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Contents

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Original Paper

User Perceptions of an mHealth Medicine Dosing Tool for Community Health Workers

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Abstract

Background: Mobile health (mHealth) technologies provide many potential benefits to the delivery of health care. Medical decision support tools have shown particular promise in improving quality of care and provider workflow. Frontline health workers such as Community Health Workers (CHWs) have been shown to be effective in extending the reach of care, yet only a few medicine dosing tools are available to them.

Objective: We developed an mHealth medicine dosing tool tailored to the skill level of CHWs to assist in the delivery of care. The mHealth tool was created for CHWs with primary school education working in rural Mexico and Guatemala. Perceptions and impressions of this tool were collected and compared to an existing paper-based medicine dosing tool.

Methods: Seventeen Partners In Health CHWs in rural Mexico and Guatemala completed a one-day training in the mHealth medicine dosing tool. Following the training, a prescription dosing test was administered, and CHWs were given the choice to use the mHealth or paper-based tool to answer 7 questions. Subsequently, demographic and qualitative data was collected using a questionnaire and an in-person interview conducted in Spanish, then translated into English. The qualitative questions captured data on 4 categories: comfort, acceptability, preference, and accuracy. Qualitative responses were analyzed for major themes and quantitative variables were analyzed using SAS.

Results: 82% of the 17 CHWs chose the mHealth tool for at least 1 of 7 questions compared to 53% (9/17) who chose to use the paper-based tool. 93% (13/14) rated the phone as being easy or very easy to use, and 56% (5/9) who used the paper-based tool rated it as easy or very easy. Dosing accuracy was generally higher among questions answered using the mHealth tool relative to questions answered using the paper-based tool. Analysis of major qualitative themes indicated that the mHealth tool was perceived as being quick, easy to use, and as having complete information. The mHealth tool was seen as an acceptable dosing tool to use and as a way for CHWs to gain credibility within the community.

Conclusions: A tailored cell phone-based mHealth medicine dosing tool was found to be useful and acceptable by CHWs in rural Mexico and Guatemala. The streamlined workflow of the mHealth tool and benefits such as the speed and self-lighting were found to be particularly useful features. Well designed and positioned tools such as this may improve effective task shifting by reinforcing the tasks that different cadres of workers are asked to perform. Further studies can explore how to best implement this mHealth tool in real-world settings, including how to incorporate the best elements of the paper-based tool that were also found to be helpful.

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KEYWORDS
community health worker; cellular phone; mobile health; Mexico; Guatemala; decision support techniques; medical order entry systems

Introduction

Mobile health (mHealth) is a growing field that aims to utilize cell phone and tablet technologies to improve the delivery of health care. Pilot projects have demonstrated many potential benefits of mHealth tools, including improved patient attendance, adherence to antiretroviral medicines (ARVs), and provider adherence to treatment guidelines [1-5]. One type of mHealth tool in particular, the medical decision support tool, shows great promise in improving the quality of care provided to patients. Just as certain smartphone- or Internet-based technologies are increasingly being used by physicians to improve their work flow and quality of care [6], similar technologies may also be tailored to the skill levels of different cadres of frontline health workers (FLHWs) in a variety of settings to provide similar patient care benefits.

The community health worker (CHW) is one type of FLHW that is increasingly viewed as a viable provider of some basic primary care tasks in resource-poor settings. They have been recognized as potential agents of behavior change, as well as valuable health workers extending the reach of care [7]. Studies related to the Community Case Management (CCM) of childhood illnesses by CHWs have revealed that CHWs can assume significant clinical responsibilities traditionally reserved for nurses or physicians, including the diagnosis and treatment of common diseases [8-12]. Key factors in CHW success include adequate training and clear bedside support [13]. Although there are paper-based prescription and dosing resources occasionally available to FLHWs, such as the Nicaraguan book “Buscando Remedio” and the Hesperian Foundation book “Where There is No Doctor,” mHealth decision support tools have great potential to serve as critical references for CHWs, particularly for those working in remote areas. If well positioned and supported, CHWs may even form part of an alternative system to the unregulated medicine market that is common in many developing settings [14].

To facilitate medication prescription and dosing among community health workers in rural areas, the first author, while working with the Boston-based non-governmental organization Partners In Health (PIH), led the development of an algorithm-based medicine dosing reference mHealth software that can be run without cell phone connectivity on many commonly available Java-enabled mobile devices, including cell phones. This mHealth tool was created for use by CHWs who have only a primary school education, and is to our knowledge the first of its kind. Following an initial training session of the mHealth tool, we studied perceptions and impressions of this new technology, relative to an existing paper-based tool, among CHWs in two rural areas of Mexico and Guatemala.

Methods

Study Design

We designed the study to capture CHW perceptions of the mHealth dosing tool after an initial training aiming to introduce them to the new software. The study consisted of applying an original survey to, and conducting interviews with, participating CHWs in Mexico and Guatemala. The ethics committees of the Brigham and Women’s Hospital and Harvard Medical School exempted this study. Each CHW was individually consented to participate. The initial training lasted one full day, at no-cost to the CHWs, and was part of a larger CHW curriculum in rural primary care that included didactic lessons and bedside mentorship clinical sessions. Before the training, the CHWs were already familiar with the process of seeing patients and providing basic medicines for a limited number of well-defined clinical entities.

Study Population and Setting

CHWs aged 16 or older from the PIH-supported projects in Mexico (N=11) and Guatemala (N=6) who participated in the initial mHealth tool training were eligible to participate in the study. All 17 participants agreed to enroll. CHWs were approved to use the mHealth tool in their daily work only upon demonstrating proficiency in the tool’s function and content; at the time of this writing, the tool was still not yet being used clinically.

The small mountain towns in which these CHWs operated were generally poor and isolated, with limited access to affordable primary health care. The Mexican towns were accessible only by dirt roads, which were often impassable for part of the year due to heavy rains. They had small under-resourced government clinics with private doctors in nearby cities providing basic urgent care on a fee-for-service basis. The Guatemalan towns were reachable by paved roads and public transportation and had small government clinics with private fee-for-service options in nearby cities. At the time of the study, there was no cell phone signal available in any of the Mexican towns, whereas there was a robust cell phone system throughout the region of Guatemala where the CHWs lived.

Overview of the mHealth Tool

The cell phone-based mHealth tool utilized in this study was conceived and designed by DP and LP. Two volunteer programmers wrote the code for it to function on CommCare, an open source platform that was originally developed by the mHealth company, DiMagi Inc. The language of the program was targeted to a primary school reading level, and no calculations are required on the part of the user. The program runs on a “candy bar” Nokia phone to serve as a standalone, decision support mHealth tool. It does not require a cell network to function, but can be programmed to transmit data to, and interface with, electronic medical records or other such programs.

The platform features easy programming and a distinctive "chatter box" feature (Figure 1), which allows the user to scroll through previous decisions without losing their place in the decision tree. The mHealth tool guides users through algorithm-based medication dosing (Figure 2), which accounts for patient characteristics including age, gender, pregnancy status, breastfeeding status, allergies, the ability to combine usage with other medicines, and weight (for pediatric dosing). Certain features of the program were unique due to the nature of the electronic format: the use of short-hand symbols (such as "<" for "less than") was necessary due to space constraints, and greater specificity for the dosing categories was possible due to the ability to program as many advice points as desired (especially for weight-based dosing). Every algorithm follows a pre-determined clinical logic that limits the number of diseases for which a CHW can safely provide care. The clinical scenarios were taught in detail to the CHWs through their regular clinical training using easily understandable flow diagrams that could be referenced in a separate paper binder. Similarly, the medications included were limited to those that are essential and are adequately restocked through a typical supply chain. The program also specifies the quantity of medicine to give in order to assure a full course (eg, total number of pills, boxes, or bottles of syrup).

Overview of the Paper-Based Tool

The paper-based tool traditionally used by CHWs in the study settings is a book called Buscando Remedio (Spanish for "Searching for a Treatment"). It was written by the Nicaraguan government to serve as a primary care resource for FLHWs, and is freely available online [15]. The section primarily used in this study includes single-page information sheets for various medicines, including facts about the medicine, indications for use, cautionary advice, commonly available presentations, dosing instructions (often including a table that shows how much of the medicine to use in different weight categories), the duration of treatment, and a number of other miscellaneous comments (see Figure 3). These single-page sheets reference text presented in other sections of the book, with the expectation that users will access this information as needed.

Data Collection

Each CHW completed an in-person interview that was administered in Spanish by DP and LP. MF and DP subsequently translated the interview notes into English. Data collection focused on 4 themes central to the adoption of a new technology in resource-poor settings: (1) comfort (ie, what were the participants' assessments of the mHealth tool's navigability and ease of use?), (2) acceptability (ie, what was the degree to which participants found the mHealth tool satisfactory and appropriate for use in dosing a medicine?), (3) preference (ie, did the participants tend to favor the mHealth tool over the existing paper-based tool when given a choice?), and (4) accuracy (ie, were the participants able to identify accurate dosing information utilizing the mHealth tool?).

The interview sought information on sociodemographic characteristics, previous experience as a CHW, and self-assessed experience with mobile technologies. To assess how accurately CHWs could produce dosing information using each tool, participants were asked to complete a practice test on dosing in which they could choose to use either the mHealth tool or the paper-based tool for each question. Following the practice test, we assessed their comfort with each tool by asking them to rate whether it was very easy, easy, hard, or very hard and to justify their tool selection choice. We assessed acceptability by asking the CHWs about their general impressions of the mHealth tool, and about specific aspects of the program that they did and did not like. Last, we asked CHWs to indicate which tool (the mHealth tool or the paper-based tool) would be their tool of choice when caring for 5 hypothetical patient populations (a child, a pregnant woman, an adolescent, an elderly woman, and an adult man from outside of the community) and to justify their decisions. DP and LP scored each question in the practice dosing test on a scale of either 1-4 or 1-6, depending on the content of the answer (2 points were given for the correctly stated amount of medicine that should be provided, 2 points for the correct schedule, and 2 points for the correct duration, if the medicine was more than a single dose and if the duration was explicitly stated in the text). Half credit, or 1 point, was given for partially correct elements. These scorings were performed independently by DP and LP, and then compared for accuracy. Few conflicts arose, but when they did they were discussed and resolved by agreeing on a common interpretation of how to apply the grading rules.

Data Analysis

AD read the translated transcripts four times: first for familiarity, second for descriptive line-by-line coding, third for axial coding (isolating basic themes), and fourth for interpretive coding to capture the major specific concepts. From these codes, AD, MF, and DP agreed upon thematic variables and quantified the appearance of these variables in participants' transcripts. They also observed overlap between the qualitative thematic and quantitative measured variables. The quantitative data was analyzed using SAS version 9.2.

Figure 1. Screenshots of mHealth tool "chatter box" running through the Paracetamol algorithm for a child.

Figure 2. Sample medicine dosing algorithm (for a simple medicine–topical Clotrimazole cream).

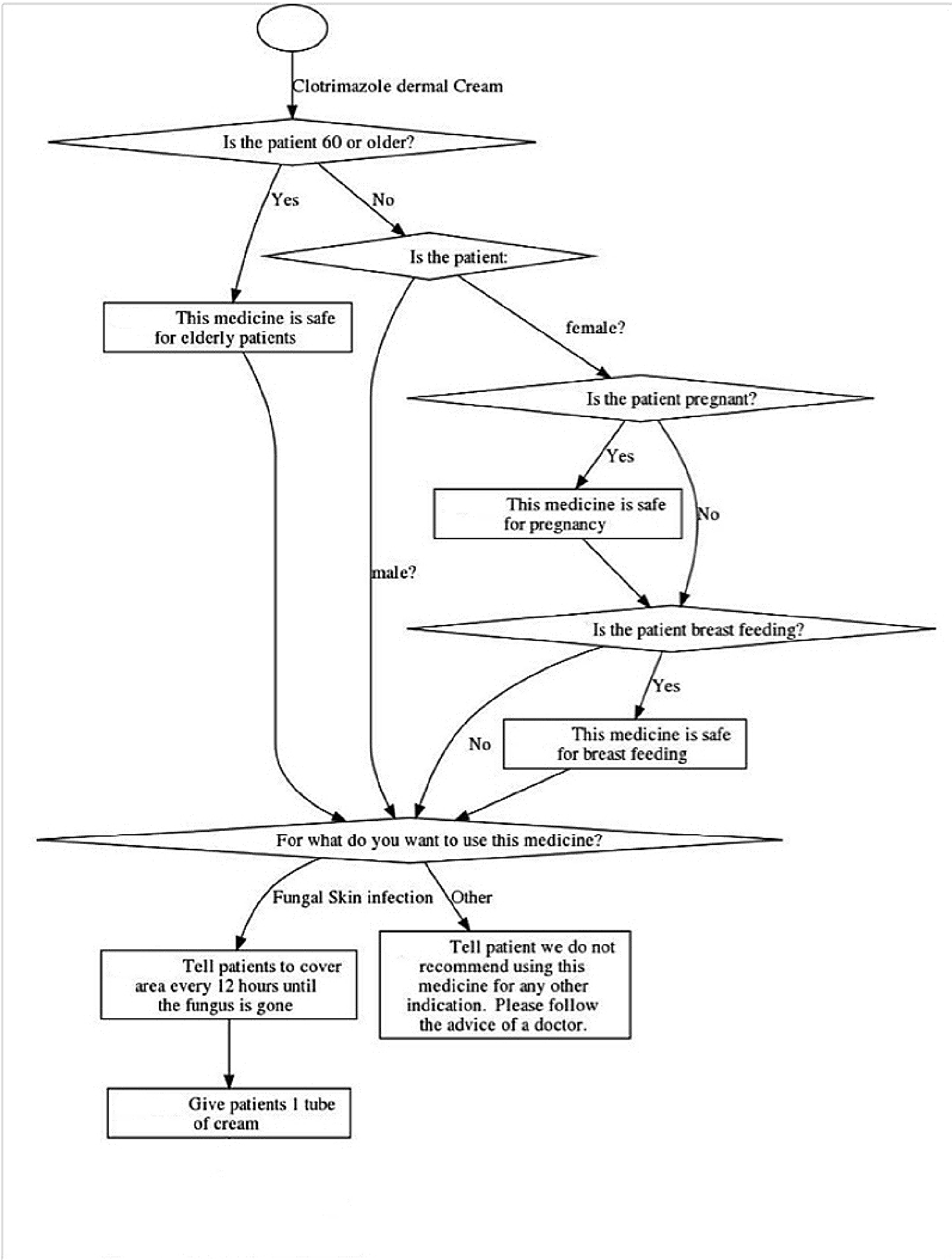
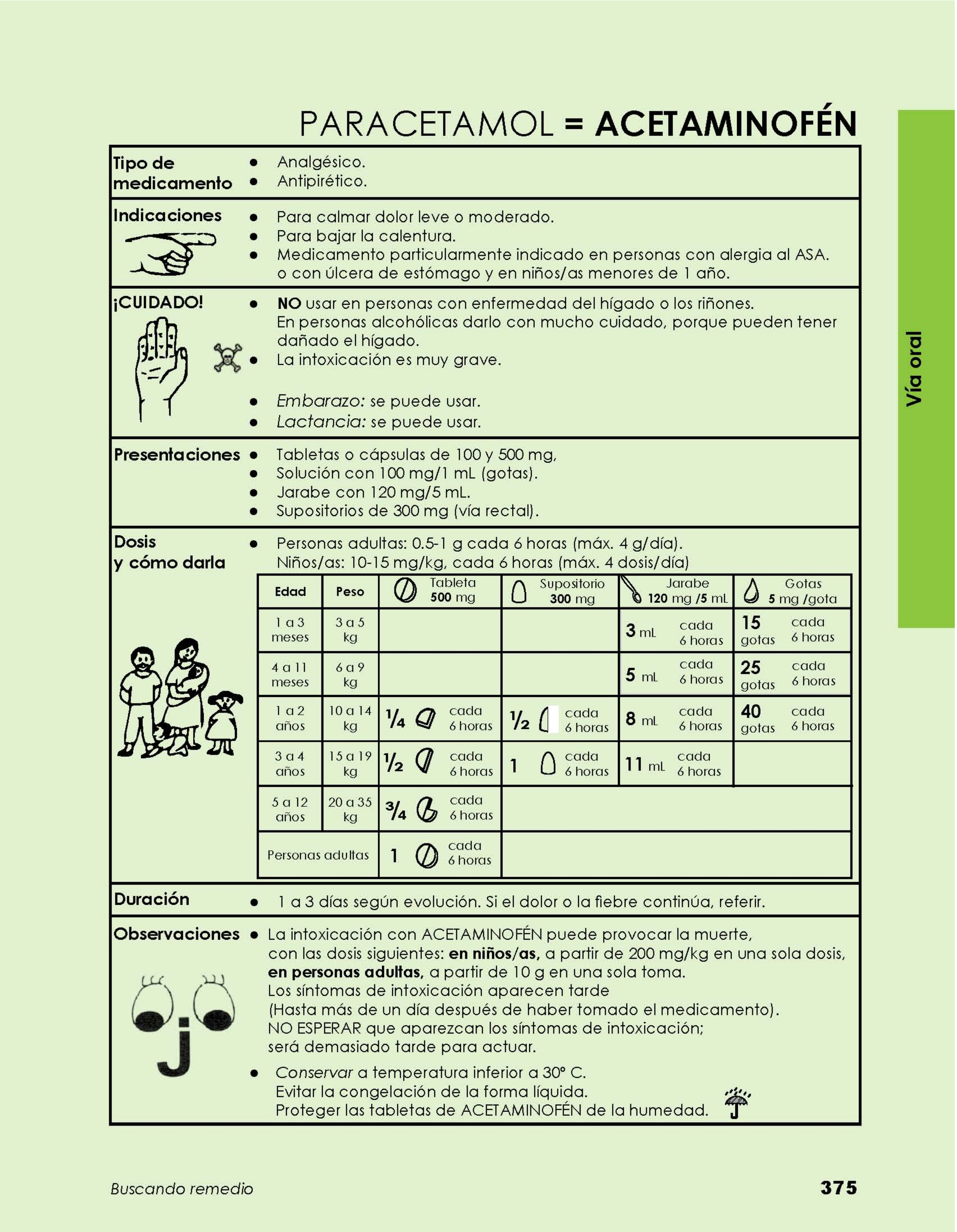


Figure 3. Single-page medicine fact sheet from “Buscando Remedio” (for Paracetamol).



PARACETAMOL = **ACETAMINOFÉN**

Vía oral

Tipo de medicamento
- Analgésico.
- Antipirético.

Indicaciones
- Para calmar dolor leve o moderado.
- Para bajar la calentura.
- Medicamento particularmente indicado en personas con alergia al ASA. o con úlcera de estómago y en niños/as menores de 1 año.

¡CUIDADO!
- **NO** usar en personas con enfermedad del hígado o los riñones. En personas alcohólicas darlo con mucho cuidado, porque pueden tener dañado el hígado.
- La intoxicación es muy grave.
- *Embarazo:* se puede usar.
- *Lactancia:* se puede usar.

Presentaciones
- Tabletas o cápsulas de 100 y 500 mg,
- Solución con 100 mg/1 mL (gotas).
- Jarabe con 120 mg/5 mL.
- Supositorios de 300 mg (vía rectal).

Dosis y cómo darla
- Personas adultas: 0.5-1 g cada 6 horas (máx. 4 g/día). Niños/as: 10-15 mg/kg, cada 6 horas (máx. 4 dosis/día)

Edad	Peso	Tableta 500 mg	Supositorio 300 mg	Jarabe 120 mg /5 mL	Gotas 5 mg /gota
1 a 3 meses	3 a 5 kg			3 mL cada 6 horas	15 gotas cada 6 horas
4 a 11 meses	6 a 9 kg			5 mL cada 6 horas	25 gotas cada 6 horas
1 a 2 años	10 a 14 kg	1/4 cada 6 horas	1/2 cada 6 horas	8 mL cada 6 horas	40 gotas cada 6 horas
3 a 4 años	15 a 19 kg	1/2 cada 6 horas	1 cada 6 horas	11 mL cada 6 horas	
5 a 12 años	20 a 35 kg	3/4 cada 6 horas			
Personas adultas		1 cada 6 horas			

Duración
- 1 a 3 días según evolución. Si el dolor o la fiebre continúa, referir.

Observaciones
- La intoxicación con ACETAMINOFÉN puede provocar la muerte, con las dosis siguientes: **en niños/as,** a partir de 200 mg/kg en una sola dosis, **en personas adultas,** a partir de 10 g en una sola toma. Los síntomas de intoxicación aparecen tarde (Hasta más de un día después de haber tomado el medicamento). NO ESPERAR que aparezcan los síntomas de intoxicación; será demasiado tarde para actuar.
- *Conservar* a temperatura inferior a 30° C. Evitar la congelación de la forma líquida. Proteger las tabletas de ACETAMINOFÉN de la humedad.

Buscando remedio **375**

Results

Participants

Characteristics of the 17 CHW participants are shown in Table 1. The majority of the CHWs (11/17, 65%) were recruited from Mexico, and the age distribution was roughly similar across the two countries. Although somewhat higher in Mexico than Guatemala, education level tended to be low overall, with no CHW having completed high school. Most participants (12/17, 70%) had 1 to 5 years of experience working as a CHW and this was similar across sites. While most CHWs had at least some experience using cell phones, one-third reported no prior experience.

Comfort

The CHWs expressed comfort with the mHealth tool after the initial training session. 14/17 (82%) of CHWs elected to use the mHealth tool for at least 1 of the 7 questions on the practice test and 9/17 (53%) used the paper-based tool at least once. Of the 14 people who rated the phone application, 13 (93%) classified it as easy or very easy to use. Of the 9 people who rated the paper-based tool, 5 (56%) classified it as easy or very easy to use).

The remaining 4/9 CHWs (45%) who rated the paper-based tool as hard or very hard to use noted the lack of self-illumination with this tool and the length of time it took to find information (Table 2). A few participants noted that the paper-based tool allowed them greater flexibility to search the range of potential diagnoses and treatments.

> *[The book] has an index and it is complete.*
>
> *[The book] is easy because the information is organized, alphabetized, and the graphics are easy to understand.*

Narrative responses about the mHealth tool revealed that many CHW users enjoyed its ease, speed, and completeness.

> *[I liked it] because you enter the information and the result comes out. In the book you have to divide and multiply. The phone is much smoother.*

Additionally, participants appreciated the mHealth tool because it afforded a light source for times when CHWs work in low light conditions (Tables 2 and 3).

> *Because of my age, I do not see well and with the phone I see better because it has light.*
>
> *[The phone] will be better in an emergency because it is fast and has its own light (sometimes there is no electricity).*

One potential drawback to the mHealth tool was highlighted by some CHWs, who were troubled by having to learn a new technology and information interface (Table 2).

Acceptability

Overall, the CHWs in both countries accepted the mHealth tool as a satisfactory tool that was appropriate for use in dosing a medicine. Narrative responses about the mHealth tool again described this tool as being fast, easy, complete, and well organized (Table 3). In addition, some CHWs noted that using the mHealth tool on a phone would be a way to gain credibility in the community.

> *The people, upon seeing us look in the book, think badly of us. With the phone, they think we are important.*
>
> *The phone is a more acceptable way to access information in front of the patient so as to not lose face.*

Perceived challenges with the mHealth tool centered on the start-up investment needed to learn a new interface, and on the need to care for the technology that is more delicate and requires periodic maintenance (Table 3).

Preference

CHWs consistently demonstrated a preference for the mHealth tool over the paper-based tool in different clinical scenarios (Figure 4). Narrative responses about this preference revealed a number of themes surrounding how CHWs would capitalize on the factors unique to each tool to best interact with the patient receiving care (Table 4). For example, in providing care to someone not from the same community, one CHW would use the mHealth tool because it is "faster and easier. He comes from far away so he will probably want to return to his house right away." On the other hand, in providing care to a pregnant woman, participants were divided between choosing the mHealth tool or the paper-based tool, depending on which they felt they were more likely to use correctly. For many, this was the first time that they had used the mHealth tool so they were concerned that without further practice and mastery of the tool, they were more likely to inadvertently misuse it and give a wrong dose. Others, who may have become more comfortable with using the new mHealth tool more quickly, would reach for it first when caring for a pregnant woman because they felt it more clearly stated "if a medication is okay or not".

Participants who chose the paper-based tool in patient scenarios repeatedly cited the ample amount of information readily available as the reason for choosing this dosing tool. This may have been referring to both the book chapters available for further reading, and the ability to simultaneously view all related dosing information on the same page (which would be difficult with the mHealth tool as it provided information in a step-by-step fashion). They appreciated having more information available for their own learning and to better explain the condition and medication to their patient.

> *Because [the book] explains more, you can explain more and show [the patient] more information.*

It is interesting to note that while some participants found the paper-based tool to provide more complete information than the mHealth tool, many also cited the completeness of the information in the mHealth tool. This was probably because both tools contained components that were perceived to provide all needed elements; the mHealth tool efficiently gave all pertinent clinical information by following a checklist, while the paper-based tool had more pictures and narratives about the diseases.

Accuracy

Use of the mHealth tool generally resulted in more accurate answers when compared to the paper-based tool. For 6 of 7 practice test questions, the mean score among those who answered with the mHealth tool was notably higher than the mean score among respondents who answered with the paper-based tool (Figure 5). In general, the difference was greatest in the questions that asked for pediatric doses based on age and weight, as opposed to standardized doses and courses for adults. Although not coded nor quantified, the majority of the errors with each tool followed a few general themes. For the paper-based tool, the CHWs often found it challenging to find the 3 different dosing elements needed (dose, schedule, and duration) as they were often in disparate locations without any clear pattern to follow. For the mHealth tool, the CHWs produced a wrong result if they inadvertently entered information incorrectly at some stage of the algorithm (ie, if they entered in a wrong gender, age, weight, etc).

Table 1. Characteristics of study population.

Characteristic (N[a])		Total n (%)	Guatemala n (%)	Mexico n (%)
Age				
	18-25	6 (35)	3 (50)	3 (27)
	26-35	7 (41)	2 (33)	5 (45)
	36-45	3 (17)	1 (17)	2 (18)
	56-65	1 (6)	0 (0)	1 (9)
Educational level (N=16)				
	Some primary school	3 (19)	1 (20)	2 (18)
	Graduated primary school	5 (31)	3 (60)	2 (18)
	Some secondary school	3 (19)	0 (0)	3 (27)
	Graduated secondary school	3 (19)	0 (0)	3 (27)
	Some high school	2 (12)	1 (20)	1 (9)
	Graduated high school	0 (0)	0 (0)	0 (0)
Years worked as community health worker				
	<1	2 (12)	1 (16)	1 (9)
	1-5	12 (70)	4 (68)	8 (73)
	6-10	2 (12)	0 (0)	2 (18)
	>10	1 (6)	1 (16)	0 (0)
Previous experience with cell phones				
	None	6 (34)	2 (33)	4 (36)
	A little	4 (24)	2 (33)	2 (18)
	Some	4 (24)	2 (33)	2 (18)
	A lot	3 (18)	0 (0)	3 (27)

[a]Mexico N=11; Guatemala N=6, unless otherwise noted.

Table 2. Narrative responses about comfort/perceived ease of use of the 2 tools.

Response	mHealth tool	Paper-based tool
Very easy	*You enter the information and the result comes out. In the book, you have to divide and multiply. The phone is smoother.* *The doses are more complete, using milligrams instead of "a half" [of a tablet] as the book does.* *Because of my age, I do not see well and with the phone I see better because it has light.* *You press a button and then it gives you everything after just entering the name [of the medication].* *The questions all come packaged together and you do not have to look for them; it's fast.* *You just have to look up the medication and it has for us the age and how many kilos and it tells us how much to give the patient.* *All of the information appears at once.*	*You just have to look up the medication and it tells you everything. It tells you the ages for the use of the medication and how much medication to give.*
Easy	*With just a name [of the medication] the phone designs and sees everything.* *You put in the information and everything appears.* *It is fast, like a calculator.* *Easy because it has all of the information.* *Enter the program [and immediately] look up the medication. You can look by age and it is easier (example: TMX_SMP for children). In the book, I imagine that is the same [but] it requires more attention (more concentration).*	*It has an index and is complete…and in order.* *It directs us to the pages to see.* *It is easy to look for information.* *It is easy because the information is organized, alphabetized, and the graphics are easy to understand.* *Everything is marked. Once you know how to use the book, it not necessary to learn another.*
Hard	*Searching via greater than ≥ or less than ≤ [was difficult]… the new concept [was difficult to master immediately].* *I got a little confused with the information and it was a bit hard for me to manage [the phone].* *One does not know how to use it for the first time. It is very hard to learn it.*	*I got confused easily with the book—it does not explain well.* *I could not find information about pneumonia.* *We don't know it well yet.*
Very hard	No responses	*It was dark; you cannot read the book well.* *The book is perfect but it takes longer—it's also dark.*

Table 3. Narrative responses about acceptability of the mHealth tool.

