented to the professional in detail in a slide presentation that explained the pain and stress management methods, behavior change techniques, and gamification aspects that were included and how they were interconnected. After the presentation, the expert tested the app (Figure 2) on a tablet (Lenovo TB-4706F). For this purpose, the app was set to a specific prerequisite to ensure all participants were exposed to the same content and features.

Testing also followed a predefined process that took 15 to 25 min for each participant (see Figure 3 for a detailed description).

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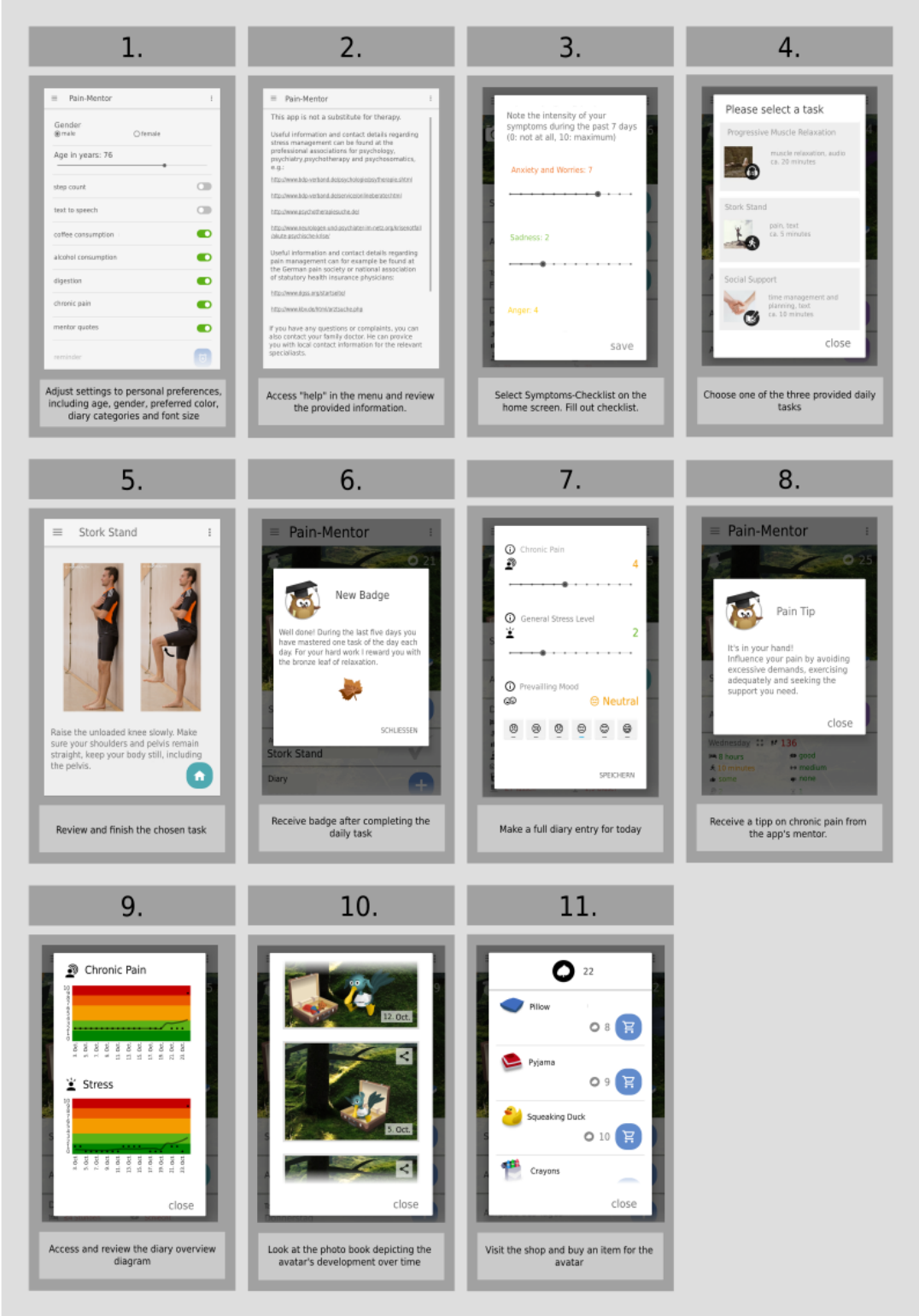
Figure 3. Sequential order of the app testing process that all experts followed.



App Quality

After testing Pain-Mentor, all experts rated the quality of the app and were asked for feedback. For this purpose, the mobile application rating scale (MARS) [67] was applied. MARS was specifically designed to assess the quality of health apps with the help of experts from health and information technology [67]. MARS comprises 6 subscales. Four of those scales (ie, engagement, functionality, esthetics, and information quality) assess the general app quality; the subjective quality section evaluates the user's overall satisfaction; whereas the app-specific section assesses the perceived impact of the app on the user's knowledge, attitudes, intentions to change, and the likelihood of actual change in the target health behavior. The complete structure of MARS [67] is listed in Table 1.

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Table 1. Structure of the mobile application rating scale questionnaire Stoyanov et al (2015) [67].

Section and subsection	Definition	Items
App quality		
A: Engagement	Fun, interesting, customizable, interactive (eg, sends alerts, messages, reminders, and feedback and enables sharing), and well targeted to audience	• Entertainment • Interest • Customization • Interactivity • Target group
B: Functionality	App functioning, easy to learn, navigation, flow logic, and gestural design of app	• Performance • Ease of use • Navigation • Gestural design
C: Aesthetics	Graphic design, overall visual appeal, color scheme, and stylistic consistency	• Layout • Graphics • Visual appeal
D: Information	Contains high quality information (eg, text, feedback, measures, and references) from a credible source	• Accuracy of app description • Goals • Quality of information • Quantity of information • Visual information • Credibility • Evidence base
App's subjective quality	Contains subjective, personal opinion of the app, including recommendation to others, estimated usage, willingness to pay, and overall star rating	• Likelihood of recommending the app to others • Estimated usage over the next year • Willingness to pay for the app • Overall star rating
App-specific	Perceived impact of the app on the user's knowledge, attitudes, and intentions to change as well as the likelihood of actual change in the target health behavior	• Awareness • Knowledge • Attitudes • Intention to change • Help seeking • Behavior change

Participants rated each of the 23 MARS items on a 5-point Likert scale (from 1=inadequate to 5=excellent). To allow for differentiated user feedback, MARS was applied as a semistructured interview. This means, after each rating, participants had the opportunity to explain their answer and give suggestions regarding further improvement of the app (open-response format). Presenting MARS and other questionnaires as semistructured interviews has been done in previous studies and promises deeper insights into the raters' reasoning and possible improvements (eg, the study by Anderson et al [68]). As the experts spent limited time trying out the app (approximately 20-30 min), an additional answer option was added to each question, namely, "I cannot assess this." This ensured that the experts were not forced to answer, if they felt that they did not have enough time with the app to assess an aspect.

Overall, 3 questions from the subscale, *subjective quality*, were removed from the questionnaire: (1) question 18, "Does the app come from a credible source?" because the source of the app was explained to the participants in detail; (2) question 19, "Has the app been tested?" because an evaluation regarding the app's effectiveness has not been conducted so far; and (3) question 22, "Would you pay for this app?" because health experts are not the target user audience of this app. In addition, question 20 was adapted to the context and changed into "Would you recommend this app to patients who might benefit from it?" The questions from the *app-specific* section were adapted to the context, ie, the term *health behavior* was replaced with *stress and pain management*.

Additional App-Specific Questions

In addition to MARS, the participants answered 7 additional questions on a 5-point Likert scale (from 1=inadequate to 5=excellent) and 1 open-response question with regard to the expected app's appeal for patients and specific app features. As with MARS, participants received the opportunity to explain their answers. See Multimedia Appendix 1 for a list of all additional questions.

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Results

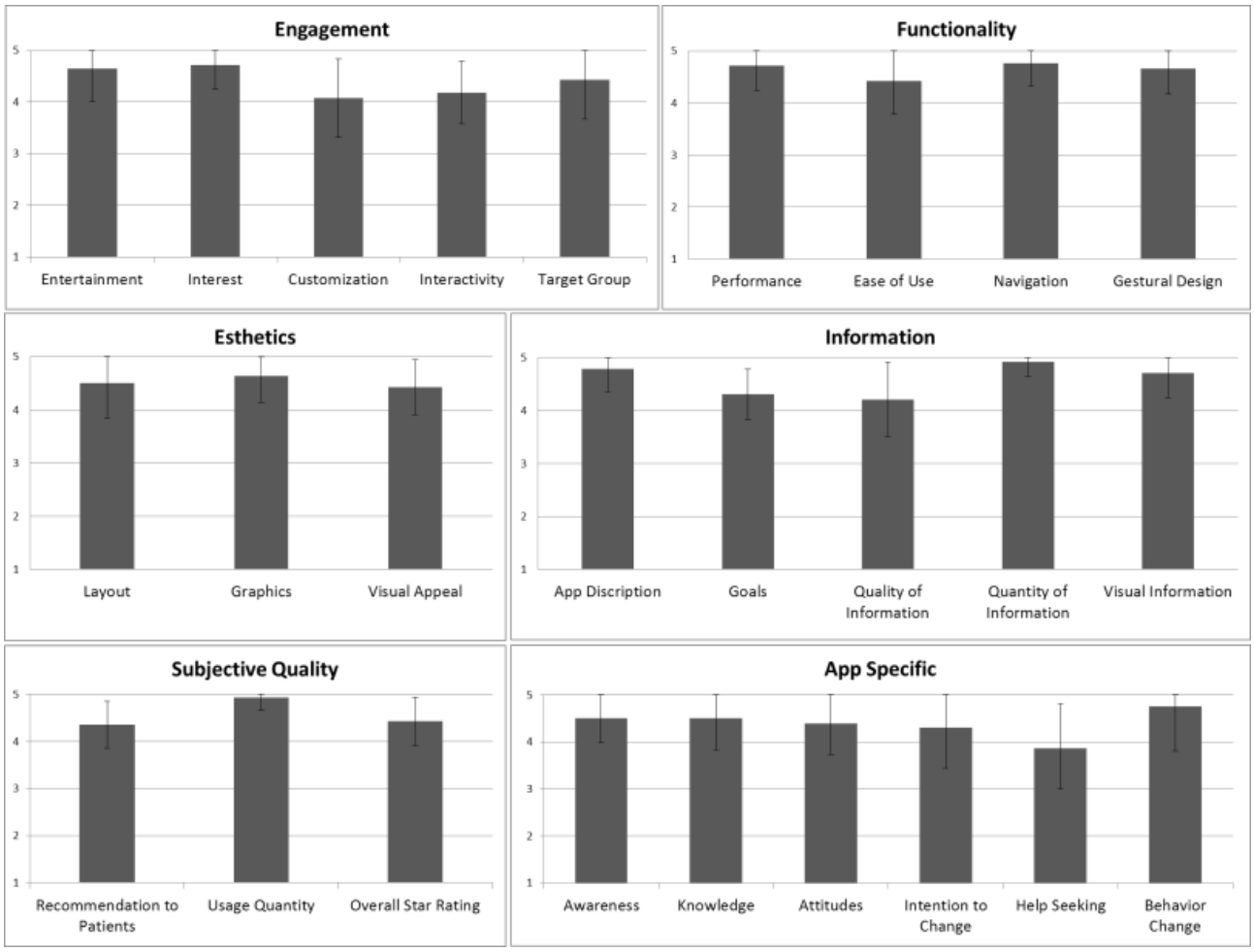
Mobile Application Rating Scale–Based Outcomes

Overall, experts rated Pain-Mentor to be of excellent quality (mean 4.54, SD 0.55). Subjective app quality was appraised as excellent (mean 4.57, SD 0.43). The app-specific questions were rated as good, with a mean of 4.38 (SD 0.75).

The MARS quality subsection, engagement, was rated as good, and functionality, esthetics, and information were rated as excellent (see Multimedia Appendix 2 for mean values and standard deviations).

Evaluating each question of these subsections in detail, the results showed a mean value ranging from of 4.07 (SD 0.76) for customization to 4.71 (SD 0.47) for interest for the subsection engagement. Functionality showed mean rating between 4.43 (SD 0.65) for ease of use and 4.77 (SD 0.44) for navigation. The app's esthetics were assessed as excellent, with mean values of 4.43 (SD 0.51) for visual appeal, 4.50 (SD 0.65) for layout, and 4.64 (SD 0.50) for graphics. The information communicated in Pain-Mentor also showed good to excellent ratings, with means ranging from 4.21 (SD 0.67) for the quality of information and 4.92 (SD 0.28) for information quantity. The subjective quality of the app showed ratings of 4.36 (SD 0.50) with regard to the recommendation of the app to patients and the overall star rating and 4.50 (SD 0.52) for usage duration. The app-specific questions of MARS showed values between 3.86 (SD 0.95) with regard to encouraging patients to seek help outside the app and 4.75 (SD 0.46) regarding the app's potential to promote behavior change. A detailed visualization of the results is included in Figure 4.

Figure 4. Experts' rating (in means and standard deviations) of the mobile application rating scale regarding Pain-Mentor.



Occasionally, experts were unable to answer a question (see Multimedia Appendix 3 for details). Participants gave several reasons for being unable to assess these questions, which will be discussed in the Limitations.

In addition to the quantitative ratings, applying MARS as a semistructured interview provided differentiated expert feedback. The experts' comments are discussed in the Principal Findings section of the Discussion.

Outcomes From Additional Questions

Good to excellent mean ratings could be observed for all additional questions (see Table 2). Experts thought that it was highly likely that Pain-Mentor would appeal to patients (mean 4.50, SD 0.52). The app's gamification concept was rated as good (mean 4.29, SD 0.61). The experts' expectations of Pain-Mentor were mostly fulfilled (mean 4.35, SD 0.63). They rated the implemented diary (mean 4.71, SD 0.61), daily tasks (mean 4.64. SD 0.63), and symptoms checklist (mean 4.79, SD 0.43) as sensible and useful. Moreover, they believed that using

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Pain-Mentor to support in-person therapy would be useful (mean 4.57, SD 0.51). All experts were able to assess all additional questions.

Table 2. Experts' ratings for additional questions regarding Pain-Mentor.

Question	Rating, mean (SD)
Do you think the app would appeal to patients?	4.50 (0.52)
Did you like the gamification concept?	4.29 (0.61)
Did the app meet your expectations?	4.35 (0.63)
How useful is the diary?	4.71 (0.61)
How useful is the concept of daily exercises?	4.64 (0.63)
How useful is the symptoms checklist?	4.79 (0.43)
How useful is it to apply the app in addition to therapy?	4.57 (0.51)

Discussion

Principal Findings

Overall, experts rated the app to be of excellent overall and subjective quality. The app-specific section of MARS was rated as good. These positive results reflect that the app and its contents (ie, diary, daily tasks, information, symptoms checklist, and gamification concept) met the experts' expectations. As expected, these results show that combining the 5 suggested self-management functionalities (ie, educational information, self-care skills, self-monitoring, goal setting, and social support) [7-11] in an app targeting chronic pain management is approved by health experts.

In addition, the experts thought that the app's gamification concept, especially the avatar, made the program engaging and interesting to use. This was mirrored by the experts' comments, eg, E4 said, "I think the app motivates those patients who want to be proactive and do something to manage their pain." This implicates that the use of gamification could pose a solution to the lack of engagement and entertainment in pain management apps as mentioned in the study by Jamison et al [28]. It also agrees with the results from a user study with the stress management app, Stress-Mentor, which showed that the app's gamified concept led to increased usage compared with a nongamified control group (Hoffman et al, unpublished data). Though this is a promising indication of the effectiveness of the concept of Pain-Mentor, a user study with patients with chronic pain is needed to show whether these results remain.

Two experts expressed concerns that the existing gamification concept, especially the choice in avatar, might be too childlike and not suitable for the elderly. Although most users prefer human avatars that match their own gender [69], it is very subjective as to which avatar appeals to a user. To solve this problem, the participants suggested providing the user a choice among different avatars and including more options to adapt the avatar to the user's preferences. Despite some experts' skepticism regarding the avatar's suitability for the elderly, other experts thought that Pain-Mentor was well suited for the target group (ie, adults with chronic pain) and that it was very likely that the app would appeal to patients. This further supports the combination of evidence-based content and gamification [43,45-47] and indicates that such approaches should not be limited to adolescents. In addition, gamification most likely had a positive impact on the app's esthetics.

Experts especially liked that they could choose the avatar's color and that the avatar's appearance was linked to both diary entries and progress (eg, E9 stated, "It's nice that the user can pick the avatar's color. Especially the visual elements invite you to explore and play around a little"), and they liked that the app's *simple visual design* allowed them to use it intuitively. This backs both personalization [70] and the use of vicarious reinforcement through avatars in health apps [51].

Although the experts were mostly satisfied with Pain-Mentor's customizability, they also suggested including more reminders to help the user remember to practice throughout the day. This shows that one reminder is the minimum, whereas the inclusion of more appears to be preferable. Nonetheless, the reminder function was generally perceived positively, and the experts thought that this feature was likely to promote the user's self-commitment. Overall, 7 experts also suggested the addition of new diary aspects. However, there was no consensus among the experts on the aspects that should be added (they suggested, eg, weight, additional dietary aspects, pain location, and notation of additional exercises). Thus, it cannot be concluded which categories would make the most sense to be added based on the feedback obtained from this study. Moreover, the addition of aspects could easily overwhelm the users and lead to a decline in the app's usability and usage [71]. Furthermore, 2 experts also commented that not all aspects are equally important for every patient. To solve this issue, the developers could add a notes section that leaves room for further patient-specific entries, as has been implemented in other pain management apps (eg, Chronic Pain Tracker and FitBack) [12,34]. Another approach could be to allow the addition of individual scales in the diary [72]. Both solutions would leave the choice of adding further diary categories to the user and his or her treating health professional.

Regardless of the suggested extensions, the diary was perceived as very useful by the experts. One participant expressly mentioned that she especially liked that the diary was not overly focused on pain, but rather allowed for tracking the patient's overall well-being, including emotional (stress level and mood) and cognitive aspects (daily hassles and daily uplifts). This goes in line with previous studies [34,35] that criticized that most

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pain management apps focused only on tracking medication and pain levels. Another aspect that was mentioned was the advantage for patients in keeping a digital diary instead of applying a pen and paper approach [73].

Though the app's interactivity was assessed as good, one expert commented that it could be further improved by giving advice based on the user's diary entries. Consequently, developers should think about further personalizing their apps by linking the users' entries (eg, from a diary) to suitable health information and tasks. For example, the app, MyBehavior, automatically provides personalized suggestions based on a health diary [74].

Participants thought that the information imparted in the app was generally well formulated and of high quality. Moreover, experts would recommend the app to many of their patients based on whether he or she would profit from using the app. This shows that the experts thought the app to be a good therapy supplement. However, their recommendation largely depends on the patients' age, disease pattern, and current state. Nevertheless, age does not necessarily impact compliance or satisfaction with a pain management app [28]. Moreover, the combination of visual features (because of the gamification concept) and content [50] was perceived very positively (eg, E9 said, "It [the app] has a good balance of simple visual design and good content-related information"). This further supports the use of gamification in the context of pain management.

There was general approval of the self-management skills that are imparted in the app. Nevertheless, 3 experts suggested including additional tasks, such as more stretching exercises, more tasks specifically aimed at dealing with pain, and exercises aimed at distracting patients from their pain. This emphasized that experts see the potential of using apps to teach a large number of stress-related self-help skills to the user, including relaxation, problem solving, and cognitive aspects [13]. However, it should be supplemented by more pain-specific aspects to provide maximal suitability.

The experts also mentioned that they would like to be able to review the app's data with their patients on a computer to monitor and discuss their patients' progress. However, automatic data transmission to the treating health professionals was seen as problematic because of the experts' limited availability of time. To avoid this problem, an optional sharing function could be added that allows patients to share their data with the health professionals on a voluntary basis [34]. Such functions provide health professionals the opportunity to gather data on a patient's behavior [75]. My Pain Diary, eg, offers the export of data to a computer [28].

The experts' positive ratings of the app's ability to positively influence patients' awareness, knowledge, attitude, intention to change, help-seeking, and behavior change are in line with the fact that health apps can enhance users' self-management of chronic conditions [27]. However, it was emphasized that the individual played an important role regarding these aspects. Nonetheless, the experts thought that it would be very useful to employ the app to supplement in-person therapy. This highlights the potential of health apps to support regular treatment [26].

In addition to using the app for therapy support, one expert suggested to use the app to bridge the time until patients can receive in-person therapy. As waiting times for therapy are often long, using health apps in this manner could further increase their potential to improve health care [22] and diminish the number of patients who do not receive adequate care [21]. This further supports the conclusion that pain management apps could be especially beneficial in out-clinic settings [29]. Therefore, this area of application should be the focus of future research.

When asked which aspects they thought would keep patients from using the app, experts mostly mentioned a lack of motivation for people to change. However, they also mentioned that it is often difficult for patients to deal with the subject matter. In addition, they mentioned a lack of familiarity with mobile devices, apps and data security. This is in line with previous studies that have shown that technical affinity [76] and data privacy and security [77] are important aspects for choosing and using health technologies. Therefore, developers should make sure they pay special attention to data security when developing health apps [75]. Pain-Mentor, for instance, only saves the user's data locally on his or her smartphone in an encrypted form.

Overall, Pain-Mentor's MARS ratings are similar to those of the best-rated pain management apps reviewed by Salazar et al [39]. Averaged across all reviewed apps, the mean functionality was assessed as good, whereas Pain-Mentor received an excellent score. Similar observations can be made for esthetics (average for Salazar et al [39] and excellent for Pain-Mentor), engagement (average for Salazar et al [39] and good for Pain-Mentor), information (average for Salazar et al [39] and excellent for Pain-Mentor), subjective quality (average for Salazar et al [39] and excellent for Pain-Mentor), and app-specific scores (poor for Salazar et al [39] and excellent for Pain-Mentor).

Although the experts' comments showed that some adjustments, such as adding more pain-specific exercises, diary categories, and reminders, could further improve the app, they still rated Pain-Mentor to be of excellent overall quality (mean rating of average for Salazar et al [39]). This shows that minor adjustments of suitable health apps (eg, from stress management) can make them useful tools that can be applied in different contexts (eg, chronic pain management). Nonetheless, whether an app will be assessed as useful or not depends on both the app's content and the suggested context of use [78]. Not every health app should be applied in or adjusted for other contexts. Underlining the importance of expert evaluations [58], this study showed that involving health experts from the target context helps to determine an app's suitability and to identify necessary adjustments.

Limitations

The experts approved of the app's gamification concept and thought that using gamification in this manner could improve patients' motivation and engagement. As experts and patients focus on different aspects [59], a next step should be to get the opinion of patients with chronic pain to further adjust the app to their needs. Though user studies showed that the app's

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gamified concept is accepted by users in the context of stress management (Hoffman et al, unpublished data and [79]), it remains unclear as to what extent the results of this study hold true in the context of pain management. In addition, further research is needed to determine the effects of gamification on users' behavior. Moreover, although experts approved of the idea to use the app to support therapy, randomized controlled trials are needed to actually determine the effectiveness of Pain-Mentor as a therapy support tool.

The inclusion of 9 experts has been suggested to be sufficient to reveal most problems within an app [64]. Thus, although only 13 experts participated, in this study, we should have identified the most important improvements that are required. Nonetheless, for future studies, it should be noted that it can be hard to obtain experts to participate. Out of 94 contacts, only a few were willing to participate. A major reason for this was the lack of time to accommodate the study within their busy work schedule.

Other aspects that future studies might encompass include the participating experts' affinity to technology and their knowledge in testing mobile apps. Though the participants' affinity to technology was not systematically collected in this study, 3 participants mentioned that they were not proficient in using smartphones and tablets. This means, not all participating experts had high technological knowledge.

As all experts were given a detailed introduction of Pain-Mentor and spent approximately 20 to 30 min using the app, they received detailed insights into how the app worked. Nonetheless, experts had trouble assessing the app's gestural design and the app's potential to positively affect behavior change. Future studies could avoid this problem through longer trial periods.

Conclusions

This study provided a first affirmation of Pain-Mentor's concept. The participating health experts approved of the app's gamification aspects and described this approach as a good way to enhance user motivation and engagement. Moreover, the app received positive ratings with regard to general and subjective quality as well as app-specific aspects (MARS). This showed that the use of gamification did not have a negative impact on the app's credibility and integrity and that the combination of gamification with the 5 recommended self-management functionalities (ie, pain-related education, self-monitoring, goal setting, social support, and the training of self-care strategies) led to an overall positive evaluation of Pain-Mentor. This indicated that the app's development is on the right track.

The study also showed that applying MARS in combination with additional, more app-specific questions in a semistructured interview can provide insights into the participants' ratings and disclose possible areas for improvement. In fact, this approach revealed areas where adjustments need to be made to further tailor Pain-Mentor for its application as a support tool for chronic pain therapy. The applied approach therefore helps to adjust health apps for a specific target audience and to identify further scenarios for application.

Acknowledgments

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Conflicts of Interest

In accordance with our ethical obligation as researchers, we report that the authors of this paper developed Pain-Mentor, which is the focus of the presented research.

Multimedia Appendix 1
List of additional questions for the semistructured expert interview.
[DOCX File , 14 KB - formative_v4i5e13170_app1.docx]

Multimedia Appendix 2
Means and standard deviations of the experts' ratings for each category of the mobile application rating scale questionnaire.
[DOCX File , 12 KB - formative_v4i5e13170_app2.docx]

Multimedia Appendix 3
List of questions that at least one expert felt unable to assess and the number of experts that were unable to assess each of these questions.
[DOCX File , 13 KB - formative_v4i5e13170_app3.docx]

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Abbreviations

MARS: mobile application rating scale
mHealth: mobile health

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Original Paper

Identifying the Needs for a Web-Based Postpartum Platform Among Parents of Newborns and Health Care Professionals: Qualitative Focus Group Study

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Abstract

Background: During the turbulent postpartum period, there is an urgent need by parents for support and information regarding the care for their infant. In the Netherlands, professional support is provided during the first 8 days postpartum and for a maximum of 8 hours a day. This care is delivered by maternity care assistants (MCAs). Despite the availability of this extensive care, a majority of women prefer to make use of a lesser amount of postpartum care. After this period, access to care is less obvious. Where parents are automatically offered care in the first 8 days after birth, they must request care in the period thereafter. To compensate for a possible gap in information transfer, electronic health (eHealth) can be a valuable, easily accessible addition to regular care.

Objective: We explored the needs and preferred content by new parents and health care professionals of a web-based platform dedicated to the postpartum period and identified barriers and facilitators for using such a platform.

Methods: We conducted 3 semistructured focus groups among (1) parents of newborns, (2) MCAs, and (3) clinicians and administrators in maternity care. A topic list based on a framework designed for innovation processes was used. Thematic content analysis was applied.

Results: In the focus group for parents, 5 mothers and 1 male partner participated. A total of 6 MCAs participated in the second focus group. A total of 5 clinicians and 2 administrators—a member of a stakeholder party and a manager of a maternity care organization—participated in the third focus group. All user groups underlined that a platform focusing on the postpartum period was missing in current care, especially by parents experiencing a gap following the intensive care ending after the first week of childbirth. Parents indicated that they would perceive a postpartum platform as a proper source of reliable information on topics regarding breastfeeding, growth, and developmental milestones, but also as a tool to support them in seeking care with appropriate professionals. They also emphasized the need to receive personalized information and the opportunity to ask questions via the platform. MCAs acknowledged added value of providing additional information on topics that they address during the early postpartum period. MCAs as well as clinicians and administrators would guide parents to such a platform for additional support. All user groups experienced disadvantages of using an authentication procedure and filling out extra questionnaires to receive tailored information.

Conclusions: Our research shows that parents of newborns, MCAs, and clinicians and administrators foresee the additional value of a web-based postpartum platform for at least the whole postpartum period. The platform should be easily accessible and personalized. Content on the platform should contain information regarding breastfeeding, growth, and developmental milestones. A chat function with professionals could be considered as an option.

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KEYWORDS

newborn; focus groups; postpartum period; postnatal care; eHealth; pregnancy; obstetrics; qualitative research

Introduction

Pregnancy, delivery, and taking care of the infant during the postpartum period are large life events. In many countries, the postpartum period (ie, the first 42 days after childbirth) is a largely underestimated period of care for parents [1,2]. It is known that they are in enormous need for information, especially regarding breastfeeding, sleeping patterns, and physical recovery after childbirth [3]. To support maternal and infant health and to prevent morbidity and mortality at the earliest moment during the life course, it is essential that this information is available and accessible [3-5].

In the Netherlands, postpartum care in the first days after birth is provided by trained professionals, so-called maternity care assistants (MCAs), supervised by community midwives (see Textbox 1 for more information). An MCA provides care for an average of 8 consecutive days, 3-8 hours a day, at the home of the parents of the newborn. All women are offered this extensive postpartum care. However, the majority of women choose to receive fewer hours or days of care than recommended [6-8].

After these first 8 days, care is less extensive and less regularly scheduled at well-baby clinics for the newborn, which are free of charge and are organized by preventive child health care (PCHC) services. The mother has only one regular postpartum checkup with the midwife at 6 weeks postpartum. This less-extensive care requires women to actively ask for support and guidance. Electronic health (eHealth), for example, a web-based platform, has the potential to support continuity of care for both parents and professionals. It is already widely used in supporting disease management, promoting healthy lifestyles, prevention, and making care more effective [9,10]. There are more eHealth tools focusing on pregnancy than in any other medical field [11,12]. Nevertheless, there is a lack of any eHealth program focusing on the postpartum period. This is a missed opportunity, because it is known that women are willing to use eHealth applications for reliable information during this new phase in life [13,14].

In countries other than the Netherlands, postpartum care is less extensive. However, independently taking care of an infant at home after early discharge from a maternity ward, without the help of a professional, is experienced as very difficult and stressful [15-17]. Parents of newborns also need compassion and companionship, as loneliness and psychological problems are main issues in the postpartum period [18]. In addition, there is a need for continuity of professional care during transition of the prenatal to postpartum period [18-22]. eHealth, in its broadest sense, can be a useful additional technique to provide tools for support in this period for parents [13,23-25]. Additionally, health care professionals recognize problems with handover of information in this period, leading to suboptimal care [26].

Textbox 1. Maternity care in the Netherlands.

Care During Pregnancy

In the Netherlands, maternity care is a complex care system. Pregnant women are allocated to three strata of care: primary, secondary, or tertiary care. Allocation is based on division of low-, medium-, or high-risk pregnancy during the first prenatal visit. Primary care is provided by the community midwife to women who have a low-risk pregnancy. Women may give birth at home or at a primary care birth center, supervised by the community midwife.

Secondary care during pregnancy and childbirth takes place at general hospitals by gynecologists or clinical midwives. Women with high-risk pregnancies (eg, severe preeclampsia prior to 32 weeks of gestation) are referred to tertiary care, provided by 12 perinatal centers in the Netherlands.

During the third trimester, maternity care assistants (MCAs) visit every woman at home for an assessment of the recommended amount of postpartum care. Postpartum care is provided by MCAs working at maternity care organizations. These are independent enterprises.

Care During the Postpartum Period

Regardless of the strata of care, women are offered postpartum care by MCAs. This care is supervised by the community midwife. Most women choose to receive postpartum care at home, but this is also possible at primary care birth centers. If there are maternal or neonatal complications, part of this postpartum care can take place at the maternity ward (eg, 48 hours of stay at the maternity ward is recommended after a cesarean section). Care by MCAs is provided during the first 8-10 succeeding days. This care includes coping with the new situation and increasing parents' confidence in the care for the infant [6]. They also promote a healthy lifestyle, such as preventing use or reuse of tobacco, and educate parents in the prevention of child abuse [4]. Most of the information and advice is transmitted orally, and information leaflets are used for further support [6].

The mother herself decides the amount of postpartum care, up to a maximum recommended by the MCA. The minimum amount is 24 hours and the recommended amount in a standard situation is 49 hours (eg, when a mother breastfeeds her baby and no problems occur during childbirth or the early postpartum period). During the first few days, postpartum care covers 6-8 hours a day. During the following days, this number of hours is reduced. On the last day, the care for the newborn is transferred to well-baby clinics of preventive child health care (PCHC) services. The woman remains under the supervision of the community midwife until 6 weeks postpartum.

Care by midwives, both community and clinical and during both pregnancy and the postpartum period; gynecologists; and PCHC services is covered by a compulsory health insurance. Postpartum care by the MCAs is partly covered by health insurance and women are required to pay an out-of-pocket amount of €4.40 ($4.77 US) per hour, as of 2019, of receipt of this form of postpartum care.

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It is unclear whether women who already receive extensive postpartum care would also appreciate a web-based postpartum platform and what the content should be. Also, health care professionals, especially in postpartum care, are not familiar with using eHealth to support their work. Therefore, the aim of this study was to explore the needs and preferred content by new parents and health care professionals of a web-based platform dedicated to the postpartum period and to identify barriers and facilitators for using such a platform.

Methods

Overview

Textbox 2 details the concept of the proposed web-based postpartum platform to support continuity of care for both parents and health care professionals.

Textbox 2. Concept of the web-based postpartum platform.

Background

Women tend to have a need for easily accessible information and support during the preconception period and pregnancy. Electronic health (eHealth) has proven its potential to support women and their partners, such as in achieving a healthier lifestyle and gaining information about pregnancy and healthy lifestyle [10,25]. A web-based platform focused on the postpartum period could be an additional support for women and their partners during the postpartum period. When this web-based platform is also available for obstetric professionals and maternity care assistants (MCAs), women who have a low postpartum care uptake may be reached more easily. A web-based platform has some advantages above other forms of eHealth, such as lower development costs, less instability caused by upgrades, and easier access for all involved health care professionals.

Aim of the Web-Based Platform

The web-based platform must be an addition to regular postpartum care by MCAs for parents of the newborn. The platform focuses on information provision and prevention.

Target Group

The platform should target parents of newborns and health care professionals, including maternity care professionals, MCAs, and preventive child health care (PCHC) service professionals. Parents will look for reliable information on the web-based platform and professionals will provide this reliable information.

Design and Setting

The design of this study was a qualitative approach with focus group interviews. The focus groups were conducted in February 2018 at the Erasmus University Medical Center (Erasmus MC) – Sophia Children's Hospital, a university medical center in Rotterdam, the Netherlands.

Study Participants

Overview

Two types of users of this web-based postpartum platform were identified: (1) parents of newborns and (2) health care professionals. Parents with a child younger than 12 months were asked to participate as a target group of future users of the platform (ie, parents of newborns), hereafter referred to as parents. Several health care professionals are involved in the care during pregnancy, childbirth, and the postpartum period. We decided to split the health care professionals into two groups: MCAs and all other professionals, hereafter referred to as clinicians.

MCAs were approached to participate as potential ambassadors but also as future users of the platform during their working routine. MCAs fulfil a different role in the care for new parents than the other maternity care professionals. Their role is of a more caring nature, as they are specialized nurses. Midwives, obstetricians, and PCHC physicians have less-intensive contact with parents of newborns and are more at a distance. Additionally, MCAs work under supervision of community midwives and may feel that they cannot express themselves freely in the presence of the other maternity care professionals. Finally, clinicians such as gynecologists, midwives, and PCHC physicians were invited to participate because of their potential contribution to the content of the platform. Also, administrators involved in perinatal care, such as managers of maternity care organizations and the Dutch Patient Federation, were invited because of their potential role in the dissemination of the platform. This group will be referred to as clinicians and administrators.

To increase objectivity and prevent barriers in expressing subjective opinions and experiences, we arranged separate focus groups. All participants were recruited by email and telephone via existing networks from other studies in the Erasmus MC - Sophia Children's Hospital, such as the Rotterdam periconception cohort (Predict Study) and the Healthy Pregnancy 4 All-2 (HP4All-2) study [27,28]. We aimed to recruit 6-10 participants per focus group. In advance of the meeting, all participants received information regarding participation in a focus group, web links to existing pregnancy-related platforms, and statements on the subject.

Parents

Inclusion criteria for parents were (1) having a child born in the past 12 months before the focus group meeting took place, (2) being 18 years of age or older, and (3) having a sufficient understanding of the Dutch language. After women gave consent to participate, a member of the research team called them to ask whether their partner also wanted to join the focus group.

Maternity Care Assistants

MCAs were recruited via managers of maternity care organizations. They met inclusion criteria if they (1) had a

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sufficient understanding of the Dutch language and (2) worked as an MCA.

Clinicians and Administrators

Clinicians were eligible to participate if they worked in PCHC services or obstetric care. Also, managers of maternity care organizations and the Dutch Patient Federation were asked to participate.

Data Collection

Before the start of the focus groups, each participant was asked to fill out a questionnaire on baseline characteristics. An experienced and trained researcher (ANR) guided all three focus groups and two research assistants took notes. Each focus group was audiotaped and started with a short introduction explaining the aim of the study. Participants were reassured of confidentiality and encouraged to speak freely.

The focus groups were semistructured and based on a topic list grounded in a framework developed by Fleuren et al [29]. This theoretical framework was developed to explain determinants of innovation within health care and recognizes four main stages of innovation processes: dissemination, adoption, implementation, and continuation. In this study, we especially focused on the first two stages: dissemination and adoption. Transition from one stage to the next can be affected positively or negatively by four different factors: the end user, the innovation itself, the sociopolitical environment, and characteristics of the organization. In order to obtain a complete overview of potential barriers and facilitators, these factors were the main themes of the topic list. Subthemes were based on literature research [12,23,30-32] and divided among the corresponding main themes.

The first part of the focus groups entailed a discussion about the needs for a postpartum platform and wishes for the content of the platform (ie, general information, specific topics, and sources). Secondly, the look and feel of the platform was discussed by showing different existing platforms regarding pregnancy or older children (see Multimedia Appendix 1 for the topic list).

Data Analysis

All transcripts were transcribed verbatim and were anonymized. The verbatim transcriptions were checked with the original audiotapes for accuracy by LTL and returned for member checking to the participants. We used the qualitative software program NVivo 11 (QSR International) to support data analysis. We intended to analyze the results according to the theoretical framework based on the model of Fleuren et al [29]. However, this framework appeared to be inefficient due to too much overlap in coding. Thematic analysis was then applied. The three different transcripts were independently coded by two researchers (LTL and LJB) to create a set of preliminary codes. These preliminary codes were discussed with a third researcher (ANR) and consensus was reached on the codes per transcript. Thereafter, these codes were arranged into different main themes and subthemes for each of the transcripts. The themes, subthemes, and codes were compared between the three groups to check for similarities and differences. Themes and subthemes corresponded between the different groups, although there were differences in preferences. Therefore, the codes in the main themes and subthemes were divided into facilitators and barriers by LTL and LJB. Finally, consensus was reached on the subdivision by the three researchers (LTL, LJB, and ANR).

Ethical Considerations

The Medical Ethics Committee of Erasmus MC declared that the rules laid down in the Medical Research Involving Human Subjects Act, also known as its Dutch abbreviation WMO, do not apply to the study protocol (NL/s/MEC-2017-1134). All parents provided written informed consent; the need for written informed consent from the MCAs as well as clinicians and administrators was waived.

Results

Participants

A total of 5 mothers and 1 male partner joined the focus group for parents (see Table 1). All mothers received postpartum care for at least 24 hours.

Table 1. Characteristics of participants: parents of newborns.

Sex	Age (years)	Marital status	Education level	Ethnicity	Parity	Age of youngest child (months)	Complicated pregnancy or childbirth	Place of most recent delivery	Amount of postpartum care
Female	32	Married	High	Caucasian	1	7	No	General hospital	Recommended amount
Female	27	Married	High	Caucasian	1	3	Yes	General hospital	Less than recommended amount
Male	26	Married	High	Caucasian	N/A[a]	7	N/A	N/A	N/A
Female	34	Together, but living apart	Moderate	Caucasian	2	9	No	General hospital	Less than recommended amount
Female	33	Married	High	Caucasian	1	8	No	General hospital	Recommended amount
Female	31	Cohabiting	High	Non-Caucasian	1	9	Yes	General hospital	Recommended amount

[a]N/A: not applicable.

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In the MCA focus group, 6 MCAs participated (see Table 2). They worked at different maternity care organizations and their work experience varied from 3 to 26 years. The third focus group (ie, clinicians and administrators) consisted of 5 clinicians working in perinatal care, 1 manager of a maternity care organization, and 1 employee of the patient federation (see Table 3).

Table 2. Characteristics of participants: maternity care assistants (MCAs).

Sex	Age (years)	Ethnicity	Work experience (years)
Female	48	Caucasian	26
Female	54	Caucasian	8
Female	35	Caucasian	3
Female	53	Non-Caucasian	14
Female	50	Caucasian	3
Female	31	Caucasian	6

Table 3. Characteristics of participants: clinicians and administrators.

Sex	Age (years)	Ethnicity	Profession	Work experience (years)
Female	24	Caucasian	Manager at maternity care organization	6
Female	38	Caucasian	Community midwife	15
Female	46	Caucasian	Gynecologist	6
Female	40	Caucasian	Clinical midwife	17
Female	65	Caucasian	Preventive child health care physician	40
Female	32	Caucasian	Policy officer at Dutch Patient Federation	3
Female	37	Caucasian	Community midwife	15

Emerging Themes

We identified three different main themes regarding the need and content of a postpartum period platform: (1) information on platform, (2) additional facilities, and (3) accessibility. These three main themes were divided into various subthemes, and facilitators and barriers within these subthemes were identified (see Table 4). The main themes and various subthemes are described in detail in the Results section.

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Table 4. Main themes, subthemes, facilitators, and barriers.

Main themes and subthemes	Facilitators	Barriers
Information on platform		
General	Need for a postpartum platform[a,b,c]	For general population[a,b,c]
	Providing general information[a,b,c]	Superficial information[a,b]
	Categorized by period[a,b,c]	Registration or extra questions[a,b]
	Uniformity among information given by health care providers[a,b]	
	Statistics on outcomes[a]	
Care guidance	Advice on when to contact professional[a,b,c]	N/A[d]
	Care guidance for domestic abuse[b]	
Information topics	Psychosocial support, sleeping, crying, breastfeeding and bottle feeding, food, birth control and fertility postpartum, and older children[a,b,c]	No moderator[a]
		Recipes[a,b]
	Healthy food and diet-specific information[a,b,c]	
	Prevention[a,b,c]	
Sources	Reliable sources[a,b,c]	Funded by industry[c]
	Visibility of the sources[a,b]	
Additional facilities		
Communication	Chat function and consultation of professional[a,c]	Fixed amount of push messages[a,b]
Findability of information on the platform	Frequently asked questions on general topics[a]	N/A
	Search option[a,c]	
Accessibility		
Language use	N/A	Complicated language[a,b,c]
		Mandatory tone[c]
Look and feel	Images and footage[b,c]	Too much text[c]
		Formal layout[c]
		Shabby layout[a,b,c]
User group	Vulnerable population[b,c,e]	N/A
Findability and guidance	Easily findable[a]	Unreliable forums are easy to find[a]
	Guidance to platform by obstetric professionals[a,b,c]	Maternity care assistants (MCAs) not trained in electronic health (eHealth)[c]
Timing	Preconception to 6 months postpartum[a,b,c]	Starting during pregnancy or postpartum period[a]
	Filling gap between MCA and preventive child health care (PCHC) service[a,b]	
Authentication	Access without authentication[a,c]	Obligation to create an account and authentication[a,b,c]
	Anonymous[a,b,c]	
Costs	N/A	Paywall[a,b,c]
Device	App[a,b,c]	Email[a,b,c]

[a]Facilitators and barriers applicable to parents.

[b]Facilitators and barriers applicable to maternity care assistants (MCAs).

[c]Facilitators and barriers applicable to clinicians and administrators.

[d]N/A: not applicable.

[e]Vulnerable populations include underserved populations with multifactorial problems, including health illiteracy.

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Information on Platform

General

All user groups indicated that a platform dedicated to the postpartum period should be an all-around platform with a wide range of information, dedicated to and classified by period of pregnancy, childbirth, and the postpartum period. All parents ensured that there is a need for general information brought to them passively (eg, not in periodic emails). MCAs stated that the platform would be a good support for parents during the postpartum period. The involvement of different professionals in the whole postpartum period, such as the community midwife, MCA, general practitioner, and PCHC service, leads to a feeling of discontinuity of care among parents, according to all user groups. Parents added to this statement that they often heard different advice from different maternity professionals and PCHC services.

Both parents and MCAs acknowledged the added value of a platform that provided the same information as MCAs, offering parents a possibility to reread orally given information.

Parents also expressed the need for a platform that collected all existing reliable information of other websites. Clinicians and administrators agreed on this. All user groups stressed the existence of several platforms about pregnancy, focused on information for a general population, and that they missed personalized information; for example, specific information on how to address certain problems with the infant (eg, sleeping problems) or psychological problems as a new mother. Filling out extra questions in order to receive personalized information was, however, perceived as bothersome. This was supported by MCAs. In contrast, all groups indicated that filling out extra questions on diet and receiving personalized advice to improve their diet would be desirable. Parents and MCAs feared that generalized information could lead to anxiety among parents if their infant did not reach a developmental milestone. A solution for this was brought up by parents: providing statistics on the incidence of certain preconditions or milestones could be helpful.

> *Err what I... for example, the statistics say 10 percent of [postpartum] women gets a postpartum depression. Well, if you hear that then you think, "All right, it's not that unlikely that I don't feel well occasionally."* [Parent focus group, female]

Care Guidance

All groups experienced barriers among parents to contact the appropriate professional when problems occurred. Clear information on the platform on when to contact which professional was suggested. One of the aspects MCAs are responsible for is sharing specified information on topics regarding domestic abuse and violence. MCAs often share their private telephone numbers—although officially not allowed—with women suspected of being a victim of domestic violence. MCAs thought that providing lists of institutions and telephone numbers in different languages on the platform might be helpful and safer for themselves.

Also, MCAs felt that sometimes they had to provide information on prevention (eg, shaken baby syndrome and postpartum depression) too early, and if they could refer to the platform, new parents could read the information again and use the information when needed.

> *And it also applies to me personally, that if I would search for something [on the web-based platform] and the advice on the platform would be "consult a health care professional," then I would be more encouraged to eventually call [the professional].* [Parent focus group, male]

Information Topics

Parents stated that a platform dedicated to the postpartum period should contain specific information on several main topics regarding the mother and the infant. They felt that information on psychosocial support, physical recovery, and birth control was important. Regarding the infant, sleeping patterns, crying, and breastfeeding or artificial milk were key topics.

Clinicians and administrators mainly recognized the physical recovery as an important topic, while MCAs named breastfeeding. All user groups also suggested that the platform should contain specific information on healthy food for both mother and infant. Extra information on diet-specific information (eg, vegetarian lifestyle) was desired. Providing healthy recipes was perceived as a barrier by parents and MCAs, because this was found to be culture specific. Parents suggested that they would prefer specific information on healthy food for their infant, such as which vegetables should be introduced first. All user groups stated that coaching by periodic emails containing messages, questions, tips, and facts on a healthy lifestyle and maintaining a healthy lifestyle may be less well-placed during the postpartum period.

Both clinicians and administrators as well as parents emphasized the added value of the possibility to share experiences with other new parents. Parents commented that posting about experiences online often leads to negative comments by other parents. They thought it would scare people off if the experiences and replies were not moderated by a professional.

Sources

The information on a platform must be reliable and must be composed by decent sources, such as professionals from a hospital or professional organizations. These sources should be visible on the platform to increase the sense of reliability. This was stated by clinicians and administrators, as well as by MCAs. Parents confirmed this, and also emphasized that commercial sources reduced the perceived reliability of the platform.

> *No, those websites where you can see "this text is revised by a certain lung specialist so-and-so, from such-and-such hospital." Then I acknowledge that written text more than Parents From Now [a commercial magazine with a website, focused on young parents: Ouders van Nu, in Dutch], which is sponsored by Zwitsal [Dutch baby products brand]...* [Parent focus group, female]

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Additional Facilities

Communication

Provision of information via the platform was also discussed. MCAs and parents mentioned the possibility of push messages. Parents felt that push messages regarding healthy lifestyle were too demanding and too paternalistic. They suggested the possibility to adjust the frequency of messages. Clinicians and administrators added that push messages following a parent's question on the platform would be more convenient, and MCAs stated that messages should have a positive tone.

Both parents as well as clinicians and administrators advised to provide a chat function with a professional on the platform that would be focused on acute problems. This could be used to reassure parents regarding topics such as crying, but also to guide parents to the right professional. The clinicians and administrators remarked that the responder needed to be a trained professional. They suggested 24-hour coverage, as they experienced parents calling them during the night with problems, while parents preferred a chat function during the daytime until early in the evening.

Findability of Information on the Platform

MCAs suggested reserving a part of the platform for frequently asked questions (FAQ). Parents proposed that the questions asked most frequently during a chat conversation could be collected and added to a FAQ topic on the platform.

In order to increase the findability of information on the platform, the platform should have a search option. This was experienced as essential by parents as well as clinicians and administrators, so that the platform becomes more personalized.

> *Because at the moment you have a chat function [on the web-based portal], you will notice which questions are asked more. And then a commonly asked subject, for example, I would really like to have that [collected] in a question-and-answer database. So, accordingly, one can search for questions or complaints.* [Parent focus group, male]

Accessibility

User Group and Language Use

All user groups agreed on the use of accessible language. Clinicians and administrators perceived the use of patronizing language as a potential barrier for parents. All user groups underlined that the use of scientific words scared off potential users. MCAs as well as clinicians and administrators stated that a platform was particularly desirable for a vulnerable population with low health literacy. They agreed that the language had to be adjusted to that population accordingly, even though clinicians and administrators doubted whether this vulnerable population could be reached by a platform, as illustrated in the following quotes.