Preference	Characteristic	Comment
Like		
	Speed	
		Good, it is a big help because everything is faster.
		Yes, it is more practical, easier to use, and saves time.
	Perceived importance	
		Interesting; the people, upon seeing look in the book, think badly of us. With the phone, they think we are important.
		The phone is a more acceptable way to access information in front of the patient so as to not lose face.
		It is nice looking.
	Self-sufficient tool	
		It will be better in an emergency because it is fast and has its own light (sometimes there is no electricity).
		It has everything—it has how to transmit, you can take photos.
	Improves health provider confidence	
		It is good for us as health providers because we do not feel capable to give a consult, but with this book and the cell phone, we are going to be more confident that we can help the patient.
	Easy to understand	
		It is good because it has all of the information in a way that is easy to understand.
		I like it a lot because it is fast. If we can manage the phone, we can manage the book too.
	Complete Information	
		Yes, I like it because it is easier to use and gives more information.
		I liked all parts because everything had a place. I like it very much because it has all of the information for many examples (adults, children, age, weight, pregnant women, elderly).
		It tells you whether it [the medicine] can be used for pregnant women.
	Organization of tool	
		It is structured; it is very fast for looking things up. It seems very well written.
	Fun	
		It is more fun.
Dislike		
	Needs learning investment	
		It took time to learn it.
		I could not manage as it should be (as it would be by someone who knows). It is hard to learn to manage it.
	Technical difficulties	
		There is no signal here.
		It is blocked [asleep]; the letters are small.
	Requires more care	
		You have the commitment of taking care of it so that you don't break it. You have to treat it delicately.

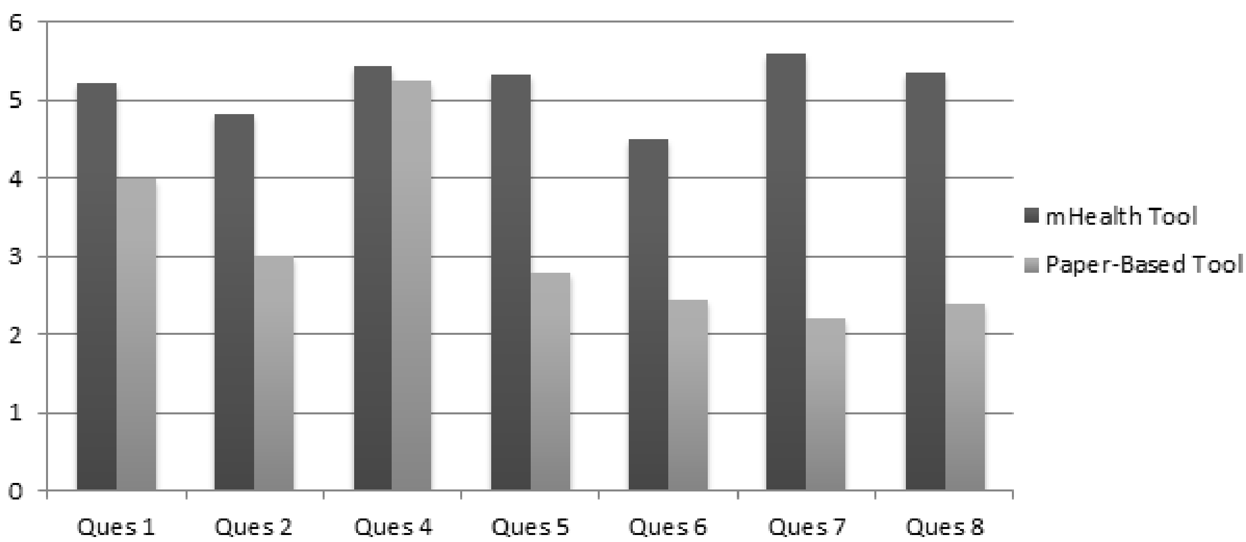
Table 4. Narrative responses about tool preference in 5 hypothetical clinical scenarios.

Scenario	mHealth tool	Paper-based tool
A child	• Self-sufficient tool *It saves time; you don't need a pen or paper.* • Multitask *While I am talking I can be looking at the dose, extracting information because it gives the information easily.* • Well organized *The book is confusing (tangled)... The phone gives information fast and is easier to understand.* • Exact dosing *It gives you the exact dose.* • Provider confidence *I looked in the phone and then afterward in the book to see if it was correct, and it was!* *I can eliminate doubts quickly and later check in the book to see if they coincide.* • More information *It has more information. Aside from the doses, it has more recommendations to make sure the parents understand.*	• More information *It explains the disease and gives all of the information.* • Time given to patient *Because it has more information about the illness (the phone may be so fast that you do not give time to the person and he/she may think badly about the appointment/consult.)* • Easier to understand *I can understand [the book] better because the phone needs more [attention/comprehension/education].*
A pregnant woman	• Speed and readability *Faster and easier to read.* • Fear/confidence in tool *It can be used in pregnant women so as not to make a mistake because it tells me if a medication is okay or not.*	• More information *More information about pregnancy.* • Confidence in tool's content/ fear in misuse *You can't give a pregnant woman the wrong drug.* *If I use the phone badly, I could hurt a pregnant woman and her baby.*
A teenage boy	• Easier to use *It is smarter, it tells you everything you need to know, it is more clear and well-explained.* *It is fast and easier to understand.* • Fear/confidence in tool—verification *Depends on the disease. I will also check the book.* *The illness is probably mild so it can wait, I will verify it using both methods.* • Ensure thoroughness *I like it because I am lazy to ask questions. It is hard for me to learn about the medications.*	• More information *[The book] explains more so you can explain more and show [the patient] more information. The book has more information. But if they come in a hurry, I'm going to use the phone.* • Fear/confidence in tool *Less risky to give him medications."*
An old woman	• Patient expectations *To know, it is more clear and well-explained. They come in a hurry and they say "If she starts reading, she must not know."* *She is not going to be able to wait.* *It is a delicate case. You have to know to give her information. The phone has more information.* • Well organized *The book is confusing (tangled) and confuses me. The phone gives information fast and is easier to understand.* • Fear/confidence in tool—verification *Check in the phone and double check in the book.* *It tells you whether the medicine is good or bad if you are 60 years old.* *Because it talks specifically about the elderly.*	• Patient demands/questions *I would prefer the book because she would want more information/explanation* • More information *More information—it gives more information.*

Scenario	mHealth tool	Paper-based tool
An adult man not from your community	• Fear/confidence *[The Phone] ensures that what I am thinking is correct at the time of giving the diagnosis.* • Faster *Faster (he is coming from far away so will not want to wait).* *[The phone is] faster and easier; he comes from far away so he will probably want to return to his house right away.*	• More information *Here I look for what type of illness he has, how old he is, and how long he has it and later depending on the illness and the pills, the book has indications and conflicting drugs.* • Phone functionality *Sometimes the phones are not charged.* • Learning *To continue learning more.* • Use both *I am going to keep practicing a little more (the book), but it is always slower—I will probably use the two together but what happens if the phone breaks? Then I have the book and I understand it.*

Figure 4. Tool preference, by potential patient demographic.

Figure 5. Mean dosing scores for practice test, by tool choice.



Discussion

Key Findings

This study demonstrated that, following an initial introductory training session, the majority of CHWs were comfortable using a new cell phone-based mHealth tool, accepted the tool, and often preferred it relative to an existing paper-based dosing tool that they had been using. In a practice dosing test that asked CHWs to identify doses for certain conditions, accuracy tended to be higher among individuals who used the mHealth tool, relative to those who used the paper-based tool. With the growing interest in CCM and mHealth as resources available to improve and expand the performance of CHWs in resource-poor settings, this tool may be an important addition to the armamentarium for improving the quality and safety of care provided by such FLHWs.

The narrative responses collected about the 2 tools revealed a number of observations that will be important when implementing the mHealth tool in any large-scale program. For example, while many CHWs noted that the mHealth tool quickly provided the information needed, they enjoyed the expansive amount of information provided in the paper-based tool as it allowed them to continue learning on their own and gave them more information to share with patients. Knowing this, future users of the mHealth tool may also be concurrently provided with a variety of patient education sheets that will deepen and broaden the amount of information available to the CHW. It is also possible that the mHealth tool and these education sheets could be integrated so that there are bidirectional links between them.

One factor that most likely contributed to the usability of the mHealth tool was its streamlined workflow, designed to achieve effective task shifting by guiding CHWs to accurately dose medications for only a limited list of primary care ailments. The paper-based tool, on the other hand, was written to be understandable by a variety of providers but is not tailored for use by one cadre in particular; since it includes information on a wider range of medications and clinical entities, it will likely present information to some groups that is beyond their scope of practice. Simplified but well designed tools, such as this mHealth tool, may clarify and reinforce the tasks reserved for different FLHW cadres, be it CHWs, nurses, or doctors, so that each can achieve mastery in their sphere.

Indeed, an important feature of the mHealth tool's platform is the ability to transparently customize the medicines, indications, and dosages in the mobile dosing software based on the local context. CHWs in different regions work with different formularies of medicines in their kit, and it is important that the system can be easily adapted to local needs so that it remains streamlined for that health worker's workflow. The mobile dosing software has been designed to use a simple plain text programming language that can be quickly tailored locally as needed. In the future, it could also be modified and linked to medication inventory, potentially saving busy FLWHs from laborious paper reports.

Even though the use of the mHealth tool was observed to improve dosing accuracy, errors were still made with both tools. The goal for the clinical use of any tool should be close to 100% accuracy, so future iterative improvements will have to be made in order to achieve this goal. This can be done through a variety of strategies. First, while the mHealth tool already has a "chatter box" function that allows the user to review the data previously entered, further safety confirmation screens can be programmed in order to assure that one small slip does not lead to erroneous advice in the end. Next, implementers can provide simulated clinical encounters for CHW trainees in order to assure that they master the tool's interface before using it with patients.

Limitations

This study was conducted among a small group of CHWs working at 2 project sites where the mHealth tool was to be implemented as part of routine care. The small number of participants precludes us from drawing formal statistical comparisons between the mHealth and paper-based tools, and between the participants at the two sites. Because the mHealth tool was introduced as part of programmatic activities, the individuals who led the software development also conducted the trainings and research interviews. While it is possible that this may have resulted in a social desirability response bias if participants felt pressured to speak positively about the mHealth tool, we minimized this to the greatest extent possible by setting a tone of trust during interviews, encouraging participants to speak freely without fear of judgment, and assuring that their opinions would not affect their standing in the program. Lastly, participants were able to select which tool they wanted to use for each practice test question. If participants who better understood dosing in general tended to select the mHealth tool, this could at least partly explain higher accuracy scores for questions answered by this tool; however, this seems unlikely given that nearly all participants used the mHealth tool at least once during the practice test.

Conclusions

The mHealth tool described in this study is one of many similar new technologies that are poised to make important contributions to how care is delivered in a variety of contexts. While the observations reported suggest that tools such as these hold great promise, further studies will be needed to assure that use of the mobile tools in actual clinical contexts improves outcomes. These studies should not try to answer a binary question about whether or not the tool is useful, but instead should explore how the tool can be improved and personalized to function best in its unique context. Similarly, appropriate technology supports, such as hand-crank chargers, solar chargers, and protective cases to prevent equipment damage, will also need to be utilized in order to maximize on-site functioning.

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Conflicts of Interest

Conflicts of Interest: None declared.

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Abbreviations

ARV: antiretroviral medicines
CCM: Community Case Management
CHW: community health worker
FLHW: frontline health workers

PIH: Partners In Health

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Original Paper

Usage of Multilingual Mobile Translation Applications in Clinical Settings

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Related Article:

This is a corrected version. See correction statement: http://mhealth.jmir.org/2013/2/e19/

Abstract

Background: Communication between patients and medical staff can be challenging if both parties have different cultural and linguistic backgrounds. Specialized applications can potentially alleviate these problems and significantly contribute to an effective, improved care process when foreign language patients are involved.

Objective: The objective for this paper was to discuss the experiences gained from a study carried out at the Hannover Medical School regarding the use of a mobile translation application in hospital wards. The conditions for successfully integrating these technologies in the care process are discussed.

Methods: iPads with a preinstalled copy of an exemplary multilingual assistance tool ("xprompt") designed for use in medical care were deployed on 10 wards. Over a period of 6 weeks, approximately 160 employees of the care staff had the opportunity to gather experiences with the devices while putting them to use during their work. Afterwards, the participants were asked to fill out an anonymous, paper-based questionnaire (17 questions) covering the usability of the iPads, translation apps in general, and the exemplary chosen application specifically. For questions requiring a rating, Likert scales were employed. The retained data were entered into an electronic survey system and exported to Microsoft Excel 2007 for further descriptive analysis.

Results: Of 160 possible participants, 42 returned the questionnaire and 39 completed the questions concerning the chosen app. The demographic data acquired via the questionnaire (ie, age, professional experience, gender) corresponded to the values for the entire care staff at the Hannover Medical School. Most respondents (35/39, 90%) had no previous experience with an iPad. On a 7-point scale, the participants generally rated mobile translation tools as helpful for communicating with foreign language patients (36/39, 92%; median=5, IQR=2). They were less enthusiastic about xprompt's practical use (36/39, median=4, IQR=2.5), although the app was perceived as easy-to-use (36/39, median=6, IQR=3) and there were no obvious problems with the usability of the device (36/39, median=6, IQR=2).

Conclusions: The discrepancy between the expert ratings for xprompt (collected from the App Store and online) and the opinions of the study's participants can probably be explained by the differing approaches of the two user groups. The experts had clear expectations, whereas, without a more thorough introduction, our study participants perceived using the app as too time consuming in relation to the expected benefit. The introduction of such tools in today's busy care settings should therefore be more carefully planned to heighten acceptance of new tools. Still, the low return rate of the questionnaires only allows for speculations on the data, and further research is necessary.

Trial Registration: This study was approved by the local institutional review board (IRB), Trial ID number: 1145-2011.

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KEYWORDS

medical informatics applications; nursing care; cultural deprivation

Introduction

Patients with a different cultural background and language than their health nursing staff are more likely to be disadvantaged in their access to the health system [1]. These patients often have unfavorable health outcomes compared to those who can competently converse with their health care providers in the same language [2-5]. It can be speculated that the presence of a language barrier can result in increasing dissatisfaction from both the patients as well as medical staff, and may therefore negatively influence the quality of care. Several studies have shown evidence for these patients to have an increased risk of suffering from adverse events [5-8]. Also, problems caused by language barriers may unnecessarily increase costs, due to higher consumption of health care resources caused by misunderstandings [9,10] resulting in more frequent visits.

The various problems posed by not being able to overcome language barriers are often also encountered at the Hannover Medical School, which is a maximum care facility and, especially for certain specialties, often attracts patients from abroad. Although translators are usually called upon for communicating about important aspects of the treatment, particularly for uncommon languages not spoken by any staff members, they are not always readily available for everyday communication, which may unnecessarily complicate a patient's care. Thus, one would expect that the staff would welcome any tool that can aid them when communicating with foreign language patients.

In this context, a mobile electronic translation tool that is ubiquitously available, hassle-free, and provides quick translations for users seems attractive at first glance. Several mobile device applications are already available for mobile devices (eg, MediBabble Translator [11] by NiteFloat, Inc, or Universal Doctor Speaker [12] by Universal Projects and Tools SL).

Nevertheless, little is known about the acceptance by the nursing staff or usability and efficiency of mobile translation tools in clinical settings and whether it is possible to properly integrate such applications into existing workflows. In order to be able to make future deployment of mobile devices and their preinstalled applications a success, it is important to identify the steps that need to be taken during the introductory phase in order to be able to address the needs, expectations, and fears of potential users (eg, benefits that users can expect, or limitations that might be encountered). We conducted a preliminary study at the Hannover Medical School to gain insight on the actual value of such apps in a real world setting based on staff feedback after using iPads equipped with an exemplary translation app.

Methods

Overview

For our study, 10 clinical wards selected by the nursing management were provided with iPads (one per ward) containing a copy of the "xprompt—multilingual assistance" application, as well as other reference material and applications. Since our study regarding the use of xprompt (descriptive, cross-sectional, post test only design) was part of a larger study dealing with the use of mobile devices such as iPads in nursing, the selected wards covered a wide range of surgical as well as non-surgical specialties, such as neurology and neurosurgery, urology, nephrology, plastic surgery, otolaryngology, pneumology, trauma surgery, thoracic surgery, and maxillofacial surgery. Both normal as well as private wards were included. After obtaining the informed consent from the staff, the iPads were distributed to the wards and the potential users were encouraged to install additional applications from the App Store or to research content on the Web.

Altogether, over a period of 6 weeks, about 160 staff members were given the opportunity to familiarize themselves with the device and its content, including xprompt. As the focus of the overall study was on the nursing staff, patients were not given the chance to use xprompt on their own on the provided iPads. The purpose of xprompt was simply to provide additional means for alleviating communication problems between the nursing staff and non-German speaking patients. After the trial phase, an additional, anonymous evaluation was conducted over the course of 2 weeks. The study was approved by the Institutional Review Board of the Hannover Medical School, Trial ID number: 1145-2011.

The Application

"xprompt—multilingual assistance" is a commercial application (Blue Owl Software LLC, Boston, MA, USA) available for the iDevice ecosystem (ie, iPhones, iPads, and iPods). According to the developers, it was designed with the goal of improving the communication process between the nursing staff and patients in situations where language barriers exist [13].

The app was included into the study's application portfolio based on the highly positive reviews it received from health care professionals. For example, the special review portal, iMedicalApps, stated that this app had "tremendous clinical utility to facilitate an interactive dialogue and maximize the healthcare provider-patient relationship" [14].

The application can be helpful in many different settings as it contains a large phrase set (800 phrases, currently available in 23 languages), covering nursing care as well as daily life communications. Although no official study on the quality of the content or the usability of the xprompt application is currently available, the available phrase set was deemed trustable since all translators had a medical education, and the quality of their translations had been verified by native speakers with a medical background [15]. Both the customer reviews given in the App Store and the positive ratings from iMedicalApps were interpreted as expert opinions.

The application usage is simple. The phrases are provided in tailored menus for the nursing staff and the patients, grouped according to the situation in which they might be used with a quick navigation to the desired content. Via simple point and touch actions, selected phrases are translated into the target language. As an example, 3 short interactions are shown in Figure 1. The results are presented in text form as well as either an audio output for spoken languages or video sequences for sign languages (Figure 2). Users have the option to respond by using the language of the person they are interacting with by changing the language mode and choosing the desired phrases. Source and target languages can be freely combined (Figure 3).

Figure 1. Three examples for basic communication between nurses (left) and patients (right) based on the phrases integrated into xprompt. "#" indicates the phrase chosen in the application, and "→" the corresponding translation. Notes in "[ ]" describe the reactions of the participants.

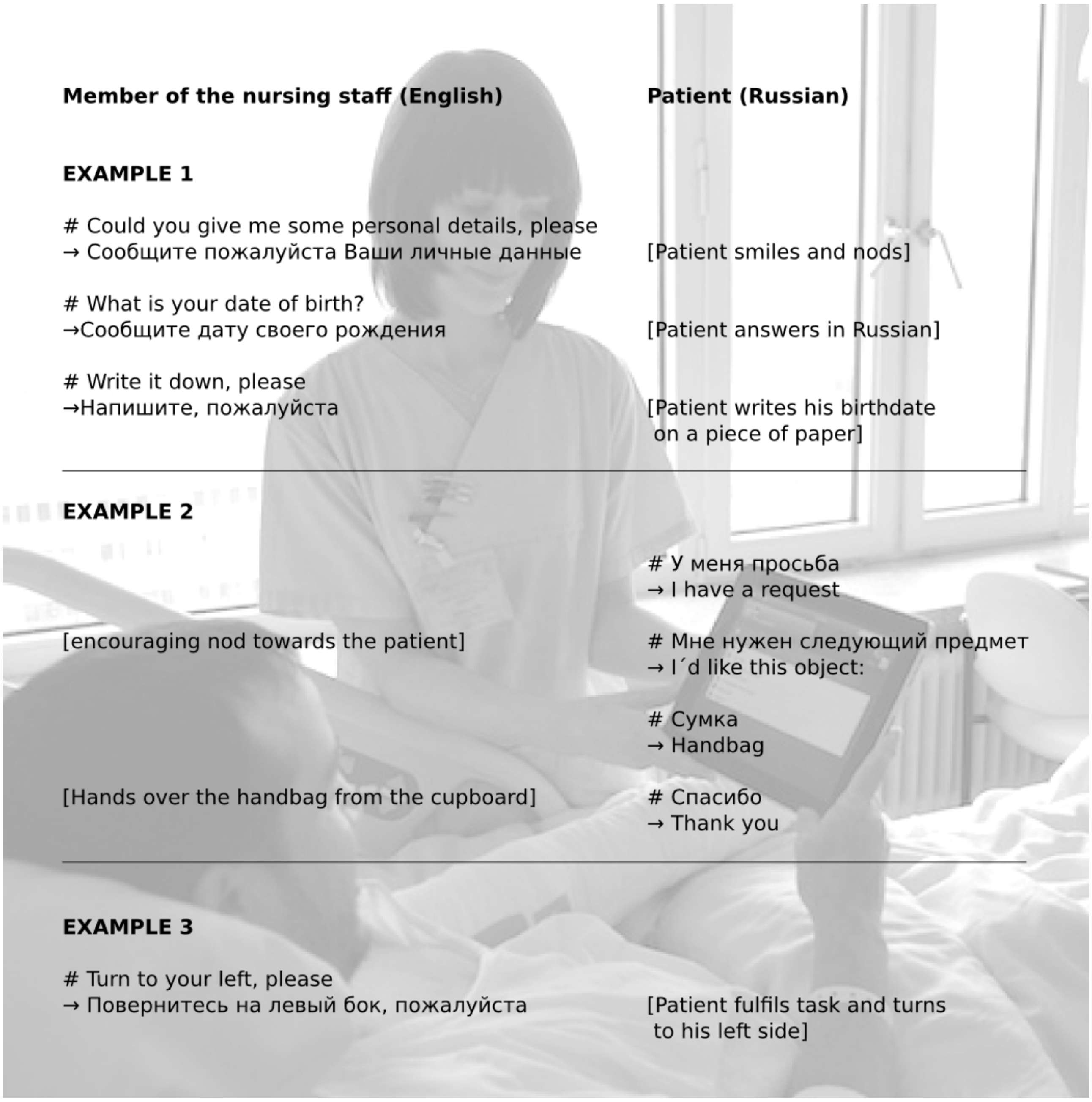


Figure 2. A search for specific phrases in xprompt (left), a phrase in Russian language (center), and video translation into British Sign Language (right).

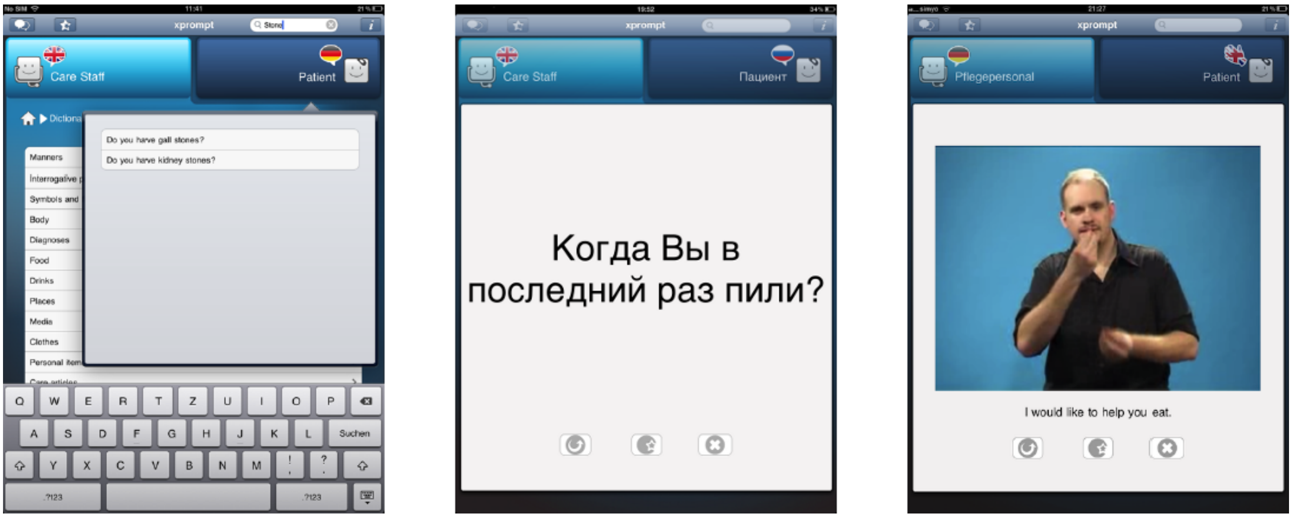


Figure 3. Choosing the languages to be used in xprompt (left). Typical menu entries for the care staff (right).

The Questionnaire

After the trial phase of the study, the aforementioned evaluation was performed. In total, the questionnaire contained 17 questions relating to either xprompt or basic usage of the devices. The questions we asked about using xprompt were integrated into the survey for the larger study that covered a wide range of aspects dealing with the general usage of mobile devices in a clinical setting. Due to time constraints, it was not feasible to cover all separate aspects with individual standardized usability questionnaires, which would have been desirable to guarantee comparability with other studies. We did not want to overly tax the patience of the personnel who agreed to answer our survey.

The Likert scale was employed for rating the intensity of various question items (eg, “not at all”, “very little”, “a little”, “somewhat”, “fairly”, “strongly”, “very strongly” for a 7-point scale, and “never”, “rarely”, “sometimes”, “often”, “very often” for a 5-point scale). Also, non-verbal 6- or 7-point Likert scales were used to discriminate between poles (eg, “several times per day” and “never”, or “totally agree” and “totally disagree”). The topics covered the iPad usage within the project as well usage of the iPad in general, the availability of the distributed devices during the project, the experienced usability of the device, relevance of the iPad related to work, expectations of working with the iPad in the future, and the general attitude towards the usefulness of translation apps (7 items). Another group of two items dealt with the usability aspects of xprompt.

A third group asked about the experience of the usage of xprompt in communication with patients and colleagues and in which way the application was helpful for overcoming communication problems between the nursing staff and patients (3 items). Regarding sociodemographic information, the study participants were asked about their age in years, their gender, work experience in years, and whether they had had any previous experience with the iPad before the study (4 items). The participants were also encouraged to provide short free-text comments to express their overall opinion on xprompt (1 item). The questionnaire was pretested using the thinking-aloud technique with 4 members of the nursing staff. Filling out the interview took no longer than 10 minutes time in the pretest.

Due to the anonymous nature of the evaluation, it was impossible to initiate individual follow-up attempts. Anonymization was granted by providing a randomized digital alpha-numerical code written on the questionnaires. After filling out the interviews, the participants returned them using unmarked envelopes that were collected on each ward. All envelopes were returned to the Institute for Medical Informatics where they were opened and the documents were scanned for automatic data collection using an electronic survey system [16]. The data were stored anonymously on a password-protected computer with no connection to the Internet. The survey and the evaluation software were also password protected. Subsequently, the data were exported to Microsoft Excel 2007 for further descriptive data analysis.

The available free text comments were analyzed systematically with respect to the actual use of the system, the type and content of any communication/interaction that had taken place using xprompt, the type of patients, problems that occurred, and whether there were any reasons for not using the system in specific situations. Additionally, to gain deeper insights into how the nurses had actually used the system, we asked 5 members of the nursing staff to reveal themselves as participants, regardless of whether they had employed the system for their daily work or not. These 5 users were also asked to fill out the system usability scale (SUS) questionnaire by Brooke [17], a standard tool for usability testing following ISO 9241/11, which can be used to determine effectiveness, efficiency, and user satisfaction of a system [18]. Although the SUS questionnaire contains only 10 questions (Table 1) and leads to a single score, according to [19], it actually contains 2 factors that measure usability and learnability aspects, which can also be used separately with similar effectiveness. The SUS score correlate well with the individual scores of usability and learnability, which are also intercorrelated. In [20], this 2-dimensional structure of the SUS was confirmed. When answering the questionnaire, users could choose the desired value on a 5 point Likert scale that ranges from “totally disagree” to “totally agree”. Based on the answers, a simple score (range: 1-100) was calculated that could be used to rate the user-friendliness of the system, with 100 representing the ideal value [17]. The SUS questionnaire was translated into German language and used in this study.

Table 1. Median and IQR for all SUS items (original scores), based on N=5 interviews.

No.	SUS-Item	Median	IQR
1	I think that I would like to use this system frequently	3	1
2	I found the system unnecessarily complex	2	1
3	I thought the system was easy to use	4	1
4	I think that I would need the support of a technical person to be able to use this system	2	1
5	I found the various functions in this system were well integrated	3	1
6	I thought there was too much inconsistency in this system	3	1
7	I would imagine that most people would learn to use this system very quickly	4	2
8	I found the system very cumbersome to use	2	2
9	I felt very confident using the system	4	1
10	I needed to learn a lot of things before I could get going with this system	2	0

Results

From all potential users who were given the opportunity to gather firsthand experiences with the devices and their software, 42 participated in the final evaluation. Of these, 39 also answered the questions regarding xprompt. It was not possible to determine the exact number of employees who had the chance to work with the iPads since there were no data about vacations and sick leave. Still, it can be assumed that the number of employees amounts to approximately 160. Thus, the return rate of completely filled out questionnaires was approximately 24% (39/160). For each question, only the participants who provided a valid answer were counted.

Even with the low return rate, the study population was a typical sample of the nursing staff at Hannover Medical School, based on the proportion of female employees compared to a previous statistic. At the end of 2012, 83% of the total 2596 employees were female, which parallels with the demographics of this study, where 87% (34/39) of the participants were female. Participants also had a comparable age distribution of 69% (27/39) up to 45 years of age and 31% (12/39) for older participants (Table 2). Other important demographics were 50% (19/39) of the participants had a work experience of 10 years or less. 90% (35/39) of the participants were regular nurses and 10% (4/39) were specialized nurses (Table 3). 90% (35/39) of the interviewed nursing staff stated that they had had no experience with the iPad before the project.