> *I think [use of] language is also very important.* [Respondent #1, clinician and administrator focus group]
>
> *Yes, just basic language.* [Respondent #2]
>
> *Yes, that you will not be patronized.* [Respondent #1]
>
> *Yes, [language level] B1, everything as much as possible in B1, yes. And explain difficult words by, for example, clicking on it. A lot of images.* [Respondent #3]

Look and Feel of the Platform

The look and feel of the platform was found to be very important by all user groups. This influenced the degree of attractiveness for the users. Clinicians and administrators as well as parents underlined the importance of a neat layout. Shabby look and feel as well as a too-formal layout were considered to be barriers for parents to visit the platform. Clinicians and administrators, especially, emphasized the use of images and footage instead of large amounts of text, in order to reach parents with lower health literacy skills.

Findability and Guidance to the Platform

In order to reach different populations, parents underlined that the platform must be easily found on online search engines. They said that unreliable forums pop up more often in search engines, and this might result in fewer people finding the platform.

Parents also indicated that if their obstetric professionals would advise them to visit the platform, that would increase the findability and value of the platform. They missed the guidance to additional information such as eHealth during regular care, especially when they were transferred multiple times between the strata in maternity care.

Clinicians and administrators as well as MCAs also stated that guiding parents to an approved platform would be better than letting parents find information on the internet themselves. Also, MCAs perceived that some of their colleagues were not able to work with a platform.

> *If my doctor would have said or something that I should do it [visiting the web-based platform], then I think I would have... if you get the advice to do it, then I would make the effort to do so.* [Parent focus group, female]

Timing

Parents indicated that they were more likely to change their lifestyle prior to pregnancy. They stated that they would more often use the platform for obtaining information during their pregnancy and postpartum period if they already used it before pregnancy. They also felt that the platform should provide information until 6 months after childbirth.

MCAs as well as clinicians and administrators saw the regular checkups during pregnancy as an important moment to refer to such a platform. MCAs underlined that parents need more guidance, particularly in the gap between the first week postpartum after the MCA has left and the start of more intensive guidance by the PCHC service.

> *And I notice that the gap, so to say, from the end of the postpartum care by MCAs until [the start of] the PCHC services, those four weeks, that is actually too long.* [Respondent #1, MCA focus group]

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Yes. [Several other respondents]

Authentication

A perceived barrier among all user groups regarding the accessibility of the platform was the obligation to create an account and log on (ie, authentication). The possibility to ask questions anonymously on the platform was preferred by all user groups. MCAs as well as clinicians and administrators experienced problems with other platforms when they had to create an account and thought that would be a problem for parents also.

> *The moment I have to log on and create an account with a password, it puts me off.* [Parent focus group, female]

Costs

The same barrier was perceived regarding paying for using the platform. Parents said that a free platform would be preferred, but if it was really useful, they would consider paying a small amount of money to gain access. Both clinicians and administrators as well as MCAs feared a paywall; they thought that, in particular, the population they wanted to reach with the platform—the vulnerable population—would not be reached if they had to pay.

> *Look, I work with very different families [during the first week postpartum], I work with families that, so to say, can't even buy a half bread, and with well-off families. Yes, you know, the communication lines [with health care professionals] are shorter, especially compared to those who have money problems.* [Respondent #1, MCA focus group]
>
> *Yes, and especially for those people—* [Respondent #2]
>
> *—you need... you need this [web-based postpartum platform].* [Respondent #1]
>
> *You really need this.* [Respondent #3]

Device

Finally, it was discussed in all three focus groups that the platform should be mobile-phone friendly. Parents said that during breastfeeding they often check their mobile phones and that this would be a great moment to search for information. MCAs as well as clinicians and administrators pointed out that even among the poor families, almost everybody has a mobile phone with internet access and that sending messages to their phones would be more convenient than emailing.

Discussion

Principal Findings

In order to develop an eHealth platform to be used by new parents but also by maternity care professionals, we aimed to explore the need for and content of a web-based platform to be used during the postpartum period. Our research showed that there is a need for such a platform, preferably until 6 months after childbirth in addition to regular postpartum care. The platform and the information on the platform should be easy to find. Also, platform developers should pay special attention to the look and feel of a platform in order to increase the usability. Topics on the platform should focus on general information about pregnancy, childbirth, and the postpartum period, but also on more personalized information. A difficulty with this is that parents emphasized the need for personalized information, but they also have a problem with authentication and filling in additional questions about their personal situation; therefore, personalization of information was limited.

Strengths and Limitations

One of the strengths of this study was the safe environment created by arranging three separate focus groups guided by an experienced moderator. Additionally, all participants were given the opportunity to express their opinions and experiences equally. Another strength was the proper qualitative health method that was used for the focus groups and analysis of the data. Furthermore, by using a framework approach, a clear topic list was used to guide the discussions in which all facets of innovation were covered. The transcripts were independently coded by two researchers, resulting in a high level of intercoder agreement.

In addition, all potential user groups of a postpartum period platform were represented. By including not only parents, MCAs, and midwives but also PCHC professionals and administrators, we had the opportunity to consider the need for a postpartum platform and the content from all perspectives. This contributed strongly to the usability and robustness of our results.

In terms of limitations, there is a possible selection bias. The participants in the parent focus group were generally of Caucasian origin and highly educated. Despite intensive attempts, only one partner, who was male, participated. This may influence the external validity of the results. On the other hand, the MCAs added rich descriptions of their experiences with clients with low socioeconomic status that were in line with the opinions expressed by the parents. Therefore, the overall influence of selection bias on the results may be limited. Another limitation of this study is that some topics were only briefly discussed due to time limitations and, therefore, depth is lacking on some topics. However, by using this approach we were able to cover a wide range of topics. This enabled us to investigate the preconditions for such a platform from a broad perspective.

Comparison With Prior Work

All user groups stated that there is a need for a platform dedicated to the postpartum period because continuity of care is missed and parents hear different advice from different professionals. Problems with handover of information and care among professionals in maternity care has gained more awareness, but was not discussed in our focus groups [26]. The feeling of a lack of continuity of care and receiving conflicting advice among parents is also supported by Baas et al [33].

Furthermore, it is well known that women experience stress, loneliness, insecurity, and feelings of isolation after childbirth [1,31]. eHealth could provide a partial solution to this problem [13,18,23,34]. However, parents in our focus group felt that eHealth is more important for access to fast and reliable

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information than to solve feelings of loneliness. A possible explanation can be the presence of the MCA during the postpartum period. Additionally, parents would like to use a platform dedicated to the postpartum period up to several months after childbirth.

The needs for the content of the platform were in line with the findings of Slomian et al [23]. General topics, such as information regarding breastfeeding, physical recovery after childbirth, postpartum depression, among others, were mentioned [23]. Accordingly, the underlying need for reassurance and empowerment was also mentioned and this is recognized among other postpartum women around the world [2]. All user groups acknowledged the added value of care guidance to the appropriate professional and it is known that eHealth can contribute to this process [9]. Push messages were experienced as essential in order to receive important information but also as irritating by parents if the content does not match topics that are important to them and could lead to extra stress. This equilibrium has been recognized in previous research [35,36]. In addition to Slomian et al, we showed that even women who receive extensive postpartum care prefer the use of a platform during the postpartum period [23,34].

Parents find it stressful if they cannot contact a professional directly [36]. A chat function is required and this may reduce the stress. This chat function does not require 24-hour coverage according to the parents, in contrast to the findings of Danbjørg [36]. The intensive presence of an MCA during the first week postpartum in the Netherlands may be an explanation for this difference.

In general, the knowledge on the importance of a healthy lifestyle before conception and during pregnancy for both mother and infant is increasing [37-39]. eHealth has the potential to support women to achieve a healthy lifestyle during the preconception period and pregnancy [12,40]. However, parents in our focus group study rejected the idea of achieving a healthy lifestyle with the use of eHealth specifically during the postpartum period and would rather see a platform with information about factors other than lifestyle, such as physical recovery and sleeping patterns of an infant. A combination of both might strengthen the platform.

To ensure the usage of the platform, maternity care professionals should guide women and their partners toward this platform, especially vulnerable women and their partners. Commercial companies already use online websites to inform pregnant and postpartum women about their products and are very experienced with this concept. Collaboration with these commercial companies may increase the knowledge on proper ways of attracting parents to the platform.

Future research should focus on cost-effectiveness and improvement of quality of care of such a platform, since it is an addition to regular postpartum care. Also, the needs and accessibility of a postpartum platform for vulnerable parents or parents with low health literacy should be taken into account in further research. For example, separate interviews with these parents could be undertaken, especially to adapt the content of the platform to their needs and preferences. A randomized controlled trial could be undertaken, targeted to a vulnerable population, in order to investigate the relationship between reliable information via a platform and maternal empowerment.

Conclusions

Parents and involved maternity care professionals foresee a need for a web-based postpartum period platform, despite the presence of MCAs during the first week after childbirth. This web-based platform ideally connects to preconception and pregnancy platforms and is accessible until 6 months after childbirth, and parents should be referred to this platform by professionals working in perinatal care. There is a need for information provision that is both easily accessible and reliable. Information on the platform should focus on general topics, such as breastfeeding, psychological support, and physical recovery after childbirth. However, the web-based platform should also be tailored to the individual needs of the parents and a chat function is advised. eHealth in the form of a web-based platform may be a suitable solution to this.

Acknowledgments

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Authors' Contributions

LTL, LJB, and ANR analyzed and interpreted all data and wrote the first version of the manuscript. RPMS-T and ANR designed the study. ANR moderated the focus group discussions. All authors revised all versions of the manuscript and approved the final version.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Topic list for a postpartum platform.
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Abbreviations

eHealth: electronic health
Erasmus MC: Erasmus University Medical Center
FAQ: frequently asked questions
HP4All-2: Healthy Pregnancy 4 All-2
MCA: maternity care assistant
PCHC: preventive child health care

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WMO: Medical Research Involving Human Subjects Act

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Original Paper

Improving Quality of Care in Rheumatoid Arthritis Through Mobile Patient-Reported Outcome Measurement: Focus Group Study

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Abstract

Background: Patient-reported outcomes (PROs) for chronic disease management can be integrated into the routine workflow by leveraging mobile technology.

Objective: The objective of our study was to describe the process of our quality improvement (QI) efforts using tablets for PRO collection in a busy, academic rheumatology practice to support a treat-to-target (TTT) approach for rheumatoid arthritis (RA) management.

Methods: Our QI team designed a process for routine collection of PROs for RA patients at the Arthritis Center, employing information technology and an electronic medical record (EMR) system. Patients received a tablet at the clinic check-in desk to complete the Routine Assessment of Patient Index Data 3 (RAPID3) survey, a validated RA PRO. RAPID3 scores were uploaded to the EMR in real time and available for use in shared decision making during routine office visits. Weekly data were collected on RAPID3 completion rates and shared with front desk staff and medical assistants to drive improvement. Patients in our patient family advisory council and focus groups provided informal feedback on the process.

Results: From May 1, 2017, to January 31, 2019, a total of 4233 RAPID3 surveys were completed by 1691 patients. The mean age of patients was 63 (SD 14) years; 84.00% (1420/1691) of the patients were female, and 83.00% (1403/1691) of the patients were white. The rates of RAPID3 completion increased from 14.3% (58/405) in May 2017 to 68.00% (254/376) in September 2017 and were sustained over time through January 2019. Informal feedback from patients was positive and negative, relating to the usability of the tablet and the way rheumatologists used and explained the RAPID3 data in shared decision making during the office visit.

Conclusions: We designed a sustainable and reliable process for collecting PROs from patients with RA in the waiting room and integrated these data through the EMR during office visits.

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KEYWORDS

quality improvement; rheumatoid arthritis

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Introduction

Background

Patient perspectives must be incorporated into chronic disease management to improve the quality of care. Patient-centered care integrates patient preferences and values into clinical decisions, and according to the Institute of Medicine, it is one of the six pillars of quality health care [1]. However, there remains a gap in how patient values and preferences are integrated into busy clinical workflows. Patient-reported outcomes (PROs) represent validated tools providing patients' perceptions of well-being and functional status [2]. PROs have been used successfully in clinical settings where the intervention can often lead to a significant change in outcome, such as oncology and joint replacement surgery [3].

Rheumatoid arthritis (RA) can lead to joint destruction and impaired functional status. Treat-to-target (TTT) approach serves as the prevailing treatment strategy for RA management, requiring clinicians to measure disease activity regularly and use these data to guide medication changes, with a goal of achieving remission or low disease activity [4-6]. In Sweden, a national rheumatology quality registry captures 85% of patients with RA and incorporates PRO in routine RA care, using a dashboard to allow patient participation and engagement in RA disease management [7]. PROs offer the promise of increasing value, improving efficiency, and enhancing shared decision making for chronic disease management; however, PROs must be implemented in a thoughtful manner that fits within busy clinical workflows [8].

The Routine Assessment of Patient Index Data 3 (RAPID3) is an RA PRO widely used in RA that has been validated and recommended as a reliable measure of disease activity and can be completed in less than 1 min by patients using a paper form [9-12]. The RAPID3 questionnaire consists of 3 sections: a physical function assessment, a global assessment for pain, and a global assessment of overall health. The RAPID3 questionnaire exclusively relies on patient-derived assessments and does not require input from the clinician.

Objectives

We describe our initial quality improvement (QI) process leveraging mobile technology by using tablets to collect the RAPID3 disease activity scores from RA patients before office visits. The RAPID3 data are immediately available to rheumatologists in the electronic medical record (EMR) and can be used for shared decision making between rheumatologists and patients. We assessed patient satisfaction on the usability of tablets and their perceptions of how RAPID3 data were used within the clinical visit.

Methods

Setting

We conducted our QI work at an outpatient rheumatology practice within a large academic medical center, which uses a vendor-based EMR (Epic) and a patient portal for EMR access. Approval from the Partners Institutional Review Board was waived as this study was part of a larger QI initiative. There were 55 rheumatology attendings and fellows who see RA patients at the Arthritis Center with full-time and part-time schedules and 5 medical assistants. Front desk staff were shared with our adjacent orthopedics outpatient practice and radiology outpatient suites. There were approximately 500 rheumatology patients seen per week, with 15.0% (75/500) having a diagnosis of RA and thus eligible for a tablet to complete the RAPID3 PRO questionnaire.

Software Development and Information Technology Support

The Arthritis Center purchased tablet devices for PRO collection. Tablets were approved and encrypted by our health care delivery system information technology and PRO team. Tablets were placed in a protective case for storage, charged nightly, and kept on a cart behind the front desk. Staff sanitized the tablets between each use and at the beginning and end of each day. The health care delivery system information technology and PRO team provided support for (1) customizing the tablets with the RAPID3 questionnaire, (2) programming International Statistical Classification of Diseases-Tenth Revision (ICD-10) codes for RA into the tablets, (3) repairing and replacing tablets, and (4) conducting staff training pertaining to the use of tablets in the clinic. The PRO team customized the initial programming and data displays for the tablets based on input from the QI team.

Patient Perspective

We obtained patients' perspective on the tablet questionnaire completion and the use of RAPID data in discussions with the rheumatologist during the office visit informally. We conducted seven focus groups as part of our broader QI initiative, 3 focusing on general experience of RA patients and four focusing on shared decision making [13]. We also created an RA patient family advisory council (PFAC), which is a group of patients who are invited to serve as members to help provide patient feedback and input on various RA clinic processes. During our focus groups and our regularly scheduled RA PFAC meeting, we asked patients about their experiences with the RAPID3 questionnaire completion in the waiting room and their perceptions of the use of RAPID3 during office visits.

Quality Improvement and Process Redesign

This pilot for using tablets to collect RAPID3 PROs was a part of a larger QI initiative designed to integrate a TTT approach for the management of RA into the outpatient rheumatology practice. A team of stakeholders, including rheumatologists, nurses, pharmacists, medical assistants, front desk staff, practice leadership (managers and medical director), project coordinators, and QI leadership, met to develop the pilot program. We assessed patients' perspective regarding the use of tablets for the collection of PROs through informal qualitative feedback from patient focus groups and our RA PFAC [13].

Multiple small group meetings were held, and a series of small plan-do-study-act (PDSA) cycles took place to develop a workflow that was effective for reliable and sustainable PRO collection. In PDSA cycle 1, front desk staff were given instructions on how to provide RA patients with tablets;

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however, given the lack of a clear reminder, patients were often missed. In PDSA cycle 2, a project coordinator created a daily list of all RA patients with appointments and gave this list to the front desk staff. As the daily list was not used in the busy front desk staff workflow, patients continued to be missed. In PDSA cycle 3, front desk staff were trained on how to identify eligible RA patients through the schedule view in the EMR; however, we found that not all front desk staff could reliably use this visual cue when there were multiple patients checking in for appointments, and patients continued to be missed.

In PDSA cycle 4, we convened the administrative leadership of the clinic and the front desk staff together to meet with our QI team and discuss barriers and workflows and redesigned the workflow. We found that if patients received the tablet but were brought from the waiting room to the examination room for their visit, they did not always have enough time to complete the RAPID3 questionnaire, leading to a higher volume of questionnaires that were started but not completed. We educated our medical assistants, the staff who bring patients from the waiting room to the examination room to do vital signs, to remind patients to complete the questionnaires. We also started sending weekly emails with the rates of RAPID3 completion to the front desk staff and administrative leadership. With the combination of leadership support and accountability and a better understanding of front desk workflows, we found that by month 4 of our pilot, rates of completion had increased substantially.

Workflow and Process

All rheumatology patients presented to a central front desk area that was shared by the rheumatology, radiology, and orthopedic departments. Patients with a diagnosis of RA were identified through the initial programming of the tablets via ICD-10 codes, and an icon was displayed on the EMR scheduling interface used by the front desk staff, denoting that a particular patient should receive a tablet during their check-in process.

The front desk staff entered patients' appointment codes into the tablet and provided patients with the tablet along with instructions to fill out the RAPID3 questionnaire while in the waiting room. A medical assistant was responsible for bringing patients from the waiting room to the examination room. If patients did not complete the RAPID3 questionnaire before the medical assistant called them for their appointment, patients were instructed to bring the tablet into the examination room and complete the questions before the rheumatologist entered the room (see Figure 1). Used tablets were given to the medical assistant, who then returned the tablets to the front desk staff.

Figure 1. Process flow map of patients and Arthritis Center staff for RAPID3 completion on tablets in waiting room. This figure delineates the process from when patients present to the front desk for their rheumatology office visit to completion of the Routine Assessment of Patient Index Data 3 patient-reported outcome either in the waiting room or in the examination room. EMR: electronic medical record; MA: medical assistant; RA: rheumatoid arthritis; RAPID: Routine Assessment of Patient Index Data.

Pilot Study

In May 2017, we began piloting the use of tablets for the RA PRO RAPID3 questionnaires for all RA patients in our Arthritis Center. Weekly emails were sent out to the front desk staff and practice leadership identifying the total number of eligible patients who should have received the tablet but did not, patients who received the tablet but did not complete the RAPID3 questionnaire in its entirety, and patients who received and fully completed the RAPID3 questionnaire. Selected rheumatologists participated in a QI initiative that included attending monthly meetings to promote engagement in a TTT approach for RA through education and training on the use of RAPID3 for RA patients.

Data Analysis

We present proportions and means of sociodemographic characteristics of patients who completed the RAPID3 questionnaire. We used the SPSS version 24 software for the analysis.

Results

Between May 1, 2017, and January 31, 2019, a total of 4233 RAPID3 surveys were completed by 1691 patients. Table 1 shows the sociodemographic characteristics of patients who completed the RAPID3 questionnaire. We found that 82.70% (1398/1691) of patients were female, with a mean age of 61.6 (SD 14.4) years, 82.30% (1391/1691) were white, 60.00% (1014/1691) reported that they were married or in a civil union, and 54.70% (890/1691) had a college degree or higher level of

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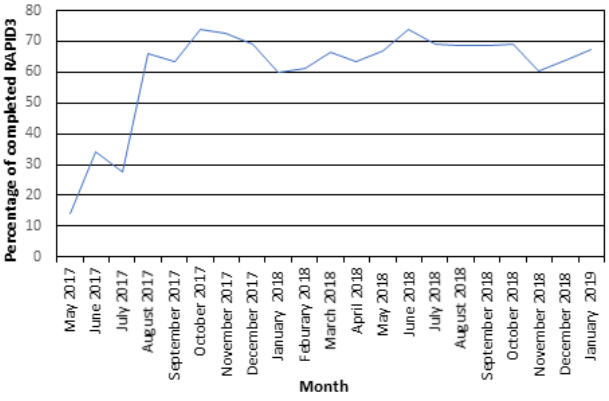
education, and 45.30% (766/1691) of the patients who completed the questionnaire did not have a college degree.

During the study, the overall monthly completion rate of RAPID3 PROs improved, increasing from 14.3% (58/405) in May 2017 to 67.5% (254/ 376) in January 2019, with a sustained rate of greater than 63.3% (210/331) after September 2017 (Figure 2). Informal feedback from patients in our focus groups and our PFAC was both positive and negative: positive feedback centered around the ease of use of the tablet-based PRO and short duration needed to complete the RAPID3 questionnaire; however, patients perceived that rheumatologists did not use RAPID3 data during office visits.

Table 1. Characteristics of rheumatoid arthritis patients who completed the Routine Assessment of Patient Index Data 3 questionnaire (May 2017 to January 2019; N=1691).

Patient characteristics	Values
Female, n (%)	1398 (82.70)
Age (years), mean (SD)	61.8 (14.40)
Race (white American), n (%)	1385 (82.30)
Marital status (married or/civil union), n (%)	1014 (60.00)
Education level (graduated from college, graduated from school, or postgraduate), n (%)	890 (54.70)

Figure 2. Routine Assessment of Patient Index Data 3 rheumatoid arthritis patient-reported outcomes percent completion rate from May 2017 to January 2019. This figure shows the rate of Routine Assessment of Patient Index Data questionnaire completion 14.3% (58/405) in May 2017 to 67.5% (254/ 376) in January 2019, with a sustained rate of greater than 63.3% (210/331) after September 2017. RAPID3: Routine Assessment of Patient Index Data.



Discussion

Principal Findings

These pilot data illustrate that the use of tablets to collect RA PROs in real time while patients are awaiting their rheumatology appointment can be integrated successfully into the clinic workflow. We demonstrated that these efforts can be sustainable through the use of a multi-stakeholder collaboration between our Arthritis Center staff, our information technology staff, PROs teams, and our QI team. We used an iterative, continuous QI approach with PDSA cycles to modify our process over time.

RAPID3 data reporting was a challenge at times because of changes in the governance within and developing infrastructure of our PROs team. For example, calculating weekly completion rates of RAPID3 questionnaires was conducted through data extraction from a centralized reporting dashboard by our QI team. However, to measure RAPID3 scores, as the centralized dashboard had as yet to offer data export, we had to conduct manual chart reviews in the EMR and link this with a data extract obtained manually from our IT PROs team. Moving forward, the PROs team has created a new centralized data infrastructure to support local ambulatory practices and to support teams extracting customized data and reports to drive improvement efforts. Incorporating PROs within the clinic visit presents a major challenge in a busy ambulatory clinic setting. In other conditions where PROs are collected, questionnaires may be distributed to all patients to facilitate the ease of data collection. Electronic PROs have also been implemented system wide with more general health-related quality of life questionnaires but require strong senior administrative leadership support and local clinic buy-in for success [14]. In our study, we provided the RAPID3 questionnaire only to RA patients. However, patients present with competing clinical priorities during routine follow-up visits; therefore, reviewing and discussing the RAPID3 data may not always be a shared priority for patients and rheumatologists. Within focus groups, some patients reported that the rheumatologist might state the RAPID3 score, but the patient did not know what the score meant and thus could not understand how the RAPID3 score was being used in the clinical discussion.

Much of the value in PROs in clinic comes from assessing symptom severity, informing treatment decisions, tracking outcomes, and prioritizing patient-provider discussions [15]. As the RAPID3 questionnaire measures global patient pain and functional status for RA patients, the completed answers on the questionnaire are readily available to rheumatologists during the office visit and can promote shared decision making when

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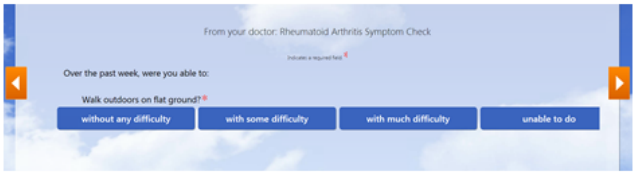
patients are not doing well. The RAPID3 data can be trended over time graphically, allowing the rheumatologist to show these data to the patient during the office visit. The drawback of the RAPID3 questionnaire is that the pain score may be driven by non-RA–related pain; this can confuse patients and clinicians when considering whether treatments require changing.