One out of four nurses (9/38) worked part time and thus did not have as much of a chance to work with the provided iPad (Table 3). Since nursing education in Germany does not take place at a university level, 74% (28/38) of those answering the survey had reached an education equivalent of Secondary School Level I before their training in nursing (Table 3).

The results from the interviewed group showed that 76% (27/36) had "rarely or never" used xprompt during the study, and 71% (27/38) stated that the iPad was almost always available when desired. Mobile translation tools such as xprompt were found to be helpful for daily communication with foreign-language patients (median=5, interquartile range (IQR)=2, scale 1-7, N=36) although xprompt itself received more neutral ratings (median=4, IQR=2.5, scale 1-7; N=36, see Figure 4). This difference cannot be attributed to the usability aspects of the application (see Figure 5) as xprompt was perceived to be easy-to-use (median=5, IQR=2, scale 1-7, N=36) and users did not have to spend much time to familiarize themselves with the application (median=5.5, IQR=2, scale 1-7, N=36). It was primarily used with patients (median=5, IQR=1, scale 1-6, N=36), but also with colleagues (median=5, IQR=2, scale 1-6; N=35, see Figure 6).

The device usability was rated positively by 90% (32/36, median=6, IQR=2) and 33% (12/36) assumed the iPad as relevant for their daily work routine while 19% gave it a more neutral rating (7/36, median=4, IQR=3). Altogether 82% (27/33, median=4, IQR=1) stated they would be able to use the device. Of these, (67%, 22/27) required no further introduction, while 15% (5/27) felt that they required the manual for continued use at their wards.

Nevertheless, Hannover Medical School—a facility providing maximum care—attracts patients from abroad. According to internal statistics, there are between 300 and 400 foreign patients per year from a variety of countries whose treatments are not being paid for by the German health insurance system; these are usually interested in certain specializations that are not available where they come from or in being treated by specific experts. Patients with a migration background who live in Germany are often able to communicate sufficiently. Thus, patients requiring help with communication are not evenly distributed between all wards and as was to be expected, during our evaluation, some of the wards that had been equipped with iPads simply did not have any patients that were unable to communicate due to inadequate language skills. All in all, the patients fitting the profile were a heterogeneous group of both sexes and ages ranging from the early twenties to the late seventies. They were mainly treated on surgical but also gastroenterological wards and were of Libyan, Syrian, Turkish, Pakistani, Polish, Ukrainian, and Russian origin.

The analysis of the free text comments and additional in-depth interviews made it clear that xprompt was used for professional communication during patient care. The emphasis was on basic communication/interaction (examples given in Figure 1). There were also several attempts to communicate about more complex issues, although when attempting to provide information about delicate procedures (eg, surgical procedures or other interventions), the members of the nursing staff often indicated that they had avoided using the system.

Some elderly patients had problems to use and to "get in touch" with the devices since they were unfamiliar with such technology. Also, older members of the nursing staff were more cautious and skeptical about using the devices and xprompt. In some cases, only the nursing staff was able to really use the app since the patients were unable to read the menus due to either visual impairment or analphabetism. In these cases, since there is always audio output available, it was at least possible for the staff to provide patients with some basic information if they were not hard of hearing as well. At times, the desired target language was not available. The staff also experienced problems when trying to explain the menus to foreign language patients. In one case, a patient who had been severely traumatized by war refused any communication and in another case, poor overall compliance did not allow any conclusions to be drawn about whether communication worked at all.

On some wards, another reason for not employing xprompt was that a single iPad per ward was simply not sufficient; the staff would have liked to have separate iPads for each nurse since it was a hassle to share a single device and to have to ask around for the device whenever it was needed.

Also, some nurses stated that their problems with using xprompt and the iPads stemmed from being unfamiliar with such technology and that they had not received any introduction to the devices and the installed software; colleagues , mostly head nurses, who had been trained, were often not available when they needed help. One suggestion given in the free text answers was to offer several training sessions open for all staff members, another request was to provide direct bedside teaching. Although an introductory booklet that covered the basics had been distributed along with the devices, it was not always readily available. Other key statement were that at times, the tablet PCs had simply been locked away when someone wanted to use them or that they could not be used as frequently as desired due to the high workload, which the users found unfortunate.

Table 2. Male-to-female ratio and age distribution in the final survey (N=39) and for the Hannover Medical School (N=2569, data for 2012 obtained from the human resources department).

Category		Survey n (%)	Hannover Medical School n (%)
Sex			
	Female	34 (87)	2126 (83)
	Male	5 (13)	443 (17)
Age			
	Up to 45 years	27 (69)	1721 (67)
	46 years and older	12 (31)	848 (33)

Table 3. Job functions (N=39), work experience (N=38), work model (N=38), and educational level of the participants.

Category		n (%)
Function		
	Regular nurse	35 (90)
	Specialized nurse	4 (10)
	Trainee	0 (0)
Work experience		
	Up to 5 years	11 (29)
	6-10 years	8 (21)
	11-15 years	5 (13)
	16-20 years	1 (3)
	>20 years	17 (34)
Work model		
	Part time	9 (24)
	Full time	29 (76)
Educational level		
	Secondary school level I	28 (74)
	Secondary school level II	8 (21)
	College / applied sciences	2 (5)
	University	0 (0)

Figure 4. Details regarding usefulness. White bars: a translation system like xprompt is very helpful for communication with non-German speaking patients. Cross-hatched bars: with xprompt, I was able to provide assistance with language problems.

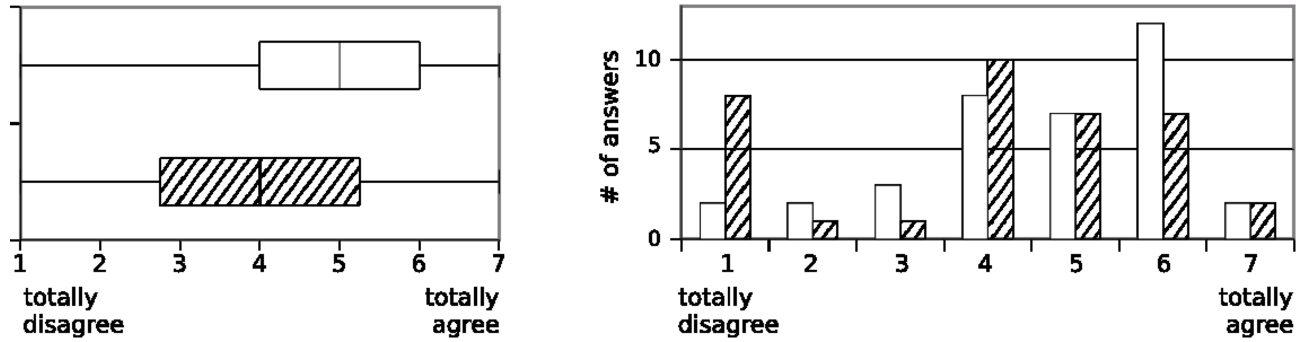


Figure 5. Ability to use and learn xprompt. White bars: the handling of xprompt is uncomplicated. Cross-hatched bars: I was able to learn the usage of xprompt in a short time.

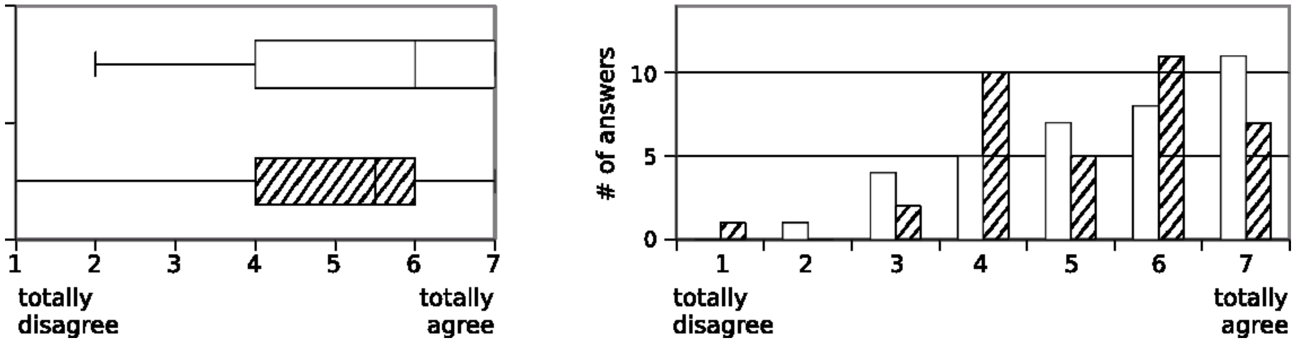
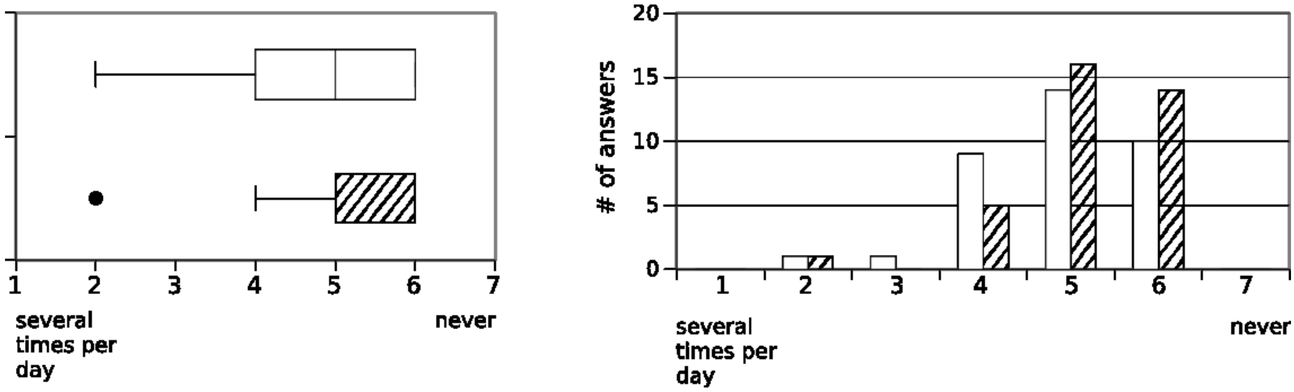


Figure 6. Frequency of using xprompt with patients (36 answers, cross-hatched bars) and alone or with colleagues (35 answers, white bars).



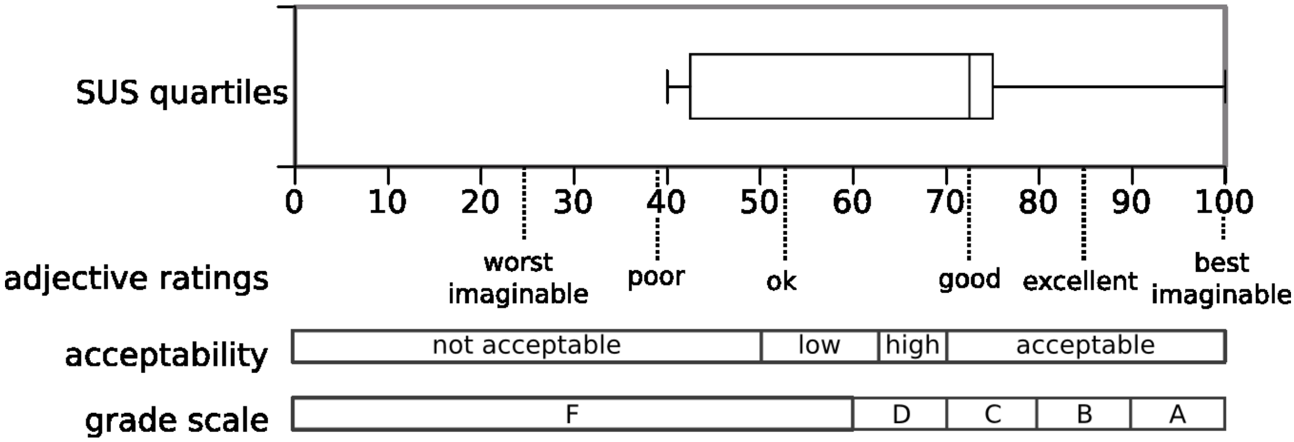
Discussion

Principal Findings and Conclusions

The results showed an obvious discrepancy between the expert assessments of xprompt, stated in the user comments on the App Store [13] and on iMedicalApps [14] and the actual usefulness attributed to xprompt by the participants of our study. When looking at the other ratings given for xprompt, it can be ruled out that individual problems with the usage of xprompt were the reason for the neutral ratings it received with respect to supporting the communication process. Users at Hannover Medical School perceived the translation app as useful for basic communication; in this context, xprompt's restriction to basic, predefined phrases was accepted, that is, one participant stated "small things could be sorted out but for complex issues, due to time constraints caused by high workload, it seems sensible to wait for an interpreter". Another statement given in the free text answers was that the application was well structured and the menu could easily be used for navigating the content. One user thought that over time, he would become familiar with the application and thus be more at ease and feel more secure in using it. Since a considerably large proportion of participants reported that they did not use the system at all, we conducted additional short-scaled usability testing based on the SUS specified by Brooke [17] in order to determine whether these findings lead to any distortions concerning the usability, task orientation, and general user satisfaction. The results of the SUS evaluation (SUS score=72.5) showed that xprompt seems well adapted for its task (Figure 7). Based on the answers of 5 volunteers who participated (Table 1), the suspected distortion could not necessarily be confirmed and it can be assumed that it does indeed not play an important role. According to Nielsen and Virzi, even small sample sizes are sufficient for detecting major usability problems [22,23]. Nevertheless, since xprompt is not overly complex, there should be no major deviations from results one might obtain using a larger number of participants; other reasons aside from usability seem to be responsible.

As shown by previous studies, in health communication situations where a language barrier existed, professional translators were not always requested even if they were available [24-26]. Diamond et al hypothesized that the staff make "decisions about interpreter use by weighing the perceived value of communication in clinical decision-making against their own time constraints" [26]. Results from our study supported this claim, where the great time pressure that medical staff are subjected to was reflected in their assessments of xprompt. Evidence for this can be found in the free text entries of the interviewees. For example, one female participant specified that "it is simply not possible to spend 'hours' on language problems because shortness of time".

Figure 7. Score of the SUS sub-study [21]. The SUS score (median) was 72.5 (IQR=34.5). Three female and two male members of the nursing staff (N=5), 18-25 years of age (2/5), 26-35 years of age (1/5), 36-45 years of age (1/5), and 46-55 years of age (1/5) voluntarily answered the SUS questionnaire. All were regular nurses working in a full time scheme. The work experience included time spans of under 5 years (2/5), 11-15 years (1/5), and 26-30 years (2/5). Educational levels were Secondary School Level I (2/5) and II (3/5).



Adequately dealing with language problems was often viewed as too time consuming, but the nursing staff generally viewed translation tools such as xprompt as useful for solving such problems and saving time. But initially, using such tools always requires additional work to adapt to the change. During the study, it was obvious that the nursing staff had difficulties in explaining the program's use to foreign language patients, as stated by one of the participants, "without any explanation, the application was too complicated to work with". Although a language-independent video tutorial explaining its use was integrated in the application, the nurses did not use it at the bedside due to their perception of time constraints and too much personal distance to the patient when just passively showing a video instead of interactively introducing the application. To properly show the application's functionality, the nursing staff would not only have to understand the app but to plan how to best present it to the patients and spend additional time on the actual explanation.

The above appears to indicate that ultimately, a distinction must be made between the individual use of xprompt and its use in the context of nursing care. For integrating it in the daily routine of inpatient care, detailed instructions with respect to the application's use must be provided.

It can be assumed that individual users who installed xprompt on their own initiative had clear expectations about the program. They were searching the App Store for solutions to a specific problem they had encountered, that is, an "always available mobile medical translation". With proper research on the topic, they were able to learn about and compare strengths and weaknesses of the available solutions. When downloading the application and testing it, there would not be excessive expectations regarding the functionality of the app, biasing their opinion about its potential. Users would have a realistic idea of the application's features and limitations they might encounter.

Due to their research into possible solutions, the individuals who had voluntarily chosen to use xprompt had a "head start" and were well informed about what they could expect from the application. The users in our study setting did not actively choose to use xprompt and did not have as much information about the app or similar competing products. Rather, the nursing staff was provided with a solution right away, without being able to familiarize themselves with all the aspects (ie, possibilities and limitations) of applications for overcoming the language barrier. Instead they found themselves in a situation with very little time but much work dealing with the patients, while having to personally understand the usage and functionality of the application and at the same time already having to explain it to the patients.

The results regarding the deployment of xprompt showed that, when introducing new technologies, it is especially important to adequately train the nursing staff and adapt the training according to their job requirements. Appropriate steps must be taken to ensure that users do not simply consider the provided technology as a gadget rather than as a useful tool. They must become aware of the opportunities mobile technologies can offer. Otherwise there will be little chance to integrate such tools in their daily routine. Thus, simply training users and providing information about how to use the devices and the apps installed on them can contribute to an improved acceptance. One approach that can be taken to establish improved acceptance on new technologies is to provide realistic information about the capabilities of specific applications and technologies, such that users will not overestimate the power of the technology and be appreciative of the advances brought by the technology.

The use of mobile translation tools may certainly support the communication between patients and nursing staff in the absence of a common language. Nevertheless, certain restrictions must also be observed, for example, the application may not be used in highly sensitive situations, especially if a patient's life is in danger. The main objective was to alleviate health communication problems posed by language barriers and thus promote empowerment and medical autonomy of the patients in situations where no interpreter can be reached.

Limitations and Further Research

Due to the limited nature of the study with only one iPad per ward, patients did not have much opportunity to familiarize themselves with the application. As the application was used with patients of many different cultural and linguistic backgrounds and the focus of the study was on the acceptance of the application by the nursing staff, we refrained from preparing separate questionnaires for patients for each of the available languages.

Although one might argue that the low number of responders in the survey is correlated to poor interest toward the application, it is more likely due to the way the iPads and their software were introduced on the wards. At the end of the project "iPads in Nursing" in which our evaluation of xprompt was embedded, the iPads were collected from the wards with the aim of using them in other projects. Since then, there have been numerous urgent requests by wards that traditionally have a large number of foreign speaking patients, such as the department of trauma surgery, to again provide them with iPads equipped with xprompt and we happily complied whenever possible. When asked what makes a solution such as xprompt attractive, the requesting personnel stated for example that they needed it to communicate with Arabic or Russian speaking patients, and that due to the program's clear structure, it really simplified the basic communication process if no other help was available. In order to provide deeper insights, we would like to conduct a more detailed study using a pre/post design, specifically addressing the limiting factors we identified. Such a follow-up study might include the introduction of solutions to the issues discussed above, including time constraints and the education of nurses regarding mobile technologies, in order to influence the perceived usability. Also, this time, the focus should be only on those wards that traditionally treat a large number of foreign patients.

Of course, staff and patients have different motivations when using xprompt. For patients, their expectations, needs, and fears during a medical emergency, a diagnostic procedure, treatment, or care situation is very different from what their professional counterparts perceive. Based on their professional experience, nurses will often already have found some other, possibly nonverbal, way to ensure basic communication. Therefore, in our forthcoming, more extensive study, we would also like to put an additional emphasis on aspects relating to patients using systems such as xprompt.

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Conflicts of Interest

Conflicts of Interest: None declared.

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Abbreviations

IQR: interquartile range
SUS: system usability scale

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Original Paper

Challenges in the Implementation of a Mobile Application in Clinical Practice: Case Study in the Context of an Application that Manages the Daily Interventions of Nurses

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Abstract

Background: Working in a clinical environment requires unfettered mobility. This is especially true for nurses who are always on the move providing patients' care in different locations. Since the introduction of clinical information systems in hospitals, this mobility has often been considered hampered by interactions with computers. The popularity of personal mobile assistants such as smartphones makes it possible to gain easy access to clinical data anywhere.

Objective: To identify the challenges involved in the deployment of clinical applications on handheld devices and to share our solutions to these problems.

Methods: A team of experts underwent an iterative development process of a mobile application prototype that aimed to improve the mobility of nurses during their daily clinical activities. Through the process, challenges inherent to mobile platforms have emerged. These issues have been classified, focusing on factors related to ensuring information safety and quality, as well as pleasant and efficient user experiences.

Results: The team identified five main challenges related to the deployment of clinical mobile applications and presents solutions to overcome each of them: (1) Financial: Equipping every care giver with a new mobile device requires substantial investment that can be lowered if users use their personal device instead, (2) Hardware: The constraints inherent to the clinical environment made us choose the mobile device with the best tradeoff between size and portability, (3) Communication: the connection of the mobile application with any existing clinical information systems (CIS) is insured by a bridge formatting the information appropriately, (4) Security: In order to guarantee the confidentiality and safety of the data, the amount of data stored on the device is minimized, and (5) User interface: The design of our user interface relied on homogeneity, hierarchy, and indexicality principles to prevent an increase in data acquisition errors.

Conclusions: The introduction of nomadic computing often raises enthusiastic reactions from users, but several challenges due to specific constraints of mobile platforms must be overcome. The ease of development of mobile applications and their rapid spread should not overshadow the real challenges of clinical applications and the potential threats for patient safety and the liability of people and organizations using them. For example, careful attention must be given to the overall architecture of the system and to user interfaces. If these precautions are not taken, it can easily lead to unexpected failures such as an increased number of input errors, loss of data, or decreased efficiency.

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KEYWORDS

hospital information systems; computers, handheld; equipment design; nurses; mobile health; pilot projects; user-computer interface

Introduction

Hospitals are increasingly using Clinical Information Systems (CIS). The introduction of computers to manage patient information has deeply modified the workflow of the care provider [1]. It has numerous positive effects, such as reduced archiving costs, facilitated administrative tasks, eased access to patient data, structured information, and more generally, improved patient safety through decision support and better access to information.

While dematerialization is one of the major advantages of computerization, it is surprisingly often associated with decreased mobility. This apparent contradiction is well observed in clinical settings with a strong dependence on computers [2]. As long as patient data were kept on paper, care providers could carry and access patient information easily, everywhere in the hospital. With the introduction of CIS, information is no longer stored on physical media. Consequently, caregivers rely on the presence of a computer to access the information.

There is a long history of attempts to provide a ubiquitous access to clinical information. This history begins in 1975 with the first laptop produced by IBM. A new step was reached with the joint appearance of the first PDA and of wireless technology in 1996. Despite a long history, the numerous attempts to provide ubiquitous access to clinical information with these technologies cannot be considered completely successful. The use of wireless networks considerably improves the situation [3], but only to a limited extent. Laptops still require being moved on a trolley, and their autonomy, while improving, is often limited. The other attempts to provide ubiquitous access to clinical information with these technologies have been performed with PDAs. Unfortunately, this technology was not mature enough for the numerous constraints of a medical environment [4]. All these attempts have revealed that using mobile devices to offer ubiquitous computing is a challenging task.

The recent evolution of mobile devices, such as decreased size and cost, better screen resolution, increased computational power, and extended power autonomy, has opened new possibilities to providing strongly integrated mobile tools in health care. Thus, it is now possible to consider having one highly mobile device per care provider, perhaps their personal device, always in their pocket. However, adapting existing applications to these new platforms is a delicate task and requires new models of interactions. History demonstrates that the transition has to be done carefully [5]. Several papers show that mobile devices can lead to increased time for data acquisition, increased errors, and omissions rate [6,7].

This paper presents the major challenges inherent in the deployment of a mobile clinical application. In order to identify these challenges, a group of experts relied on several years of experience with the development of various applications on devices available on the market, such as medical knowledge management on the Palm in the early 2000s and more recently, applications to manage nurse daily interventions on Android and iOS applications for the Geneva community [8,9].

Mobile Computing for Clinicians

Until recently, most mobile medical applications were developed on Personal Digital Assistants (PDAs) such as Palm platforms. The first generations of PDAs did not have the functionality to manage complete electronic medical records or store large graphics. However, such handheld devices were considered by users as excellent tools for managing clinical information and accessing it at the point of care. Indeed, they were one of the few platforms with an interface supporting input via a stylus, expandable memory, software upgradability, a method of developing custom-built software for the device, and network connectivity [10].

Most applications running on these devices were generic but not directly connected to the clinical information system (CIS) [11]. As early as 2002, Porn and Patrick [12] identified the following health care applications that could be run successfully on a mobile device:

- E-prescription: It allows care providers to access basic patient information and check formulary compliance before writing prescriptions. Potentially harmful events can be detected. Prescriptions can be transmitted directly to a pharmacy. The main benefits are a reduction in medication errors and fewer calls from pharmacies due to illegible handwriting [13].
- Workload capture: The application allows care providers to view schedules, capture patient care, and access or update patient information all at the point of care.
- Order entry: Applications to order certain tests can be scheduled, delivered to a central processing unit, and acted upon. This reduces errors due to misplacement of application forms.
- Test result reporting: Test results can be delivered directly to the mobile device. This frees doctors from having to go to a specific PC workstation to retrieve test results.
- Medical information: Access to the latest medication formulary, disease description, symptoms, and treatment as well as access to clinical procedures can be provided on a mobile device [10].

Recently, clinical applications have smoothly shifted from PDAs to smartphones and tablets because of their numerous advantages. Smartphones can be used to maintain multiple calendars or contacts at numerous locations (eg, office, home) by synchronization using several methods (by Bluetooth, Wi-Fi, or a USB connection). Many devices now have built-in keyboards that allow for rapid data entry. Almost all new devices have touch screens that allow data to be entered interactively. Memory and processing power are no longer issues: most of them have either adequate internal memory or the ability to expand the data storage by inserting extensions and have multicore processing power. The use of certain typical phone-based features, such as short message service (SMS), can, however, experience very significant lag time or reliability problems and should be considered as not appropriate for critical applications, except if there is a specific infrastructure [14].

Methods

With the help of a team of experts we have identified the challenges that must be faced in the implementation of a mobile application in health care and illustrated them in the context of an application that manages the daily interventions of nurses.

Background

The University Hospitals of Geneva (HUG) is a consortium of public hospitals in Geneva, Switzerland. It provides primary, secondary, tertiary, and outpatient care for the whole region with 50,000 inpatients and 950,000 outpatient visits a year. The CIS of the HUG is mostly an in-house developed system. It is a service-oriented and component-based architecture with a message-based middleware. It is written in Java with J2EE and open frameworks.

The CIS of HUG has been developed to access all medical information through personal computers. It allows managing most modern CIS tasks such as e-prescription, clinical pathways, care management, laboratory imaging, etc. Despite all the advantages brought by the use of electronic health records, caregivers have rapidly expressed the need for improved mobility. The deployment of a large number of laptops on wheels as an attempt to solve this problem has only partially improved nurses' mobility. The situation remains unsatisfactory, but the recent explosion of smartphones offers new opportunities that need to be better exploited.

The Target Application

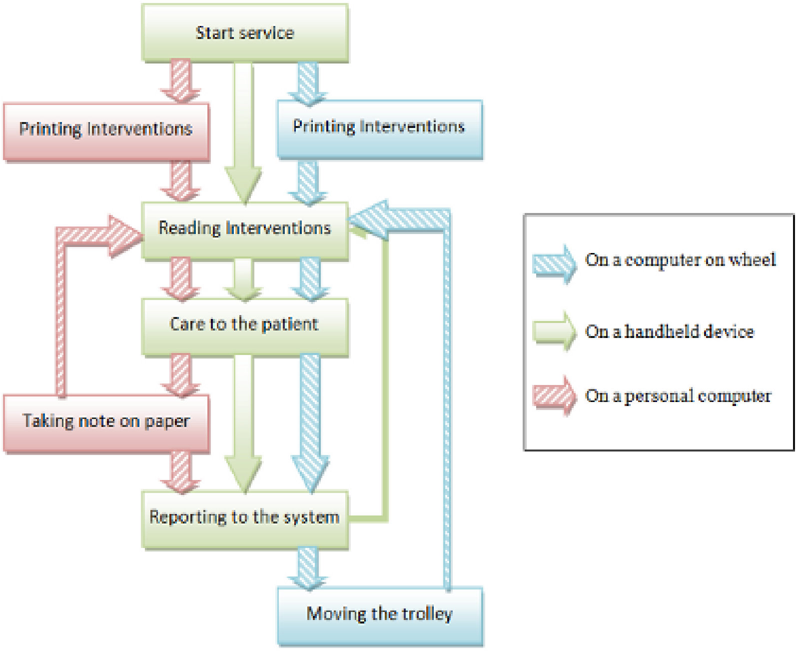
The purpose of developing our mobile application is to provide bedside management of nurses' daily interventions. Interventions cover all type of treatments that can be provided to a patient, such as care, drug administration, counseling, and discussions. An intervention is defined by several parameters such as its type, whether it is floating or it has strict timing, date planning, and start/end dates, etc. Depending on their types, interventions are planned by various care providers, such as physicians or nurses. When a clinician prescribes an intervention such as giving a drug, the drug, delivery, dose, duration, and the frequency of the treatment are defined. Each intervention can then be executed, at some time, some place, and in some context. It can also be partially executed or not at all, or rescheduled. All these actions have to be documented.