Strengths and Limitations

The use of the RAPID3 tool itself has both strengths and limitations. Key strengths are the ease and speed to complete the RAPID3 questionnaire without medical professional supervision, and the lack of additional components to calculate the score such as laboratory results or joint counts (Figure 3). In particular, our project shows that the RAPID3 questionnaire can be completed by patients with varying educational levels because we found that less than half of our patients who completed the questionnaire did not have a college degree.

Figure 3. Screenshot of the Routine Assessment of Patient Index Data 3 patient-reported outcome questionnaire. This figure is a depiction of what the patient sees when they are completing the Routine Assessment of Patient Index Data 3 questionnaire on the tablet with a single question per screen in an easy-to-use display.



Limitations include the fact that the RAPID3 global pain score is generic, so pain that is attributable to etiologies other than RA may hyperinflate the RAPID3 score; this issue can negatively impact the buy-in from rheumatologists to use the data to inform shared decision making for RA management. However, we recognize that patient engagement in shared decision making is an important aspect of medical care delivery and patient satisfaction with medical care, and PROs can help achieve this [16]. Literacy may also impact the completion of a PRO.

Conclusions

We plan to expand the use of RAPID3 as an RA PRO across all of our rheumatologists and to integrate shared decision making into our daily practice of RA management following the TTT strategy. By reviewing RAPID3 scores with patients during office visits, discussing their meaning in relation to RA and other medical conditions, and integrating the routine measurement of disease activity into RA management, we can increase the use of a TTT approach for improving the quality of RA care.

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Conflicts of Interest

None declared.

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Abbreviations

EMR: electronic medical record
ICD-10: International Statistical Classification of Diseases-Tenth Revision
PDSA: plan-do-study-act
PFAC: patient family advisory council
PRO: patient-reported outcome
QI: quality improvement
RA: rheumatoid arthritis
RAPID: Routine Assessment of Patient Index Data
TTT: treat-to-target

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Original Paper

Reliability, Feasibility, and Patient Acceptance of an Electronic Version of a Multidimensional Health Assessment Questionnaire for Routine Rheumatology Care: Validation and Patient Preference Study

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Abstract

Background: A multidimensional health assessment questionnaire (MDHAQ) that was developed primarily for routine rheumatology care has advanced clinical research concerning disease burden, disability, and mortality in rheumatic diseases. Routine Assessment of Patient Index Data 3 (RAPID3), an index within the MDHAQ, is the most widely used index to assess rheumatoid arthritis (RA) in clinical care in the United States, and it recognizes clinical status changes in all studied rheumatic diseases. MDHAQ physical function scores are far more significant in the prognosis of premature RA mortality than laboratory or imaging data. However, electronic medical records (EMRs) generally do not include patient questionnaires. An electronic MDHAQ (eMDHAQ), linked by fast healthcare interoperability resources (FIHR) to an EMR, can facilitate clinical and research advances.

Objective: This study analyzed the reliability, feasibility, and patient acceptance of an eMDHAQ.

Methods: Since 2006, all Rush University Medical Center rheumatology patients with all diagnoses have been asked to complete a paper MDHAQ at each routine care encounter. In April 2019, patients were invited to complete an eMDHAQ at the conclusion of the encounter. Analyses were conducted to determine the reliability of eMDHAQ versus paper MDHAQ scores, arithmetically and by intraclass correlation coefficient (ICC). The feasibility of the eMDHAQ was analyzed based on the time for patient completion. The patient preference for the electronic or paper version was analyzed through a patient paper questionnaire.

Results: The 98 study patients were a typical routine rheumatology patient group. Seven paper versus eMDHAQ scores were within 2%, differences neither clinically nor statistically significant. ICCs of 0.86-0.98 also indicated good to excellent reliability. Mean eMDHAQ completion time was a feasible 8.2 minutes. The eMDHAQ was preferred by 72% of patients; preferences were similar according to age and educational level.

Conclusions: The results on a paper MDHAQ versus eMDHAQ were similar. Most patients preferred an eMDHAQ.

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KEYWORDS

patient reported outcomes; health status measures; electronic version; rapid3; mdhaq

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Introduction

A multidimensional health assessment questionnaire (MDHAQ) [1-3] has been completed by all patients at all visits to one of the authors (TP) since 1982, based on initial evidence that patient questionnaire scores for physical function are significant in the prognosis of work disability and premature death in rheumatoid arthritis (RA) [4]. Paper MDHAQ data for all patients were entered into databases (Paradox, Access) in the 1990s to provide serial flowsheets of patient scores, laboratory data, and medications, which informed clinical decisions [5]. Clinical research using MDHAQ databases has advanced knowledge concerning the prognosis of mortality [6-8], importance of socioeconomic status [7,9,10], value of methotrexate [11,12], value of low-dose glucocorticoids [13], and recognition of depression [1,14] in RA and other rheumatic diseases.

The MDHAQ is completed by all patients at several rheumatology sites, including New York University Hospital for Joint Diseases (since 2005), a private practice in Ridley Park, PA (since 2006), Rush University Medical Center (since 2006), and Liverpool Hospital in Australia (since 2013) [15]. However, the patients continue to complete a paper MDHAQ despite the use of electronic medical records (EMRs) at each of these sites, as the EMR generally has not included patient questionnaires. Databases of paper MDHAQ data from routine care have been entered into electronic research databases to recognize that disease burden in osteoarthritis is similar to RA [15], and to develop indices such as routine assessment of patient index data 3 (RAPID3) [16-18] and a fibromyalgia assessment screening tool (FAST3). RAPID3 is the most widely used RA index in the United States [19,20], and comparable to disease-specific indices to recognize changes in clinical status in patients with all other rheumatic diseases which have been studied [21-23].

An electronic MDHAQ (eMDHAQ), linked to an EMR through fast healthcare interoperability resources (FHIR), could enhance clinical care with serial flowsheets, enable remote patient completion before or between scheduled visits to report problems, and reduce costs and errors in retrospective data entry of paper versions for clinical research. This report presents analyses of the reliability, feasibility, and patient acceptance of an eMDHAQ.

Methods

Ethics and Consent

The Rush University Institutional Review Board waived the requirement for patient consent in the completion of patient questionnaires, as the questionnaire is a component of routine care, analogous to a laboratory test, that provides quantitative quality measures to guide clinical decisions. The database used in this study is part of the Rush University Patient-Reported Outcomes Studies approved by the Rush University Institutional Review Board, with a waiver for patient consent for retrospective data analysis (14090502-IRB02-AM03). The eMDHAQ is regarded as an extension of efforts to implement quality measures.

Patients

Since 2006, all patients with all diagnoses seen by all clinical rheumatologists at Rush University Medical Center (14 in 2019) have been asked to complete a paper MDHAQ at each visit to provide quality measures in routine care [24]. Since the introduction of the Epic EMR at Rush in 2011, all completed MDHAQs have been scanned into the EMR as PDFs, incorporated into each patient's encounter record.

In April 2019, all rheumatologists were asked to request that patients older than 18 years complete an eMDHAQ on an iPad at the conclusion of the encounter, indicating that the patient could decline for any reason. This study was conducted during routine care, as has been the case in all development of the MDHAQ/RAPID3 other than retrospective analyses of clinical trial results to compare RAPID3 to traditional RA indices [24]. Clinicians were not asked to collect formal records of how many patients were asked to volunteer or how many refused. An informal query indicated that most patients declined because of a need to leave the clinic.

The MDHAQ

The paper MDHAQ was developed over 25 years as a 2-page patient self-report questionnaire, completed in 5-10 minutes, although no formal studies of time for completion have been reported. The MDHAQ includes patient self-report quantitative scores for physical function (FN), 3 visual numeric scales (VNS) for pain, patient global assessment (PATGL), and fatigue, a self-report painful joint count, termed the rheumatoid arthritis disease activity index (RADAI) [25], which is informative in many rheumatic diseases [26], a 60-symptom checklist [27,28], exercise status [29], morning stiffness, and change in status [27]. The MDHAQ queries recent patient medical history information, including possible surgery, hospitalizations, new medications, adverse medication events, changes in medications, and demographic data such as gender, ethnicity, and years of education. A long version of the MDHAQ (termed "4 page version" in paper format) for new patients includes past medical history, illnesses, allergies, family history, social history, comparable to a standard "intake" questionnaire for new patients [24].

MDHAQ scores have been developed into 4 indices. RAPID3 includes 3 scores of 0-10 within the MDHAQ for physical function, pain VNS, and PATGL VNS, which are compiled into a score of 0-30 [16,23,30,31]. FAST3 is a 0-3 cumulative index based on RADAI ≥16 (=1), symptom checklist ≥16 (=1), and pain and/or fatigue VNS ≥6 (=1) [32,33]; a score ≥2/3 for FAST3 agrees more than 80% with the polysymptomatic distress scale, which is the basis for the 2011 revised formal fibromyalgia criteria [32,33]. PSYCH3 (Psychological Index 3) includes queries for sleep quality, anxiety, and depression [1,14]; as a screening tool, it shows good agreement with the Centers for Epidemiologic Studies Depression Scale [1]. MEDI60 is based on the symptom checklist and has been used for remote electronic monitoring of adverse events and patient status without face-to-face patient visits [28].

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Databases

As noted above, all completed MDHAQs have been scanned as PDFs into the Epic EMR since its introduction at Rush University Medical Center in 2011 as a quality component of the encounter record. A proposed eMDHAQ/RAPID3 presented by Epic in 2015 lacked flowsheets to depict serially patient scores, reports of specific new symptoms on the MDHAQ checklist to facilitate a physician's review of systems, and other features that had enhanced the efficiency of patient care in the pencil-and-paper data entry versions as early as the 1990s and early 2000s [24]. As features beyond straightforward scores could not be made available, an electronic MDHAQ was developed in 2015-16 with the FHIR interface to be compatible with the Epic EMR, which is termed ClinDat.

The ClinDat software is managed by ZiteLab, a Copenhagen information technology company that has managed a Danish rheumatology registry called DANBIO (initially designated "Danish Biologics Registry") since 2002. DANBIO currently includes self-report data from more than 50,000 patients; these data have been analyzed in more than 200 published reports [34,35]. The ClinDat software was designed to be compliant with the Health Insurance Portability and Accountability Act (HIPAA), with direct patient entry of MDHAQ responses linked to an EMR through FHIR. Database management includes flowsheets depicting MDHAQ scores, laboratory test results and medications, and possible automated encounter reports, as was previously available with paper entry in the 1990s [5].

Relatively early adoption of ClinDat for routine patient care was anticipated; however, administrative delays have persisted to date. Therefore, in 2016, a decision was made to ask a research assistant or associate to enter selected scanned MDHAQs into ClinDat for specific research protocols. Protected health information, including name, date of birth, and medical record number, has not been entered into ClinDat pending approval by Rush University. ClinDat assigns a unique identifier to each patient; the unique ClinDat number is linked to protected health information in a local Excel spreadsheet on the Rush University server.

Research studies based on retrospective analysis of the ClinDat database were conducted at Rush University from 2016-2019. In one such study, it was found that according to RAPID3 and other MDHAQ scores, the disease burden in patients with osteoarthritis is similar to and often greater than that seen in patients with RA, contrary to traditional paradigms [15,36]. Discordance of global assessments by patients and physicians was found to be significantly associated with female gender, low socioeconomic status, and high pain scores [37]. MDHAQ/FAST3 was found to be in 80% agreement with formal fibromyalgia criteria [33]. The MDHAQ/MEDI60 symptom checklist has been used in remote electronic monitoring to recognize adverse events and their resolution with clinical improvement [28].

The content of the eMDHAQ is identical to that of the paper version; it is presented on 6 screens to minimize scrolling. For the study described in this report, the ClinDat unique identifier of each volunteer (or a new number for a few "new" patients) was entered into the tablet by office staff before the tablet was given to the patient. The patient then completed all eMDHAQ items on the tablet without any further interaction with the staff member before returning the tablet to the staff member.

The patient was then asked to complete a brief paper self-report questionnaire with 3 items. The first 2 items were VNS queries which were identical to those for pain, global assessment, and fatigue on the MDHAQ: A. "How helpful do you feel the questionnaire is to you to help communicate with your doctor?" B. "How helpful do you feel the questionnaire is to your doctor to help communicate with you?" The anchors were "0=not helpful at all" and "10=very helpful." The third item was a simple query: "Which version do you prefer?" with 3 response options: "computer," "paper," and "doesn't matter."

The comparison of the eMDHAQ to the paper version is regarded as a quality improvement project and is exempt from patient consent by the Rush University Institutional Review Board. The paper MDHAQ was entered into the ClinDat database at a later time.

Data Analysis

Descriptive statistics were calculated for mean, range, and SD or proportion of patients according to demographic data and diagnosis. The paper and electronic MDHAQ scores were compared for reliability using paired t-tests for continuous variables and the McNemar test for binary variables. Reliability was also examined according to the intraclass correlation coefficient (ICC) with 95% CI; values less than 0.5 indicate poor reliability, 0.5-0.75 indicate moderate reliability, 0.75-0.9 indicate good reliability, and >0.90 indicate excellent reliability [38]. Feasibility was analyzed as the time to complete the eMDHAQ. Patient preference was analyzed according to the proportion of patients who responded that they preferred the eMDHAQ or paper MDHAQ or had no preference; the proportions were calculated for all patients, and according to age (≤65, >65 years) and formal education (<12, 12, or >12 years). The level of statistical significance was set as $P<.05$. All analyses were conducted using STATA 12.0 for Mac (StataCorp LP).

Results

Among the 98 patients in the study, the mean age was 53.8 years (range 21.0-88.0, SD 16.6); 87 (89%) were female, 47 (48%) were white, 26 (27%) were black, and 25 (25%) were members of other ethnic groups. The patients had various ICD-10 diagnoses, which were assigned by the treating rheumatologist (Table 1). These patients appear to represent a typical cross-sectional group of patients seen in an academic rheumatology setting according to age, gender, and diagnosis.

The electronic and paper MDHAQ mean scores (SD) were almost identical (Table 2).

Differences ranged from –0.4 to 0.7 and were all within 2% of one another; no scores differed significantly, either clinically or statistically. The ICC for the symptom checklist was 0.86, indicating good reliability, and all other ICCs were greater than 0.92, indicating excellent reliability (Table 2).

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None of the volunteer patients reported difficulties using the iPad. The mean time to complete the 6-screen eMDHAQ was 8.2 minutes, indicating good feasibility. For the patient self-report paper questionnaire, the mean VNS rating (0-10, where 10=very helpful) of how helpful the MDHAQ was to the patient was 8.8 (SD 1.7); the mean rating of how helpful the MDHAQ was to the physician was 8.7 (SD 1.9). Patient preferences were 72% for the electronic version versus 7% for the paper version, while 21% noted no preference. Preferences did not differ meaningfully according to age or level of education (Table 3).

Table 1. Demographic characteristics and diagnoses of the patients included in the study (N=98).

Characteristic	Value
Age (years), mean (range, SD)	53.8 (21.0-88.0, 16.6)
Female gender, n (%)	87 (89)
Ethnicity, n (%)	
White	47 (48)
Black	26 (27)
Other	25 (25)
Education level (years), mean (range)	14.6 (4-20)
Diagnosis, n (%)	
Rheumatoid Arthritis	18 (18)
Osteoarthritis	15 (15)
Systemic lupus erythematosus	11 (11)
Osteoporosis	6 (6)
Fibromyalgia	5 (5)
Spondyloarthropathies	3 (3)
Vasculitis	3 (3)
Other	37 (38)

Table 2. Scores and test-retest reliability of patient-reported measures on the MDHAQ in paper versus electronic format for patients seen in routine care (N=98).

Paper iPad Diff. (95% CI) ICC (95% CI)	Paper MDHAQ[a] score, mean (SD)	Electronic MDHAQ score, mean (SD)	Difference (95% CI)	ICC[b] (95% CI)
Physical function (0-10)	1.8 (1.6)	1.8 (1.6)	0.003 (–0.4 to 0.5)	0.97 (0.97 to 0.98)
Pain VNS[c] (0-10)	4.7 (3.1)	4.9 (3.2)	–0.1 (–1.0 to 0.7)	0.95 (0.92 to 0.97)
PATGL[d] VNS (0-10)	4.2 (2.7)	4.4 (2.8)	–0.2 (–1.0 to –0.6)	0.96 (0.95 to 0.98)
Fatigue VNS (0-10)	3.3 (3.0)	3.5 (3.1)	–0.1 (–1.0 to 0.7)	0.95 (0.93 to 0.97)
RAPID3[e] (0-30)	10.8 (7.0)	11.2 (6.9)	–0.4 (–2.3 to 1.6)	0.98 (0.97 to 0.99)
60- Symptom checklist (0-60)	9.9 (8.8)	9.7 (8.6)	0.3 (–2.1 to 2.7)	0.86 (0.79 to 0.91)
Self-report RADAI[f] painful joint count (0-48)	10.5 (10.1)	9.7 (9.4)	0.7 (–2.0 to 3.5)	0.92 (0.88 to 0.95)

[a]MDHAQ: multidimensional health assessment questionnaire.

[b]ICC: intraclass correlation coefficient.

[c]VNS: visual numeric scale.

[d]PATGL: patient global estimate.

[e]RAPID3: Routine Assessment of Patient Index Data 3.

[f]RADAI: Rheumatoid Arthritis Disease Activity Index.

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Table 3. Preferred version of the MDHAQ according to patient age and education level, n (%).

Patient demographic	Paper MDHAQ[a]	eMDHAQ	No preference
Age (years)			
≤65 (n=69)	5 (7)	50 (72)	15 (21)
>65 (n=28)	2 (7)	19 (71)	6 (22)
Education (years)			
<12 (n=9)	1 (11)	7 (78)	1 (11)
12 (n=18)	1 (6)	13 (72)	4 (22)
>12 (n=68)	4 (6)	48 (70)	16 (24)
Total (N=95)	6 (6)	68 (72)	21 (21)

[a]MDHAQ: multidimensional health assessment questionnaire.

Discussion

The eMDHAQ performed similarly to the traditional paper MDHAQ. All ICCs were greater than 0.86, indicating good to excellent reliability of the 2 versions; these values are as high as those seen in most comparisons in clinical medicine. For example, an earlier report compared electronic and paper versions of RA core data set measures [38,39], indicating ICCs for a swollen joint count of 0.78 and for a tender joint count of 0.83; ICCs for RA indices which include a formal joint count were 0.85 for Disease Activity Score 28 and 0.89 for the Clinical Disease Activity Index. In an earlier study, the ICC for the self-report physical function was 0.96, that for pain was 0.88, that for patient global assessment was 0.78, and that for RAPID3 was 0.90 [38], compared to 0.97, 0.95, and 0.96, and 0.98, respectively, in the present study (Table 2). The higher ICCs in the present study may be explained in part by the 5-7 day interval between measures in the earlier study compared to 1-2 hours in the present study; also, patients seen at Rush University Medical Center have extensive experience with the MDHAQ. The previous data are presented to document that the ICCs of the measures reported by patients were somewhat higher than those obtained by physicians.

The mean time required to complete the eMDHAQ was 8.2 minutes, which appears to be acceptable. Formal studies have not been reported for the time to complete a paper MDHAQ, although informal observations over more than 30 years suggest that 5-10 minutes are required. In general, <10 minutes appears to be acceptable, although some patients likely will require more time, as is the case with the paper version.

Approximately two-thirds of patients expressed a preference for the electronic version of the MDHAQ. However, no specific information was collected concerning the number of patients who declined to complete an eMDHAQ in the routine care setting. It is reassuring that no meaningful differences in preference or reliability were seen according to age or education level, although it is anticipated that problems with completion of an eMDHAQ will be more likely in older or less educated patients, as has been seen with the paper MDHAQ; thus, differences may emerge with larger numbers of patients. However, several reports indicating poor clinical status associated with low formal education level [7,9,40] required completion of a patient questionnaire by the patients analyzed in the studies. A small fraction of patients preferred the paper version, and it is anticipated that a paper version will be offered to some patients even after the eMDHAQ is incorporated into routine care.

Clinical decisions in rheumatology patients are based more on information from a patient history than in many chronic diseases in which decisions are dominated by a “gold standard” biomarker, such as blood pressure in hypertension or serum glucose in diabetes [41]. A patient self-report questionnaire depicts components of a “subjective” [42] patient medical history as structured, quantitative, standard, protocol-driven, data which meet criteria for the scientific method [43,44]. Physical function reported on a patient questionnaire is far more significant in the prognosis of premature mortality in RA than any laboratory or imaging data [4,6,45] and is as significant as smoking to predict mortality in a nondiseased elderly population [46].

The value of RAPID3 in rheumatology care [19,20,22] is attributable in part to its capacity to depict change in clinical status in all rheumatic diseases studied to date [21,22], while the patient does almost all the work. Nonetheless, availability of additional MDHAQ scales provide a clinician with considerably more information than only RAPID3, for fatigue [47], RADAI self-report painful joint count [26], adverse events of medications and their resolution [28]. Traditional medical history queries on the MDHAQ save time for patients and doctors [31].

Quantitative RAPID3 scores are highest in patients with fibromyalgia [48], which is seen as a comorbid condition in 20–40% of patients with RA, OA, and many rheumatic diagnoses [49-51]. Clinical improvement is far less likely in patients with comorbid fibromyalgia with any diagnosis than in patients who have this diagnosis and no evidence of fibromyalgia. A further MDHAQ index, FAST3 (fibromyalgia assessment screening tool) may be used to screen for fibromyalgia [32,33], and potentially explain unchanged RAPID3 scores in RA patients with comorbid (secondary) fibromyalgia. FAST3 includes the RADAI self-report painful joint count and symptom checklist [32,33], and therefore is not available when only RAPID3 is queried.

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The eMDHAQ was developed using FHIR as an internal format to save data in a Zope object database, with capacity to interface with any EMR in the management of individual patients. Further description of such integration is beyond the scope of the present study, which was focused on reliability of the eMDHAQ and its acceptability to patients. Establishment of these features is regarded as an important future stage in development of an eMDHAQ for implementation in routine clinical care.

This study has several important limitations. First, all patients completed the paper MDHAQ as a usual component of routine care before seeing the rheumatologist, and they completed the eMDHAQ at the conclusion of the visit. Ideally, half might have completed the eMDHAQ initially in a formal study, but such a study would have presented increased costs, logistic complexities, and an extra burden to patients in a setting at which all patients complete an MDHAQ routinely. Second, patient recall of previous completion of the MDHAQ approximately 30-90 minutes earlier could have influenced the second recording. Third, neither the number of patients who declined to participate nor the reasons for declining were recorded in a routine care setting; in general, clinicians reported informally that patients who declined participation noted other scheduled activities, but some patients may have wished to avoid the computer version. Fourth, patient preference for the electronic version may be attributed in part to a "Hawthorne effect," with further attention from a research professional and a new approach. At the same time, many patients had completed many paper MDHAQs previously, and a bias to favor the familiar paper version could have been present. The eMDHAQ appeared acceptable to most patients, although provision for a paper version for some patients is anticipated in clinical implementation of an eMDHAQ for routine care.

The analyses reported here focused on cross-sectional reliability, which is regarded by institutional information technology professionals and developers as a prerequisite for further work toward use of an eMDHAQ in routine care. Several adjustments to the workflow will be needed to implement an eMDHAQ in routine care; these details remain to be addressed in the next phases of development. Further programming and collaboration with EMR vendors for exchange of eMDHAQ data with the EMR, using FHIR available within the software, is anticipated.

An eMDHAQ presents advantages to allow completion at home before scheduled visits, rather than in the waiting area, and remotely between visits to document status when patients report disease flares or adverse medication events. Data entered by patients can be transferred to the hospital EMR using FHIR and can be made available on the physician's computer screen. The ClinDat software for the eMDHAQ described in this report may partially overcome the problem of incompatibility of different EMRs [52] and the costs of data entry to analyze long-term outcomes of multiple rheumatic diseases in routine care, as it may be possible to facilitate pooling of deidentified data from multiple settings to establish a cost-effective multicenter database to assess clinical status and responses to therapies [34,53,54]. The preliminary results presented in this report suggest further steps toward implementation of an eMDHAQ for routine care.

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Conflicts of Interest

TP is the president of Medical History Services LLC and holds a copyright and trademark on MDHAQ and RAPID3 for which he receives royalties and license fees, all of which are used to support further development of quantitative questionnaire measurements for patients and doctors in clinical rheumatology care.

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Abbreviations

EMR: electronic medical record
eMDHAQ: electronic multidimensional health assessment questionnaire
FAST3: Fibromyalgia Assessment Screening Tool 3
FHIR: fast healthcare interoperability resources
ICC: intraclass correlation coefficient
MDHAQ: multidimensional health assessment questionnaire
PATGL: patient global assessment
RA: rheumatoid arthritis
RADAI: Rheumatoid Arthritis Disease Activity Index
RAPID3: Routine Assessment of Patient Index Data 3
VNS: visual numeric scale

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Original Paper

Assessing Feasibility of an Early Childhood Intervention Using Mobile Phones Among Low-Income Mothers of Newborns: Qualitative Interview Study

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Abstract

Background: Many children aged younger than 5 years living in low- and middle-income countries are at risk for poor development. Early child development (ECD) programs are cost-effective strategies to reduce poverty, crime, school dropouts, and socioeconomic inequality. With the spread of low-cost mobile phones and internet access in low- and middle-income countries, new service delivery models such as mobile phone–aided interventions have a great potential to improve early childhood development.

Objective: This study aimed to identify the beliefs on importance of ECD, feasibility of a proposed intervention using mobile phones and factors that may affect the usability of the intervention among mothers of newborns in a poverty-stricken area in southwestern China.

Methods: We conducted an in-depth, semistructured interview study of 25 low-income mothers of newborns recruited from two county hospitals in Yunnan Province. We applied the health belief model and cultural competence theories to identify the facilitators, barriers, and preferences among the target population for parenting knowledge.

Results: The results showed that the participants had low health literacy and high perceived needs for learning ECD knowledge. At the same time, they experienced several barriers to learning parenting information and following evidence-based instructions including having limited time, limited financial resources, and different opinions on childcare among family members. Many participants preferred to receive personalized messages tailored to their specific needs and preferred videos or graphics to text only in the messages. Many favored a separate module to support postpartum mental health.

Conclusions: The study assessed the acceptability of an early childhood intervention using mobile phones to meet the needs of the target population based on their beliefs, traits, and preferences and provided suggestions to refine the intervention to improve its usability.

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KEYWORDS

mobile health; interview; health belief model; early child development

Introduction

Early child development (ECD) has been shown to link with long-term health outcomes and well-being. Between 2004 and 2010, the number of children aged younger than 5 years who were at risk for poor development in low- and middle-income countries (LMICs) decreased from 279.1 million to 249.4 million [1-4]. There were 17.43 million at-risk children in China, and geographic disparities remained significant [1]. Prevalence of developmental delays in a low-income rural county in Northeast China was found to increase from 13.4% when the infants reached 6 to 12 months to 50.4% when they reached 24 to 30 months, while in most urban areas of China this prevalence remained under 10% [5,6]. In certain regions of China, risk factors for developmental delays such as inadequate learning resources and activities were prevalent [7]. A household survey conducted among a representative sample of children aged 3 to 6 years in southwestern China found that 72% of the primary caregivers had not played with their children and 47% did not read to them in the past year [8].

ECD programs are cost-effective strategies to reduce poverty, crime, school dropouts, and socioeconomic inequality [9-12]. Targeted interventions have been implemented in the poorest areas of China focusing on nutrition supplement and early stimulation [13]. Parenting education provided in health check-ups, home visiting, and ECD centers have shown to be efficacious in some pilot studies [7]. However, it is challenging to scale up those programs due to limited resources available for a population of huge density, especially in remote areas where medical professionals are in short supply.

Currently, with the spread of low-cost mobile phones and internet access in LMICs, new service delivery models such as mobile phone–aided interventions (mHealth) have a great potential to influence ECD at the population level [14,15]. Short message services (text messages) and smartphone apps have proven to be successful in changing parents' beliefs and behaviors surrounding early child development. The intervention for parenting education covers a wide range of topics such as breastfeeding, nutrition, developmental milestones, anticipatory guidance, language and cognition-oriented activities, car seats, fire safety, etc. However, it has been found that compared with well-off families, caregivers with lower income, education, and literacy were less likely to enroll in mHealth programs, so the programs were of less benefit to the low-income people [16].

Previous studies identified possible incentives for low-income people to engage in mHealth programs, including financial incentives and need for better health for their children. However, barriers were also found such as culture and beliefs, limited battery life of mobile phones combined with the lack of readily available electricity, rates of interrupted mobile phone services, mistrust or stronger desire to preserve privacy, and lower technological literacy [16-19]. These issues must be elucidated and addressed before well-designed interventions can reach their intended audience and produce meaningful public health outcomes. Previous reviews have found that most effective public health programs are based on an understanding of the health behaviors and the contexts in which they occur with behavior change theories [20]. The health belief model (HBM), one of the most widely used theoretical models of health behaviors, has been applied most often for health concerns that are prevention-related and asymptomatic, where beliefs are as important or more important than overt symptoms [21]. As early child development lies more on the desire of parents of achieving better health and development rather than just management of certain diseases, we believe it is most suitable for our study.

This study aimed to identify the demand for ECD knowledge, acceptability of a promising ECD intervention using mobile phones, and factors that may affect the usability of the intervention among mothers of newborns in a poverty-stricken region of China. We employed a qualitative research method in this study because the rich data obtained through this method regarding participants' perceptions, preferences, and barriers are highly aligned with the study's purpose and scope. Results from this study will be used to support the design and implementation of the ECD intervention using mobile phones.

Methods

Interview Sites

In March 2019, we conducted 25 semistructured in-depth interviews among mothers of newborns recruited from two county hospitals in Yunnan Province, southwestern China: the Maternal and Child Health Hospital in Nanjian County and the People's Hospital in Jinggu County, both large hospitals where the majority of infants in the two counties were delivered. These two counties compose China's most poverty-stricken area based on the percentage of people below the national poverty line. The study was approved by the institutional review board at the University of Georgia (STUDY00005670).

Theoretical Framework

We applied the HBM and cultural competence theories to identify the preferences and barriers among the target population for receiving and practicing evidence-based parenting knowledge [22]. HBM has been used in a broad range of behavioral interventions including interventions to increase screening, reduce risky behavior, and improve adherence to medication regimen [23-26]. In its latest version, the key constructs of the model include cues to action and self-efficacy and perceived susceptibility, severity, benefits, and barriers [27]. Studies have shown that parental perception regarding the healthy development of their young children often involves perceived barriers to take action [28-30]. Behavioral change will not occur if parents' perceived barriers outweigh perceived benefits [31].

In addition, although our target population did not have language barriers when reading ECD messages, they might have cultural beliefs that were not consistent with the evidence that supports

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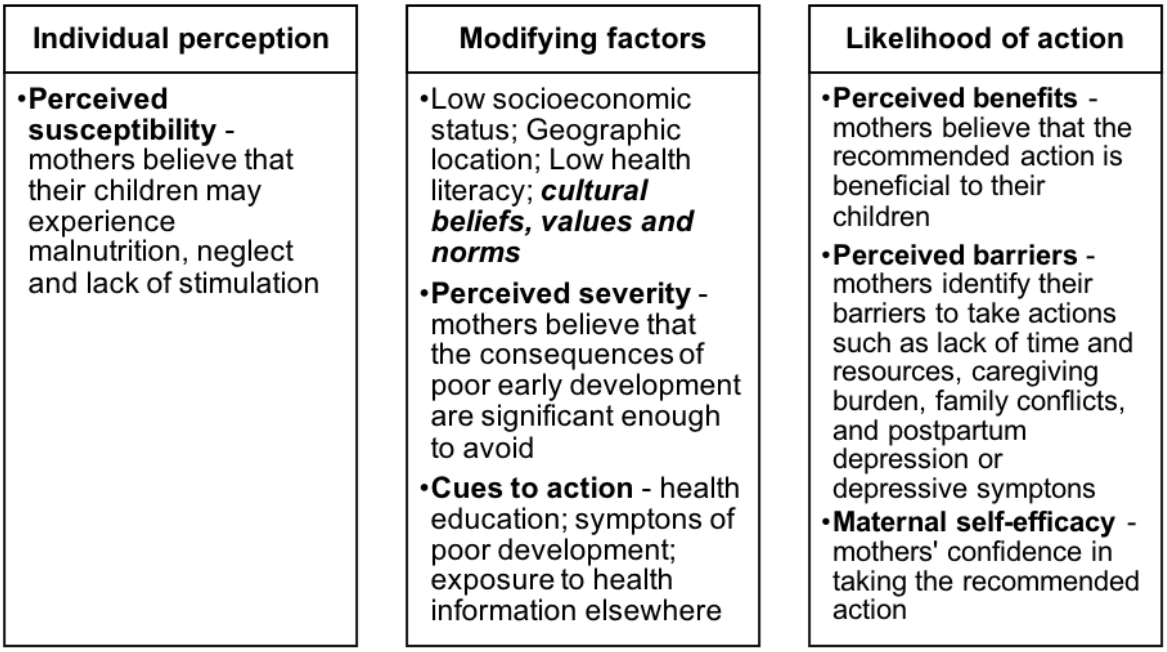
child healthy development. Culturally competent approaches recognize and respect the cultural beliefs, norms, and values of the target population and aim to improve effectiveness of the intervention [32,33]. Therefore, in our theoretical framework, cultural beliefs and norms were included as a modifying factor (Figure 1).

Figure 1. Theoretical framework based on the health belief model.



Study Sites and Participants

The inclusion criteria were the study participants should be in good health with no severe delivery complications or clinical diagnosis of postpartum depression and have a healthy infant aged less than 1 month.

Two physicians assisted in identifying and recruiting potentially eligible participants through the hospital wards. The 25 participants were recruited in the local hospitals through criterion sampling. We reached sample saturation with 25 participants, until a point where additional interviews did not develop new theoretical insights. In other words, sampling was stopped when the data were repetitive and our research questions had been answered. To examine their eligibility for the study based on the criteria, electronic medical records were retrieved to scan for any recorded delivery complications or diagnosed depression. Informed consents were obtained from all participants who met the inclusion criteria and agreed to participate in the study.

Data Collection

Two trained interviewers (DZ and YZ) conducted the in-depth interviews in private rooms at the hospitals. We developed an interview guide based on the theoretical framework (Figure 1) pertaining to the design of the mobile health intervention. These topics included (1) mothers' individual perceptions about the importance of avoiding adversities in the early years; (2) benefits and barriers when feeding and nurturing newborns according to recommendations sent over the phone; (3) family socioeconomic status, family structure, relationship, beliefs, and values related with adhering to the recommendations; (4) concerns about privacy; and (5) preferences for the frequency of receiving messages. During the interview, the Edinburgh Postnatal Depression Scale, Chinese version, was used to evaluate mothers' mental health status [34,35]. Participants were shown sample text messages and were asked questions about the messages. The message included about 600 Chinese characters and two pictures with four sections: (1) weekly achievement, showing easily identifiable developmental milestones; (2) weekly care, providing relevant information on baby's daily care; (3) weekly game, showing examples of age-paced games and parent-child activities including playing games, singing nursery rhymes, reading, and drawing; and (4) weekly question and answer, providing answers to common questions asked by parents. The interview was designed to begin with sociodemographic questions followed with questions according to each construct in the HBM.

Interviews were conducted on a one-on-one basis. Each interview lasts approximately 60 to 90 minutes. To aid in recruitment, ¥100 (US $15 in 2019) was provided to each participant. All interviews were tape recorded with participant permission.

Data Analysis

Interviews were transcribed verbatim and entered into qualitative analysis software NVivo 12 (QSR International). A coding structure based on the interview guide was iteratively developed to label specific content from the interviews. The transcripts were coded separately by two members of the study team (DL and RG). After coding, the two team members met to discuss the results and resolve any disagreements in coding by consensus.

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Results

Participant Demographic Characteristics

Table 1 shows the characteristics of the 25 participants. Their average age was 28 years. More participants lived in urban regions than in rural regions (56% [14/25] vs 44% [11/25]). Most participants (10/25, 40%) were ethnically Han Chinese, 32% (8/25) were Yi, and 16% (4/25) were Dai Chinese. Overall, 48% (12/25) of newborns were male. The majority of the infants' primary caregivers (18/25, 72%) were mothers, while 12% (3/25) were grandparents. A total of 40% (10/25) of the mothers finished middle school, and 28% (7/25) obtained some college education, while 16% (4/25) finished only elementary school. Half of the participants (13/25, 52%) were unemployed, and 28% (7/25) had a full-time job; 48% (12/25) of participants reported that the main source of family income was from their husband. About half (13/25, 52%) of the participants had household income below ¥5000 (US $750) per month, whereas 52% (13/25) of them reported they were willing to spend between ¥1000 (US $150) and ¥2000 (US $300) on childcare, and 28% (7/25) reported they were willing to spend more than ¥2000 (US $300). A majority of the participants (23/25, 92%) were not receiving public financial aid. Most (23/25, 92%) were married, and 40% (10/25) lived in extended families with 7 or more family members.

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Table 1. Participant demographic characteristics (n=25).

Characteristics	Value
Age in years, mean (SD)	28.08 (6.55)
Region, n (%)	
Urban or township	14 (56)
Rural	11 (44)
Race/ethnicity, n (%)	
Han	10 (40)
Yi	8 (32)
Hui	2 (8)
Dai	4 (16)
Yao	1 (4)
Sex of the newborn, n (%)	
Male	12 (48)
Female	11 (44)
No response	2 (8)
Primary caregiver of the baby, n (%)	
Self (mother of the baby)	18 (72)
Grandparents of the baby	3 (12)
Self and grandparents	3 (12)
No response	1 (4)
Education of the mother, n (%)	
Elementary school	4 (16)
Middle school	10 (40)
High school	1 (4)
Some college	7 (28)
Four-year college	3 (12)
Employment of the mother, n (%)	
Full-time employment	7 (28)
Self-employed	5 (20)
No employment	13 (52)
Household main income source, n (%)	
Double income	7 (28)
Husband’s income	12 (48)
Family farm or business	4 (16)
Income from parents-in-law	1 (4)
No response	1 (4)
Estimated household income per month (¥), n (%)	
<5000	13 (52)
5000-10,000	8 (32)
≥10,000	4 (16)
Expenditures on the baby per month (¥), n (%)	
<1000	2 (8)
1000-2000	13 (52)

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Characteristics	Value
≥2000	7 (28)
Don't know	3 (12)
Receiving government financial aid, n (%)	
Yes	2 (8)
No	23 (92)
Marital status, n (%)	
Married	23 (92)
Married but live separately	1 (4)
Married with no official certificate	1 (4)
Number of family members in the household, n (%)	
3 or 4	5 (20)
5 or 6	10 (40)
7 and more	10 (40)
Number of children in the household, n (%)	
1	5 (20)
2	18 (72)
3	2 (8)

Participant Health, Work, and Breastfeeding Behavior

Table 2 shows participant health status and lifestyle. All participants self-reported having good health. Most participants had a low risk of postpartum depression with a depression scale score below 13, but 6 people (24%) had a relatively high risk of depression, although no clinical diagnosis of depression was reported. A total of 76% (19/25) of participants reported light to moderate workload for doing housework, and 64% (16/25) of participants would spend more time on childcare than on other things, while 20% (5/25) reported that they would spend more time on family business, housework, or farm work. Most participants (16/25, 64%) had no difficulty in breastfeeding, while 28% (7/25) did not start breastfeeding, and one participant reported having no breastfeeding plan because she had hepatitis B. A majority of the participants (18/25, 72%) planned to breastfeed for 6 months to 1 year, and 12% (3/25) planned to breastfeed for less than 6 months.

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Table 2. Mothers' health, work, and breastfeeding behavior (n=25).

Characteristic	Value, n (%)
Self-reported health status, good health	25 (100)
Depression scale	
Yes (≥13)	6 (24)
No (<13)	19 (76)
Housework load	
Light	19 (76)
Heavy	4 (16)
Don't do housework	1 (4)
No response	1 (4)
Time allocation on childcare and other things	
Spend more time on business, housework, or farm work	5 (20)
Spend more time on childcare	16 (64)
Spend equal amount of time on childcare and work	3 (12)
No response	1 (4)
Breastfeeding status	
Having no difficulty in breastfeeding	16 (64)
Not having started breastfed	7 (28)
Formula feeding	1 (4)
No plan to breastfeed	1 (4)
Breastfeeding plan	
6 months	3 (12)
6 months to 1 year	18 (72)
More than 1 year	2 (8)
No plan to breastfeed	2 (8)

Interview Themes

Perceived Needs for Learning Early Child Development Knowledge

Around half of participants were concerned about baby's health issues such as having a cold, fever, acute diseases, adverse reaction to vaccination, tobacco exposure, sleep, and other illnesses, and 3 participants worried about baby's behavioral problems—for instance, they expressed concerns about their child being spoiled by grandparents and developing bad habits (Multimedia Appendix 1). Two participants expressed the need to learn baby's cognitive development, and another 2 participants worried about safety issues. Most participants thought it was necessary to learn ECD knowledge. When asked to describe interesting topics in ECD, most participants mentioned baby's growth and milestones, nutrition, breastfeeding, and complementary feeding. Some participants mentioned that they were interested in parent-child interactions and baby's social-emotional development. Several participants were interested in mental health support for mothers. Sample responses included: "I want to learn whether his growth is normal, and how parents should interact with him." "My first child often caught cold probably because I did not have enough breastmilk. For my second child I want to know how to prevent cold" and "I would like to learn about safety issues. My home is near the street. It is dangerous for the kids. I worry about safety when he starts to learn walking."

Some participants reported that they did not learn parenting knowledge before giving birth to this child, whereas many learned parenting knowledge from books and the internet, and only 2 reported having learned ECD knowledge from health care professionals. A majority of the participants perceived that they had limited ECD knowledge, and some didn't feel the need to learn parenting knowledge. One response was, "I want to know more about how to take care of my baby when he is getting old, and how to help him recover without taking medicines when he is sick." Some participants thought that parenting information they found online was inconsistent, and they perceived the necessity to promote the child's early development.

Perceived Usefulness and Barriers to Learn and Practice Parenting Knowledge

Many participants were willing to learn ECD knowledge from health professionals. One response was, "I want to learn parenting knowledge from experts. If it doesn't take a lot of

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time, I am willing to follow experts' suggestions. I can read the messages after my baby sleeps at night. I don't have time during the daytime."

Some participants responded that they did not have barriers in following experts' advice, but many expressed that they had difficulties following experts' suggestions because they had limited time and financial resources, limited experiences, and their children did not react as expected or they had different opinions with family members. Some examples were, "I have to go to work. I may not have time to follow experts' suggestions on childcare," "I think the biggest obstacle for me is that if the experts recommend a new-brand formula which is very expensive, I will not follow their suggestions," and "I may not follow the experts' recommendation when my child's grandparents have different opinions on parenting."

Maternal Self-Efficacy

Many participants illustrated that they made decisions on childcare by themselves or together with their husband. Some participants responded that their husband made the decision about childcare, and some illustrated that their mother-in-law made the decision.

Overall, most participants said they had good relationships with family members, while some expressed that they did not have good relationships with their parents-in-law. Many participants said they preferred to follow health professionals' suggestions in caring for their babies when there was a conflict between experts' and family members' suggestions, while 2 participants replied that they preferred to follow family members' suggestions. However, only 4 participants were willing to communicate with their family members the knowledge they learned from professionals or persuade them to take the evidence-based advice, and some participants said they would not persuade family members because their parents had limited ability to understand the knowledge.

Preferences for the Design of the Intervention

Almost all participants had a smartphone and had access to internet on their phones, and only 1 person shared the smartphone with her husband. Almost all participants preferred to receive messages via smartphone apps, and half of them preferred to receive the messages once a week, while 9 participants preferred to receive the messages every day or twice a week. Overall, most participants responded that they would keep and share the messages and won't delete them. A majority of the participants were willing to receive personalized information based on their child's characteristics. One response was, "I would prefer to receive personalized suggestions. My child is different from other kids." However, several mothers preferred to receive general messages and stated that they would like to keep their baby's information confidential.

When asked if they were willing to search for answers from health professionals when having questions, many participants preferred to consult with pediatricians at the county hospital, some preferred to communicate via phone with professionals in large hospitals remotely, and some of them would search for answers online. Most of them expressed that they did not trust village doctors and were more likely to ask for opinions from doctors at larger health care facilities.

Raised Suggestions to Modify the Message Contents

When shown the sample text message, 11 mothers spent on average less than 3 minutes to read one message, and 10 mothers spent 3 to 5 minutes to read one message, and 4 of them spent more than 5 minutes.

Some participants emphasized that they were very interested in the weekly game section. One participant illustrated, "parent-child interaction is very beneficial for the healthy development of the child's personality." Another participant described that "I like the section of parent-child interaction. Every mom enjoys playing games with their child." Some mothers expressed that they liked the weekly care section on nurturing, teething, or mood management.

Most participants considered the message understandable, and some indicated that they preferred videos and pictures to text. A few said that they did not understand even though they were literate enough to read the text. One response was, "it may be better if the messages can be conveyed via a video. I can easily understand the messages by watching a video." Further, 3 participants suggested that the messages should include a platform for interaction between receivers and health care professionals. One response was, "I like the weekly question and answer section because I would like to have a platform where specific questions are answered by the experts."

Discussion

Principal Findings

This study focused on assessing feasibility of an ECD intervention using mobile phones to meet the needs of mothers of newborns based on their beliefs, traits, and preferences. By interviewing 25 mothers, we enhanced our understanding of the necessary elements for an ECD intervention to be acceptable to low-income communities and determined the factors that may affect the usability of the intervention. From the demographic information, the samples in our study were distributed evenly in rural and urban areas and covered a variety of races. The majority of mothers we interviewed reported under ¥5000 (US $750) estimated household income per month. Overall, the samples in our study fitted our targeted ECD intervention, which was mothers of newborn children from the poverty-stricken area.

The results indicated that mothers living in high-poverty regions of China had strong perceived demand for understanding the risk of poor childhood development. They had limited knowledge on ECD and needed evidence-based information. They were concerned that children may experience health problems such as malnutrition and poor cognitive development. From this perspective, we believe that the general guidance on how to deal with common disease and malnutrition as well as anticipatory guidance on development should be easily accessed in the mHealth program to increase the motivation of use. Furthermore, they realized that parent-child interaction played a vital role in ECD. The participants expressed their interests to learn how to read books and play games with their child.

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Therefore, education information on those aspects should be maintained in the mobile phone–aided intervention.

In terms of likelihood of action, the participants believed that learning parenting knowledge would help them better understand the child's needs. However, perceived barriers such as having limited time and resources, different opinions in childcare among family members, and distrust of village doctors exist, which may affect whether participants follow the evidence. Therefore, it might help to expand the mobile health program to incorporate training for local doctors and community health workers, in order to build a trustworthy relationship between parents and local health professionals [36]. In addition, many participants lived with their parents, who may influence their decision making, and several participants reported that their husband or mother-in-law made decisions on childcare. Although some indicated that they would prefer to follow the evidence-based information, they were still concerned that their parents or parents-in-law would insist on the traditional beliefs. A potential approach to address this barrier is to create a shared account among family members so that everyone in a household can learn ECD knowledge. It is worth noting that some participants had a high risk of postpartum depression based on the cutoff point of our screening tool, and messages/sections on postpartum mental health support should be incorporated in the ECD intervention.

As for the feasibility and ideas on the ECD app content, we found most participants had access to the internet and smartphones, thus the mobile health program was feasible for this population. However, the participants had relatively low breastfeeding rate/attempts and low health literacy, and thus multimedia (eg, video, graphics, and text) and plain language should be applied to make the content more understandable. Visuals help make the information more persuasive and memorable [37], which is particularly important for people with low health literacy [38]. Plain language with a concise and organized writing style helps participants better understand the messages. Moreover, since the participants indicated that they didn't have much time due to childcare responsibilities, text message that took more than 5 minutes to read might be lengthy for them. Prior studies have proven that media-assisted interventions, such as video episodes, can increase the reach and reduce the cost and time for parent education; these are also parents' strongest preferences [39,40]. Therefore, instead of using text, we plan to create 1-minute videos in the new designed app conveying parenting knowledge and early childhood interventions to decrease learning time and make learning more convenient and attractive for the parents.

Limitations

We did not specifically interview mothers whose children are at older ages, and their needs for parenting education could be different with those moms who have a newborn child. However, we did interview several moms who already have an elder child, so we were able to retrieve some information on this end.

Conclusion

Our study proposed that mHealth should be considered as one of the techniques in interventions on ECD due to its feasibility, low cost, and potential to cover a wide range of the population. This was the first study to ever understand the beliefs and barriers for a mobile phone–based intervention to improve ECD in a high-poverty region in southwestern China. We conclude that even in poverty-stricken areas, both the technology and the health literacy meet the requirement for the implementation of mHealth programs. Furthermore, this study brought out some potential ideas to make it more feasible when applied on the ground. The results of the study will aid in the development of potentially effective early childhood programs in underserved regions in LMICs.