There are no global standardized guidelines regarding the way nurses have to manage their daily interventions. While there are a lot of differences in the way nurses work from one country to another, for example because of the legal framework (eg, self drug dispensation is generally country specific) or the working context (eg, ICU), there are some general similarities. Before the introduction of mobile computers, their workflow usually followed a sequence of actions relying on printed lists of interventions. These printouts are used by nurses to follow tasks and record their remarks before reporting everything to the system when possible. This process has only partly changed since all wards have laptops. Indeed, the trolley often stays at patients' room doors preventing access to the CIS at bedside.

In the HUG, nurses are made aware of their daily interventions through a service of the CIS known as the "interventions manager". This service allows handling interventions lists in numerous ways such as by shift, by type, by room, by nurse, etc. The interventions list guides nurses during their shifts and indicates the tasks to perform. Every time nurses perform one of these interventions, they have to document how the task has been done. When working without laptops, they have to go back to the desk to input the information in the system.

By introducing handheld tools, we can try to suppress all these cumbersome steps to keep the process as simple as possible. There is a strong demand for highly mobile devices that could be carried in a pocket while keeping a decent screen size, such as five inches. Such a device is considered is much better for those using laptops and is expected to replace paper for those still preferring this form. Thus, it is expected that the efficiency of nurses will increase once they are provided with more effective mobile tools (Figure 1), especially in decreasing errors and speeding up the process.

Figure 1. HUG nurses' workflow according to different devices.



Development Methodology

The development team consisted of 5 people: a computer scientist, an ergonomist, and 3 domain experts (1 physician and 2 nurses) working in focus groups. The 2 nurses were selected by the Director of Nursing of the HUG (about 4000 nurses). All were research nurses with a strong clinical background and substantial experience in health care and transversal understanding of the problems faced in nursing.

After defining the general architecture of the project, the team went through an iterative process that frequently switched between programming steps and meetings where the prototype graphical user interface (GUI) was tested and discussed (agile methodology). Testing the tool in real working conditions would have been very complicated as it would have implied the connection of our system with the institution's CIS. It would have required obtaining many authorizations and involved substantial risks to alter the coherence of the clinical data. Consequently, the tool was tested only in a test environment, with predefined care scenarios. The purpose of adopting such an approach for the implementation of the GUI was to emphasize the requirement of a concerted and scientifically grounded approach to develop a GUI. This is still rarely the case, as most GUIs are developed as a result of direct interactions between users and developers, or worse, users and commercial representatives. Most GUIs are also a historical evolution of additive changes.

During the discussions, many interrogations have naturally emerged, not only about the GUI, but also regarding the deployment of such tools. The points discussed were about:

- hardware, form factor, speed, connection, battery autonomy, reliability, maintenance, cost, etc
- architecture, generic mobile device bridge, security, efficiency, etc
- programming languages, portability reusability, ease of finding developers, environments, etc
- privacy, authentication, etc
- ergonomics, user interface; how to have something user-friendly but most of all, prevent increase of acquisition errors
- governance, who pays for the device, is it possible to use one's own private device, etc

For each of these challenges, the team of experts performed a risk/benefit analysis based on their experiences and on findings from the literature [15]. The group did not proceed to a systematic literature review; however, most papers published these last years have been carefully read to search for methodological approaches that could help the introduction of handheld devices in bedside care.

Results

The introduction of mobile devices into the care workflow implies dealing with many constraints. The workflow of caregivers must be modified to benefit from the advantages of the new platform. Financial resources must be freed up for the acquisition of the material. Moreover, specific constraints related to mobile environment must be handled with care. Mobile platforms have limited power; they access information through wireless local area networks (WLAN) and have a much smaller screen than any personal computers. All these constraints are emphasized by those related to the health care environment. In such environments, data must be handled with special care. The life of a patient may depend on the integrity and availability of the data.

All these constraints have been regrouped under five different challenges concerning the required financial resource, the hardware, the architecture, the security, and the interface.

Dealing With Limited Financial Resources

Challenge

In the long term, technological changes can lead to substantial financial benefits. However, these changes often require a strong initial investment. The introduction of mobile devices in a care facility is no exception. In the transition from personal computer to mobile device, important costs are incurred.

- The cost of the device: Even if the computational power of the device has increased, their costs have not dropped significantly.
- The cost of the development: The applications running on a personal computer must be adapted for the new platform.
- The cost of the training: Using a new tool induce a change in the workflow of the user and to learn the optimal way to employ the new tool.

Solution

As mobile devices become more and more widespread among the general population, it is likely that in a few years, everybody will be equipped with their own device. According to this hypothesis, caregivers could use their personal devices to host clinical applications. Bringing caregivers' own devices into the hospital has many implications that should not be underestimated. Technically, the development should be multiplatform and allow complete encapsulation of the code and the data. The different display sizes should be taken in account to insure that the developed interface can scale properly. Regarding the security, there are some serious concerns about the applications installed by users that can possibly transfer sensitive information to a third party. Finally, there is concern about the workflow interruptions that can happen frequently when users receive personal notifications on their devices.

Example

Being able to run a program on every device on the market is obviously a prerequisite to use the heterogeneous devices owned by caregivers. To make it possible, one solution is to use multiplatform languages, such as Flex or HTML 5, or to be able to compile/translate applications from one operating system to another.

Choosing Appropriate Hardware

Challenge

The choice of mobile device is very important as it constrains or facilitates visibility, usability, and dictates the available computational power. For instance, a large size device (10-inch screen) offers good visibility and allows the display of different information at the same time. However, it is difficult to hold with one hand and impossible to carry in a pocket due to its weight and size; it forces caregivers to put the device on the patient's bed or table during care. On the other hand, a small device (4-inch screen) can be manipulated easily with one hand and held comfortably in a pocket. However, it provides a limited area to display information [16,17].

Solution

Due to the numerous mobile devices available in the market, it is difficult to identify the best device for the clinical environment. Each device possesses their own advantages and drawbacks, and not one stands out in the crowd. With our focus groups, we defined the following criteria:

- Best hand ergonomics: Every user should be able to carry the device in one hand.
- Pocket: When providing care, there must be a way to put the device in the pocket, as there is no good other place to put it.
- Maximum screen size: On small screens, the necessity for scrolling can be a source of problems as the information that is not directly displayed on the screen can be easily missed by the user.
- Best screen resolution: Screen resolution is another parameter that will influence the amount of information that can be displayed on the screen and thus influence the scrolling.
- Lowest weight: Carrying a heavy device all day long is cumbersome.
- Longest battery life: The device's battery must last at least long enough to perform all the daily tasks of a user.

Example

In June 2012, many devices were available on the market all with their own characteristics. As it had been a cumbersome process to compare all of them, we decided to perform the comparison on three devices each representative of a different format (Table 1). The devices selected at the time of this work were (1) the common mobile phone device, the Samsung GALAXY S (Figure 2, left), (2) an intermediate format with the Samsung GALAXY Note (Figure 2, middle), and (3) the tablet format with the Samsung GALAXY Tab 7.0 (Figure 2, right).

Table 1. Comparison of three different devices.

Model	Inches	Height	Width	Resolution	Weight	Screen
GALAXY S	4	122.4 mm	64.2 mm	233 ppi	119 g	480 x 800
GALAXY Note	5.3	146.9 mm	83 mm	285 ppi	178 g	800 x 1280
GALAXY Tab 7.0	7	193.7 mm	122.4 mm	170 ppi	384 g	600 x 1024

The unique format of Samsung GALAXY Note has played a crucial role in its adoption by the focus group. Its display is significantly larger than most smartphones, but it remains small enough to be kept in one hand and stored in a large pocket such as in nurses' and doctors' garments [18].

Figure 2. Comparison of device sizes (GALAXY S, GALAXY Note and GALAXY Tablet).

Sustainability

Challenge

One of the most disruptive paradigmatic changes that has occurred with the explosion of smartphone is the “App”. The concept of applications has brought many great changes, such as ease of installation, freedom of choice, explosion of products. It has also brought some problems, such as quality assessment and, most of all, the end of sustainability. Whereas the extremely short life cycle and life expectancy of apps are nice for many aspects, it is a potential problem in the clinical informatics: There is a need for a quality software, clear liability, strong life cycle with backwards compatibility, etc.

Solution

There is no clear solution, except a set of rules mostly for the governance level. For example, the choice of a programming language that is sustainable and supports nonregression tests, teams, and code management, such as Java.

Linking the Mobile Device With the Existing Clinical Information System

Challenge

Mobile devices must be connected with the CIS to access clinical information. It is mandatory to remain independent of any legacy system to insure easy evolution and effortless maintenance, both for the CIS and the devices used.

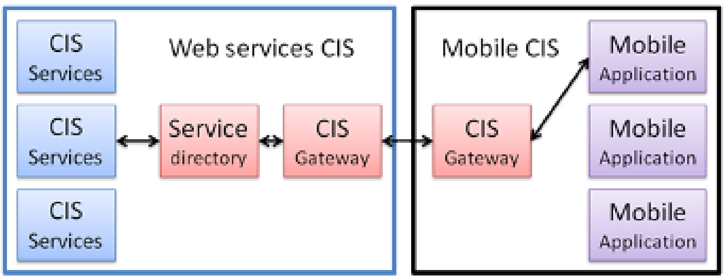
Solution

The most promising approach is to define a generic bidirectional bridge. The definition of a bidirectional gateway server provides centralized access to any required information between the mobile application and the CIS. Thus, integrating any mobile application requires only integrating this bridge. In addition, the bridge separates the services that are available remotely from the ones proposed as normal Web services. The gateway server is responsible for formatting the data properly before sending it to the appropriate application on the device. Once the mobile device receives the data, its embedded software is responsible for displaying the data through its interface and allows the interaction with the user.

Example

Figure 3 shows the link between our mobile application and the current CIS. The CIS of our organization is a component-based architecture, is services and message oriented, with full Java and J2EE. A specific “bridge” component (CIS gateway) has been built to ease communication with mobile devices, providing secure access to data structures and potentially using specific features such has geolocalization. This bridge is generic. It allows also the transport of a description of the interface that can be entirely dynamically built. When a mobile application requires data from the CIS, it communicates with the mobile gateway that transmits the request to the CIS gateway. The service directory is then queried to identify the appropriate service where the required information can be retrieved. The information then returns through the same channel. All data transiting through the channel are formatted in XML [18].

Figure 3. Communication architecture between mobile applications and existing CIS.



Data Protection and Authentication

Challenge

Data security is crucial in a health care environment. The diffusion of medical information about a patient can have disastrous consequences on his/her life. Thus, correct authentication of authorized users on mobile devices to ensure appropriate data access is a central issue. Common strong authentication policies on desktop computers such as a one-time password, challenges, and pin card are not adapted for mobile devices. Indeed, mobile devices require frequent authentication as they often lock themselves automatically when not in use for a short period. Therefore the chosen authentication method must be free from cumbersome manipulations.

Another risk related to the use of mobile device is theft. This risk is especially strong in a semipublic environment like a hospital where no physical access restriction is applied in most areas. Whereas personal computers are difficult to steal due to their size and the fact that they can be easily secured, a mobile device can easily be stolen or lost. A theft would result in loss of information and confidentiality. In such cases, the access to patient data could have much more serious consequences than unauthorized access to a corporate network [19-21].

Solution

As an alternative solution to external hardware, such as the pin card, it is possible to use built-in mobile features, such as embedded cameras or graphical patterns, to authenticate users. The presence of cameras on most mobile devices could allow us to leverage facial recognition [22]. On the other hand, as there is no simple way to prevent a theft, no information about the patient can remain on the device in case the mobile device is stolen. That is, all patient-related information is only continuously stored on the server side or strongly encapsulated on the client side.

Example

In the current CIS deployed at HUG, when a user logs in on a personal computer, login requires a "Smartcard" with a pin code. Unfortunately, the use of such authentication methods cannot be applied to mobile devices due to the practical impossibility of linking a smartphone to a card reader. Instead, we investigated face recognition, which some new generation devices with good processing power offer in real-time. The authentication is almost immediate when looking at the device and requires no specific manipulations. In order to minimize the problem in case of theft, data are not stored locally, but the devices are regularly synchronized to store original data on the central server. However, a sufficient amount of information must remain, encapsulated on the client volatile memory, in order to provide availability on the local device in the case of a network crash.

Designing an Effective Interface

Challenge

The proper implementation of user interfaces and interaction models in clinical contexts is often underestimated. The lack of visibility of some information can easily lead to errors and jeopardize the health of the patient. This problem is accentuated when working with mobile devices. There is little research analyzing the impacts of these new interfaces, such as using eye tracking to evaluate the screen exploration or evaluating cognitive load and cognitive tunneling.

The transition of a program developed for personal computers to mobile devices is not as simple as performing a downsizing of the desktop interface to fit the mobile device screen. Indeed, the unique characteristics of mobile devices often require an entire rebuild of the existing interface. Regardless of performance offered by the technology, the usability of mobile information services consequently suffers from interfaces being very compact and cluttered with information and use thus demanding the user's full attention. In mobile use contexts (eg, finding one's way through a building, listening to a conversation), the constant change of focus from activities in the real world towards operating technology can be problematic. In order to insure a high usability while actually being mobile, the user interface must remain relatively simple and minimizes the required interactions [23,24]. The selection of the pertinent information to be shown or acquired becomes a major objective.

Solutions

In order to build a usable and useful mobile interface, five main principles should be respected.

Homogeneity

This first principle recommends keeping a familiar and homogeneous interface. It takes much more time to train users for an application with an interface designed completely differently from a former known version. Giving an interface unfamiliar features, colors, and figures is not appreciated and makes the working process more prone to human errors. Applications with a familiar design increases user acceptance as well as security [17].

Hierarchical Organization

Hierarchical organization is a good way to deal with the problem of small displays, especially because it still remains difficult for systems to have an a priori selection of what will be pertinent. The hierarchical organization of information allows the users to increase granularity as needed. It is always possible to increase the depth of hierarchies with additional regroupings. However, it is also important to minimize the learning curve that is associated with the complexity of the hierarchy and to keep the user's interactions as simple and fast as possible. Therefore, hierarchy must be handled with care as the deeper the hierarchy, the more interactions required by the user are numerous [25,26].

Dynamic Organization

Even with the hierarchical organization, all the items cannot be displayed on the screen at once. Some important elements can be hidden to users and require actions such as scrolling to be shown. In order to minimize the risk of missing important information and to minimize the need for user's interactions, we can capitalize on the real-time usage of the devices. The dynamic organization of the data can optimize the information shown at any time according to the actions to be performed, such as nursing interventions in our case.

Context Awareness

It is possible to present only information relevant to a specific situation by making mobile computer systems aware of the user's contextual setting [27-29]. The idea of context awareness is based on the user's situation and context, so that the information already provided by the context becomes implicit and does not need to be displayed. Hence, the user's environment becomes part of the interface

Indexicality

The last principle relies on semiotics theory to advise the use of contextual information to improve the user experience. Semiotics concerns the meaning and use of signs and symbols. From a semiotic perspective, information is viewed as representations of something else (their object). Faced with an interpreter, these representations cause a reaction or interpretation. The semiotics operates with three types of representations: symbolic (conventional), iconic (similarity), and indexical (material/causal). Symbols and icons are ways of representing information independent of context, eg, text and graphical illustrations. Indexical signs, on the other hand, are ways of representing information with a strong relation to something else. Indexical representations are, eg, used on signposts and information boards [30].

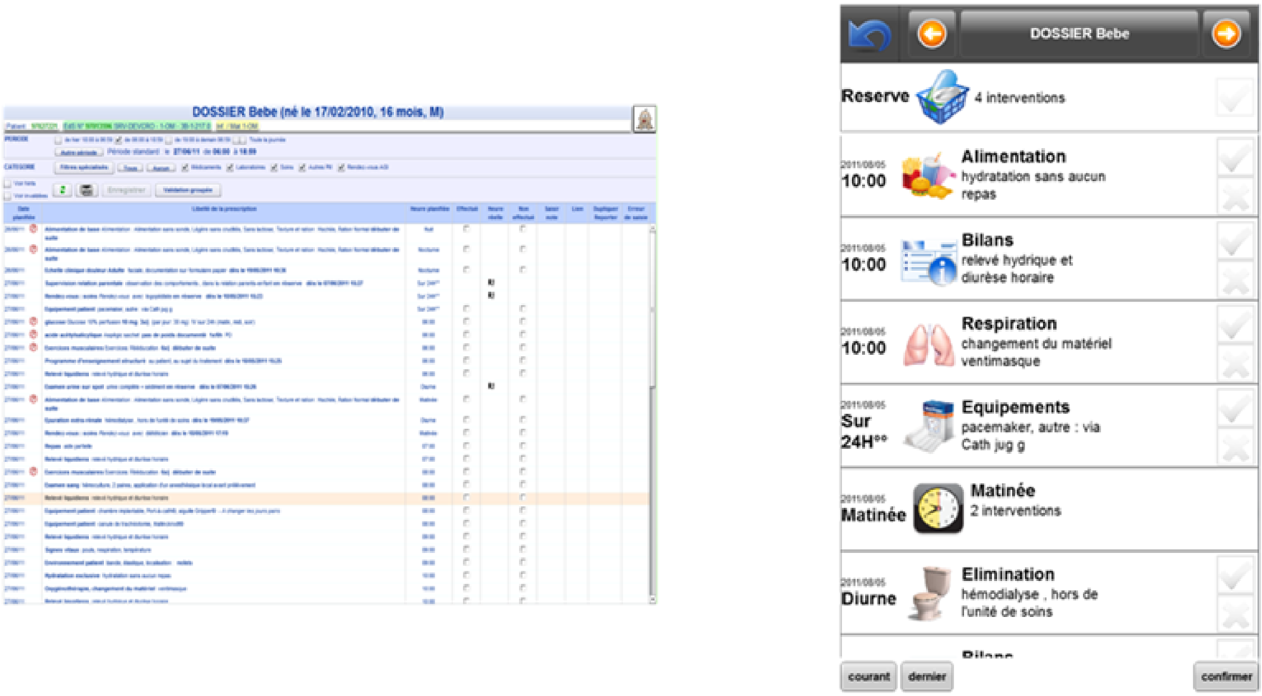
Example

Homogeneity

The mobile device being used with an existing CIS, some characteristics of the existing interfaces, such as naming and color charts, are reused in order to build an impression of “déjà-vu”. This can be achieved while exploiting at their best the new paradigms of mobile devices.

Figure 4 shows the intervention management interface of the HUG CIS on a personal computer. Each line represents a single intervention. An intervention is described by its date, description, and execution time. The height of the screen allows displaying almost 30 interventions at once. Moreover, the sufficient width permits the display of the full description of the intervention on a single line. To continue with a familiar display on the mobile phone, we have kept this overall organization and respected the naming of elements while keeping only the most significant semantic content and a global chronologic sorting.

Figure 4. Intervention management interface on a computer screen in the HUG CIS and on the mobile device application.



Hierarchical Organization

The hierarchical organization has been performed as follows:

1. Interventions of a similar top level are regrouped in a common item. Based on the hypothesis that tasks of a similar type are usually performed at the same time by the care provider, all the interventions happening at a similar time are regrouped, if they share a similar top-level type. For instance, if a nurse must dispense several drugs at the same time, they can be regrouped under a single task with various actions. Regrouping the interventions of a similar type not only helps organize the work in a clever way but also offers a much better overview of the tasks to perform (Figure 5Error: Reference source not found).
2. Nonscheduled interventions are regrouped in a single group. Nonscheduled interventions, such as PRN (Pro re nata) drug orders, are not compulsory but are available according to certain situations, in a given frame. For example, there may be some pain treatment held in reserve for the patient. These are “floating” actions, possible until they are made and that have to follow strict rules, such as a maximal dose per 24h. As these interventions remain always available, displaying them in the main screen can take all the space available. To avoid this, all interventions in reserve are regrouped in a single item that remains always at the top of the list and only as long as they have not been completely used. This ensures improved visibility at any time.

When the user selects such groups, the contextual information is displayed (Figure 6). If actions are required, they can be directly entered in this contextual frame, such as in the example displayed. If an alert or decision support is available, it is also directly shown at the right place.

Figure 5. Expansion of an hierarchical item of the mobile interface.

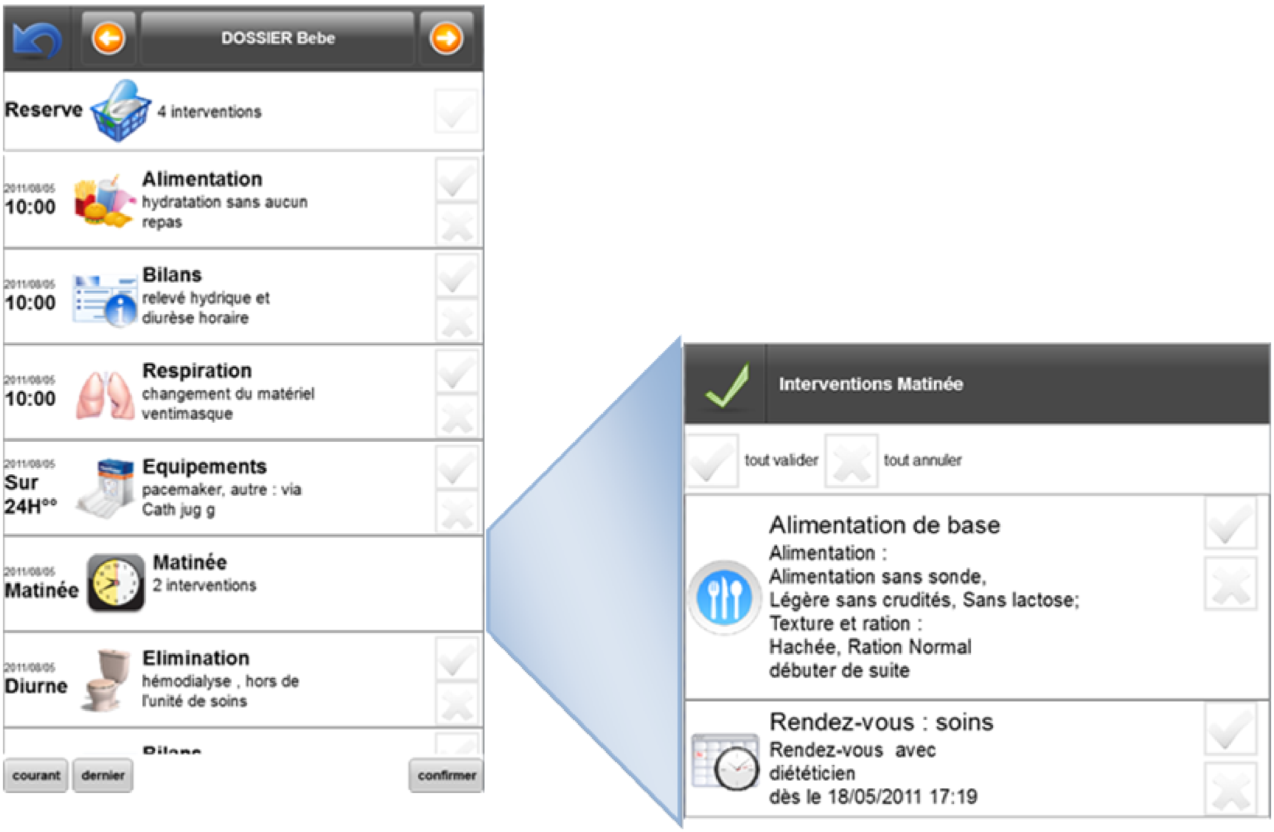
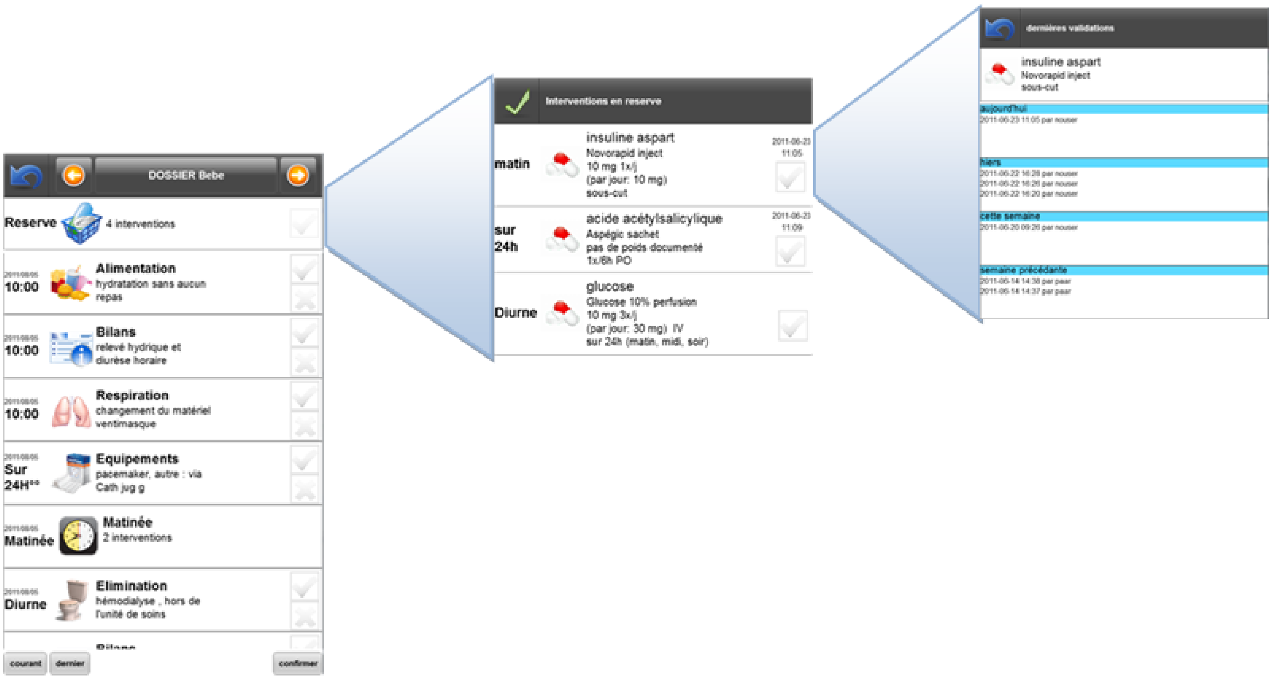


Figure 6. Hierarchical navigation through PRN drugs.



Dynamic Organization

The dynamic organization has been performed as follows:

1. By default, the first displayed intervention is the one to be performed at the current time: The real-time usage of the mobile device allows focusing the display on the intervention to perform at the exact time the device is used. In case older interventions remain invalidated, nurses still

have the possibility to return to the older interventions that must be validated. This strategy minimizes the number of manipulations required by the user and saves precious time while focusing on relevant information.

2. The interventions valid over a range are ordered dynamically: Whereas the ranking of interventions scheduled at a precise time is logical, there are no clear rules about the interventions to be executed in a period of time, such as “in the morning”. After several iterations, the solution implemented is to regroup all interventions of periods covering the current time in the next 1 hour period. Therefore, these interventions will slide in time all day as long as they are valid and not yet completed. For example, at 3AM, any intervention scheduled in the “morning” period, according to its definition for this ward, will be shown in the 4AM frame. At 4AM, they will slide to 5AM, and so on, as long as the time is in the period, and the interventions must or can be executed. This solution has been chosen to minimize the risk of missing the intervention.

Context Awareness

Every nurse followed a succession of steps (Figure 7) to define the working context: (1) Choice of ward: if the nurse has access to more than one ward, it is possible to select the one for the daily tasks (2) Choice of room: In large wards, nurses are not responsible for every room; therefore, nurses can select the rooms containing patients they have to visit, and (3) Choice of the patients: Once the rooms have been selected, nurses can choose the patient to start work with. Afterwards, they can switch from one patient to another directly in the intervention view.

Once a patient has been selected, nurses get access to all the patient interventions. This list of interventions is ordered and displays tasks to perform at a given time according to rules mentioned above.

Figure 8 shows a screenshot of the interface displayed to choose the rooms in the selected care unit. Each room is represented by a panel with the number of the room as title. The names of the patients are displayed inside the panel. Once one or several rooms have been selected, nurses get to a screen similar to the one in Figure 9. On this screen, every patient occupying one of the selected rooms is displayed. Patients are presented with their picture, if available, and some demographics.

Figure 7. Steps to select the relevant interventions.

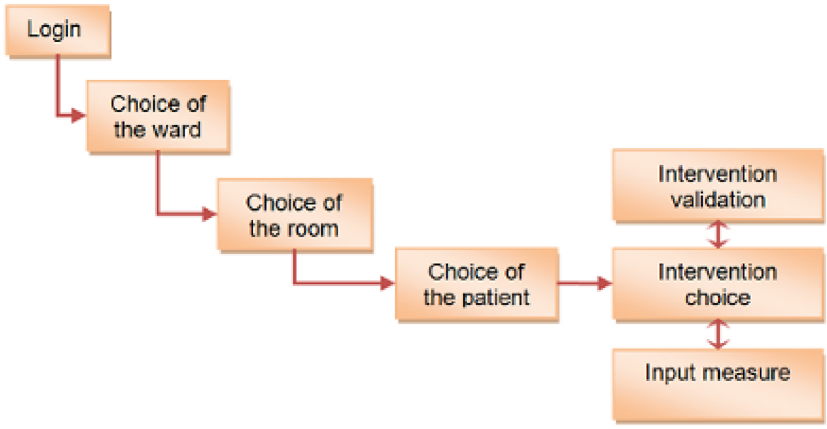


Figure 8. Screen for the selection of the rooms in the care unit.