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Authors' Contributions

FJ designed the framework and coordinated the fieldwork. For any further questions regarding the study design and content, please contact: fanjiang@shsmu.edu.cn.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Interview questions and answers based on the health belief model.
[DOCX File , 20 KB - formative_v4i5e17179_app1.docx]

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Abbreviations

ECD: early child development
HBM: health belief model
LMIC: low- and middle-income countries
mHealth: mobile health

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Original Paper

A Patient Safety Educational Tool for Patients With Chronic Kidney Disease: Development and Usability Study

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Abstract

Background: Chronic kidney disease (CKD) is a health condition that threatens patient safety; however, few interventions provide patient-centered education about kidney-specific safety hazards.

Objective: We sought to develop and test the usability of a mobile tablet–based educational tool designed to promote patient awareness of relevant safety topics in CKD.

Methods: We used plain language principles to develop content for the educational tool, targeting four patient-actionable safety objectives that are relevant for individuals with CKD. These four objectives included avoidance of nonsteroidal anti-inflammatory drugs (NSAIDs); hypoglycemia awareness (among individuals with diabetes); temporary cessation of certain medications during acute volume depletion to prevent acute kidney injury (ie, “sick day protocol”); and contrast dye risk awareness. Our teaching strategies optimized human-computer interaction and content retention using audio, animation, and clinical vignettes to reinforce themes. For example, using a vignette of a patient with CKD with pain and pictures of common NSAIDs, participants were asked “Which of the following pain medicines are safe for Mr. Smith to take for his belly pain?” Assessment methods consisted of preknowledge and postknowledge surveys, with provision of correct responses and explanations. Usability testing of the tablet-based tool was performed among 12 patients with any stage of CKD, and program tasks were rated upon completion as no error, noncritical error (self-corrected), or critical error (needing assistance).

Results: The 12 participants in this usability study were predominantly 65 years of age or older (n=7, 58%) and female (n=7, 58%); all participants owned a mobile device and used it daily. Among the 725 total tasks that the participants completed, there were 31 noncritical errors (4.3%) and 15 critical errors (2.1%); 1 participant accounted for 30 of the total errors. Of the 12 participants, 10 (83%) easily completed 90% or more of their tasks. Most participants rated the use of the tablet as very easy (n=7, 58%), the activity length as “just right” (rather than too long or too short) (n=10, 83%), and the use of clinical vignettes as helpful (n=10, 83%); all participants stated that they would recommend this activity to others. The median rating of the activity was 8 on a scale of 1 to 10 (where 10 is best). We incorporated all participant recommendations into the final version of the educational tool.

Conclusions: A tablet-based patient safety educational tool is acceptable and usable by individuals with CKD. Future studies leveraging iterations of this educational tool will explore its impact on health outcomes in this high-risk population.

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KEYWORDS

patient safety; chronic kidney disease; patient education; mhealth

Introduction

Chronic kidney disease (CKD) is characterized by progressive loss of kidney function and increases the risk of adverse patient safety events [1]. As kidney function declines, renal clearance is reduced, which can result in elevated and potentially hazardous circulating levels of medications. For example, individuals with CKD and concomitant diabetes who are on antidiabetic medications are at heightened risk of developing hypoglycemia due to the delayed renal clearance of these therapies [2]. Furthermore, as CKD progresses, susceptibility to hemodynamic changes or nephrotoxins such as nonsteroidal anti-inflammatory drugs (NSAIDs) is amplified, significantly increasing the risk of acute kidney injury (AKI) development and accelerated renal function decline [3,4].

Despite these well-established risks, patient awareness of CKD and of its potential safety hazards remains low, which limits the effectiveness of current CKD treatment strategies [5,6]. A high prevalence of limited health literacy among individuals with CKD [7] and poor patient-provider communication about CKD and its risk factors all contribute to low awareness and ineffective patient self-management among individuals with kidney disease [8]. Consequently, behaviors linked with CKD risk and progression, such as NSAID use, are commonly reported by individuals at high risk of adverse outcomes [9]; however, few interventions have been developed to address these challenges and attenuate risks.

We hypothesized that educational tools tailored to audiences with low health literacy can increase disease awareness and improve self-management among individuals with kidney disease. Therefore, we sought to develop a digital educational tool to promote patient awareness of relevant patient safety issues in CKD. Here, we describe the development of this educational tool; our experience usability testing its digital platform among the target patient population; and the results of our assessment of the users' experience with the educational tool.

Methods

Educational Tool Development

This tablet-based educational tool was developed to support patient awareness of important disease-specific patient safety topics relevant for individuals with CKD. The tool was designed to evaluate participants' awareness of common safety risks associated with reduced kidney function and to provide education regarding optimal patient-centered behavior to minimize risk. Materials were designed for low health literacy audiences, as it is estimated that the health literacy of approximately 25% of the general CKD population is inadequate [10]. The educational content was developed using Adult Learning Theory and plain language principles [11]. The andragogy theory of adult learning by Malcolm Knowles (Adult Learning Theory) postulates that adult learning is motivated by 6 principles: (1) the need to know, or "why" a person should learn; (2) a foundation or experience that provides the basis for learning activities; (3) a self-concept, or the idea that adults need to be responsible for and take charge of their learning; (4) readiness to learn stemming from perceived relevance of the knowledge to be gained; (5) orientation, or the concept that adults learn best with task-oriented learning that exercises their problem-solving ability; and (6) internal motivation [11]. The educational content of the tool draws on this framework to promote CKD awareness and self-management.

The educational objectives of the tool were based on patient safety topics relevant to individuals with reduced renal function based on prior work examining adverse safety events in CKD [1,12-14]. Educational content was created using previously derived educational materials addressing patient safety in CKD [15]; this content was reviewed and refined by adult educational curriculum experts using a rubric based on Adult Learning Theory [16]. The educational material encompassed four patient safety objectives pertaining to CKD: (1) avoidance of NSAIDs [17,18], (2) hypoglycemia awareness (among individuals with diabetes) [19], (3) temporary cessation of certain medications during acute volume depletion (ie, "sick day protocol") [5,20,21], and (4) iodinated contrast risk awareness [22-24] (Table 1).

The developed teaching strategies optimized human-computer interaction and content retention. The hypothetical experiences of 2 diverse patients (Mr. Smith and Mrs. Johnson), with Hispanic and African American backgrounds, respectively, were used to provide clinical context (Figure 1). Simple animations accompanied the audio presentations in real time and emphasized key concepts [11,25]. Visual images and audio were chosen in consideration of information clarity, participant involvement, and captions to meet participant comprehension needs [26,27] (see Multimedia Appendices 1 and 2).

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Table 1. Patient safety objectives, aims, instructional content, teaching strategies, and assessment methods of the developed tool.

Patient safety objective and aim	Instructional content	Teaching strategies	Assessment methods
NSAIDs[a]			
To distinguish safe pain medications for individuals with CKD[b] from unsafe ones	Description of common pain medications available over the counter, their common names/brands, and their safety for use by individuals with CKD	Auditory explanations with complimentary graphics that include photographs of common brands of pain medication and their safety for CKD, linked with a clinical scenario and questions regarding a hypothetical patient experiencing pain	Clinical scenario of a second hypothetical patient experiencing pain, interactive questions that use photographs of common brands of pain medications and ask the learner to distinguish between safe and unsafe pain medications
"Sick day protocol"			
To be aware of the symptoms of volume depletion and the potential danger associated with taking certain medications during volume depletion	Description of common scenarios linked with volume depletion (eg, diarrhea, vomiting, fever); list of different medications that can harm the kidneys if taken during volume depletion (eg, diuretics and ACE[c] inhibitors)	Auditory explanations with complimentary graphics that include photographs of medications to be withheld during volume depletion, linked with a clinical scenario and questions regarding a hypothetical patient experiencing volume depletion	Clinical scenario of a second hypothetical patient with volume depletion and interactive questions that ask the learner to choose which medications should be withheld during a "sick day"
Hypoglycemia			
To understand the concept of hypoglycemia and the elevated risk of hypoglycemia in individuals with CKD	Description of the link between CKD and diabetes, how diabetic therapies can lead to hypoglycemia, and common symptoms of hypoglycemia	Auditory explanations with complimentary graphics that include photographs of a glucometer with a low blood sugar reading, linked with a clinical scenario and questions regarding a hypothetical patient experiencing signs and symptoms of hypoglycemia	Clinical scenario of a second hypothetical patient with hypoglycemia and interactive questions that ask the learner to choose medications that could lead to hypoglycemia and steps that should be taken if the patient suspects they have hypoglycemia
Contrast dyes			
To understand how medical tests that use contrast dyes can further harm already weak kidneys	Description of common medical tests that use contrast dyes and emphasis on the importance of informing health care providers about their CKD	Auditory explanations with complimentary graphics that include descriptions of common medical tests, linked with a clinical scenario and questions regarding a hypothetical patient undergoing a medical test	Clinical scenario of a second hypothetical patient undergoing a medical test and interactive questions that ask the learner to distinguish between safe and unsafe medical tests for individuals with CKD

[a]NSAIDs: nonsteroidal anti-inflammatory drugs.

[b]CKD: chronic kidney disease.

[c]ACE: angiotensin-converting enzyme.

Figure 1. Example of an educational tool vignette.

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Usability Testing

We recruited 12 patients receiving care from outpatient CKD clinics at Duke University Hospital in fall 2016 and again in early 2018. Individuals who were non–English-speaking, illiterate, physically unable to use a tablet (ie, individuals with limb amputation, debilitating arthritis, or legal blindness), on dialysis, or under the age of 18 years were excluded. If interested, patients were taken to a private room, where written consent was obtained and testing was initiated. The study was approved by the Institutional Review Board of Duke University. All participants were compensated for their time.

Testing Protocol

The usability testing was based on the performance of the users and their ability to answer questions and navigate the educational tool on a tablet device. Participants were given a pair of headphones connected to an Android tablet (Samsung Galaxy Tab A, model SM-T550). Once seated comfortably, participants were asked to complete a series of tasks designed to evaluate their ability to interact with the technical aspect of the safety tool (Multimedia Appendix 3). All participants were asked to complete a minimum of 52 tasks and a maximum of 67 tasks based on their diabetes status. The study facilitator remained in the room with the participant and monitored the ease or difficulty with which tasks were completed as well as participant commentary about the activity. Task completions were categorized as no error, noncritical error, or critical error. If the participant had no difficulty completing the task independently, the task was marked as no error (easily completed). A noncritical error was defined as a task that was completed with an alternative strategy. For example, if a participant chose a wrong answer but made the correction before selecting "check my answers," the error was categorized as noncritical. A critical error was defined as a task that could not be completed independently by the participant without assistance from study personnel. After completing the tool, participants were asked to evaluate their user experience with the tool.

Statistical Analysis

No formal hypothesis testing was performed in this analysis due to the qualitative study methods of usability testing. Participants' demographic characteristics and their typical use of the internet and mobile devices were described using counts and percentages. Participant satisfaction using the educational tool and the tablet was recorded. Critical and noncritical errors were evaluated for each subject along with the time to complete each exercise. Errors and completion times were analyzed to recognize any significant differences between participants who regularly use the internet and mobile apps and participants who do not.

Results

Usability Testing

Twelve participants took part in the usability testing of the patient safety educational tool. The majority of participants were aged 45 years and older (11/12, 92%) and were female (7/12, 58%) (Table 2). The races of the participants were diverse. All participants had at least completed high school and owned a mobile device that they used daily. Half the population owned a tablet they used for internet and mobile apps. Most participants used mobile apps (9/12, 75%) and the internet (8/12, 67%).

Figure 2 illustrates user performance by displaying the numbers of critical errors, noncritical errors, and easily completed tasks out of the total assigned tasks. Out of 725 tasks, 15 critical errors (2.1%), 31 noncritical errors (4.3%), and 679 easily completed tasks (93.7%) were recorded. Of the 12 participants, 10 (83%) easily completed at least 90% of their tasks. The median time to complete all tasks was 19 minutes (SD 3.4 minutes, range 11-26 minutes). The median time for internet users to complete all tasks was 18 minutes (range 11-21 minutes); in contrast, participants who did not use the internet completed all tasks with a median time of 21 minutes (range 20-26 minutes). There was 1 outlier who completed all tasks in 11 minutes. The participants who used the internet had fewer errors than those who did not: 4/725 errors versus 42/725 (0.55% versus 5.8%, respectively). The 3 participants who did not use the internet or mobile apps were all aged 65 years or older. Five participants completed the testing without any errors, and 2 others completed it with only 1 error. Participants 4 and 8 had the most difficulty, with 7 and 30 errors, respectively. Both of these participants were over the age of 65, did not own a tablet, did not use the internet, and did not use mobile apps. All subjects completed more than 50% of the exercises without any errors, and 11/12 subjects (92%) completed more than 90% of the tasks without critical errors.

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Table 2. Usability study participant demographics (N=12).

Characteristic	n (%)
Age (years)	
<45	1 (8)
45-64	4 (33)
≥65	7 (58)
Gender	
Male	5 (42)
Female	7 (58)
Race	
Black/non-Hispanic	6 (50)
White/non-Hispanic	5 (42)
Hispanic	1 (8)
Education	
High school (grades 9-12) or GED[a]	3 (25)
Some college but did not graduate	4 (33)
College	1 (8)
Graduate or professional school	4 (33)
Mobile devices used	
Cell phone	12 (100)
Tablet	6 (50)
Frequency of mobile device use	
Daily	12 (100)
Type of mobile device use	
Apps	9 (75)
Internet	8 (67)

[a]GED: General Educational Development

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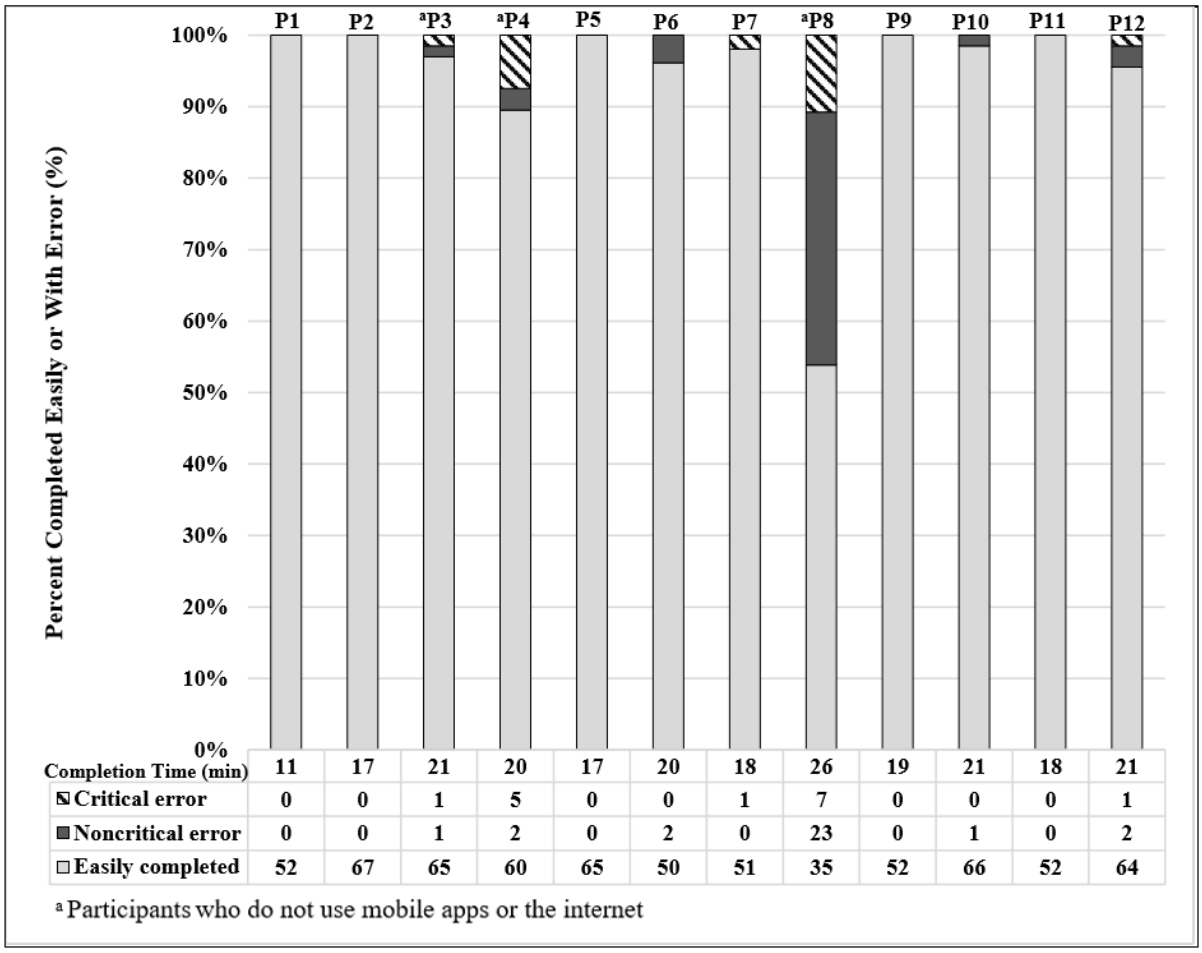
Figure 2. Usability testing results by participant.



User Experience Survey

The Likert scale used to evaluate user satisfaction using the tablet application is shown in Table 3. Participants were asked questions about their experience using the app and provided a ranking for the activity from 0-2 or 0-4, with lower numbers indicating higher satisfaction. The median and range for the ranking of the tool were used to determine the results. The median ranking for the overall activity was 0 (range 0-4), which describes the activity as “very easy.” Participants found the tablet to be very easy to use based on the median ranking of 0 (range 0-4). The length of time to complete the activity had a median ranking of 1 (range 0-2), indicating that the length was “just right.” The subjects ranked the patient story examples and audio as 1 (range 0-4), stating they agree that these aspects of the app helped them to understand the information. When participants were asked if they would recommend the activity to others, the median ranking was 1 (range 0-4), indicating that the participants agree they would recommend the app to others. Lastly, the participants were asked how they would rate the activity on a scale of 1-10 (10 being the best); they provided a median rating of 8 (range 0-10).

After completion of the activity, participants were given the opportunity to provide feedback and comments about the tool, such as what changes they would make, what they liked or did not like, and their overall thoughts about the exercise. Most comments reiterated the helpfulness and quality of the material learned using the app. Other comments suggested ways to improve the tool by stating that the exercise should be faster to navigate, while others expressed the need to simplify some medication names. The majority of participants found the educational tool to be a worthwhile experience that helped them learn about adverse safety events (Multimedia Appendix 4).

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Table 3. Survey indicating user satisfaction with the patient safety tool.

Question	Response, median (range)
Overall, this activity was…[a]	0 (0-4)
The mobile tablet was…[a]	0 (0-4)
The length of time it took to complete the activity was…[b]	1 (0-2)
Using stories about patients helped me to understand the information.[c]	1 (0-4)
The use of audio helped me to understand the information.[c]	1 (0-4)
I would recommend this activity to others.[c]	1 (0-4)
How would you rate this activity?[d]	8 (0-10)

[a]Possible responses: 0=Very easy, 1=Somewhat easy, 2=Neither easy nor difficult, 3=Somewhat difficult, 4=Very difficult.

[b]Possible responses: 0=Too long, 1=Just right, 2=Too short.

[c]Possible responses: 0=Strongly agree, 1=Agree, 2=Neutral, 3=Disagree, 4=Strongly disagree.

[d]Possible responses: 1-10, where 1 is the worst and 10 is the best.

Discussion

The CKD educational tool was designed to help audiences with low health literacy learn about potential safety hazards associated with kidney disease through an interactive and simple-to-use digital interface. Our findings demonstrate that the majority of participants found the digital tool to be helpful and easy to navigate and would recommend it to others. Most participants were proficient in using the tablet without significant guidance and without errors; those with critical errors were older than 65 years and less familiar with digital technologies in general but still predominantly completed the programming without difficulty. The participants' ability to complete the tasks did not appear to be related to their degrees of education, which supports our intent to provide an educational tool for populations with low health literacy regardless of educational background. Although some participants did not regularly use the internet or mobile apps, the task completion times in this group did not greatly differ from those of regular internet users. Together, these findings suggest that further testing to evaluate the impact of the CKD educational tool on outcomes is warranted.

CKD places individuals at high risk for developing adverse safety events, and effective tools that attenuate this heightened risk are needed. The principal feature of CKD that can influence patient risk is the reduced level of renal function or glomerular filtration rate (GFR), which is typical of the condition. A low GFR affects the clearance of many drugs, confounds therapeutic interventions, and increases susceptibility to acute kidney injury [28]. Moreover, CKD is frequently associated with several comorbidities, such as diabetes and cardiovascular disease [28]. The clustering of these health conditions leads to increased inpatient and outpatient medical encounters, with potential consequences of polypharmacy and high self-management burden. Compounded by low patient awareness of kidney disease [29] and poor knowledge of contributory health behaviors [5,30], potential adverse outcomes in CKD are abundant.

Our previous work demonstrated high acceptance of digital tools and general ease of use among individuals with CKD, supporting mobile health (mHealth) as a feasible mechanism through which patient-centered programming can be delivered to CKD populations [31-33]. Other studies using mHealth tools in non-CKD populations have demonstrated similar results for provision of tailored educational programming across an array of health conditions, such as obesity, asthma, and diabetes [34-37]. For individuals with CKD, responsiveness to the high degree of limited health literacy in the CKD population [10,38] is fundamental to the development of any educational curriculum, and use of audio and visual support can address differences in learning styles. We developed our app using plain language principles to address this need. Similarly, user experience testing of such digital tools in the CKD population can unearth interface difficulties by users and inform refinements to optimize user understanding and retention. The importance of such assessment is evidenced by one recent study that systematically evaluated all available and updated patient-facing CKD mobile apps. Of the 174 unique applications found, only 38 were related to kidney disease, were patient-facing, and had been updated in the previous 4 years. The quality of app content widely varied, and the authors found high levels of discordance between patient and provider app reviewers regarding value and usability [39]. These findings highlight the need for digital health content that is developed with a patient-centric approach and tested for ease of use in the target population *prior* to implementation in clinical care and broad dissemination. Similar content should also be made available through alternative platforms, such as on paper or via a website, to address differences in digital readiness and access.

Empowering patients with proper information and education in a manner they can comprehend can improve self-efficacy and self-management and, in turn, improve health outcomes [40]. The patient-actionable tool we developed emphasizes the importance of a patient-centered approach to educating CKD patients about self-care at home. Further, developing digital tools for patient education can bridge the digital gap between younger and older generations. When provided with online tools to manage chronic illnesses, older individuals access the digital

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content more frequently and sustain its use over longer periods than their younger counterparts [41]. This engagement by older populations is particularly relevant in CKD, as its onset typically occurs later in life. Digital tools can also narrow disparities in accessibility between rural and urban CKD populations, especially with the widespread availability of smartphones and the mobile web as well as the increasing use of telehealth applications for clinical care [42,43]. However, in kidney disease, few tools have been appropriately developed for use in a low health literacy population or have undergone formal usability testing. Fewer still tools are available outside of the research setting, which creates opportunities for such tools to be integrated into clinical care and evaluated in pragmatic studies [44,45].

Our study has limitations that are worthy of mention. Although our sample size is within the recommended range of 5-7 participants for usability testing [46,47], our sample size is small, and we recognize that this limits the inferences was can draw from our findings. Further, our participants were recruited from the Duke University Hospital nephrology clinics and may not be representative of the general CKD population, particularly given that only half our study participants were elderly. We also restricted our usability testing to individuals with CKD, which may not be generalizable to individuals with other kidney-related (eg, acute kidney injury) or non–kidney-related conditions. Finally, the specific patient safety conditions included in our educational curriculum may not be comprehensive, although they do represent many common patient safety events reported and detected in patients with kidney disease [1,48].

In summary, usability testing of a patient-centered digital tool to promote safety among patients with CKD demonstrated general ease of use and acceptability. The impact of the intervention on mitigation of safety events in a CKD population has yet to be determined. However, the information derived from this study strengthens the growing consensus that tailored digital tools can be used effectively by high risk populations, including older persons and persons with low health literacy. Future studies are needed to evaluate the benefit of such tools in clinical care.

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Conflicts of Interest

None declared.

Multimedia Appendix 1
Screenshots of the app.
[PDF File (Adobe PDF File), 287 KB - formative_v4i5e16137_app1.pdf]

Multimedia Appendix 2
Transcript of the app audio.
[PDF File (Adobe PDF File), 102 KB - formative_v4i5e16137_app2.pdf]

Multimedia Appendix 3
Task descriptions.
[PDF File (Adobe PDF File), 147 KB - formative_v4i5e16137_app3.pdf]

Multimedia Appendix 4
Participant testimonials about using the app.
[PDF File (Adobe PDF File), 75 KB - formative_v4i5e16137_app4.pdf]

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Abbreviations

AKI: acute kidney injury
CKD: chronic kidney disease
mHealth: mobile health
NSAIDs: nonsteroidal anti-inflammatory drugs

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Original Paper

Testing Usability and Feasibility of a Mobile Educator Tool for Pediatric Diabetes Self-Management: Mixed Methods Pilot Study

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Abstract

Background: Mobile interventions hold promise as an intervention modality to engage children in improving diabetes self-management education, attitudes, and behaviors.