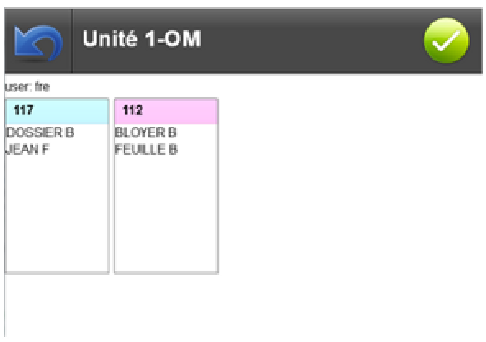


Figure 9. Screen for the selection of the patients in the rooms.

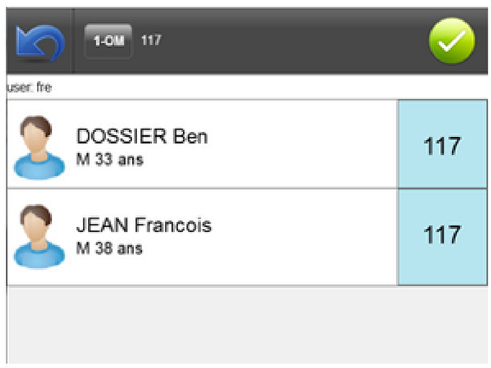
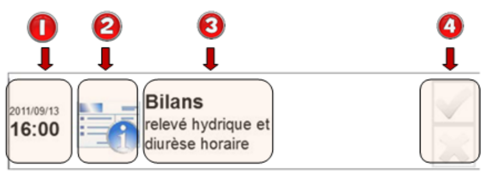


Figure 10. Indexicality indicators of every intervention item.



Indexicality

In our development, every item relies on semiotics to improve visibility, simplify information retrieval, and thus decrease the learning curve and errors (Figure 10). There is an icon representing the task to be performed and a temporal indication showing the date and time of validation. This representation allows users to locate easily the task to perform, as they are organized in a logical order. Moreover, the task is clearly identifiable by simply viewing the iconic representation and helps give an overall view of the tasks to perform.

Discussion

In this study, we evaluated the potential problems related to the deployment of a mobile clinical application and tried to find solutions based on scientifically validated evidences. This approach was motivated following the unexpected increase in acquisition errors observed in using mobile devices.

Define a Clear Strategy

A clear strategy must be defined for the institution, taking into consideration all aspects of the deployment. The choice to buy and deploy devices involves finding out which platform is most suited for maintenance, sustainability, fast and large automatic deployment of applications, etc. The same questions go for the software: how will it be maintained and deployed, if it is an app running on the client side, etc. Maintenance, sustainability, costs, authentication, data safety, learning curve, and acquisition errors among others are all important aspects.

Do Not Underestimate the Hardware

Choosing appropriate hardware is rarely taken seriously in a domain that is mostly market driven. However, it is an important step, and not only for technical reasons. There is a long list of elements such as autonomy, device hygiene, and device size that can be evaluated, according to needs, context of use, local IT culture, etc. For example, despite initial enthusiasm, the experience we had with tablets for nurses was not successful after a few months simply because these tablets did not fit in the pockets of professional garments.

Generic Interoperability Framework

Technical and semantic interoperability is probably one of the most important challenges of the field of biomedical informatics. In nomadic computing, which is an emerging technology, there should be efforts made to start with a clear and coherent, semantically oriented framework from the start, such as openEHR, CEN 13606, or RDF. In the future, more formalized data formats such as those employed in the SMArt project [31] can be adopted to facilitate the link between the mobile platform and any CIS.

Safety of Data

Data security is crucial in a health care environment. The diffusion of medical information about a patient can have consequences, for the patient and for the organization's image and liability. Data integrity is also crucial, especially in making sure that no data are lost, data are stored and retrieved in a proper manner, that there is a coherent management of concurrent editing, etc. This has a huge influence on nomadic devices, especially when deciding if an intermittent connection is supported [19].

New Human-Machine Interaction Paradigms

Small screens have a huge influence on information organization, display and retrieval. Jones et al [32] performed an experiment where users had to find information on the Internet using two types of screens. They report that users of the small screen answered half as many questions correctly as the large screen group. Moreover, 80% of users of small screens indicated that they felt screen size impacted on their ability to complete the tasks, compared to 40% for large screen users. The increased amount of scrolling needed plays a large part in both degrading speed and retrieval performance [33]. Marsden, Cherry, and Haefele [34] found that users often do not scroll down on a page because they simply did not see the scrollbar and were unaware that more information was available. If users do not scroll down, options on the first few lines of a display will be selected faster than options further down in a list, even if such an option is not correct. Scrolling and paging also more often results in errors because users try to select an option from the visible options instead of scrolling down to the end or looking at more than one page. This is a complication that might lead to the preference of narrower hierarchies on smaller screens, to prevent users from scrolling unnecessarily [35].

Conclusion

Working in a clinical environment requires mobility and constant access to clinical information. The necessity for switching continuously from paper to computer, or to carry a laptop at all times, or to walk back to offices to access computers, creates an enormous amount of work and represents a source of errors. With the maturity of personal mobile assistants such as tablets and smartphones, it is now possible to imagine a fully integrated tool to access and manage clinical information anywhere, anytime in the hospital. However, the deployment of a clinical application on mobile platform is not a simple task. Unexpected side effects have been described in the literature, one of the most important being decreased perception of the information and increased errors during data acquisition. This paper identifies some of the challenges raised when using such devices. Currently, there is a lack of clear evidence identifying the risks, benefits, and solutions related to the various contexts for using these devices.

Conflicts of Interest

Conflicts of Interest: None declared.

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Abbreviations

CIS: Clinical Information System
GUI: Graphical User Interface
HUG: University Hospitals of Geneva
PDA: Personal Digital Assistant
WLAN: Wireless Local Area Networks
XML: Extensible Markup Language
RDF: Resource Description Framework
SMArt: Substitutable Medical Applications, reusable technologies

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Original Paper

User Behavior Shift Detection in Ambient Assisted Living Environments

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Abstract

Identifying users' frequent behaviors is considered a key step to achieving real, intelligent environments that support people in their daily lives. These patterns can be used in many different applications. An algorithm that compares current behaviors of users with previously discovered frequent behaviors has been developed. In addition, it identifies the differences between both behaviors. Identified shifts can be used not only to adapt frequent behaviors, but also shifts may indicate initial signs of some diseases linked to behavioral modifications, such as depression or Alzheimer's. The algorithm was validated using datasets collected from smart apartments where five different ADLs (Activities of Daily Living) were recognized. It was able to identify all shifts from frequent behaviors, as well as identifying necessary modifications in all cases.

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KEYWORDS

shift detection; intelligent environments; disease detection

Introduction

Ubiquitous computing [1] refers to a paradigm in which a new type of relation between users and technology is established. It provides a widespread and transparent technology to the user. Modern computing devices of various types are ubiquitous, embedded in different objects that users can interact with and that consequently influence users' lifestyles. An important further development of this concept has resulted in concepts including intelligent environments [2], ambient intelligence (AmI) [3], smart environments [4], pervasive computing [5], and Ambient Assisted Living (AAL) [6]. These refer to digital environments that proactively, but sensibly, support people in their daily lives [7]. Being sensible demands recognizing the user, learning or knowing her/his preferences and, given the current situation, acting in accordance with it. Several systems have been developed for learning users' frequent behaviors without disturbing them, ie, in a transparent way. The Learning Frequent Patterns of User Behavior System (LFPUBS) [8] takes as a starting point the data collected from sensors, discovers users' frequent behaviors, and represents such patterns in a comprehensible way.

Once frequent behaviors of a user have been discovered, depending on the needs and situation of that specific user, such patterns can be used for many different purposes. An important application is behavior shift detection by comparing the current user's behavior with the previously discovered frequent behaviors. A shift from the frequent behaviors is not necessarily abnormal. This is because users can change their behaviors over time. Nevertheless, these shifts provide valuable information to the environment because they:

- can show initial signs of some diseases (eg, Alzheimer's disease, depression) or the beginning of unhealthy habits
- can be very helpful to confirm disease diagnoses, eg, the environment can record historical data about shifts so that experts in the domain can use them as additional information
- can show change of preferences, ie, users can change their frequent behaviors for several reasons and therefore, the

environment should adapt the patterns based on the user behavior shifts

This paper develops an algorithm that compares the current behavior of a user with previously discovered frequent behaviors and identifies shifts. In addition, the proposed algorithm determines the criticality of different shifts for certain users and specific applications.

Related Work

Understanding human behavior has attracted a significant number of researchers, and much work has been devoted to modeling human behavior in order to act accordingly. Mozer et al [9] and Chang et al [10] were among the first to report on applications for ambient intelligence environments where user patterns were considered. Based on residents' lifestyles, models to predict occupancy were created. The models then were used for lighting control. Several other methods for identifying users' patterns have been proposed [11,12]. Holistic approaches considering the special features of intelligent environments have been also investigated [8]. A survey of these methods is given in Aztiria et al [13].

Due to the novelty and characteristics of intelligent environments, complex model-based applications have not been developed. Artificial Intelligence techniques in relation to Alzheimer's disease have been used. Zhou et al [14] used multitask regression models in order to track markers that allow identification of the progression of the disease. Bouchard et al [15] developed a hybrid plan recognition model, based on probabilistic description logic, which addressed the issue of recognizing the activities and errors of Alzheimer's patients.

Shifts in human behaviors have been analyzed in many domains such as Web navigation and activity workflow [16,17]. However, it is necessary to obtain a specific solution taking into account the special features of intelligent environments, such as importance of the user, transparency, nature of collected data, etc.

Methods

General Architecture

Identifying shifts involves several steps as shown in Figure 1. The first step is environment monitoring for collecting data. This monitoring task should be carried out as unobtrusively as possible. The next step is to infer meaningful information from the collected data. The objective of the transformation layer is to identify actions defined as interesting. The set of actions to be identified is denoted by A={ai}. The output of this layer is stored in the observation matrix, X. The observation matrix represents the occurrences of different actions, ai ∈ A, in different timestamps.

Given the observation matrix, the learning layer discovers the set of frequent behaviors. Frequent behaviors are obtained using the LFPUBS method given by Aztiria [8]. LFPUBS first discovers the set of actions that frequently occur together and then it identifies the order of such actions, defining each frequent behavior as a Markov chain.

Let F denotes the set of frequent behaviors of a user. Then fi ∈ F is a set of actions, $\{fi_k : fi_k \in A\}$, that forms a Markov chain with initial probability, $P_0=Pr(fi_0)$ and the transition matrix P=[Pk,j] where $Pk,j=Pr(fi_j \mid fi_k)$. Apart from this definition, LFPUBS can discover time relationship between different actions of the model (eg, Michael needs approximately 10 minutes to go to the bathroom) and identify under what conditions this pattern occurs (eg, under what conditions Michael has a shower or not).

The following scenario exemplifies the common behavior of a user. On weekdays, Michael's alarm clock goes off ('Alarm, on') a few minutes after 08:00AM. Approximately 10 minutes after getting up, he usually steps into the bathroom ('Bathroom, on'), and sometimes he takes a shower ('Shower, on') and some other times he does not. Then, he goes to the kitchen ('Kitchen, on'), and after having breakfast ('Breakfast, on'), he takes his daily pill ('Pill, on').

Michael's morning behavior is discovered by the learning algorithm and represented as a Markov chain as shown in Figure 2. The transition probabilities shown in the chain indicate the frequency of that relationship.

Finally, the application layer allows the development of applications that can benefit from the discovered frequent behaviors. This paper proposes an algorithm for shift detection in user behavior, which compares the current set of observed actions from the user, C={ci : ci ∈ A}, with all frequent behaviors, fi ∈ F, obtained in the learning layer. If the current behavior matches any of the frequent behaviors, the algorithm returns a likelihood value. Otherwise, the algorithm calculates the shift of the current behavior, C, from all frequent behaviors and determines the criticality of these differences (see Textbox 1.

Textbox 1. Identifying Shifts From Frequent Behaviors.

Algorithm: calculate Shifts (F, C)

Input: Set of frequent behaviors F and current behavior C.

Output: Likelihood (LL), number of modifications, and criticality.

```
for each fi ∊ F compute LL(C|fi)
  if LL(C|fi) != 0 then return LL(C|fi)
  else
    calculateAllPossiblePaths(fi)
    for each path ρij ∊ fi
      calculateNecessaryModifications (ρij ,C)
      return numberModification, modificationsCriticality
```

Figure 1. General architecture for identifying shifts.

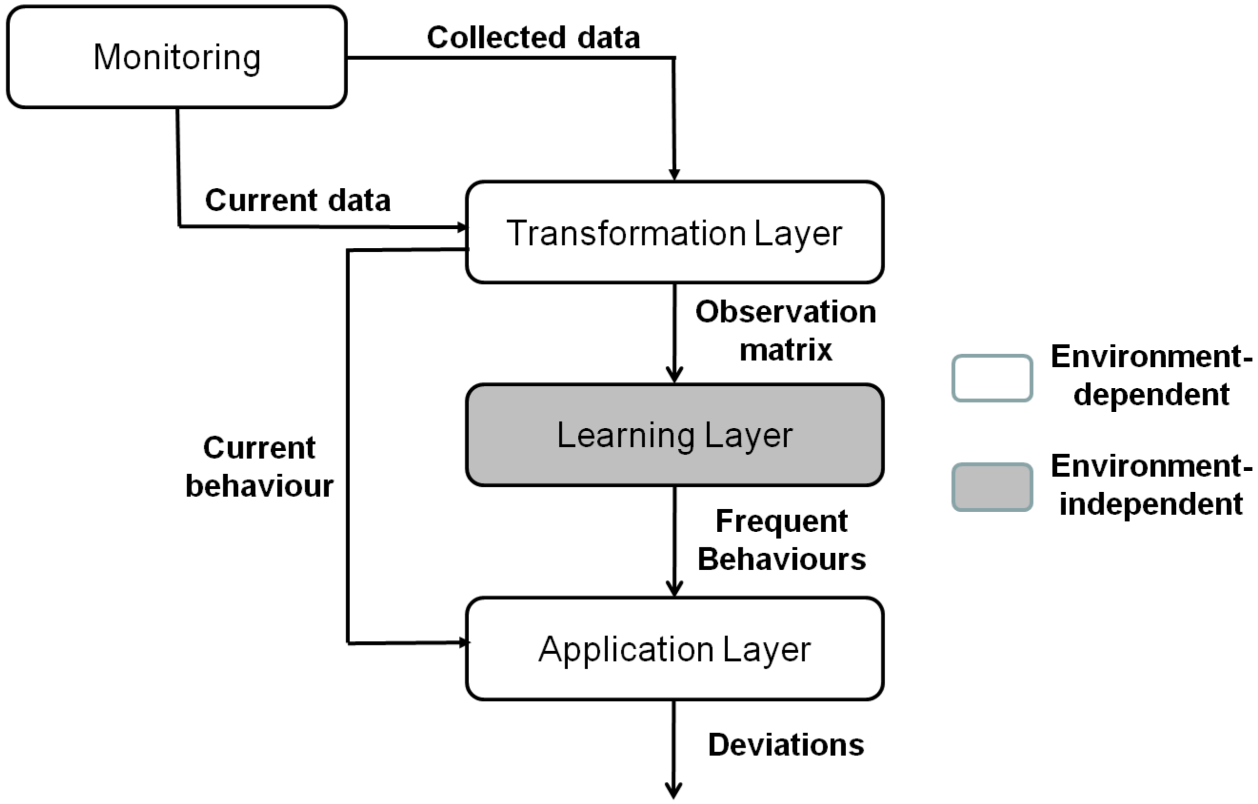
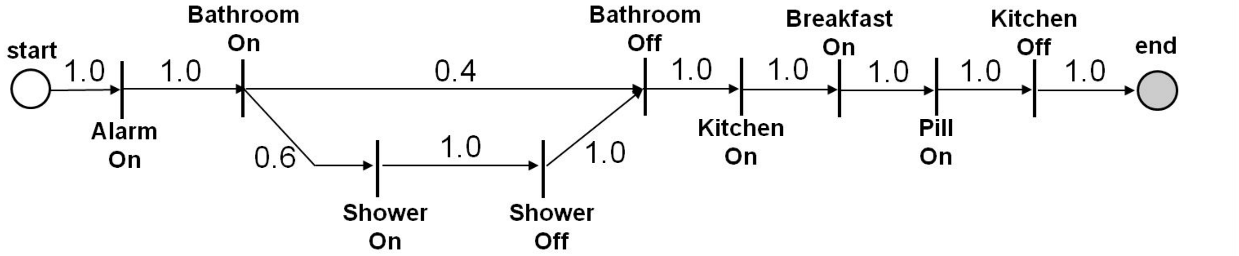


Figure 2. Michael's morning ritual represented in a Markov Chain.



Calculating Likelihoods

Given the current behavior, C, the first step is to determine if that behavior is part of user frequent behaviors, F. This requires comparing the current behavior with all previously discovered frequent behaviors fi ∊ F ∀i. Recall that each frequent behavior fi is represented as a Markov chain. Then, the likelihood is obtained as in Equation 1 in Multimedia Appendix 1, where |·| denotes the cardinality of the set and Pr (ck → ck+1) is given by the transition probability matrix for the frequent behavior fi.

In general, the likelihood value implies the frequency of that behavior. On the other hand, having LL(C|fi)=0 ∀fi ∊ F indicates the current behavior is not frequent.

For example, consider the following three current behaviors and the transition matrix defined by the likelihoods shown by Figure 2:

C1 = ‘Alarm, on’, ‘Bathroom, on’, ‘Shower, on’, ‘Shower off’, ‘Bathroom off’ ‘Kitchen, on’, ‘Breakfast, on’, ‘Pill, on’, ‘Kitchen off’

C2 = ‘Alarm, on’, ‘Bathroom, on’, ‘Shower, on’, ‘Shower off’, ‘Bathroom off’ ‘Kitchen, on’, ‘Breakfast, on’, ‘Kitchen off’

C3 = ‘Alarm, on’, ‘Bathroom, on’, ‘Shower, on’, ‘Shower off’, ‘Bathroom off’ ‘Kitchen, on’, ‘Pill, on’, ‘Breakfast, on’, ‘Kitchen off’

Then, LL(C1|f1)=0.6, LL(C2|f1)= LL(C3|f1) = 0.

However, note that having a behavior that differs from frequent behaviors (ie, zero likelihood) is going to be common. For example, in Michael’s case, although the likelihoods of current behaviors C2 and C3 are zero, it is clear that they slightly differ from the frequent behaviors. Therefore, it is necessary to determine how different a behavior is from frequent behaviors.

Calculating Paths

In order to be able to identify how different a current behavior is from a frequent behavior, it is necessary to calculate all the possible behaviors that can be represented by the frequent behavior. Thus, all the possible behaviors that can be represented by the frequent behavior should be obtained. Possible paths included in a frequent behavior fi ∊ F are obtained using the depth-first search algorithm [18]. In addition, the likelihood of each path serves as a criterion to discard all the behaviors whose likelihoods are below a certain threshold. This condition is necessary because loops or self loops in the Markov chain can lead to infinite numbers of paths. Let ρij = $\{\rho ij_k : \rho ij_k \in A\}$ denote the set of actions over the j^{th} path for the i^{th} frequent behavior, fi ∊ F. Then, the likelihood of the path is given by Equation 2 in Multimedia Appendix 1, where $Pr(\rho ij_k \rightarrow \rho ij_{k+1}$)is given by the transition probability matrix for the frequent behavior fi. Recall Michael’s morning frequent behavior, f1. It consists of two sequences of actions:

ρ11: ‘Alarm, on’, ‘Bathroom, on’, ‘Bathroom, off’, ‘Kitchen, on’, ‘Breakfast, on’,‘Pill, on’, ‘Kitchen, off’ where LL(ρ11)=0.4

ρ12: ‘Alarm, on’, ‘Bathroom, on’, ‘Shower, on’, ‘Shower, off’, ‘Bathroom, off’, ‘Kitchen, on’, ‘Breakfast, on’,‘Pill, on’,‘Kitchen, off’ where LL(ρ12)=0.6

Calculating Modifications and Criticality

Once all possible paths have been calculated, the next step is to compare C with all them. It is worth remembering that in order to reach this point, the likelihood (C|fi) must be 0.0, so that it needs some modifications to match any of the paths. For that, C is compared to all the paths of fi and needed modifications are calculated, as well as their criticality.

Recall that for LL (C|fi) = 0, ∀fi ∊ F, the algorithm should obtain the minimum number of modifications that matches the current behavior with any fi ∊ F. For each fi ∊ F, the algorithm compares the current behavior, C, with all the paths, ρij, and obtains the set of modifications as well as the corresponding criticality values.

Identifying Modifications

The process to identify modifications is an adaptation of the Levenshtein distance [19]. Given two sequences of actions, C and ρij, it calculates the set of modifications in C to get ρij. In intelligent environments, the set of all possible modifications denoted by H is the union of:

- H1= {*insert* (ai): ∀ai ∊ A}: Insertion of an action if the user forgets to do an action.
- H2= {*delete* (ai): ∀ai ∊ A}: Deletion of an action if the user does an extra action.
- H3= {*subs* (ai,aj): ∀ai,aj ∊ A}: Substitution of action ai with action aj if the user does action aj instead of ai.
- H4= {*swap* (ai,aj): ∀ai,aj ∊ A}: Swapping of two actions if the user does the actions in reverse order.

The algorithm for identifying modifications is based on the constructing of *distance matrix*. D=[dm,n]$|C|\times|\rho_{ij}|$, is constructed as in Textbox 2

Textbox 2. Constructing Distance Matrix.

```
Algorithm: constructDistanceMatrix (C, ρij )
Input: C and ρij
Output: distance matrix (D) and number of modifications
for m=0 to m=|C|
  for n=0 to n=|ρij|
    if C(m) == ρij(n) then
      dm,n=dm−1,n−1 // no modification needed
    else
      dm,n=minimum(
        dm−1,n + 1 // insertion
        dm,n−1 + 1 // deletion
  dm−1,n−1 + 1 // substitution
        if((C(m − 1) == ρij(n − 2))&(C(m − 2) == ρij(n − 1)) then
          dm−2,n−2 + 1 // swap )
  return D, d|C|,|ρij|
```

The number of modifications is given by the value of $d_{|C|,|\rho_{ij}|}$. In addition, the construction of the distance matrix allows to identify the set of modifications Mij = $\{mij_k : mij_k \in H\}$. For each value, the distance matrix records what modification(s) has been considered. The set of modifications is identified using the algorithm identifyModifications (D, |C|, |ρij|) (see Textbox 3).

Textbox 3. Identifying Modifications Based on Distance Matrix.

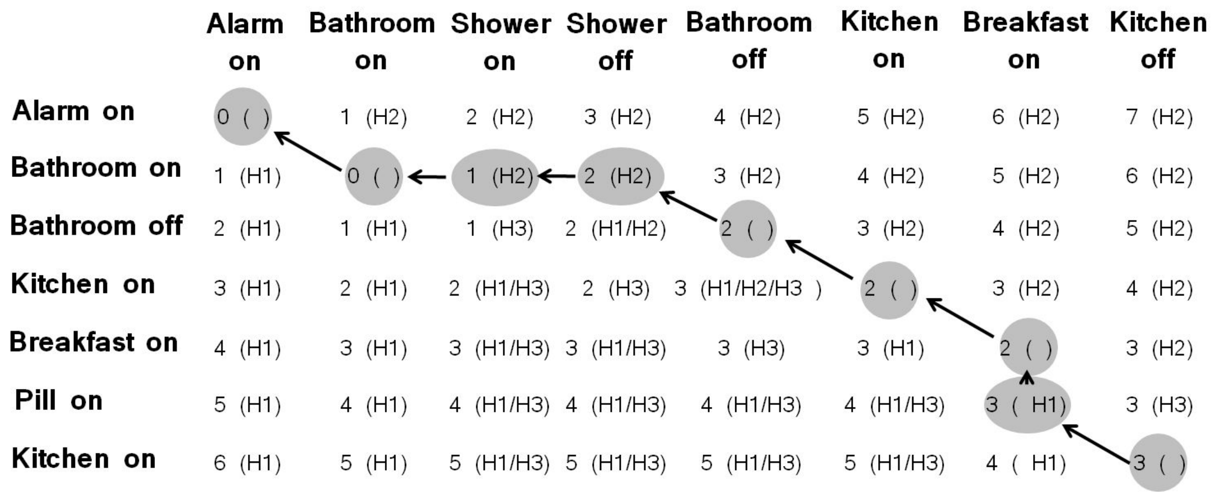
```
Algorithm: identifyModifications (D, m, n)
Input: D and H
Output: set of modifications Mij
if (m, n)! = (0, 0) then
  if modificationsToConsider (dm,n) == empty then
    modificationsToConsider (D, m − 1,n − 1)
  if modificationsToConsider (dm,n) == H1 then
    Mij.add(insertion);
    modificationsToConsider (D, m − 1,n)
  if modificationsToConsider (dm,n) == H2 then
    Mij.add(deletion);
    modificationsToConsider (D, m, n − 1)
  if modificationsToConsider (dm,n) == H3 then
    Mij.add(substitution);
    modificationsToConsider (D, m − 1,n − 1)
  if modificationsToConsider (dm,n) == H4 then
    Mij.add(swap);
    modificationsToConsider (D, m − 2,n − 2)
return Mij
```

For example, the distance matrix for Michael’s current behavior C2 and his frequent behavior ρ11 is given by Figure 3. In this case, 3 modifications are needed, specifically deletion (‘Shower, on’), deletion (‘Shower, off’) and insertion (‘Pill, on’). Figure 3 shows how the set of modifications is identified.

The current behavior C2 needs only one modification, insertion (‘Pill, on’), in order to match the path ρ12. The current behavior

C3 requires 3 modifications for the path ρ11, while it needs only 1 modification, swap (‘Pill, on’, ‘Breakfast, on’), for the path ρ12.

Figure 3. Generated distance matrix and identification of the set of modifications.



Identifying Criticality

The importance of each modification is different. In Michael’s example, the consequence of not taking the pill is far more important than forgetting to take the shower. Experts also advised him not to take the pill before having breakfast, whereas some other swaps could have no consequences. Depending on each environment and the knowledge collected from experts, relatives, etc, a criticality value can be assigned to each possible modification. Let g define a mapping from set H to a set of all possible criticality values V={vi = g(hi): ∀hi ∊ H}. Then, the criticality for a set of modifications, Mij, is obtained as in Equation 3 in Multimedia Appendix 1.

For example, given the criticality mappings (the lower the value, the more critical) shown in Multimedia Appendix 1, we have Cr(M12)=0.2 and Cr(M12)=0.4 for the current behaviors C2 and C3, respectively. For a set of observed actions, C, the algorithm can consequently determine the behavior risk factor defined as in Equation 4 in Multimedia Appendix 1, for all fi ∊ F. If ϕi is greater than a certain threshold, the current behavior C is declared as an anomalous behavior.

Experimental Results and Discussion

This algorithm was validated using datasets collected from the Washington State University (WSU) Smart Apartment environment [20]. Data collected in the WSU Smart Apartment represent participants performing the same five ADLs (Activities of Daily Living) in the apartment: make a phone call, wash hands, cook, eat, and clean. Inside, there were motion sensors, cameras, and computers to control a variety of tasks, such as opening blinds or turning up heat or air conditioning. For example, there was automated computer software in the kitchen that handily provided a needed recipe and kept track of ingredients needed for recipes. Although the participants did not have Alzheimer’s disease and had to perform the same five ADLs, the performed set of actions could vary depending on each participant. The actions involved in each one of the activities are shown in Table 1.

Table 1. Actions involved in each ADL.