Objective: This pilot study aimed to explore the usability, acceptability, and feasibility of delivering a mobile diabetes educational tool to parent-child pairs in a clinical setting.

Methods: This mixed methods pilot study comprised two concurrent phases with differing study participants. Phase 1 used user testing interviews to collect qualitative data on the usability and acceptability of the tool. Phase 2 used a single-arm pre- and poststudy design to quantitatively evaluate the feasibility and preliminary efficacy of the intervention. Study participants (English-speaking families with youth aged 5-14 years with insulin-dependent diabetes) were recruited from an urban hospital in Massachusetts, United States. In phase 1, parent-child pairs were invited to complete the intervention together and participate in 90-min user testing interviews assessing the tool's usability and acceptability. Interview transcripts were analyzed using a directed content analysis approach. In phase 2, parent-child pairs were invited to complete the intervention together in the clinical setting. Measures included parental and child knowledge, attitudes, and behaviors related to diabetes management (self-report surveys) and child hemoglobin A1c levels (medical record extractions); data were collected at baseline and 1-month follow-up. Pre- and postoutcomes were compared using paired t tests and the Fisher exact test.

Results: A total of 11 parent-child pairs (N=22) participated in phase 1 of the study, and 10 parent-child pairs (N=20) participated in phase 2 of the study. Participants viewed the mobile educational tool as acceptable (high engagement and satisfaction with the layout, activities, and videos) and identified the areas of improvement for tool usability (duration, directions, and animation).

Conclusions: The findings from this pilot study suggest that the mobile educational tool is an informative, engaging, and feasible way to deliver diabetes self-management education to parents and children in an urban hospital setting. Data will inform future iterations of this mobile diabetes educational intervention to improve usability and test intervention efficacy.

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KEYWORDS

diabetes mellitus; self-management; health education; mHealth; mobile health; child health

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Introduction

Background

Type 1 diabetes (T1D) and type 2 diabetes (T2D) are among the most common chronic illnesses in children. Rates of T2D are disproportionately higher among American Indian, Hispanic, and black youth compared with white youth in the United States [1]. Pediatric diabetes adversely affects quality of life, productivity, and life expectancy and contributes to enormous health care costs, particularly given its increasing prevalence [2-5]. Earlier onset of diabetes also increases the risk and severity of diabetes-related complications [6,7]. Developing strategies to help youth and parents succeed in diabetes self-management is needed to promote positive health outcomes.

Extensive education is required to equip youth and families with the knowledge and skills needed to manage diabetes. Current diabetes management educational tools provided to families in the clinical setting are inadequate and text heavy, with parents often reporting that the educational process is overwhelming and lacks a patient-centered approach [8-10]. Furthermore, current diabetes self-management educational materials are not child centered (developed based on the needs and interests of children). As children transition into adolescence, the responsibility for diabetes management shifts from parents to the children [11]. Educational materials designed specifically for children, particularly those in preadolescence and early adolescence, are needed to facilitate the transition from parent-initiated diabetes management to self-management. To ease this transition, educational materials need to (1) engage youth and (2) facilitate positive, productive communication between parents and youth [12].

A growing number of studies have used mobile health to target diabetes self-management among adolescents [10,13-17]. The findings from such studies indicate the potential for mobile health interventions to enhance diabetes education, motivate behavior change, and have widespread dissemination. However, prior studies on mobile diabetes self-management interventions have focused primarily on adolescents (aged 12 to 19 years) [15-17]. The extent to which mobile diabetes self-management tools may be applicable for younger children and facilitate productive parent-child communication has not been extensively explored. In-depth research with parents' and children's perceptions and experiences with a child-centered, mobile diabetes educational intervention can inform the development and improvement of such tools.

Objectives

This pilot study aimed to (1) gather qualitative data on the usability and acceptability of the Mobile Diabetes Educator (MDE) prototype through user testing interviews with parent-child pairs (phase 1) and (2) assess the feasibility and preliminary efficacy of delivering the MDE in a clinical setting among parent-child pairs through a single-arm pre- and posttrial (phase 2). Phases were run concurrently with differing study participants using a mixed methods approach to achieve study aims. We hypothesized that trends in improvements in diabetes knowledge, attitudes, and self-management behaviors at 4- to 6-week follow-up would be observed.

Methods

Mobile Diabetes Educator Intervention Prototype

In collaboration with children's educational media consultants, the study team developed a prototype of the MDE [18]. This mobile educational program (interactive electronic book) was designed for school-aged youth and intended to be navigated by parents and children together to facilitate communication. The MDE prototype consists of eight animated, interactive modules that feature an ethnically ambiguous preadolescent character named Kara who has T1D (Figures 1 and 2). Topics covered include diabetes etiology, managing glucose levels, and diet and exercise recommendations. Multimedia strategies (eg, images and videos) were used for information delivery as they play a crucial role in learning. Images serve to improve perception, understanding, and memory and to encourage engagement by the user [19,20]. Using visuals is also an important mode of risk communication because the visual cortex of the brain becomes activated during high-stress situations [21,22].

The tool can be accessed through any mobile or computer device with internet access, although it was specifically designed for touchscreen navigation on a tablet. The interactive modules were designed to be completed in segments, self-directed at the patient's own pace, to replace text-based educational materials in the clinical setting after an initial diabetes diagnosis. For the purposes of this study, the modules were completed in one sitting (approximately 45-60 min).

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Figure 1. A page in the Mobile Diabetes Educator (MDE) that features interactive learning. This activity asks the patient to drag various steps needed for blood glucose monitoring into the correct order and check their results.

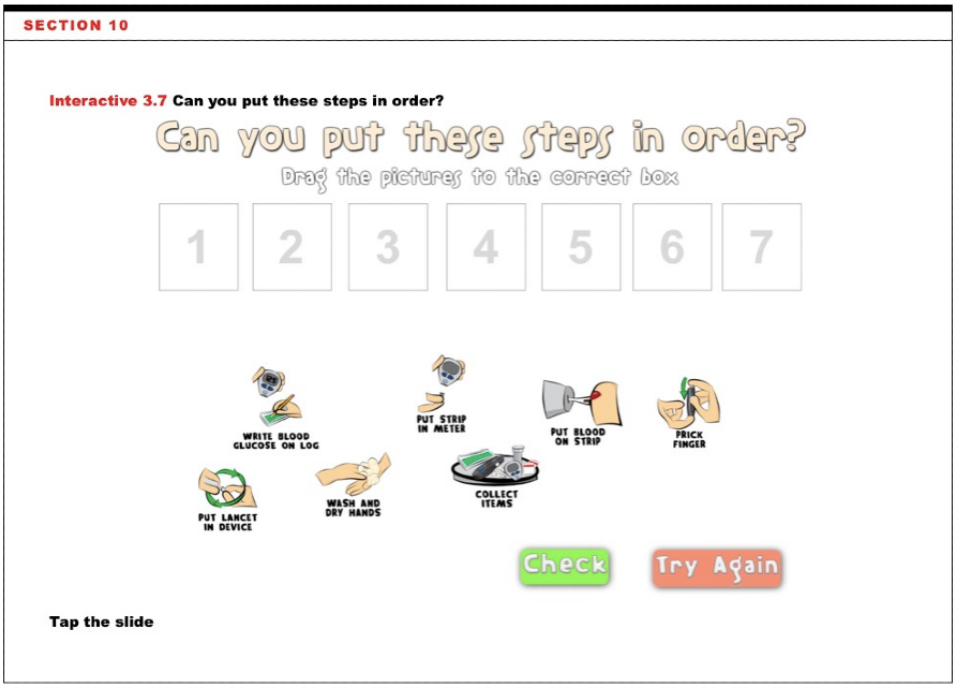
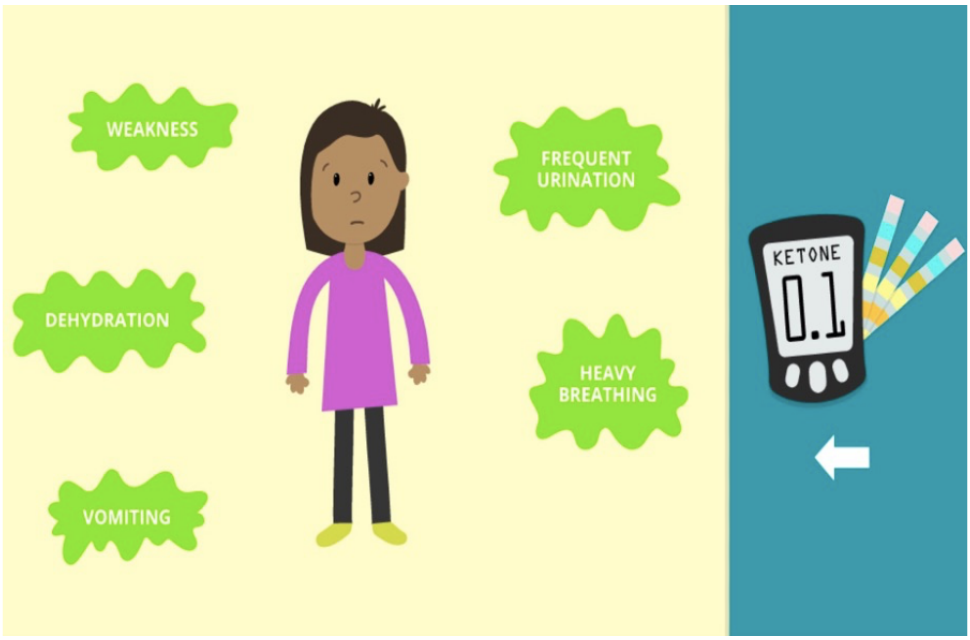


Figure 2. A page in the Mobile Diabetes Educator (MDE) that presents symptoms of hyperglycemia.



Study Participants and Setting

In both phases of the study, child participants and their parents or caregivers were recruited through the Pediatric Diabetes and Endocrinology Section at Boston Medical Center (BMC), a safety net urban hospital in Massachusetts, United States. A wide age range (elementary school–aged and middle school–aged youth) of child participants was used to examine the extent to which the tool was acceptable, engaging, and relevant across different age ranges. Eligibility criteria for child participants included (1) being aged 5 to 14 years, (2) being diagnosed by a clinician as insulin dependent (T1D or T2D), (3) currently receiving diabetes care at BMC, (4) parent consent to participate, and (5) being able to read and converse in English. Eligibility criteria for parent participants included (1) being aged 18 years or older and (2) being able to read and converse in English. All study procedures took place in the BMC clinical setting.

Phase 1: User Testing Interviews and Measures

Phase 1 consisted of collecting qualitative data to assess usability and acceptability through user testing observations and interviews, an appropriate method given the low literacy level of our target population and the cognitive developmental stage of some of our child participants (eg, children aged 5-7 years may not understand how to answer standardized measures of

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usability, whereas study team observations and open-ended questions may generate more insights). User testing lasted approximately 90 min and consisted of an observational component and a semistructured interview. The study team provided participants with a tablet with the intervention preloaded and asked participants to use the tool and explain their thinking out loud as they navigated the tool. Study staff silently observed how participants navigated the tool and noted areas for improvement in *usability* (ease of navigation and problems encountered, time taken to complete the tool, and identification of the primary user [parent, child, or equal use between parents and children]) and *acceptability* (frequency, content, and tone of parent-child communication for pair users and level of participant engagement). Immediately after completing the tool, study staff conducted semistructured interviews and asked participants to evaluate the tool in terms of additional *acceptability* measures (clarity of content, acceptability of contexts [eg, characters and settings], perceived purpose of the tool, overall satisfaction, and areas for improvement; see Multimedia Appendix 1).

Phase 1: Qualitative Analysis

Interviews were audio recorded, transcribed verbatim, and thematically analyzed by study staff. The analysis used a directed content analysis approach [23]. An initial codebook was developed based on the interview guide. Following transcript coding by study staff, codes were revised to incorporate additional themes as needed. Thus, both a priori and de novo themes were identified and given an operational definition. Coders also identified quotes that represented each theme.

Phase 2: Feasibility Trial and Measures

Phase 2 consisted of collecting quantitative data to assess preliminary efficacy using self-reported surveys and medical record information. Parent and child participants completed a baseline assessment immediately before participating in a 1-hour intervention session and a postassessment 4 to 6 weeks later (all completed in the clinical setting). For the intervention session, parent-child pairs were provided with a tablet and asked to complete the intervention (self-administered) together. The following four measures on diabetes: knowledge, self-efficacy, self-management, and communication were each completed separately by both child and parent participants using self-report, self-administered surveys. *Diabetes knowledge* was assessed using 25 multiple-choice items from the Revised Brief Diabetes Knowledge Test [24], with the percentage of correctly answered items calculated. Sample diabetes knowledge topics covered included nutrition, glucose testing, glucose reactions, and insulin. Sample questions included (1) A low blood glucose reaction may be caused by too much insulin, too little insulin, too much food, or too little exercise and (2) Which of the following is highest in carbohydrates? Baked chicken, swiss cheese, baked potato, or peanut butter. *Diabetes management self-efficacy* was measured using 19 items from the Diabetes Self-Efficacy Scale [25], which asked respondents to rate their confidence in their ability to manage diabetes (eg, glucose self-monitoring, insulin injections, and meal planning) using a 5-point Likert scale, ranging from 1 (very sure I cannot) to 5 (very sure I can). *Perceived readiness for diabetes self-management* was measured using two items from the Readiness to Change the Balance of Responsibility Scale [26]. These items included “I feel ready to manage diabetes on my own” and “I feel ready to take on some, but not all, of diabetes management on my own,” which were assessed using a 5-point Likert scale, ranging from 1 (very sure I cannot) to 5 (very sure I can). The *frequency of parent-child diabetes management communication* was assessed using three items from the Self-Management of T1D in Adolescence subscale [27]. Participants were asked to report how often they talk to their parents about diabetes, when they have questions about diabetes, and when they have problems managing diabetes using a 4-point frequency scale (always, sometimes, occasionally, and never). Child sociodemographics included gender, age, race and ethnicity, and type of insulin-dependent diabetes diagnosis (T1D or T2D). Child hemoglobin A_{1c} (HbA_{1c}) levels were extracted from child participants’ medical records by a trained patient navigator. Parental sociodemographics included gender, age, race and ethnicity, annual household income, highest level of education completed, and occupational status (employed full time, employed part time, or other).

Phase 2: Statistical Analysis

Distributions, descriptive statistics, and missing values were examined for all measures. Changes in parent and child outcomes from pre- and postassessments were analyzed using paired *t* tests for continuous outcomes and the Fisher exact test for categorical outcomes. Statistical analyses were conducted using SAS version 9.4. The data were considered to be statistically significant at an alpha value of .05.

Results

Sociodemographics

The phase 1 study sample consisted of 11 parent-child pairs (N=22). Among child participants, the mean age was 10.3 (SD 2.2) years, and nearly two-thirds (7/11, 64%) of them were female. Almost all (10/11, 91%) participants had T1D. Among parents, the mean age was 39.5 (SD 11.0) years. The majority of parent participants were female (10/11, 91%), had less than a college degree (10/11, 91%), and had an annual household income less than US $50,000 (9/11, 82%). See Table 1 for additional sociodemographics on phase 1 participants.

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Table 1. Baseline characteristics of the parent-child pairs participating in phase 1 and phase 2 of the Mobile Diabetes Educator pilot study (2018-2019).

Baseline characteristics	Phase 1 (N=11)	Phase 2 (N=10)
Child		
Gender, n (%)		
Female	7 (64)	5 (50)
Male	4 (36)	5 (50)
Age (years), mean (SD)	10.3 (2.2)	10.8 (2.9)
Race, n (%)		
White	1 (9)	1 (10)
Black	6 (55)	5 (50)
Hispanic or Latino	1 (9)	1 (10)
Other	3 (27)	3 (30)
Type of insulin-dependent diabetes, n (%)		
Type 1	10 (91)	9 (90)
Type 2	1 (9)	1 (10)
Parent		
Gender, n (%)		
Female	10 (91)	8 (80)
Male	1 (9)	2 (20)
Age (years), mean (SD)	39.5 (11.0)	40.8 (11.2)
Race, n (%)		
White	2 (18)	3 (30)
Black	8 (73)	6 (60)
Hispanic or Latino	1 (9)	1 (10)
Other	0 (0)	0 (0)
Annual household income, n (%)		
Less than US $30,000	4 (36)	5 (50)
US $30,000-$49,999	5 (45)	3 (30)
Greater than or equal to US $50,000	2 (18)	2 (20)
Education, n (%)		
Less than or equal to high school degree	6 (55)	6 (60)
Some college	4 (36)	3 (30)
Greater than or equal to college degree	1 (9)	1 (10)
Occupation, n (%)		
Employed full time	6 (55)	4 (40)
Employed part time	2 (18)	2 (20)
Other (disabled, retired, unemployed, or homemaker)	3 (27)	4 (40)

The phase 2 study sample consisted of 10 parent-child pairs (N=20). Among children, the mean age was 10.8 (SD 2.9) years, and half (5/10, 50%) of them were female. Almost all (9/10, 90%) participants had T1D. Among parents, the mean age was 40.8 (SD 11.2) years. The majority of parent participants were female (8/10, 80%), had less than a college degree (9/10, 90%), and had an annual household income less than US $50,000 (8/10, 80%). See Table 1 for additional sociodemographics on phase 2 participants.

Phase 1: User Testing Observations

Study staff's observations of parent-child interactions during user testing provided insight into the usability and acceptability of the MDE tool (Table 2). The majority (6/11, 55%) of parent-child pairs demonstrated shared use of the tool (ie, taking

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turns holding the tool, reading content, and completing activities), although in some (4/11, 36%) instances, the child was the primary user. Although most (9/11, 82%) users encountered problems using the tool, the overall navigation of the tool appeared either easy (5/11, 46%) or moderately easy (4/11, 36%) according to study staff's observations. Parental and child engagement with the tool was distributed by engagement level. Observers noted that 55% (6/11) of parents and 36% (4/11) of children were highly engaged, whereas 27% (3/11) of parents and 36% (4/11) of children demonstrated a moderate level of engagement. Observers also noticed high (5/11, 46%) and moderate (3/11, 27%) parent-child communication during user testing.

Table 2. User testing observations of 11 parent-child pairs participating in phase 1 of the Mobile Diabetes Educator pilot study (2018-2019).

Staff-rated observations	Values, n (%)
Ease of navigation	
Easy	5 (45)
Moderate	4 (36)
Difficult	2 (18)
User problems encountered	
Yes	9 (82)
No	2 (18)
Primary user	
Parent	1 (9)
Child	4 (36)
Equal use	6 (55)
Parent engagement	
High	6 (55)
Moderate	3 (27)
Low	2 (18)
Child engagement	
High	4 (36)
Moderate	4 (36)
Low	3 (27)
Parent-child communication	
High	5 (45)
Moderate	3 (27)
Low	3 (27)

Phase 1: User Testing Interviews

Thematic analysis of semistructured interviews with parent-child pairs further explored the usability and acceptability of the MDE tool. In total, seven themes were identified and coded based on the semistructured interview guide: usability, comprehension, high engagement, low engagement, purpose, satisfaction, and suggestions for improvement. These themes, alongside illustrative quotes, are summarized in Table 3 and discussed below.

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Table 3. Illustrative quotes by theme from user testing interviews with 11 parent-child pairs participating in phase 1 of the Mobile Diabetes Educator pilot study (2018-2019).

Theme	Illustrative quotes
Usability	
Somewhat user friendly	"I think certain areas were just a little confusing so you couldn't really tell whether or not you're supposed to tap on it or are you just supposed to go to the next screen."
Comprehension	
High comprehension	"It got to the point. It explained the situations and what to look for in the situations. It explained it a lot. A kid would understand it."
High engagement	
Layout	"I liked that it alternated with videos and then text."
Activities	"I think they are helpful in the sense that they kind of test your knowledge and help you to get a better understanding of it."
Chapters	"My favorite part was basically explaining why people have diabetes."
Videos	"I liked the animated videos. I think that keeps you going. Looking at the lady sitting there just talking [whereas] looking at the animation, they're doing things so it makes you want to look at it more."
Low engagement	
Activities	"Some of them were confusing and some of them were boring. And then some of them were just 'meh.'"
Chapters	"Too many chapters."
Characters	"I just thought it was weird they had no arms and legs."
Purpose	
Health education	"To educate kids about diabetes in a fun way. To let them know it's ok to have diabetes. This stuff happens in normal life, it happens in school. It tells them what to do also, but in a fun way."
Health management	"Learning about it and how to maintain it, and keep yourself healthy."
Motivation for diabetes self-management	"To tell us that it is not easy to take care of [diabetes] but you have to try your best and eat more healthy food so you won't get sick."
Satisfaction	
Moderate satisfaction	"I say 7 [out of 10] because like I said from earlier, just those little kinks that need to be worked out. But outside of that, I think it's a really good tool to educate and inform others about diabetes, especially for a child that is new to it and kind of clueless and going through it. So, it's a good way to help them to understand it on their level."
Suggestions for improvement	
Usability	"A little more instruction at the top of the screen on what's expected on that particular screen, that slide."
Comprehension	"I would only suggest doing the content a little bit more on the kids' level–especially for younger kids–so they could really grasp the content just a little bit more. [For example], with the video with the nutrition, just doing all the way around on an animated level for kids if they're going to be the ones engaging on the iPad. But if it's more like older kids or adults, then yeah keep it the way it is."
Layout	"A little more videos and quizzes."
Chapters	"I think they should have added more about the carbs. They should have at least given more clarification on how you would...how much insulin and how many carbs...they should have put that together more."
Activities	"Drawing. Maybe have the kids draw their idea of the pancreas and all that stuff."
Characters	"I think she should sound more like a kid. I think all of them should."
Settings	"More settings would be nice. Especially when we're taking trips out and then to know what you need or how to do things when you're in a car. Stuff like that."

Usability

Most participants described the tool as somewhat user friendly. Any difficulty using the tool was attributed to two main reasons: a lack of directions and malfunctioning activities. Given that there is a mix of text, videos, and activities throughout the tool, users felt unclear at times of what they were supposed to do on any given slide (eg, whether it was an interactive slide or not and what to press to engage in activity). Users also expressed frustration with some activities that did not work (eg, press button and nothing happens). However, in some cases, what appeared to be a malfunction was just difficulty navigating the activity because of a lack of directions (eg, unclear that the user must select icons sequentially for an activity to work).

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Comprehension

Participants found the tool to be informative and thought the material was easy to understand, signifying an appropriate literacy level. Both parent and child users could demonstrate that they learned diabetes-related information after completing the tool. Notably, the visuals used throughout the tool (eg, pictorial representation of symptoms) helped increase comprehension of the information being conveyed.

High Engagement

As participants discussed parts of the tool they liked the most, several subthemes emerged, including layout, chapters, activities, and videos. The overall layout of the tool, which included a mix of text, videos, and activities, provided both passive and active learning opportunities for users, thereby increasing their engagement with the tool (eg, was able to hold children's attention by giving them things to do). Participants largely felt that the chapters covered all the basic topics. The chapters on diabetes etiology and celebrities with diabetes were particularly engaging for children, whereas the chapters that demonstrated diabetes management and care (eg, insulin injection) were of interest to parents. The activities were often cited as the most engaging aspect of the tool and a positive way to reinforce the knowledge learned. Participants also enjoyed the videos, as they made the information easier to understand (eg, animated cells and organs were helpful in understanding diabetes etiology). Although participants liked the balance of animated and nonanimated videos, some cited the animations as slightly more engaging, especially for children.

Low Engagement

As participants discussed parts of the tool they found less interesting, the following subthemes emerged: duration, characters, and setting. The average time it took for users to complete the tool was 56 min (SD 15), which many felt was too long and contributed to a general feeling of boredom. Although participants typically liked the main character and her personality, they repeatedly expressed dissatisfaction with the robotic voice and appearance (eg, missing arms and legs) of the animated characters. Similarly, although the school-based settings of the animated videos felt true to life, participants would have liked to see more settings, particularly when children are on the go (eg, in the car) or without their parents (eg, birthday party and sleepover).

Purpose

Most participants thought the main purpose of the tool was to provide health education (eg, target knowledge). Participants described the target audience for this tool as newly diagnosed patients or people who do not already know about diabetes. Other main purpose subthemes that emerged included health management (eg, target behaviors) and motivation for diabetes self-management (eg, target attitudes).

Satisfaction

The majority of participants reported high satisfaction with the tool. On a scale of 1 to 10, with 10 being the best, participants' average rating was 8.7 (SD 1.5). High satisfaction was often attributed to the fact that the tool was entertaining and provided a great deal of information. Factors that lowered users' satisfaction scores included the long duration and, thus, boringness of the tool as well as the aforementioned usability issues with some activities.

Suggestions for Improvement

Participants suggested several ways to improve the tool in relation to the following subthemes: usability, comprehension, layout, activities, characters, duration, and dissemination. To improve the tool's usability, clear directions should be included on each slide, and malfunctioning activities should be fixed. Comprehension could be enhanced by increasing the use of child-friendly explanations of information (eg, pictures to complement or replace words and more animation). Similarly, participants thought more engaging, creative features, such as videos and activities, should be added to enrich the overall layout of the tool. Suggestions for new activities included a word search, summary quiz, drawing, or having the user watch a video on how to perform a behavior and then practice doing so on a cartoon. According to participants, animated characters should have a less robotic voice and more realistic appearance. The use of superhero characters was also suggested. Finally, participants agreed that the duration of the tool should be shortened, yet they found it difficult to identify ways to do so (eg, information that could be cut). However, disseminating the MDE as an app was recommended to allow users to cover the material at their own pace at home.

Phase 2: Outcomes

Participants spent an average of 59.2 (SD 5.4) min to complete the intervention in one sitting. The retention rate for follow-up assessments was 80% (8/10). No significant changes in child participants' diabetes self-management knowledge test scores, self-efficacy, parental communication, or HbA_{1c} levels were observed at 4- to 6-week follow-up (Table 4). Among parent participants, no significant changes were observed for the diabetes knowledge, attitudes, and behavioral measures. Although not statistically significant, we did find trends toward increasing knowledge and decreasing self-efficacy for diabetes management among both children and parents.

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Table 4. Pre- and postchanges in knowledge, attitudes, and behaviors of 10 parent-child pairs participating in phase 2 of the Mobile Diabetes Educator pilot study (2018-2019).

Outcome	Pretest (N=10)	Posttest (N=8)	*P* value[a]
Child			
Diabetes Knowledge Test score (percentage correct)[b], mean (SD)	51.6 (21.8)	65.0 (9.5)	.08
Child self-efficacy in diabetes self-management score[b], mean (SD)	59.9 (11.6)	55.3 (17.6)	.51
Children who report "always" talking with their parents when they have problems managing their diabetes[c], n (%)	6 (60)	5 (63)	.35
Children who report a score of 4 or a 5 for believing they can manage diabetes by themselves (high confidence)[c], n (%)	2 (20)	3 (38)	.36
Hemoglobin A_{1c} levels[b], mean (SD)	9.6 (1.6)	9.9 (1.5)	.71
Parent			
Diabetes Knowledge Test score (percentage correct)[b], mean (SD)	60.0 (14.9)	70.8 (13.9)	.12
Parental self-efficacy in helping their child manage diabetes score[b], mean (SD)	78.5 (6.2)	70.5 (22.1)	.29
Parents who report that their child "always" tells them when he or she is having problems managing diabetes[c], n (%)	8 (80)	4 (50)	.50
Parents who report a score of 4 or a 5 for believing that their child can manage diabetes on his or her own (high confidence)[c], n (%)	4 (40)	3 (38)	.66
Average number of times their child had a blood glucose checked in the last 24 hours[b], mean (SD)	4.4 (2.0)	3.6 (2.1)	.05

[a]*P* values are from paired *t* tests for continuous measures, and *P* values are from the Fisher exact test for categorical measures.

[b]Continuous measure.

[c]Categorical measure.

Discussion

Principal Findings

This pilot study demonstrated that the MDE was an acceptable and appropriate mobile health intervention for insulin-dependent children and their parents in a clinical setting. Participants were particularly satisfied with the overall layout of the tool (ie, mix of text, videos, and activities) and the information conveyed. The activities were often cited as the most engaging aspect of the tool and a positive way to reinforce the knowledge learned. Although the MDE was well received by participants, qualitative data indicated a need for improvements to the usability of the tool. Specifically, participants suggested adding directions to each slide and fixing malfunctioning activities. Participants also expressed a strong desire for a shorter duration.

Overall, no significant differences were observed between baseline and follow-up assessments among child and parent participants' knowledge, attitudes, behaviors, and outcomes related to diabetes self-management. Given that this was a small feasibility study that was not powered to detect changes in outcomes, null findings were expected. With respect to our clinical outcome (child HbA_{1c} levels), null findings may also be because of the short follow-up period and the nature of the intervention. There is mixed evidence of educational and mobile-based interventions and their ability to affect HbA_{1c} in pediatric diabetes populations [8,10,28], especially during adolescence when glycemic control typically worsens [29]. Although not statistically significant, slight decreases in parental self-efficacy and the percentage of parents who perceived that their child could manage diabetes on their own were observed. One potential explanation for this finding is that the MDE highlighted gaps of knowledge and understanding of how to manage diabetes among parents, and the finding suggests that such tools may be used to help identify and target the lack of understanding or misperceptions of diabetes management among children and parents. We also observed a notable, although statistically insignificant, decrease in the percentage of parents who reported that their child *always* tells them when they are having problems managing diabetes. This trend could be the result of parent-child communication facilitated by the MDE about diabetes self-management that helped identify gaps in the child's ability to manage diabetes.

Lessons Learned

The findings from this mixed methods pilot study provide useful insight into the usability and acceptability of the MDE. Key recommendations regarding usability focused on directions and malfunctioning activities, whereas recommendations to improve acceptability focused on duration and animated characters. In regard to intervention delivery, we learned that youth with diabetes and their parents would also be interested in using this tool outside of the clinical setting (eg, at home via app). These lessons learned will be used to shape the next prototype of the MDE. A responsive website design, ideal for the burgeoning predominance of mobile Web browsing, could be included in the next iterative developmental stage along with translation to

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Spanish to further extend the target of this diabetes intervention tool to another high-risk underrepresented patient population.

Comparison With Prior Work

Prior research demonstrates that mobile health interventions can be used to target knowledge, self-efficacy, and self-management behavior among patients with diabetes [30-32]. Characteristics of prior mobile health interventions for diabetes include *access to educational information* (eg, text pages, videos, and Web-based simulation), *health information storage* (eg, blood glucose readings and medication tracking), *social networking* (eg, storyboard, blog, and discussion board), and *communication* (eg, with health professionals, among parents and children) [12,15,30,31,33]. One key feature of our tool was the *activities* that engaged children in diabetes education (Figure 1).

Suggestions to improve mobile educational tools from our study are consistent with research on educational mobile tools for the self-management of other chronic diseases among youth. For example, adolescents with asthma suggested that *informative videos* covering asthma topics (eg, visual demonstration of inhaler technique) and *quizzes* be included in an asthma self-management app [34], two specific suggestions that were also voiced by participants in our user testing interviews. To date, mobile health intervention studies for patients with diabetes have largely focused on adolescents [10,14-17,31,32]. Our pilot study targeted a younger age range (5-14 years) as well as parents to explore the feasibility and acceptability of a mobile educational intervention among parent-child pairs. Additional content may need to be tailored for this younger population, such as school accommodations and communication, special events (eg, parties and camp), strategies for injection, and instructions about foods. Our sample also consisted of youth from low-income and racial minority populations, who experience disproportionately higher rates of T2D and diabetes-related adverse events [35,36] and are inadequately represented in diabetes intervention research. These sample characteristics are significant, given that the data gathered from this pilot study (eg, user testing feedback) will be used to further develop the MDE prototype, better ensuring that the needs and preferences of affected populations are reflected in the design of interventions.

Strengths and Limitations

Strengths of this study include the in-depth qualitative methods used to examine intervention usability, acceptability, and feasibility and the recruitment of underserved study participants from an urban hospital setting to inform intervention refinement and study procedures for a larger trial. Limitations of this study include the small sample size, the absence of a control group for comparisons, a short follow-up period, and limited generalizability. Although it was a strength that our sample consisted of ethnically diverse, primarily low-income families, this limited our ability to control for race and ethnicity and income.

Conclusions

Given the ubiquity of mobile devices, a child-centered mobile health intervention that engages children and parents has the potential to enhance pediatric diabetes management. The findings from this pilot study will be used to inform the next iteration of the MDE tool so that the user testing feedback can be incorporated and the intervention efficacy can be tested on a larger scale.

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Conflicts of Interest

None declared.

Multimedia Appendix 1
Semistructured interview guide.
[DOCX File , 15 KB - formative_v4i5e16262_app1.docx]

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Abbreviations

BMC: Boston Medical Center
HbA_{1c}: hemoglobin A_{1c}
MDE: Mobile Diabetes Educator
T1D: type 1 diabetes
T2D: type 2 diabetes

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Original Paper

A Mobile Health Coaching Intervention for Controlling Hypertension: Single-Arm Pilot Pre-Post Study

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Abstract

Background: The seminal Dietary Approaches to Stopping Hypertension (DASH) study demonstrated the effectiveness of diet to control hypertension; however, the effective implementation and dissemination of its principles have been limited.

Objective: This study aimed to determine the feasibility and effectiveness of a DASH mobile health intervention. We hypothesized that combining Bluetooth-enabled data collection, social networks, and a human coach with a smartphone DASH app (DASH Mobile) would be an effective medium for the delivery of the DASH program.

Methods: We conducted a single-arm pilot study from August 2015 through August 2016, using a pre-post evaluation design to evaluate the feasibility and preliminary effectiveness of a smartphone version of DASH that incorporated a human health coach. Participants were recruited both online and offline.

Results: A total of 17 patients participated in this study; they had a mean age of 59 years (SD 6) and 10 (60%) were women. Participants were engaged with the app; in the 120 days of the study, the mean number of logged blood pressure measurements was 63 (SD 46), the mean number of recorded weight measurements was 52 (SD 45), and participants recorded a mean of 55 step counts (SD 36). Coaching phone calls had a high completion rate (74/102, 73%). The mean number of servings documented per patient for the dietary assessment was 709 (SD 541), and patients set a mean number of 5 (SD 2) goals. Mean systolic and diastolic blood pressure, heart rate, weight, body mass index, and step count did not significantly change over time (P>.10 for all parameters).

Conclusions: In this pilot study, we found that participants were engaged with an interactive mobile app that promoted healthy behaviors to treat hypertension. We did not find a difference in the physiological outcomes, but were underpowered to identify such changes.

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KEYWORDS

eHealth; mobile; telemedicine

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Introduction

By 2030, hypertension is expected to affect 41.4% of American adults [1]. However, blood pressure remains insufficiently controlled in almost half of patient cases [2]. The enormous burden of hypertension creates a need for effective interventions with minimal patient burden to encourage successful behavior change. The seminal Dietary Approaches to Stopping Hypertension (DASH) study, published 20 years ago, demonstrated effective control of hypertension through diet [3]. Since then, DASH has been implemented in clinical settings with limited success, partly due to the original intervention design that required substantial in-person participation [4].

DASH for Health, a web-based version of the program, was developed in 2008 to combine the success of the DASH dietary approach of controlling hypertension with evidence-based lifestyle changes (eg, physical activity) and novel internet delivery, thereby reducing the burden of DASH's original in-person design [5]. DASH for Health has been shown to be effective in hypertension management for those who stay engaged with the program for an extended period [5]; however, web-based interventions are still affected by severe drops in patient utilization after the initial weeks of intervention participation [6]. Mobile versions of DASH have been developed but relied on self-reporting for measures of blood pressure, weight, and physical activity, which increase patient burden and may not be accurate [7]. To overcome these limitations, we developed DASH Mobile, a mobile platform that leveraged smartphone technology with Bluetooth-enabled devices, along with human coaching, to facilitate behavior changes.

The widespread use of smartphones among all sociodemographic groups presents a disruptive opportunity to deliver a more accessible version of DASH while increasing patient adherence to the program [8]. By automatically collecting data outside of the clinic and delivering real-time, personalized messaging to each user, smartphone technology minimizes patient burden while creating a positive feedback loop for behavior change.

Our strategy was to adapt DASH to a smartphone-based platform (DASH Mobile) that leveraged automatic data collection with behavior change support from a human coach to replicate the success of DASH in a less burdensome digital context. The purpose of this study was to evaluate the feasibility and potential clinical effectiveness of DASH Mobile, including its effects on engagement (use and acceptability), physiological (blood pressure), and behavioral (diet and physical activity) outcomes.

Methods

Study Design

This was a single-arm pilot study conducted from August 2015 through August 2016 with a pre-post evaluation design to evaluate the feasibility and preliminary effectiveness of a smartphone version of DASH that incorporated health coaching. This study was approved by the Boston University Medical Campus Institutional Review Board.

Recruitment and Participants

Participants were recruited from the greater Boston area via recruitment materials in the local paper and research registry, using an opt-in paradigm. In addition, emails with information about the study were sent to those deemed eligible from Boston University's research volunteer registry. Participants were eligible if they were aged 18-65 years, owned an iOS or Android smartphone with a data plan, were English speaking, were currently taking hypertension medication, or had a diagnosis of prehypertension or Stage 1 hypertension, and were able to give informed consent. Prehypertension was defined as a systolic blood pressure of 120-139 mm Hg, and Stage 1 hypertension was defined as a systolic blood pressure of 150-160 mm Hg for adults aged ≥60 years, 140-160 mm Hg for patients with diabetes or chronic kidney disease, or 140-160 mm Hg for all others.

Participants were excluded if they were pregnant or nursing, held a terminal diagnosis, had a diagnosis of secondary hypertension, were unable to easily navigate apps on their smartphone; their baseline blood pressure was in the normal range without blood pressure medication; or they had any contraindications to physical activity. We also excluded patients with medical conditions including dementia, active cancer, or anorexia.

A research assistant obtained informed consent, including HIPPA authorization, from interested participants. The mobile app was then loaded onto the participant's smartphone, and behavior-tracking devices (pedometer, scale, blood pressure cuff) were synced.

Intervention

We have previously described the development of DASH Mobile [9]. The intervention consisted of a smartphone app to track diet, blood pressure, weight, and physical activity daily, combined with a human coach. During the introductory training session with the DASH health coach, participants were taught how to use the app. The home screen of the app defaults to the current day, where participants self-tracked their diet using a novel, simplified data entry tool based on the DASH portions-based approach to dietary intake (Figure 1). At the bottom of the screen, participants could navigate to any of several tabs: Progress, where they could view all tracked behavior, including diet, blood pressure, weight, and steps; Goal, where editable active and achieved goals were listed (Figure 2); Chat, where participants could communicate with their coach (Figure 3); and Education, which linked to DASH-related resources.

Participants were instructed to track other data several times a day via the wireless devices provided. Bluetooth-enabled wireless sensors (iHealth Labs) from these devices transmitted data for blood pressure, weight, and physical activity to the app. Syncing of data occurred manually when the app was opened; data were uploaded to a web-based coaching portal for patients and the health coach to view the participants' progress. All information transmitted between the phone app and the server was encrypted.

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Figure 1. Simplified data entry tool based on the DASH portions-based approach to dietary intake.

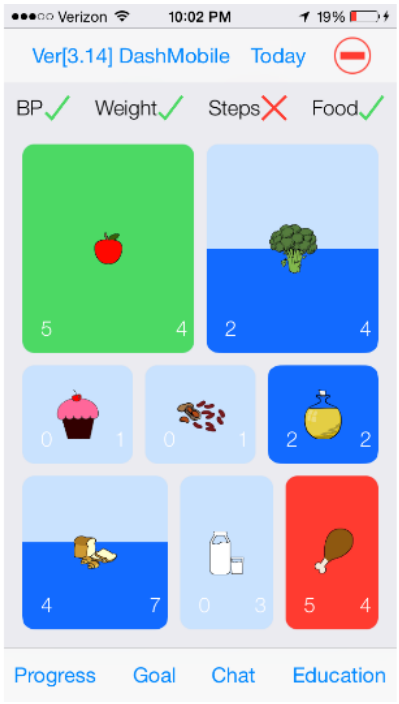

Figure 2. Editable active and achieved goals are listed in the Goals window.

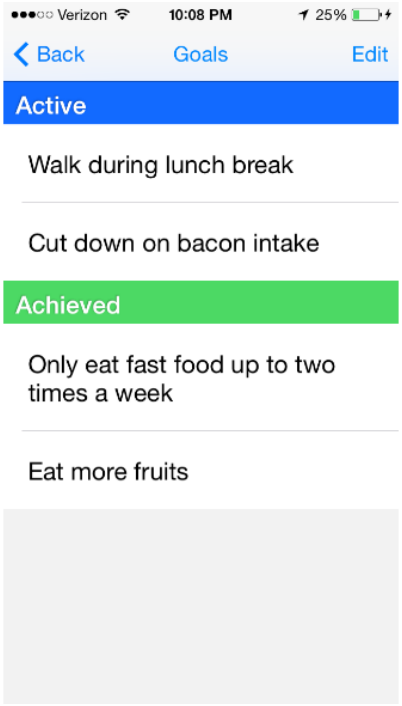

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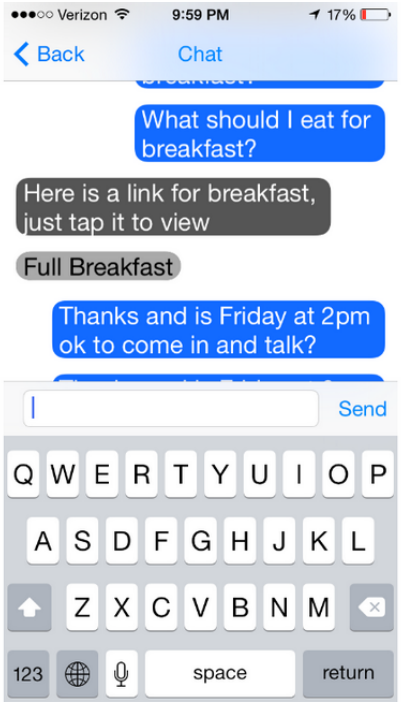
Figure 3. The Chat window, where participants can communicate with their coach.



The coach was a master's student trained to use motivational interviewing as a counseling framework to address behavioral health change. Over the course of 13 weeks, the coach interacted with study participants on a weekly basis through a structured, yet flexible, program that consisted of both telephone calls and asynchronous sessions through the communication channel of their preference (instant message, SMS, or email). In addition, over the course of the study, the DASH health coach logged dietary and physical activity data based on assessments made during 6 phone calls during the study period. Based on this data, the DASH coach assisted participants in setting goals for changing behaviors consistent with their hypertension behavior change plan by reviewing collected data with the user, assigning educational tasks, and engaging in problem solving.

Outcomes

Engagement and Acceptability

To assess participant acceptability of and engagement with the program, the number of blood pressure measurements, weight measurements, and daily steps were logged. Daily step counts of ≤250 were considered invalid. The number of coaching phone calls attempted and completed, servings documented in the dietary assessment, and goals set were also assessed.

Physiological Parameters

Blood pressure, heart rate, weight, and steps were collected to assess changes pre- and postintervention. Wireless behavior-tracking devices (blood pressure cuff, scale, and pedometer) were synced via Bluetooth to the mobile app on the participant's smartphone, which uploaded data to the web-based coaching portal.

Statistical Analysis

Descriptive analyses were performed to summarize the characteristics of our study population. A Wilcoxon signed rank test comparing the first and last documented physiologic measures (blood pressure, heart rate, weight, body mass index, and calories) was performed to assess significant changes post-intervention. The same method was applied to examine changes between the baseline (days 1-7) and follow-up (days 46-120) for the average daily steps. For all tests, P values <.05 were considered statistically significant. Analysis was conducted using SAS 9.4 (SAS Institute).

Results

Overview

A total of 17 patients participated in this feasibility pilot study. The mean age of the participants was 59 years (SD 6), and 10/17 (60%) were women. The participants in the study had an average baseline BMI of 33.6 (SD 7.46), an average baseline systolic blood pressure of 138.6 (SD 21.47), and average baseline diastolic blood pressure of 86.9 (SD 16.10).

Engagement and Acceptability

As detailed in Table 1, participants were engaged with the app. All participants logged their weight, steps, and dietary intake and received messages from the coach. Most of the participants (15/17, 88%) utilized the chat feature to send messages to the coach, and 16 participants (94%) logged their blood pressure and recorded goals. Over 120 days, the mean number of logged measurements per patient was 63 (SD 46) for blood pressure, 52 (SD 45) for weight, and 55 (SD 36) for step counts. Of 102 coaching phone calls, 74 (73%) were completed. The mean number of food entries per day per patient was 5.9 (SD 4.5), and patients set a mean number of 5 (SD 2) goals.

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Table 1. Engagement measures.

Engagement measures[a]	Engagement over study duration[b]		Engagement per day, mean (SD)
	Mean (SD)	Median (IQR)	
Messages sent to the coach per person	19.3 (16.2)	14 (66)	0.16 (0.14)
Messages sent from the coach per person	31.6 (16.1)	31 (74)	0.26 (0.13)
Number of times blood pressure was logged	63.1 (46.0)	69 (178)	0.52 (0.38)
Number of times weight was logged	51.5 (45.1)	41 (76)	0.43 (0.38)
Number of times steps were logged	55.1 (35.7)	63 (103)	0.46 (0.30)
Logged food entries	708.9 (541.2)	616 (1473)	5.9 (4.5)
Goals recorded	5.1 (1.8)	5.5 (5)	N/A[c]

[a]Data represented reflect those who used the respective features.

[b]The study duration was 120 days.

[c]N/A: not applicable.

Physiological Results

Mean systolic and diastolic blood pressure, heart rate, weight, body mass index, calories, and step counts did not change significantly over time (Multimedia Appendix 1).

Discussion

Overview

In this pilot study, we found that an interactive mobile app (DASH Mobile) to promote healthy behaviors that reduce hypertension was feasible and engaged participants. We did not find a difference in physiological outcomes, but we were underpowered to identify such changes.

The average participant routinely logged their blood pressure, weight, steps, food servings and communicated with their DASH Mobile health coach, demonstrating active participation. The engagement findings compare favorably with outcomes for the original web-based implementation of DASH (DASH for Health), which reported only 26% participation by the end of the 12-month trial in 2008 [5]. More recently, our findings were similar to another web-based implementation of DASH that reported 71% participation [10].

Mobile interventions are more successful with participant adherence [6,11,12]. Adherence promotion can be designed through several approaches including participant-tailored content, providing real time feedback to the participant, and automated or human support to reinforce the behavior change potential of the digital intervention [13-15]. Combining these approaches may increase the effectiveness of an intervention [16]. For example, a recent weight loss study that compared a solely mobile intervention to a mobile intervention blended with in-person components demonstrated that participants in the blended model experienced a greater average weight loss than those who received a purely mobile intervention [16].

We also identified challenges to engagement. Although the Bluetooth-enabled devices were meant to make the experience of collecting physiologic and behavioral data seamless, we experienced difficulties in pairing the devices with the app, resulting in the need to transition to another company's devices. Additionally, scheduling synchronous telephone counseling presented a challenge when the coach's availability did not mesh well with participants' schedules. Like other behavior change programs, motivating participants to read the educational materials remained a challenge. A potential opportunity for improvement could be to tie these closer to the user-facing data visualizations. Finally, while we used line graphs to illustrate data over time, further work should explore patient preferences.

Given the level of engagement in our study, particularly in the area of tracking, a mobile app intervention may be an effective way to integrate and sustain behavior change in hypertension management. Our study did not have enough participants to determine a change in clinical outcome. A power calculation indicates that at least 140 participants would be needed to evaluate the effectiveness of DASH Mobile. Our favorable engagement findings support such a trial. Successful lifestyle change interventions require substantial patient motivation, engagement, and access to experts.

Limitations

This study is limited in its generalizability, as all participants were required to be English speaking and own a smartphone. Though 77% of all Americans own a smartphone, only 46% of Americans aged 65 years or older do [8]. In addition, all measurements were self-administered and thus subject to inaccuracy and bias. Furthermore, the intervention is not autonomous, as it included human-based coaching. However, the incorporation of human-based support is a common feature of effective behavior change programs and does not necessarily preclude dissemination [17-19].

In 2017, the American Heart Association/American College of Cardiology published updated hypertension guidelines [20]. Stage 1 hypertension is now defined as a systolic blood pressure of 130-139 mm Hg or a diastolic blood pressure of 80-89 mm Hg, and Stage 2 hypertension is defined as a systolic blood pressure ≥140 mm Hg or a diastolic blood pressure ≥90 mm Hg. However, treatment for Stage 1 and Stage 2 hypertension still include the lifestyle changes promoted by DASH.

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Conclusion

This pilot study demonstrates the feasibility of delivering a digital DASH intervention by leveraging off-the-shelf wireless devices. Participants were engaged, suggesting that a smartphone-based app can be used to deliver behavioral interventions. Future implementations might employ integrated calendars, alarms, social networks, and other smartphone tools to further enhance patient engagement and ultimately clinical outcomes. In summary, our data support the growing interest in using mobile platforms to strengthen user engagement and the accessibility of health behavior change interventions.

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Conflicts of Interest

None declared.

Multimedia Appendix 1
Change in physiological outcomes from baseline to follow-up.
[DOCX File , 16 KB - formative_v4i5e13989_app1.docx]

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Abbreviations

DASH: Dietary Approaches to Stopping Hypertension

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