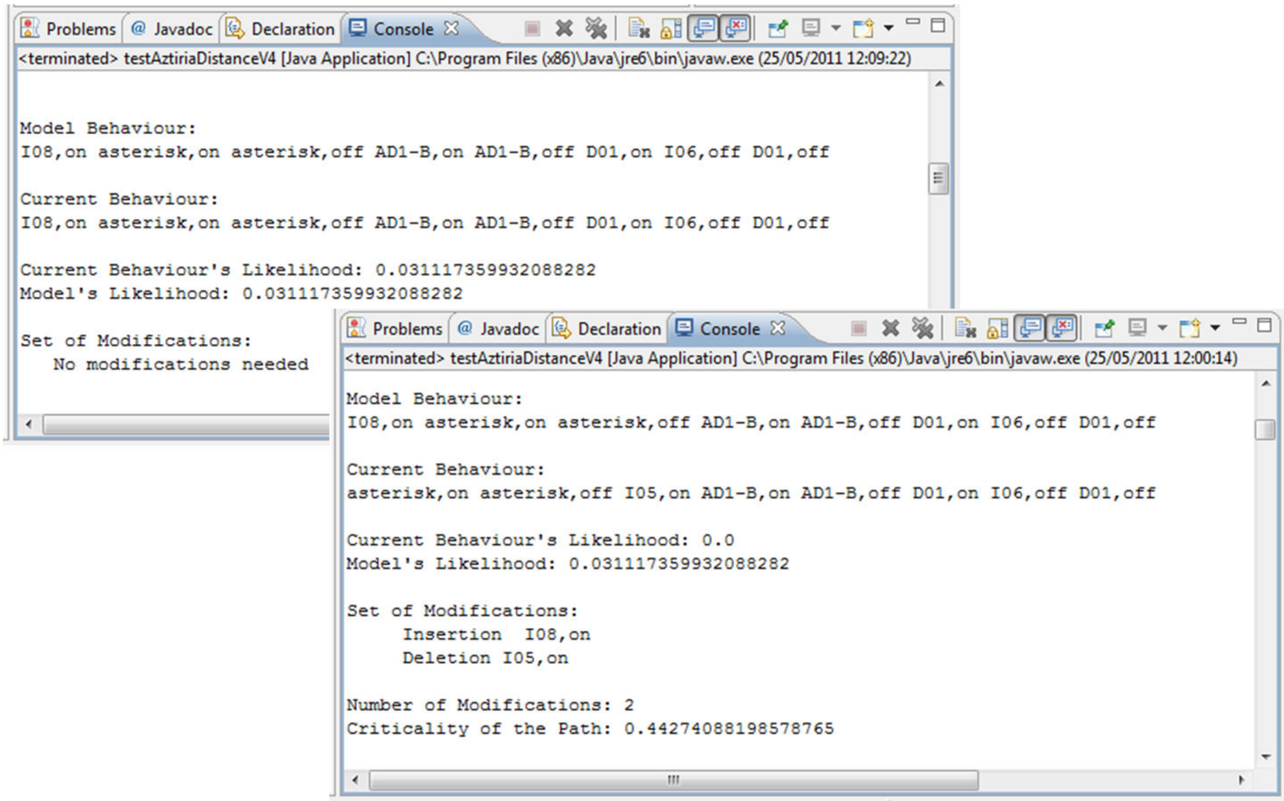
Activity	Involved Actions
Make a phone call	‘PhoneBook On’ →‘Phone On’ → ‘Phone Off’
Wash hands	‘Water On’ → ‘Water Off’
Cook	‘Cabinet On’ → ‘Raisins On’ → ‘Oatmeal On’ → ‘MeasuringSpoon On’ → ‘Bowl On’ → ‘Sugar On’ → ‘Cabinet Off’ → ‘Water On’ → ‘Water Off’ → ‘Pot On’ → ‘Burner On’ → ‘Burner Off’
Eat	‘Cabinet On’ → ‘Medicine On’ → ‘Cabinet Off’ → ‘Water On’ → ‘Water Off’ → ‘Cabinet On’ → ‘Medicine Off’ → ‘Cabinet Off’
Clean	‘Water On’ → ‘Water Off’

In order to validate the proposed algorithm, an adapted 10-fold cross validation process is performed. A simple 10-fold cross validation validates the frequent behaviors obtained using LFPUBS algorithm. Adapted cross-validation validates if the algorithm identifies shifts from frequent behaviors. As a result of this validation, carried out in an offline way, it has to be said that it was able to identify in all the cases (100%) if it matched a path, and its correspondent likelihood. When it did not match a frequent behavior, the algorithm was able to identify necessary modifications in all the cases (100%).

Figure 4 shows how results are provided by the system. On one hand, it shows a first example where the current behavior matches a path of the model, so that it does not need any modification. On the other, a current behavior that is not covered by the model is shown. In that case, necessary modifications were calculated (two modifications in this case) and the importance of those modifications is provided by the criticality parameter.

It is quite difficult to compare to other approaches due to the lack of shift detection approaches. Compared to activity recognition approaches, being able to identify all shifts is a very good result.

Figure 4. Example of outputs obtained in the validation process.



Conclusion

Intelligent environments suggest a new paradigm where environments adapt their behaviors based on preferences and habits of users instead of the other way around. For that, environments must learn users' frequent behaviors. But, at the same time, users will not always behave in accordance with those patterns. Users typically modify their habits over time, but some other factors (eg, age-related diseases) may influence the behavior.

This paper developed an algorithm that compares users' current behaviors with their frequent behaviors and identifies possible shifts. If users' current behavior is frequent, the algorithm determines its frequency. Otherwise, the algorithm identifies the shifts. Generally, such shifts can be used to adapt patterns. These shifts can also be used to detect early signs of diseases. In this case, the algorithm determines the criticality of a shift.

The algorithm was tested using a dataset collected in the WSU Smart Apartment. The algorithm showed the capacity to identify if a behavior was frequent or not as well as to identify the shifts.

As future work, we plan to extend this algorithm to an online algorithm in order to analyze behaviors online, so that reminders (eg, reminding the user to take a pill) can be issued if critical deviations or abnormal behaviors are identified. Adaptation of patterns based on deviations will also be addressed.

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Conflicts of Interest

Conflicts of Interest: None declared.

Multimedia Appendix 1

Equations and mapping.

[PDF File (Adobe PDF File), 243KB - mhealth_v1i1e6_app1.pdf]

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Abbreviations

AAL: Ambient Assisted Living
ADL: Activities of Daily Living
AmI: Ambient Intelligence
LFPUBS: Learning Frequent Patterns of User Behavior
WSU: Washington State University

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Original Paper

Long-Term Engagement With a Mobile Self-Management System for People With Type 2 Diabetes

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Abstract

Background: In a growing number of intervention studies, mobile phones are used to support self-management of people with Type 2 diabetes mellitus (T2DM). However, it is difficult to establish knowledge about factors associated with intervention effects, due to considerable differences in research designs and outcome measures as well as a lack of detailed information about participants' engagement with the intervention tool.

Objective: To contribute toward accumulating knowledge about factors associated with usage and usability of a mobile self-management application over time through a thorough analysis of multiple types of investigation on each participant's engagement.

Methods: The Few Touch application is a mobile-phone–based self-management tool for patients with T2DM. Twelve patients with T2DM who have been actively involved in the system design used the Few Touch application in a real-life setting from September 2008 until October 2009. During this period, questionnaires and semistructured interviews were conducted. Recorded data were analyzed to investigate usage trends and patterns. Transcripts from interviews were thematically analyzed, and the results were further analyzed in relation to the questionnaire answers and the usage trends and patterns.

Results: The Few Touch application served as a flexible learning tool for the participants, responsive to their spontaneous needs, as well as supporting regular self-monitoring. A significantly decreasing (*P*<.05) usage trend was observed among 10 out of the 12 participants, though the magnitude of the decrease varied widely. Having achieved a sense of mastery over diabetes and experiences of problems were identified as reasons for declining motivation to continue using the application. Some of the problems stemmed from difficulties in integrating the use of the application into each participant's everyday life and needs, although the design concepts were developed in the process where the participants were involved. The following factors were identified as associated with usability and/or usage over time: Integration with everyday life; automation; balance between accuracy and meaningfulness of data with manual entry; intuitive and informative feedback; and rich learning materials, especially about foods.

Conclusion: Many grounded design implications were identified through a thorough analysis of results from multiple types of investigations obtained through a year-long field trial of the Few Touch application. The study showed the importance and value of involving patient-users in a long-term trial of a tool to identify factors influencing usage and usability over time. In addition, the study confirmed the importance of detailed analyses of each participant's usage of the provided tool for better understanding of participants' engagement over time.

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KEYWORDS

Type 2 diabetes; self-management; user-involved design process; mobile phone; usage; usability; mHealth

Introduction

For effective medical care of chronic illness, such as Type 2 diabetes mellitus (T2DM), adequate and sustainable self-management initiated by patients is important [1-3]. Nevertheless, poor adherence to T2DM treatment is common [4]. Mobile phones have been considered promising intervention platforms to support self-management of lifestyle-related diseases in general because of their pervasiveness and ubiquity [5]. Especially with the emergence of smartphones, the number of mobile self-management tools for diabetes available both commercially and free of charge is rapidly increasing [6-8]. Reflecting this situation, a growing number of studies report interventions using mobile phones and development projects of mobile self-management tools for people with diabetes [9-11]. However, considerable differences in research designs and outcome measures make it difficult to conduct rigorous meta-analysis of the findings [12,13]. In addition, recent reviews [11,14,15] point out a lack of focus on detailed reporting on participants' long-term engagement with the intervention tools.

We recently conducted a literature review based on search criteria used previously [9] that cover more publication channels and more types of mobile terminals than the criteria used in the above-mentioned reviews do [11,14,15]. Our review also revealed considerable differences among the studies in terms of the level of detail regarding reports on participants' engagement with the intervention tools over time. In two studies [16,17], two groups with different intervention conditions were compared in terms of change in average level of engagement among the participants with the passage of time, but differences between the participants in each group were not explained. Ten studies [18-27] identified differences in the level of engagement between the participants, but only three of them [18-20] reported how their level of engagement changed over time and the reasons for attrition of engagement. Two [26,27] of the 10 studies however reported individual participants' levels of engagement and qualitatively analyzed participants' experience of the tool to identify factors associated with usage. Four studies [28-31] reported reasons for dropout that stemmed from dissatisfaction with the employed tool. One study [30] focused on changes in usage levels for each feature of the tool over time by assessing the number of days during the last 7 days on which each feature was used. However, the reported values were the mean and standard deviation calculated for the participants who completed each visit at 3 months and 6 months. Some participants dropped out after the 3-month visit, so the difference in reported values between two time points does not reflect usage changes for all the participants. Four studies [22,25,30,32] analyzed factors potentially associated with the level of engagement throughout the trial, but only one of them [32] also included the level of engagement for the first phase as a potential factor, which was actually the only factor that was associated with the engagement level of the later phase.

Regardless of study design, if patients are involved in a longitudinal trial of a self-management tool, mechanisms of their engagement with the tool over the period should be analyzed to identify factors associated with usage [33]: how participants used the tool; why they used, continued using, or stopped using the tool; what they experienced by using the tool; and how they perceived the tool. Many studies of Web-based health-promoting programs investigate relationships between attrition and user characteristics or design factors of the program, for example [34-39]. Especially for the early stage of development or a feasibility study, such mechanisms of engagement should be qualitatively analyzed in regard to the design elements of the tool from the perspective of user-centered design. For example, based on a 13-week field trial of DiasNet mobile by one patient, Jensen and Larsen showed that combining a usage log and subsequent interview provided good insight into usage [40]. Such qualitative analysis will not only identify design issues to be improved for better usability, but will also enable researchers to list factors to be statistically investigated for their association with engagement with the tool in a larger study. To our knowledge, no standard measure has been specifically designed to assess usability of a mobile-phone-based self-management tool for diabetes. Garcia et al [8] presented a heuristic evaluation method for mobile application for self-management of Type 1 diabetes mellitus (T1DM). Based on evidence-based guidelines and iterative discussions with patients and physicians, Chomutare et al [6] suggested a list of features that a mobile diabetes application should have. In addition to these methods, elaborating on participants' usage and experience with a tool over time will help in accumulating knowledge that will establish a solid outcome measure for feasibility and usability. Such a knowledge base will also help researchers, clinicians, designers, and developers to choose or design a suitable tool for their purpose.

The authors of this paper have developed ICT systems to support sustainable self-management of T2DM, emphasizing unobtrusiveness in patients' daily life and simplicity for ease of use. From a very early stage, the design process has involved patients with T2DM as prospective users. A self-management tool, the Few Touch application, was developed for continuous use with the purpose of improving users' blood glucose management by increasing physical activity and encouraging a healthier diet. The feasibility of the application was tested by the 12 participants in their real-life settings for half a year as the final part of the design process [41,42]. Even at the completion of the initially planned half-year testing, all the participants showed strong interest in continuing use of the application and further participation with the study. However, a decreasing tendency in measurement frequency was generally observed in statistical analysis of aggregated blood glucose readings by all the participants for 1 year [43]. In the present study, therefore, we explored mechanisms of participants' engagement with the application. We identified design factors associated with long-term usage and usability of the application by conducting a thorough analysis of results from multiple types of investigation focused on each participant's usage, experience, and perception of the application over time. By elaborating on the results of the above-mentioned analysis, this study aims to contribute toward accumulating knowledge about factors associated with use of a mobile self-management application as well as to disseminate the value of involving patient-users from an early design phase to a longitudinal trial of the product for the very last design iterations.

Methods

Long-Term Trial of the Few Touch application

The Few Touch application was tested for 1 year by 12 individuals with T2DM (4 men and 8 women; age ranged from 44 to 70 with a mean age of 55.1 (SD: 9.6) and mean disease duration was 8.1 (SD 3.8) years at the beginning of the long-term trial) who had been involved in the design process. We use the term “participants” for these 12 individuals. The local regional ethical committee approved the study protocol in 2006 (Regional komité for medisinsk forskningsetikk Nord, Ref. No. 13/2006). The recruitment process and other details about the participants are explained elsewhere [41].

The main component of the Few Touch application is the smartphone-based “Diabetes Diary”. Core features of the Few Touch application are: (1) automatic wireless data transmission from a blood glucose meter and a step counter, (2) nutrition habit recording enabled by few-touch operation on the smartphone, (3) feedback with simple analysis of these three types of data shown by the Diabetes Diary, (4) goal-setting functions for step counts and nutrition habits, and (5) general tips function for self-management of diabetes.

Figure 1 shows the structure and screenshots of each page in the Diabetes Diary. The “Phone (tlf)” button switches to the default top menu of the smartphone. Tapping the button “Angi Tidsrom” (change period) on screen (d) displays a blood glucose measure graph showing all the data for the set duration. Tapping “lav karb. (low carb.) snacks”, icons for meals, or the “status” button displays page (f). Tapping “høy karb. (high carb.) snacks” or icons for drinks displays page (g). Details of each function and the design process of the Few Touch application including reasons for the choice of technologies can be found elsewhere [41,42,44-47].

The schedule for the long-term trial and the timing of data collection is summarized in Table 1. At the introduction of the Few Touch application in September 2008, the authors explained that the frequency of using the system was up to the participants. Instead of providing detailed instructions for using the nutrition habit recording system, we challenged participants to record what they ate and/or drank in a way that was relevant for them, so that this process could evoke reflective thinking [48]. Due to the limited battery life of the step counter and the limited human resources after the end of the 6-month trial planned initially, all the step counters stopped working before the meetings held in October 2009.

Table 1. Schedule for the long-term trial and the timing of data collection.

Meetings	Time (month, year)	Events
1	September 2008 [a]	Introduction of the Few Touch application (except physical activity sensor system and tips function)
		Questionnaire 5
2	October 2008 (7 weeks after Meeting 1)	Introduction of tips function
		Focus group sessions (the participants were divided into two groups)
3	December 2008[b], January 2009[c]	Introduction of physical activity sensor system
		Individual semistructured interview
		Questionnaires 4 and 7
4	March 2009	Focus group sessions (the participants were divided into two groups)
		Questionnaires 1, 2, 4-8
		System Usability Scale (SUS) [49]
5	June 2009	Focus group session[d]
6	October 2009	Focus group sessions (the participants were divided into two groups)
		Questionnaires 3-7, 9

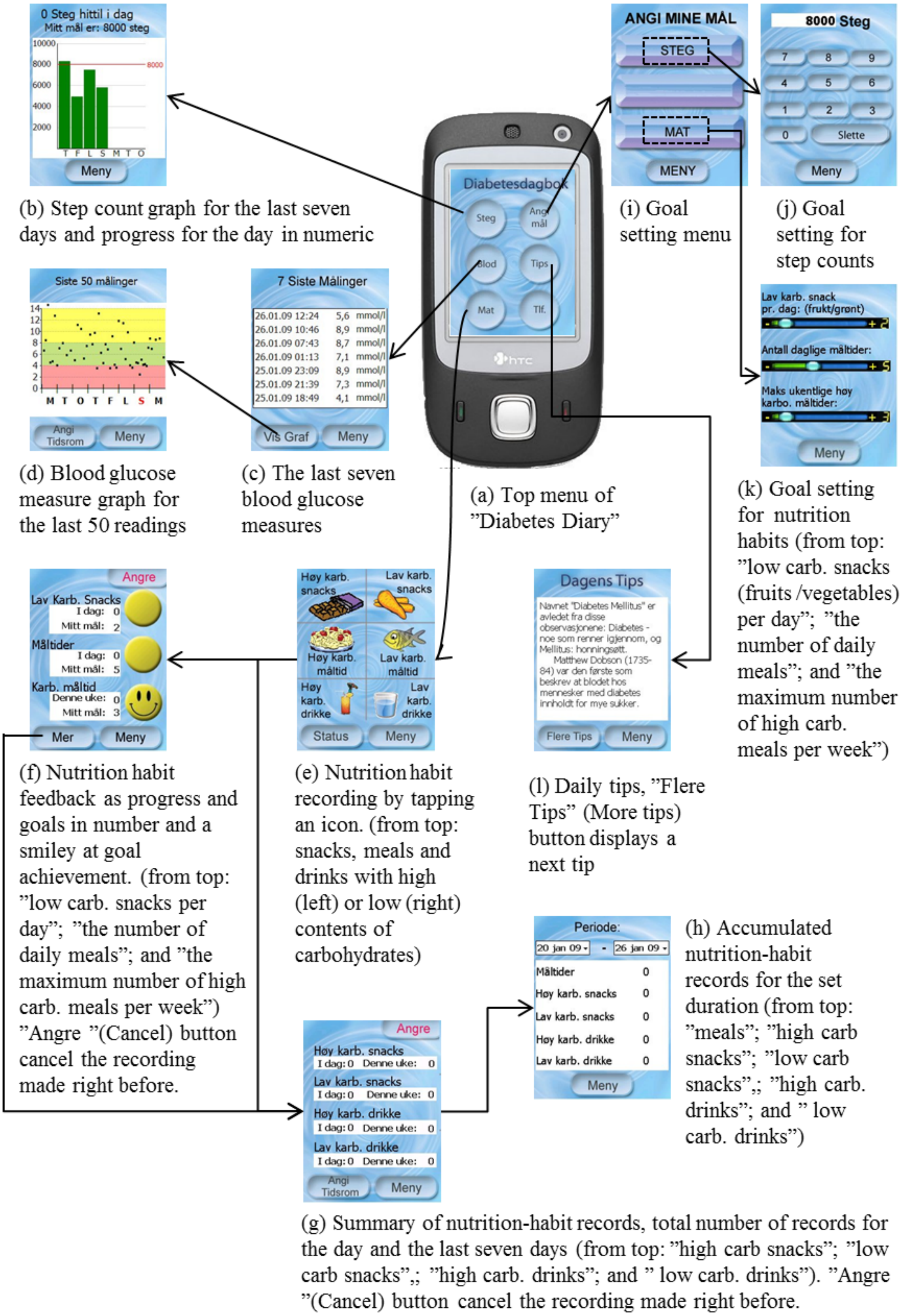
[a]For P07 and P11, the application was introduced on October 1 and 7, 2008, respectively

[b]Two participants attended an individual meeting.

[c]Ten participants attended an individual meeting.

[d]Ten participants attended the focus group session.

Figure 1. Screen design and structure of Diabetes Diary (“Diabetesdagbok”).



Data Collection and Analysis

Usage Trends and Patterns

Recorded data in the Diabetes Diary, comprising blood glucose measures and step counts that had automatically been transferred to the users’ smartphones and manually recorded nutrition habits, were collected in every meeting after each function became available. To explore usage trends over time, we defined “usage rate” as the number of days per week on which each function was used. For the physical activity system, unless participants reported any problems with it, we assumed that days with step counts greater than zero were the days on which the system was used, because the step counter automatically transmits data once a day at a regular time, even if it has not been used on that day. To evaluate usage trends (Multimedia Appendix 1), we employed the Mann-Kendall trend test [50] on usage rates for weeks in which each function was available for 7 days. This is a non-parametric test with the null hypothesis that the signs of single differences in target values sum to zero. Thus a significant result indicates an average trend in either direction. The test statistic tau is a measure of the monotonicity of the trend. Tau=1 means a monotonic increase; tau=0 indicates no trend either way; tau= -1 means a monotonic decrease. To examine overall levels of usage throughout the trial period, we looked at the number of days on which each function was used against a period in which each function was available. To investigate each participant's daily usage pattern and its change over time, we focused on the distribution of time points during the day for blood glucose measurements and nutrition habit recordings throughout the trial. We applied the same method used in [43], a kernel density estimator with Gaussian kernel smooth, on the time at which recordings were made by each participant. Each dataset for blood glucose measurements included all the data collected during the trial duration, while we divided data for nutrition habits recording into 2-month intervals in order to highlight the change over time. To find the bandwidth that highlighted characteristics of usage patterns in the best way, we tried different bandwidths, such as 0.1, 0.5 and 1 hour, on all datasets. As a result of this process, we selected 1 hour for the bandwidth for all the calculations. For blood glucose measurements, we also looked at the daily frequency of measurements.

Questionnaires

Although the questionnaires that we used covered a variety of aspects, this paper focuses on reporting the results regarding the participants' perception of usability and usefulness of the Few Touch application. Both standard and tailored questionnaires were administered. To evaluate the usability of the whole system, at Meeting 4 we administered the System Usability Scale (SUS) [49], which is widely used [51] and has been found valid [52]. Inspired by the conclusion from the case study [53], we designed and administered original questionnaires to investigate usability in more detail based on the context of the Few Touch application. The following is a list of original questionnaires that are used in this study. Questionnaires 1 and 8 comprise particular items that had been found essential or important as a mobile terminal-based self-help tool in our survey of other relevant studies [9].

1. Satisfaction with 14 design elements of the Few Touch application (5-point Likert scale)
2. Agreement with motivational effect of each function on better self-management (5-point Likert scale)
3. Agreement with effect of using the Few Touch application on behavior change in activities for self-management of diabetes (5-point Likert scale)
4. Perceived usefulness of the Few Touch application. (7-point Likert scale)
5. Satisfaction level with knowledge about diabetes and with the skills in diabetes management (5-point Likert scale)
6. Expected frequency of usage of the Few Touch application in future (multiple choice from: Daily, Weekly, Monthly, or Seldom)
7. Satisfaction level with the tips function (5-point Likert scale)
8. Agreement with possible improvement of the Few Touch application by incorporating 10 potential functionalities (5-point Likert scale)
9. Agreement with actual improvement in medication, blood glucose control, physical activity level, and nutrition habits (yes/no)

Interviews and Thematic Analysis of Collected Data

Semistructured interviews were conducted at Meetings 2-6. The questions used in the interviews were designed to identify how the participants used and experienced the Few Touch application in relation to self-management activities in terms of the whole application, each function, and usability of both the application and the smartphone. All the interviews were voice recorded. Because the questions were strongly connected to the aim of the analysis, we examined data from interviews by following the framework suggested by Braun and Clarke [54], in which codes and themes were identified at semantic level using a theoretical approach. The findings from the interview data were investigated by collating both the results of questionnaires and the results of usage patterns and trends. Identified themes were arranged into a structure that explained mechanisms of participants' engagement with the application. To identify factors associated with participants' engagement with a mobile self-management application, data extracts relevant to the application design were mainly used together with answers to relevant questionnaires.

Results

In this section, we use the code "Pxx" to indicate a specific participant, where "xx" shows the participant's ID number.

Usage Trends and Patterns

Results from the Mann-Kendall trend test on usage rates confirmed a significantly decreasing (P<.05) usage trend among 10 out of the 12 participants, though the magnitude of the decrease varied widely (Table 2). The generally decreasing trend is in line with the result for blood glucose measurements found previously [43]. However, the analyses of datasets by participant revealed that some of the participants used functions constantly and in a very determined way during the trial period. Table 3 summarizes the numbers of days on which each function was used against a period during which each function was available. Both Table 3 and trends in usage rates (Multimedia Appendix 1) show that P03 and P09 used both the blood glucose sensor system and the physical activity sensor system very consistently.

Table 2. Results from Mann-Kendall trend test on usage rate.

	Blood glucose sensor system		Nutrition habit recording system		Physical activity sensor system	
Participant	Tau-value	*P* value	Tau-value	*P* value	Tau-value	*P* value
P01	-0.19	.06	-0.58	<.001	-0.57	<.001
P02	0.22	.03	-0.01	0.91	-0.10	0.46
P03	-0.01	.96	0.16	0.14	0.21	0.16
P04	-0.35	.002	-0.37	<.001	-0.62	<.001
P05	-0.41	<.001	-0.18	0.07	-0.16	0.18
P06	-0.31	.003	-0.39	<.001	-0.43	0.001
P07	-0.11	.33	-0.58	<.001	-0.58	<.001
P08	-0.06	.56	-0.34	.002	0.12	0.47
P09[a]	-0.05	.70	-0.37	.002	-0.35	0.08
P10	-0.54	<.001	-0.42	<.001	-0.35	0.01
P11	-0.45	<.001	-0.71	<.001	-0.27	0.05
P12	-0.63	<.001	-0.61	<.001	-0.07	0.69

[a]All the recorded data on P09's smartphone were accidentally deleted at Meeting 2, and only data recorded after Meeting 2 were used for analyses.

Table 3. The numbers of days on which each function was used against a period in which each function was available.

	Blood glucose sensor system			Nutrition habit recording system			Physical activity sensor system		
Participant	Dr[a]	Da[b]		Dr	Da		Dr	Da	
P01[d]	102	395	(26%)	101	395	(26%)	71	152	(47%)
P02[d]	158	393	(40%)	51	393	(13%)	56	239	(23%)
P03[d]	390	395	(99%)	365	395	(92%)	210	219	(96%)
P04	16	393	(4%)	11	393	(3%)	33	138	(24%)
P05[d]	294	393	(75%)	277	393	(70%)	143	265	(54%)
P06	334	393	(85%)	323	393	(82%)	159	244	(65%)
P07[d]	327	374	(87%)	98	374	(26%)	61	202	(30%)
P08[d]	58	395	(15%)	357	395	(90%)	161	197	(82%)
P09[c, d]	348	352	(99%)	8	352	(2%)	129	132	(98%)
P10[d, e]	278	389	(71%)	88	393	(22%)	116	191	(61%)
P11[d]	60	380	(16%)	152	380	(40%)	86	210	(41%)
P12	209	393	(53%)	240	393	(61%)	86	147	(59%)

[a]Dr is the number of days on which records were made.

[b]Da is the number of days when a function was available.

[c]All the recorded data on P09's smartphone were accidentally deleted at Meeting 2, and only data recorded after Meeting 2 were used for analyses.

[d]The step counters had problems, so that there were periods when participants could not use their step counter.

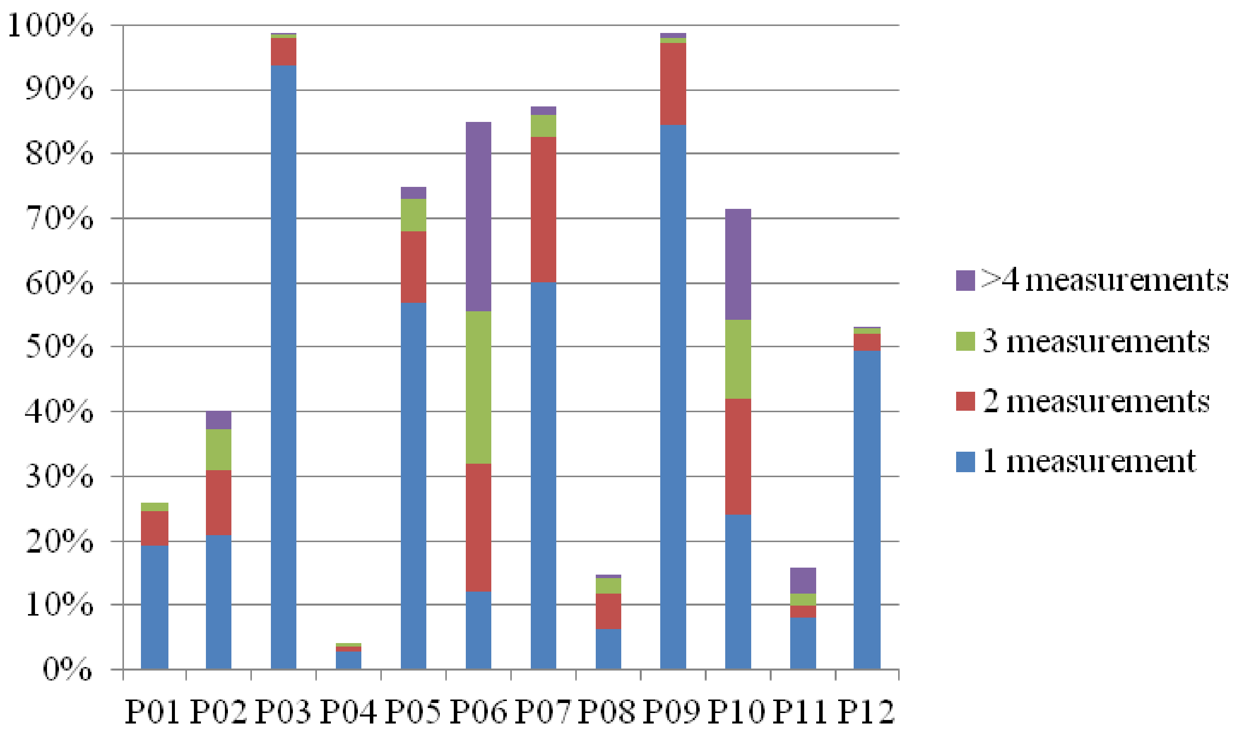
[e]P10's blood glucose sensor system did not function for 4 days.

Figure 2 shows the distribution of blood-glucose measurement frequency among days on which any blood glucose measurement was performed. From Figure 2, it is clear that P03 and P09 measured once a day for most of the days on which they had measurements (370 out of 390 days (95%) for P03 and 297 out of 348 days (85%) for P09). On kernel density estimates of distributions of time points at which blood glucose was measured (Multimedia Appendix 2), a significant single peak can be identified in the morning time for P03 and P09, which demonstrates that they are habituated to measure blood glucose in the morning almost every day. Including P03 and P09, a significant peak in the morning time was observed among most of the participants, which is also in line with the result from aggregated data for all the participants [43]. However, the kernel density estimates (Multimedia Appendix 2) also revealed that the patterns of times at which measurements were taken were quite different from one participant to another, which reflects different needs for blood glucose measurements. For example, P06 and P10 used the blood glucose sensor system for more than 70% of days when the function was available, and often they measured blood glucose more than once a day (Figure 2). From the kernel density estimates (Multimedia Appendix 2), it is observed that P10 measured in the morning more or less regularly and otherwise rather sporadically, while P06 usually measured very sporadically. P01 used the function moderately: once a day for most of the times when used (75%, 76 out of 102 days) (Figure 2). The two sharp peaks for P01's density estimates (Multimedia Appendix 2) indicate that P01 often measured either in the morning or in the evening.

Regarding nutrition habit recordings, we could observe a change in usage patterns for some participants (eg, P01, P07, and P11) in a relatively early phase (Multimedia Appendix 3). This corresponds to what 4 participants (P01, P05, P06, and P11) told us at Meetings 2 and 3: they tried to record the data right after eating, but sometimes they recorded it at the end of the day to summarize their food intake, while P07 shifted recording activity to morning time. After updating the user interface of nutrition habit recording at Meeting 4, which is explained in detail in a later subsection, P08 clearly changed his/her way of nutrition-habit recordings from "right after every eating/drinking" occurrence to "summarizing at the end of the day", whereas this modification did not seem to influence either usage patterns or usage rate for the other participants.

Regarding the physical activity sensor system, 9 (P01, P02, P03, P05, P07, P08, P09, P10, and P11) of the 12 participants had problems and their step counters were repaired or replaced. The major problem was battery attrition of the step counter. A significant decreasing usage trend (P<.05) was observed among 5 of the participants, which is less than for the other two functions. However, this result may need to be interpreted carefully due to the much shorter period in which the physical activity sensor system was available than the other two functions.

Figure 2. Distribution of blood glucose measurement frequency among days on which any blood glucose measurement was performed.



Questionnaires

The Few Touch application was generally perceived as satisfactory. The perceived usefulness of the whole application by the participants remained considerably high over time (Table 4), though several of the participants expected the frequency of usage to decrease over time (Multimedia Appendix 4, Questionnaire 6). The average score for the SUS questionnaire was 84.0 (SD: 13.5, range: 67.5-100) [41,42]. This score is high compared with other studies where the SUS questionnaire was used, considering the average score together with the conclusion on usability in each study [55-57]. The result from Questionnaire 1 shows that only one user expressed dissatisfaction about the size of the mobile phone, which is 107 x 55 x 16 mm and weighs 120 gram. No other items were perceived as explicitly unsatisfactory for the Few Touch application in this questionnaire.

Table 4. Questionnaire 4—Distribution of the answers to questionnaire about perceived usefulness of the Few Touch application (1: Not useful at all, 7: Very useful).

Elapsed time / Usefulness of the application	1-3	4	5	6	7	Mean
3-4 months (Meeting 3)	0	1	0	6	5	6.3
6 months (Meeting 4)	0	1	1	2	8	6.4
1 year (Meeting 6)	0	0	1	4	7	6.5

The blood glucose sensor system was perceived as the most motivating, followed by the physical activity sensor system and the nutrition habit recording system (Multimedia Appendix 4, Questionnaire 2). In contrast, the participants expressed lukewarm perceptions regarding the effect of using the Few Touch application on achieving adequate frequency of blood glucose measurement (Multimedia Appendix 4, Questionnaire 3). Likewise, only half of the participants answered that their blood glucose control had been improved, while slightly more participants answered that their physical activity level and nutrition habits had been improved in the course of 1 year (Multimedia Appendix 4, Questionnaire 9). No participants answered that their medication had been improved, but P03 (at Meeting 3) and P11 (at Meeting 4) mentioned in an interview and a focus group, respectively, that the number of tablets had been reduced. Also, overall satisfaction levels with their knowledge about diabetes and with skills in diabetes management were not drastically changed in the course of 1 year (Multimedia Appendix 4, Questionnaire 5). This is also reflected by the fact that participants' satisfaction level with the tips function decreased over time (Multimedia Appendix 4, Questionnaire 7). Although the participants considered the tips concise and useful, 5 participants (P01, P03, P05, P09, and P12) suggested improvements, as reported previously [42].

The results of the questionnaire that addressed the participants' preferences for potential functionalities of the Few Touch application are shown in Multimedia Appendix 4, Questionnaire 8, ranked by the total score. "A smaller step counter that is easier to wear" was highest rated, and "automatically popping-up tips" ranked as second. The other items that no one disagreed with were "automatic" functions. Besides "use of own mobile phone", all items that were disliked by some of the participants were functions that involved communication with other people. Most of the participants stated that using the application as a "self-help" tool was enough for them, though collaborative use of the application might be motivating.

We could not observe any deterministic associations between answers to any questionnaires and usage of functions.

Interviews and Thematic Analysis of Collected Data

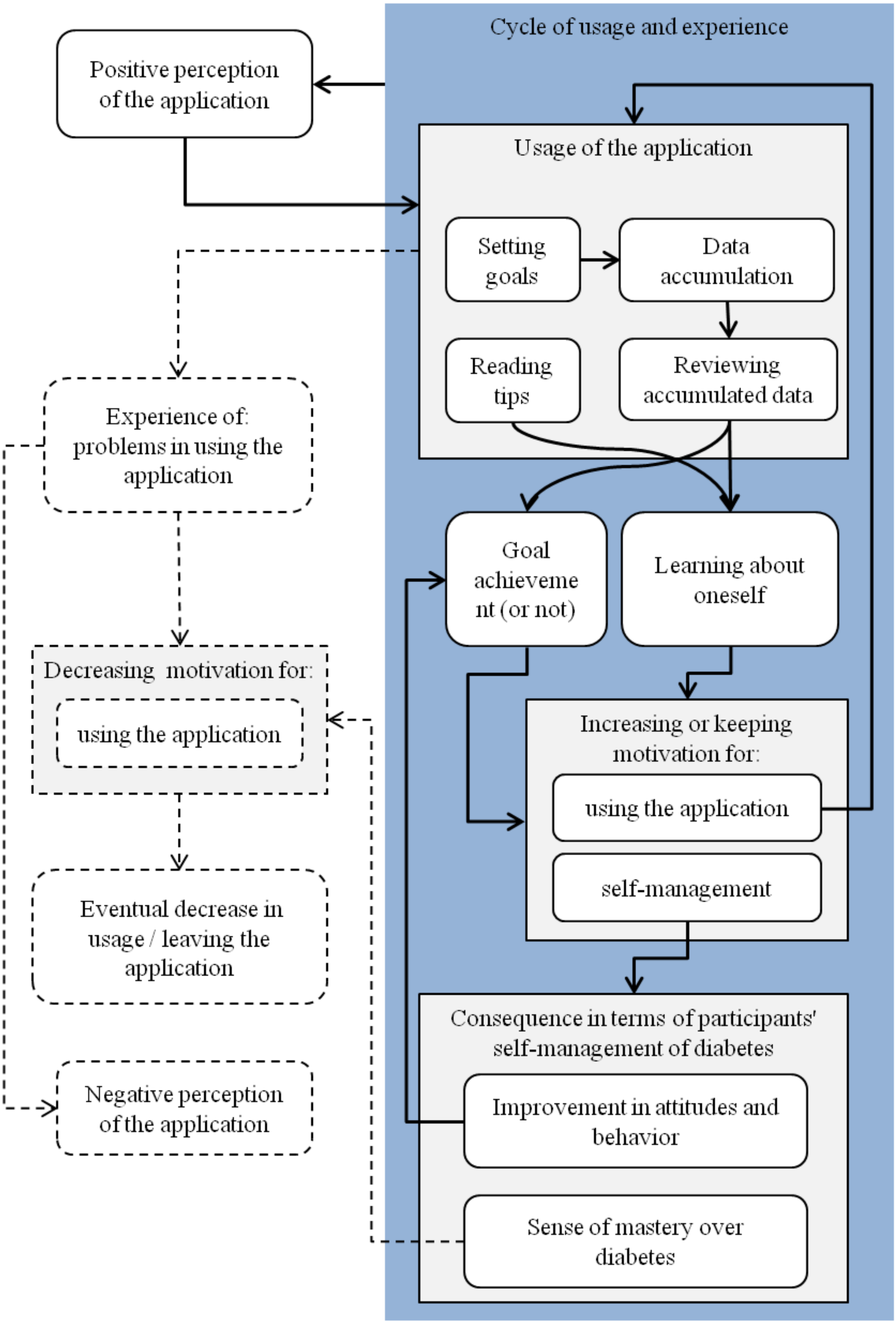
Mechanism of Engagement With the Few Touch application

The mechanism of participants' long-term engagement with the Few Touch application is illustrated in Figure 3. Note that Figure 3 was drawn to explain how participants used the application, what they experienced as a result of using the application (such as behavior change), and how they perceived the application. For this reason, each block or group of blocks in Figure 3 does not necessarily correspond to an identified theme in the thematic analysis. Multimedia Appendix 5 summarizes prominent themes, codes, and examples of quotes.

First, we could identify a cycle of usage of the application, experience, and impact of using the application expressed as elements in a box with a dark background in Figure 3. The Few Touch application was developed with the purpose of motivating people to use the tool so that they would benefit by using it over a long time. The thematic analysis indicated that the Few Touch application played a role as a flexible learning tool by which individuals with T2DM could instantly confirm how their self-management activities and other health conditions such as illness influenced their blood glucose levels. Despite a rather high age for some of the participants, all the participants were able to use the chosen smartphone and the application. Patterns of engagement with the application varied widely depending on their needs: Intensive use to find relationships between their self-management and blood glucose levels; constant and regular use for gaining an overview of blood glucose values and self-management activities over time; sporadic use in out-of-the-ordinary situations such as dining out or travel with others that limited participants' opportunities for self-management activities; and use for experimental purposes. Such a wide variety of usage shows that the application was used flexibly according to users' spontaneous purposes as well as for regular self-monitoring every day. Depending on their status, the participants increased their motivation for either maintaining their good habits or improving their attitudes and behavior, and eventually experienced a sense of control over their diabetes. This cycle caused positive perceptions of the application, as shown in results of questionnaires. The positive perceptions contributed to further use of the application to a certain degree. This cycle of positive flow expressed by bold arrows in Figure 3 explains the mechanism of participants' long-term engagement with the application.

Figure 3 also describes the process in which participants' usage of the application decreased over time. Elements with dashed lines show the process of decreasing usage. Two major reasons for the decrease in usage were identified: The first was loss of motivation to continue using the application after gaining a sense of mastery over diabetes. Some of the participants interpreted "learning about oneself" with the application as "short-term use of the application until one gets control over one's diabetes". The second reason was problems in using the application, which is explained in detail in the next subsection.

Figure 3. Mechanism of participants' long-term engagement with the Few Touch application.



Factors Associated With Usability and/or Usage Over Time

Despite generally high satisfaction with the application, experiences of problems were also reported. Problems that stemmed from outside the design concepts included battery attrition for a step counter and a Bluetooth adapter, some features of the provided smartphone that had taken some time to get used to for the first month, and problems with the smartphone. Other problems stemmed from a mismatch between design concepts and reality (Table 5). These problems caused difficulty in integrating use of the application into everyday life. Not all the issues in Table 5 were clearly specified as direct reasons for the immediate decrease in usage, but they at least degraded the usability of the application. For example, P08 admitted at Meeting 6 using the step counter extensively, despite having problems in attaching the step counter, and used it in either a pocket or a handbag. Usage attrition for the physical activity sensor system for P06 is clear compared with P08 (Table 2, Multimedia Appendix 1). Some issues in Table 5 influenced long-term usage in terms of attrition of enthusiasm. For example, at Meeting 4, P01 expressed a positive perception of the nutrition habit recording system as "it has worked" despite forgetting to record data and complaints about the categorization. However, at Meeting 5, P01 told us "it does not work for me, at least" because "it is impossible to record for the past dates though it is easy to forget recording". This was also seen in P01's usage rate for the nutrition habit recording system, which was zero for most of the weeks since week 37.

From data extracts relevant to the application design and results from questionnaires, we identified the following factors associated with usability and/or usage over time: (1) integration with everyday life, (2) automation, (3) balance between accuracy and meaningfulness of data with manual entry, (4) intuitive and informative feedback, and (5) rich learning materials, especially about foods.

Table 5. Functions and features that caused deteriorated usability of the Few Touch application.

Function and feature	Design concept	Reality	Affected components in usability
User interaction design enabling nutrition habit recording completed by just one press on the appropriate category.	Users would record each meal, snack and drink immediately. Users could record food or drink intake with minimum effort.	Participants made several records at a time or recorded nutrition habits at the end of the day to summarize their food intake so that they needed more operations at a time. (P01, P03, P05, P06, P08, P10 and P12, Meeting 2) It was not always possible to record right after eating or drinking, or due to constraints of time and place. (P07, Meeting 6)	Efficiency, flexibility
Categorization of nutrition habit recording	Categories would correspond to types of eating habits that should be improved in context of T2DM, so that it encourages users to have a healthier diet.	The categorization was not precise enough for their reflective thinking, or it did not match the participants' individual preferences based on their accumulated personal experiences. (P01, P02, P08, P11 and P012, Meeting 4)	Effectiveness, flexibility
Step counter attached on belt	A physical activity sensor should be integrated with their daily tools and outfits.	One participant (P06) did not use a belt normally. P06 had used it in a bag, but it was easy for P06 to forget about using the step counter on the next day. (Meeting 6)	Satisfaction
Step counter as a physical activity sensor	Physical activity sensor system should provide easily interpretable values to motivate a user to monitor.	The fact that other types of sports (skiing) or physical activities were not measured was disappointing. (P11, Meeting 4; [41,42] P12, Meeting 6)	Effectiveness, satisfaction
User interface of tips function and its contents	Tips function would provide a user with concise information that can be shown on a screen without necessity of scrolling or more manual operation than one button press to access to a "tip of the day".	Participants wanted better access to information that they want to read (P05, P08, and P09, Meeting 5)	Efficiency, satisfaction
		Participants wanted more and richer information (P01, P03, P09, and P12, Meeting 4), preferably delivered by SMS with tailored contents based on user's profile (P12 [42])	Satisfaction
Diabetes Diary as a software on a smartphone	Users would easily access to their records and information relevant to self-management of diabetes by integrating necessary functionalities into a software application running on their personal mobile phone.	A participant (P04) stopped using the smartphone as his/her personal mobile phone, because it had problems as a mobile phone (Meeting 6)	Effectiveness, efficiency, satisfaction

Integration With Everyday Life

The participants generally appreciated the minimal effort required for keeping track of self-management activities and for referring to them, which is the design concept achieved in the user-involved design process. Instant access to the application on the smartphone that was used as a personal mobile phone played a great role in integrating the application use into everyday life. This is supported by the fact that no participants used the history view function on the blood glucose meter and by the fact that P04, who had problems with the provided smartphone, did not continue using the application.

Many of the issues listed in Table 5 also illustrate the importance and difficulty of application design that can be easily integrated into each individual's everyday life. At Meetings 4 and 5, we updated the user interface design of some pages due to problems that were reported. A page for nutrition habit recording was originally designed to enable recording with minimum effort. However, this design actually made nutrition recordings more cumbersome when a user wanted to record more than one nutrition habit as a summary of a day. The update (Figure 4, left) at Meeting 4 enabled entry of more than one eating or drinking record at a time. Users could press each button the appropriate number of times and then press the "OK" button to record the data. The number of times that each button had been pressed was displayed in the yellow box next to the button. To reset the number of times to zero, users could press the "Cancel" ("Slett") button. Navigation in the tips function was also updated at Meeting 5 because the tips function was used for look-up despite being designed to give a "daily" tip. We added a "Back" button as well as a header and category name to each tip to make it easier to view the content and find information (Figure 4, right).

Figure 4. Modified user interface for nutrition habit recording (left), and the tips function (right).

Automation

Automation of data transfer from the blood glucose meter and the step counter played a key role in making the use of the application as effortless as possible. The participants appreciated not only that they did not have to write down the values any more but also the fact that the graphical feedback was automatically prepared based on the transferred data. Results from Questionnaire 8 also support the importance of automation.

An interesting change over time in perceptions of usefulness was observed regarding automation of recording and data visualization. P10 told us in the Meeting 2 that s/he had used to write a very precise paper diary before the trial started, so s/he found no difference in the Diabetes Diary, and even the blood glucose graph did not provide anything new. However, at Meetings 3 and 4, P10 told us of now, unlike earlier, appreciating the blood glucose graph to see how his/her blood glucose varied and to relate it to food consumed. Finally, at Meeting 5, P10 told us that s/he had recently stopped writing down measurements manually, which s/he had continued just as a habit, due to now relying on the application. P03 admitted to continuing to write down blood glucose values for a while, but s/he became used to getting the values on the smartphone.

Balance Between Accuracy and Meaningfulness of Data with Manual Entry

Although most of the participants liked and wanted to keep the simplicity of the system for nutrition habit recording, some of them found that the categorization for this system was not appropriate for their reflective thinking or that it did not match their individual preferences based on their accumulated personal experiences (Table 5). The thematic analysis showed that this became more evident and crucial in terms of usage in the latter half phase of the trial compared with the early phase. Participants indicated their need for a function enabling more detailed recording or a function to customize food types on the nutrition habit recording system without jeopardizing the simplicity of the system. Such needs correspond to the wide variety of usage of the application described earlier.

Intuitive and Informative Feedback

The participants showed different preferences for the design of feedback depending on function. At one of the focus group sessions in Meeting 4, all the participants stated that feedback showing progress toward goals was most important for encouraging daily physical activity and good nutrition habits. They also mentioned that they rarely used screen (h) in Figure 1 where they could refer to accumulated data for a period that they had set. Only 1 participant expressed the need to view the history of step counts older than a week. In contrast, the distribution of historical blood glucose measures on the background divided into three colors was perceived as intuitive and informative, enabling users to determine whether they were "doing all right" over time.

Though some other participants stated that the system was simple enough for them to see that their self-management activities influenced their blood glucose levels, 2 participants (P05 and P11) clearly expressed their need for improvement of the feedback design so that it visually showed the relationship between the three components: blood glucose level, physical activity, and nutrition habits. Both participants mentioned their difficulty in maintaining their focus and motivation in continuing self-management activities. At Meeting 3, P05 also mentioned the importance of keeping a self-management tool simple so that s/he would not become confused with complicated information. One of the suggestions for improvement of the application included a function to show a filtered list of fasting blood glucose measurements only, which also illustrates a need for feedback to be more informative.

Rich Learning Materials, Especially about Foods

Most of the participants appreciated the tips about food, and even more enriched content was requested. Many of the suggestions for improvement of the application concerned functions or learning materials about foods.

Discussion

Main Findings

Together with qualitative inquiries, detailed quantitative analyses on each participant's usage of the provided tool gave us insights into mechanisms of participants' engagement with the tool and led us to a better understanding of factors associated with usage and usability over time.

The Few Touch application served as a flexible learning tool for the participants depending on their spontaneous needs as well as for regular self-monitoring. Usage of the application was supported by the minimum effort required for keeping track of self-management activities and for referring to them, which was the design concept achieved in the user-involved design process. Except for a few participants, a decrease in the usage trend was generally observed. Having gained a sense of mastery over diabetes and experiences of problems were identified as reasons for decreased motivation to continue using the application. Some of the problems stemmed from a mismatch between design concepts and reality, even though the design concepts were obtained in a process involving the participants. The impact of such mismatches on usage and usability became critical over time among some participants.

In the following sections, we will discuss our findings by comparing them with relevant studies.

Mechanism of Engagement With the Few Touch application

The learning process based on personal experiences on top of necessary knowledge provided by diabetes education builds a foundation for designing the patient's own self-management plan. It is also claimed in previous studies that a supporting tool for people with diabetes should facilitate this learning process [48,58]. The application was perceived as easy and simple. Such characteristics played an important role not only in enhancing motivation to use the application but also in the learning process because "keeping track of performed actions in self-management activities is notoriously difficult" [48].

A wide variety of patterns of engagement with the application observed in this study is in line with findings in the two deployment studies of a health monitoring application, MAHI (Mobile Access to Health Information). MAHI was originally designed with the focus on development of reflective thinking skills through social interaction for newly diagnosed individuals [59]. The first deployment study [27] for newly diagnosed patients revealed that many participants considered that intensive and focused exchange with the educator by using MAHI would be "most beneficial at the beginning of their engagement with diabetes management". However, their second deployment study [60] confirmed that MAHI was also well accepted by people with more extensive diabetes experience as a tool for identity construction through storytelling. Consistent with the findings from the MAHI deployments, our study support the idea that design that allows divergent interpretation supports flexible appropriation [61]

Decrease in usage after gaining a sense of mastery over diabetes is in line with findings by relevant studies [30,32,62]. The application was equipped with neither "push" factors nor an advanced decision support system providing feedback based on accumulated data and other personal profiles, which are advocated for long-term usage, according to relevant studies [62-65]. Nevertheless, usage by many of the participants remained relatively high over the 1-year trial period (see Multimedia Appendix 1). This might have been caused by intrinsically high motivation of participants in the design process. As shown in Multimedia Appendix 4 Questionnaire 8, the participants expressed preferences for such features, suggesting the role these would play for stronger engagement with the application.

Factors Associated With Usability and/or Usage Over Time

Integration With Everyday Life

The mobility and pervasiveness of the smartphone as a personal mobile phone played an important role in integration of the application into everyday life. The finding strengthens the conclusions in recent studies [66,67] that smartphones would be more suitable platforms for a support tool for self-management of lifestyle-related diseases than contemporary mobile phones or PDAs.

Automation

In the present study, automation was successfully employed only to reduce unnecessary burden in tracking self-management activities, such as transcribing data, so that it would support longitudinal use of the application as advocated by Mulvaney et al [14] as well.

Balance Between Accuracy and Meaningfulness of Data with Manual Entry

Accuracy of data obtained by a sensor is critical in terms of giving proper credit to users [48,68]. On the other hand, regarding data obtained by manual entry, its accuracy level should be determined in the light of how meaningful it would be for a user who invests additional effort. The ability to customize a feature is important for the function to be meaningful for individual users, and this idea resonates with design implications described in a study by Chen et al [58].

Intuitive and Informative Feedback

Findings by Kelders et al [69] correspond to our finding that the participants regarded feedback showing progress toward goals as most important for encouraging daily physical activity and good nutrition habits. The perceived usefulness of visualizing trends in blood glucose levels is also in line with the finding in a study by Forjuoh et al [30]. To better support "learning processes", visual feedback showing the historical distribution of all three factors—nutrition habits, physical activity, and blood glucose level—would have made it easier to find relationships between them, especially for the participants who had difficulty in keeping focus or tended to easily lose motivation. This implication is consistent with findings by Russell-Minda et al [15] regarding the importance of usability to patients who need encouragement or help in self-management activities. Designing visually integrated feedback for all three factors incorporating a time perspective would however be a great challenge. In addition, such design needs to be carefully developed to avoid the risk of inadvertent reinforcement of "individuals' preconceived notions and biases" that lead to a wrong assumption between their self-management activities and blood glucose level [48].

Rich Learning Materials, Especially About Foods

Findings by Kanstrup et al [70] also show clear needs by participants for "access to information about particular things of importance, eg, the ingredients in food to make more qualified decisions". This implies that the participants experienced a need to learn more about food by referring to external information in their reflective thinking process. This is consistent with findings by Savoca et al [71] that not only the patient's experimentally accumulated personal knowledge about the relationships between foods and health, but also external knowledge of a recommended diet, comprise a part of complex and dynamic processes of behavior change in diet. Given that behavior change in diet is the most challenging of the self-management activities and that lack of knowledge about diet is the highest ranked barrier [72], this implication is plausible.

Lessons Learned: Long-Term Engagement of Patient-Users in the Designing Process

This study confirmed the importance of involving "patient-users", not only in the specification-design phase but also in the trial phase of a working prototype in a real-life setting for enough time to clarify how the chosen design works in relation to expectations and how the design can be improved [40]. Mismatches between design concepts and reality can happen even though the same participants are involved in both design-concept making and a trial. Their impact on usability and usage may become critical over time. When technical or financial constraints hinder realization of obtained design concepts through patient-user involved processes, such as our case of step counters and choice of a smartphone model, it is especially important to examine how great the impact of mismatches would be on both usability and usage in the long term. Therefore, if possible, it is wise to continue involving the same patient-users so that effective feedback will be gained during the final cycle of design iterations.

To achieve such involvement of patient-users requires their strong and long engagement in the process. The strong engagement of the participants in this study was achieved through a variety of efforts by the researchers [42]. Among them, offering frequent opportunities to meet played an important role in motivating the participants to stay in the study, as it is one of the factors influencing nonusage attrition and dropout attrition in eHealth trials [33]. Frequent meetings also facilitated quick responses to the participants' feedback by improving the prototype and by organizing new inquiries for further iterative design processes. The participants could feel that they were really contributing to the designing process through these interactive processes. Another advantage is that frequent meetings with other participants offer opportunities for them to learn from others. This was mentioned by some of the participants. Fudge et al [73] also found that learning from others in similar situations was one of patients' motives to attend meetings in a user-involved program for improvement of health services for people with stroke. They discuss this issue as a concern that the ability of user involvement to improve service may be questionable, "if this (to improve service) is not the primary motivation of those involved". In our study, we did not specifically investigate whether "learning from others" was the primary motivation for the participants to become involved in the design process or to attend the meetings. However, as far as we observed the participants in the meetings, this was a secondary effect in enhancing motivation to continue using the system.

Limitations

Though the first author of this paper understands the Norwegian language, she is neither a Norwegian citizen nor a native Norwegian speaker. On the other hand, the second author is a native Norwegian, has T1DM himself, and has the same cultural background as the participants. In addition, the second author initiated the whole design process of the Few Touch application, from the recruitment of the participants to the development and testing of the application. The first author needed some help from the second author to interpret and understand better exactly what the participants meant in interviews. This might have caused a certain bias in the analysis.

Conclusions

The present study showed the importance of the following two factors: (1) a thorough analysis of results from multiple types of investigations focusing on each participant's engagement with the tool over time, and (2) involving patient-users from an early phase of design-concept making to a longitudinal trial of the system. The value of these factors was shown by the ability to identify factors that influence usability and usage in real-life settings in a long-term perspective in relation to original design concepts.

The extent to which our findings can be generalized is limited by intrinsically high motivation among many of our participants as well as the small number of the participants. However, it is highly probable that the factors that this study identified as reducing usability or usage would do so when users were less motivated. A revised version of the Few Touch application was tested by a group of 11 patients with T2DM who were not involved in the design process in order to assess the validity of our findings, and it is now being used as an intervention tool in an ongoing randomized controlled trial [74]. In that trial, a quantitative analysis needs to be carried out to investigate association between perception of features of the Few Touch application, level of engagement with the application, and the primary and secondary outcomes. Although the participants in this study are no longer engaged in design process, the Few Touch application is evolving through many research projects in which new functions are implemented and feedback for improvement is given [75]. Such series of studies will also provide useful insights into factors associated with usage and usability of a mobile self-management system.

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Authors' Contributions

Authors' Contributions: The individual contribution of the authors is summarized in the following sections: (1) conception and design of the present work, namely analysis of the results from the long-term trial, (2) designing and performing the long-term trial, (3) developing protocols for data collection, (4) data collection, (5) data analysis, (6) writing and editing the article, and (7) revising the article critically and final approval of the version to be published. The first author contributed in all but (2) and was a main contributor in (6). The second author contributed in all sections. The third author contributed in (5), (6), and (7), particularly in the trend analysis of usage rates. The fourth author contributed in (6) and (7) and in revising the sections from (1) to (5).

Conflicts of Interest

Conflicts of Interest: None declared.

Multimedia Appendix 1

Long-term usage rates of each function by the participants.

[PDF File (Adobe PDF File), 360KB - mhealth_v1i1e1_app1.pdf]

Multimedia Appendix 2

Kernel density estimates on distribution of time points at which blood glucose measurement occurred during the day along the trial duration.

[PDF File (Adobe PDF File), 259KB - mhealth_v1i1e1_app2.pdf]

Multimedia Appendix 3

Kernel density estimates on distribution of time points at which nutrition habit recordings occurred during the day along the trial duration.

[PDF File (Adobe PDF File), 397KB - mhealth_v1i1e1_app3.pdf]

Multimedia Appendix 4

Summary of answers to original questionnaires.

[PDF File (Adobe PDF File), 258KB - mhealth_v1i1e1_app4.pdf]

Multimedia Appendix 5

Summary of prominent themes, codes, and examples of quotes.

[PDF File (Adobe PDF File), 266KB - mhealth_v1i1e1_app5.pdf]

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Abbreviations

ICT: information and communications technology
MAHI: mobile access to health information
PDA: personal digital assistant
SUS: System Usability Scale
T2DM: Type 2 diabetes mellitus
T1DM: Type 1 diabetes mellitus

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Original Paper

Health-E-Call, a Smartphone-Assisted Behavioral Obesity Treatment: Pilot Study

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Abstract

Background: Individual and group-based behavioral weight loss treatment (BWL) produces average weight loss of 5-10% of initial body weight, which improves health and wellbeing. However, BWL is an intensive treatment that is costly and not widely available. Smartphones may be a useful tool for promoting adherence to key aspects of BWL, such as self-monitoring, thereby facilitating weight loss while reducing the need for intensive in-person contact.

Objective: The objective of this study was to evaluate smartphones as a method of delivering key components of established and empirically validated behavioral weight loss treatment, with an emphasis on adherence to self-monitoring.

Methods: Twenty overweight/obese participants (95% women; 85% non-Hispanic White; mean age 53.0, SE 1.9) received 12-24 weeks of behavioral weight loss treatment consisting of smartphone-based self-monitoring, feedback, and behavioral skills training. Participants also received brief weekly weigh-ins and paper weight loss lessons.

Results: Average weight loss was 8.4kg (SE 0.8kg; 9%, SE 1% of initial body weight) at 12 weeks and 10.9kg (SE 1.1kg; 11%, SE 1% of initial body weight) at 24 weeks. Adherence to the self-monitoring protocol was 91% (SE 3%) during the first 12 weeks and 85% (SE 4%) during the second 12 weeks.

Conclusions: Smartphones show promise as a tool for delivering key components of BWL and may be particularly advantageous for optimizing adherence to self-monitoring, a cornerstone of BWL.

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KEYWORDS

obesity; behavior; weight loss; mobile phone; technology

Introduction

Overweight and obesity are highly prevalent conditions among the populations of developed countries [1], contributing to increased risk of disease [2] and behavioral disorders [3], and place a substantial burden on financial and health care systems [2,4]. Behavioral weight loss treatments (BWLs) [5], such as those developed for the Diabetes Prevention Program (DPP) [6] and LookAHEAD (Action for Health in Diabetes) trials [7], produce weight loss by teaching skills to build healthy eating and physical activity habits. These programs produce average weight loss of 7-10% of initial body weight, which are associated with clinically significant improvements in physical health, disease risk factors, and indicators of psychological well-being [8-12]. Despite the challenges of weight loss maintenance, BWLs have been shown to produce lasting improvements in health [13].

BWL is a highly intensive treatment typically delivered in 30-60 minute individual or group treatment sessions, conducted weekly over the course of several months [5]. These sessions are costly to provide and require a substantial investment of time and resources by the recipients. Thus, BWL is not widely available outside of research settings, leading to efforts to identify alternative modalities for BWL delivery that reduce costs and barriers to treatment. For example, BWL has been delivered via the Internet [14-17] and in community settings such as the YMCA [18]. The average weight loss in these trials was typically much lower than the 7-10% of initial body weight obtained via intensive in-person treatment conducted in research settings, often because of insufficient exposure to the intervention and/or poor adherence to core behavioral weight loss strategies such as self-monitoring [19,20].

Mobile phones are also beginning to be considered as a modality for BWL delivery [21]. Previous research using mobile phones relied primarily on text messaging to provide brief suggestions and reminders for healthy behavior change. Patrick et al obtained an average weight loss of 3.16% of initial body weight via an automated, interactive, 4-month text message-based weight loss intervention (compared to 1.01% in a control condition) in a study with 78 participants [22]. Using a similar text message-based approach, Happala et al obtained an average weight loss of 5.3% (SD 3.5, N=42) of initial body weight at 3 months and 6.1% (SD 5.1) at 6 months [23]. Again, the average weight loss achieved in these studies were less than the 7-10% loss obtained via intensive in-person treatment conducted in research settings.

Mobile phone technology continues to progress at a rapid pace and the advent of smartphones makes it possible to deliver BWLs in new and more sophisticated ways. Mobile smartphones have many of the same capabilities as traditional personal computers, such as a persistent Internet connection, the ability to run sophisticated software applications (ie, “apps”), and the ability to play audio and video files nearly instantly from the Internet. Smartphones are prevalent, especially among ethnic minorities. Current estimates indicated that 30% of Whites, 44% of African Americans, and 44% of Hispanics own a smartphone in the United States [24,25]. Commercial apps for weight loss are very popular. Producers of one weight loss application, LoseIt!, reported that their app has been downloaded over 12 million times from the time it was first offered in 2008 to October 2012 [26].

Smartphone applications are now being developed to target changes in weight-related health behaviors and conditions related to obesity such as diabetes, but many do not adhere to evidence-based practice and few have been tested [27]. A recent review of mobile phone interventions to increase physical activity and reduce weight found two studies in which smartphone-based interventions were tested [28]. The first study by Gasser et al studied aspects of interface design and usage patterns of a smartphone application aimed at promoting increased physical activity and consumption of fruits and vegetables using a simplified points system for self-monitoring and team-based social interaction [29]. The second study by Lee et al developed and pilot-tested a smartphone-based game that provided a personalized diet profile and promoted knowledge about nutrition [30]. Another review by Hebden et al described the development of four smartphone applications aimed at preventing weight gain in young adults by increasing physical activity and consumption of fruits and vegetables, and reducing consumption of fast food and sugar-sweetened beverages [31]. Chomutare et al reviewed commercially available smartphone applications for diabetes management, and found that many were not consistent with evidence-based recommendations for diabetes self-care [32].

Despite the popularity of smartphone technology, it has never been tested as a means of enhancing self-monitoring and delivering empirically validated BWL content and interventionist feedback in a formal weight loss program. The purpose of the Health-E-Call study was to determine whether key components of BWL such as self-monitoring, feedback, and skills training could be accomplished and potentially enhanced via smartphones, thereby reducing the need for intensive in-person treatment. Particular emphasis was placed on using the smartphone to enhance self-monitoring, given the importance of this skill for successful weight loss. Previous research has shown that use of an electronic handheld device for self-monitoring improved adherence to the self-monitoring protocol [33], the accuracy of self-monitoring [34], and improved weight loss in traditional BWLs [33]. The primary outcome measures of this study were weight loss and adherence to the self-monitoring protocol. We also measured self-reported satisfaction with the program.

Because this was one of the first studies in which smartphones were used for BWL delivery, brief weekly visits with a study interventionist were included in the protocol to obtain objective weights and to provide an opportunity to address any challenges with the smartphone technology. Brief paper weight loss lessons were provided to participants to ensure sufficient exposure to behavioral weight loss strategies.

Methods

Participants and Recruitment

Overweight and obese men and women with a body mass index (BMI) of 25-50 kg/m^2 between the ages of 18 and 70 were recruited by an advertisement posted on the website of the Brown University and Miriam Hospital Weight Control and Diabetes Research Center (WCDRC). The advertisement mentioned of the use of a smartphone for weight loss. Other inclusion criteria included English language fluency and literacy, and an ability to attend weekly treatment visits at the WCDRC in Providence, Rhode Island. Exclusion criteria included any heart conditions that limited ability to participate in physical activity, chest pain, any cognitive or physical limitation that prevented the use of a smartphone, recent serious mental illness, a history of or current eating disorder, previous or planned bariatric surgery, use of weight loss medication, pregnancy or expected pregnancy within 6 months of participation, a plan to leave the geographical region during the study period, participation in a study at the WCDRC within the previous two years, or a weight loss of greater than 5% body weight in the 6 months prior to study enrollment.

Interested individuals responded to the online advertisement by calling a phone number to be screened for eligibility and schedule an in-person individual orientation session at the WCDRC where they were given more information about the study and enrolled. Upon completing informed consent procedures, participants' height and weight were measured and baseline questionnaires were administered. Participants then used the smartphone-based intervention system for 12 weeks and attended weekly weigh-ins with a study interventionist where they were given supplementary paper weight loss lessons. Upon completing 12 weeks of treatment, participants were given the opportunity to enroll in an extended treatment program consisting of an additional 12 weeks of access to the smartphone-based intervention system and weekly weigh-ins, but no additional weight loss lessons. Participants were not told of the opportunity to participate in the second 12-week treatment until the end of the first 12 weeks. The program was divided into 2 contiguous 12-week periods because it was unknown if participants would be able to maintain engagement with the novel smartphone-based intervention system for a full 24 weeks. Objective weights were obtained weekly during clinic visits. Questionnaire measures were administered at baseline and at the end of each 12-week treatment period.

Intervention

The Health-E-Call treatment protocol was designed to deliver key components of established and empirically validated behavioral weight loss treatment such as the DPP [6] and LookAHEAD [7]. These multidimensional programs achieved weight loss through a combination of diet and physical activity education and training in behavioral strategies (eg, stimulus control) delivered in group and individual sessions and paper lessons. The program also included self-monitoring in paper diaries with written interventionist feedback returned at the next treatment session, and in-person support and accountability from treatment staff. Whenever possible, smartphones were used in Health-E-Call to implement and enhance each of these treatment components.

The Health-E-Call treatment included a smartphone-based component, a minimal in-person component consisting primarily of brief weekly weigh-ins, and supplementary paper weight loss lessons. The smartphone-based component was the focus of the intervention, and was the primary means of intervention delivery. An Apple iPhone was required for participation. Participants who did not own an iPhone were given an iPhone 3GS for the duration of the study.

The smartphone-based treatment component was divided into 3 parts including self-monitoring, feedback (automated and human), and brief videos for education and skills training. Given that self-monitoring is the cornerstone of BWL, self-monitoring with feedback was the primary focus on the smartphone-based treatment component. In this study, two separate smartphone applications, one developed by the research team (the Health-E-Call application), and one commercially available self-monitoring tool (DailyBurn) were used for self-monitoring, feedback, and delivery of video weight loss lessons.

The commercially available DailyBurn smartphone application was used for self-monitoring of daily food intake, physical activity, and body weight (Figure 1). Compared to traditional paper diaries, this program simplified self-monitoring by allowing participants to record their intake by searching for foods by name/description or by scanning barcodes on food packages. Participants were also able keep a list of favorite foods for faster entry. A simple touch interface allowed the participant to indicate the quantity of the foods consumed and the application maintained a real-time total of calories and fat grams consumed, as well as other characteristics of the diet. Similar procedures were used to record bouts of physical activity and daily body weight. The Health-E-Call team had no contact with DailyBurn prior to, or during the study. However, the intervention team was able access participants' responses in real-time via a system developed by the first author to automate retrieval of data from DailyBurn using participants' login credentials.

The Health-E-Call application developed by the authors allowed participants to monitor up to 3 additional, weight-related behaviors (Figure 2) that were completely personalized. Typically, the behavioral targets for personalized self-monitoring were selected to overcome a barrier to weight loss (eg, preparing a healthy lunch before leaving home for work). Participants also received tailored prompts consisting of a brief message and an audible tone at the times that were most relevant to the targeted behavior (eg, shortly before leaving for work). Participants were able to create these optional behavioral targets, and determine the timing for prompts (Figure 3), with the help and approval of a study interventionist during the weekly weigh-ins described below.

A combination of automated and human feedback was provided to participants via their smartphones. DailyBurn provided automatic feedback on the number of calories consumed relative to the participants' daily goal each time food intake was recorded (Figure 4). Weight was entered daily and the application provided graphed feedback of participants' weights relative to their weight loss goals. DailyBurn provided a visual tally of the number of days that participants met their calorie and physical activity goals each week. Brief messages from a study interventionist were sent to participants' smartphones 1-3 times per week by text messaging. This feedback was based on participants' self-monitoring data, which was available to the study team in real-time due to the smartphones' uninterrupted Internet connection. This feedback was primarily supportive and sometimes included tips for modifying eating and/or physical activity behaviors. While participants were able to send a text message in response to the feedback, they were not allowed to engage in a dialogue with the interventionist via text messaging.

The Health-E-Call application also provided access to 15 brief video lessons lasting approximately 5 minutes each, created by the researchers (see Multimedia Appendix 1 for an example). Each video was organized into one of the following topics: (1) Keeping Track, (2) In the Moment, (3) Planning Ahead, and (4) General Information. "Keeping Track" videos contained instructions on the use of DailyBurn and the investigator-developed self-monitoring tools. "In the Moment" videos provided skills training and behavioral recommendations for coping with immediate weight loss barriers (eg, eating in restaurants, coping with emotions, low motivation to be physically active). "Planning Ahead" videos included instructions for behavioral approaches that could facilitate healthy eating and physical activity habits in the future (eg, suggestions for grocery shopping). “General Information” videos provided education on topics such as “What is a calorie?” and “Adding Variety to Your Physical Activity Routine.”

The in-person treatment component began with an individual 60-minute session that was used to set goals for weight loss, caloric intake, fat intake, and time spent in structured physical activity. Participants were then trained in the use of the smartphone-based intervention system described above. For 12-weeks thereafter, participants attended weekly weigh-ins of 5-15 minutes with a study interventionist. These sessions were used to obtain an objective measure of body weight and address any challenges participants encountered while using the smartphone intervention system.

Paper lessons on behavioral weight loss topics (eg, choosing healthy foods, suggestions for physical activity, stimulus control, relapse prevention) were provided to participants during their weekly weigh-ins during the first 12 weeks of treatment, but not the second 12 weeks of treatment. Participants were encouraged to review these handouts on their own as the contents of the handouts were not reviewed during weigh-ins.

The contents of the smartphone-based videos and weight loss lessons were based on the approached used in the DPP and LookAHEAD [6,7]. Participants were encouraged to consume a low-calorie low-fat diet, engage in regular leisure time physical activity, and self-monitoring these behaviors as well as daily body weight. Participants set goals to lose at least 10% of their initial body weight during the first 12-week period, at a rate of approximately 0.5-1.0 kg (1-2 pounds) per week. They were given a calorie goal ranging from 1200 to 1800 kcal/day depending on their baseline weight, and were encouraged to consume no more than 30% of their diet in the form of fat. Participants were encouraged to gradually increase their time spent in moderate intensity physical activity to reach a goal of at least 200 minutes of moderate intensity physical activity weekly by the end of the 12-week program. Participants were encouraged to spread their weekly physical activity over at least 5 days, and to accrue their physical activity in bouts of at least 10 minutes. Brisk walking was recommended as the primary form of physical activity. While there was some overlap in the content of the paper and video lessons, the paper lessons tended to include more general information and education (eg, healthy vs unhealthy sources of dietary fat, the benefits of self-monitoring) while the video lessons provided more specific and targeted suggestions (eg, how to identify and remove high-fat items in cupboards, and how to record composite foods in the smartphone diary).

Figure 1. Self-monitoring of food intake via the DailyBurn application.

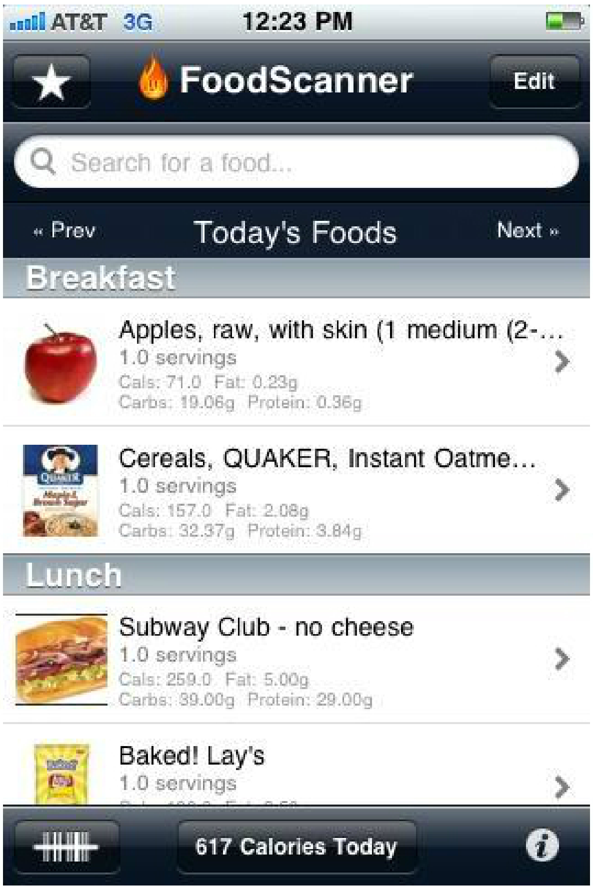

Figure 2. Self-monitoring of personalized behaviors via the Health-E-Call application.

Figure 3. Tailored prompting to facilitate planned behavior.

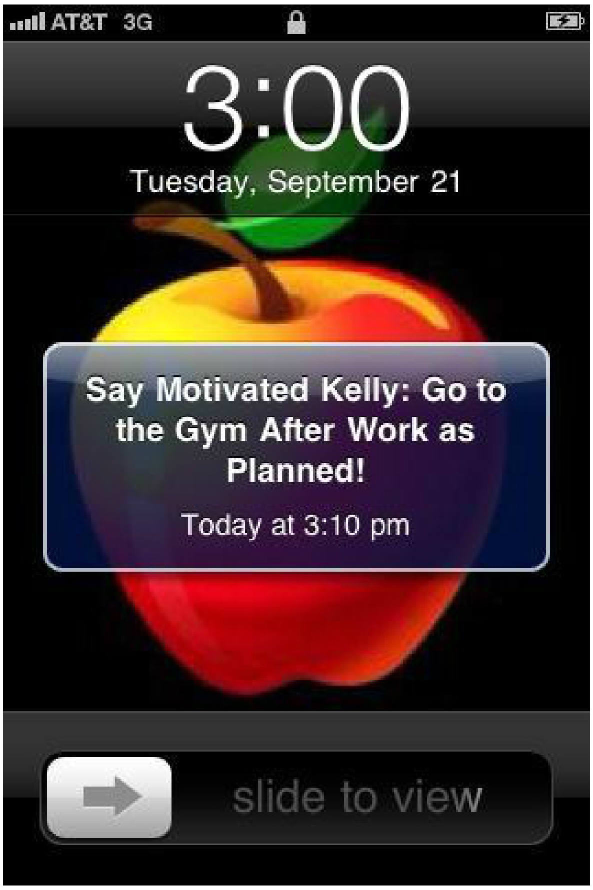

Figure 4. DailyBurn feedback on dietary intake.

Measures

Weight was measured in kilograms using a digital scale at baseline and every week of the 12-24 week program. Height was measured in centimeters at baseline using a stadiometer. Apprehension at using technology was measured at baseline using the 9-item Technology Anxiety scale (scores ranged from 7-63; higher values represent greater anxiety, [35]). Adherence to the self-monitoring protocol was recorded by the DailyBurn application. Participants were considered adherent on days they recorded their weight and had either 3 or more meals or food equaling 50% or more of their caloric goal for the day. Participants were considered non-adherent on days these criteria were not met (a similar approach has been used previously, [33]). In addition to these measures of adherence, DailyBurn recorded the average number of days per week physical activity was reported, and the average number of weekly physical activity minutes. The Health-E-Call application recorded the number of logins, videos viewed, and the use frequency of the personalized behavioral monitoring feature. The number of interventionist feedback messages provided to participants was recorded and a weekly average was calculated. Use of supplementary paper lessons on weight loss was not assessed. At the end of each 12-week treatment period, participants answered 2 questions on a 7-point likert scale to indicate their overall satisfaction with the weight loss program (very dissatisfied to very satisfied) and whether they would recommend the program to their friends, family, or coworkers (definitely would not recommend to definitely would recommend). Higher scores represented higher satisfaction and a greater likelihood of recommendation.

Statistical Analysis

PASW Statistics 19 was used for all analyses. Descriptive statistics were generated for baseline demographic characteristics and outcome variables (weight loss, adherence to the self-monitoring protocol, physical activity reporting, use of the personalized behavioral monitoring feature, treatment satisfaction, and treatment session attendance) including means and SE for continuous variables and counts with percentages for categorical variables. Primary endpoints for the analysis of weight loss, were at the end of the 12- and 24-week weight loss phase. Correlations were used to test for associations between adherence and weight loss.

Results

The 20 participants' baseline characteristics are reported in Tables 1 and 2. On average, the participants were obese at baseline with a mean BMI of 36.3 kg/m^2 (SE 1.2 kg/m^2). Most participants (16/20) were provided with an iPhone 3GS for use in the study, but 2 participants acquired their own device during the trial and chose to use it instead for the remainder of their participation. All participants completed the initial 12-week program. Fifteen participants chose to continue treatment for an additional 12 weeks and all of these individuals completed the extended treatment. Of the 5 participants who chose not to continue, 3 agreed to be assessed at 24 weeks (2 reached their weight loss goal and reported feeling that further treatment was not necessary; 1 reported no desire to making further changes to her eating and activity habits), and 2 declined to be assessed at 24 weeks (1 participant was diagnosed with a serious medical condition unrelated to body weight at 12 weeks and was unable to continue treatment; 1 reported no desire to making further changes to her eating and activity habits).

Weight loss and body weight at baseline, 12 weeks, and 24 weeks are reported in Table 2. At 12 weeks, 85% (17/20) of participants lost at least 5% of their initial body weight and 40% (8/20) lost at least 10% of their initial body weight. At 24 weeks, 100% (15/15) of the participants who completed an additional 12 weeks of treatment lost at least 5% of their initial body weight and 87% (13/15) lost at least 10% of their initial body weight. Among the total sample, with 12-week values carried forward for participants who were not assessed at 24 weeks, the proportion of participants who reached the 5% and 10% weight loss milestones at 24 weeks was 90% (18/20) and 70%. (14/20).

The average Technology Anxiety Scale score at baseline was 20.3 (SE 2.6), with a range of 9-46 (min/max was 9/63). Baseline Technology Anxiety Scale scores were not associated with weight loss at 12 weeks (r=.102, P=.67) or 24 weeks (r=-.305, P=.19).

Adherence to the treatment protocol was measured by attendance at treatment sessions, number of days adherent to self-monitoring (ie, recording daily body weight and at least 3 meals or food intake per day equivalent to 50% or more of the daily calorie goal), and viewing of video lessons. Participants attended 91.7% (SE 2.2%) of treatment sessions during the first 12 weeks and 88.9 (SE 3.3%) of sessions during the second 12 weeks (including only those who received a second 12 weeks of treatment). On average, participants were adherent to the self-monitoring protocol on 90.8 (SE 3.3%) of days during the initial 12-week treatment period. Adherence during the second 12-week period was 84.9 (SE 4.0%, including only the 15 participants in the extended treatment program). Adherence to the self-monitoring protocol was correlated with weight loss (% of initial body weight) at 12 weeks (r=.47, P=.04), but not 24 weeks (r=.42, P=.124). The non-significant results at 24 weeks might be attributed to insufficient power due to the smaller sample size at 24 weeks (n=20 at 12 weeks vs n=15 at 24 weeks). On average, participants viewed 8.3 (SE 5.2) videos during the initial 12-week treatment period, and 3.1 (SE 2.1) videos during the second 12-week treatment period. The number of video lessons viewed was not associated with weight loss (P's>.50).

Other factors related to engagement with the smartphone intervention and performance of weight loss behaviors included the reporting of physical activity minutes via DailyBurn, logins to the Health-E-Call application, and the use of the personalized goal-setting feature. Participants reported engaging in physical activity on 2.6 (SE 0.1) days per week for an average of 125.1 (SE 10.8) minutes per week during the first 12 weeks, and 2.9 (SE 0.2) days per week for an average of 140.7 (SE 12.3) minutes per week during the second 12 weeks. Participants accessed the Health-E-Call application on 3.4 (SE 0.2) days per week during the first 12 weeks and 3.1 (SE 0.2) days per week during the second 12 weeks. During the first 12 weeks, 6/20 (30%) participants used the personalized behavioral monitoring feature while 7/20 (47%) participants used the feature during the second 12 weeks. Of the 15 participants who completed the 24-week program, 3 (20%) used the behavioral monitoring feature (1 during weeks 1-12 only, 1 during weeks 13-24 only, and 1 during both 12-week periods). Participants who used this tool during the first 12 weeks used it for 1-4 weeks (mean 2.5, SE 0.5). During the second 12 weeks, the range was 1-6 weeks of use (mean 2.9, SE 0.7).

Participants rated their overall satisfaction with the program, and the likelihood that they would recommend the program to others, on a scale of 1 to 7. At 12 weeks, all participants but one (who rated satisfaction at 6) gave the maximum rating for satisfaction, and all participants gave the maximum rating for the likelihood that they would recommend the program to others. Of the 15 participants who completed the extended program, all participants endorsed the maximum rating for satisfaction and the likelihood that they would recommend the program to others.

Table 1. Participants' characteristics (N=20).

Characteristic	n (%) or mean (SE)
Gender, n (%)	
Women	19 (95)
Age in years, mean (SE), y	53.0 (1.9)
Ethnicity, n (%)	
White (Non-Hispanic)	17 (85)
African American	1 (5)
American Indian	1 (5)
Other	1 (5)
Marital status, n (%)	
Single	2 (10)
Married	11 (55)
Separated/Divorced	7 (35)
Education, n (%)	
High school or less	3 (15)
Some college	5 (25)
College or University Degree	7 (35)
Graduate degree	5 (25)
Technology anxiety, mean (SE)	20.3 (2.6)

Table 2. Changes in participants' weight at 24 weeks.

	Baseline mean (SE)	12 weeks mean (SE)	24 weeks mean (SE)
Body weight (kg)			
24-week program completers (n=15)	97.4 (3.6)	88.5 (3.1)	84.9 (3.2)
24-week assessment completers (n=18)	97.6 (3.5)	88.6 (3.0)	85.7 (3.2)
Total sample (n=20)	95.8 (3.4)	87.4 (2.8)	84.9 (3.0)[a]
Weight loss (kg)			
24-week program completers (n=15)	-	8.9 (0.8)	12.5 (1.0)
24-week assessment completers (n=18)	-	9.0 (0.8)	11.9 (0.9)
Total sample (n=20)	-	8.4 (0.8)	10.9 (1.1)[a]
Weight loss (% of intial weight)			
24-week program completers (n=15)	-	9.4 (0.6)	12.8 (0.8)
24-week assessment completers (n=18)	-	9.1 (0.6)	12.2 (0.8)
Total sample (n=20)	-	8.5 (0.7)	11.2 (1.0)[a]

[a]12-week values carried forward for the 2 participants without data at 24 weeks

Discussion

Findings and Conclusions

This study was one of the first to use sophisticated smartphone technology to enhance self-monitoring and delivery of empirically validated BWL content and interventionist feedback in a formal weight loss program. The achieved weight loss, adherence to the study protocol, and study retention were excellent and compare favorably to the outcomes observed in prior trials of BWL delivered in group and individual treatment sessions [5]. Retention was 100% (20/20) for the initial 12-week treatment program, and engagement with the smartphone-based resources was high. The average 12-week weight loss exceeded

8% (SE 0.7) of initial body weight. The weight loss results at 24 weeks were similarly favorable, with the average weight loss exceeding 13% (SE 0.8) of initial body weight for treatment completers, which is unusual for a BWL, especially one of such short duration [5]. The weight loss obtained in this trial were substantially larger than the loss of 3-5% of initial body obtained in text message-based interventions [22,23].

Self-monitoring has been highlighted to be the “cornerstone” of BWL [36]. In this pilot study, adherence to the self-monitoring protocol was approximately 91% (SE 3.3%) and 85% (SE 4.0%) at 12 and 24 weeks, respectively. This was substantially higher than rates seen in other trials of BWL using paper diaries (eg, 55%, [33]). This finding is particularly remarkable because, unlike the electronic diary used in this study, paper diaries are often completed retrospectively, which can inflate estimates of adherence and may negate much of the benefit of self-monitoring [37]. The high levels of adherence to self-monitoring in Health-E-Call likely contributed to favorable weight loss outcomes, as seen by the significant correlation with weight loss. The high rates of adherence in this study are attributable to several factors associated with the smartphone-based approach, such as ease of use, and the immediacy of feedback, which may have increased engagement. Participants were also aware that study staff could monitor their adherence to the self-monitoring protocol in real-time and prompted adherence when a lapse was noted. This extra accountability and support, which was not possible in traditional BWLs using paper diaries, also likely contributed to improved adherence.

The personalized behavioral monitoring feature was a novel and unique aspect of the smartphone-assisted intervention. Participants were encouraged to use this tool creatively and the outcome was highly idiosyncratic in both the behavioral targets and the strategy of use. Participants who used the tool commonly set one or more standing goals to facilitate the development of a new healthy habit (eg, going to the gym after work, refusing high calorie food routinely offered by a friend or family member, eating 5 servings of fruit and vegetables daily) over one or more weeks. Some participants kept the same goal(s) for multiple weeks while others changed goals routinely. Some also used the tool to send themselves encouraging and supportive messages at times of the day or week when they often experienced challenges to their healthy eating or physical activity behaviors (eg, “Remember that you are in control of your eating!”, or “If you’re feeling stressed, there are other ways to cope besides eating”). The personalized behavioral monitoring feature was also sometimes used to prompt a one-time behavior such as buying a piece of exercise equipment or asking for a family member’s support with the weight loss effort. Notably, 65% (13/20) of participants did not use this feature, primarily because they were able to reach their weight loss goals without it. Thus, future research should test the efficacy of personalized behavioral monitoring, and for whom and under what conditions it is most beneficial.

The positive outcomes of this pilot study may be due, in part, to the intensive nature of the intervention. The effect of the smartphone-based resources cannot be disentangled from the effects of other intervention components. The intention with this pilot study was to ensure that participants received sufficient contact with the research team to ensure they were able to follow the study protocol as intended. When an established treatment is translated to a new delivery modality, it may be desirable to make the transition in a series of steps that provide the opportunity to understand how best to make the transition, and reduce risk that efficacy will be substantially impaired due to unforeseen challenges with the new modality. This was felt to be particularly important in Health-E-Call, given that many participants had very little prior experience or comfort using smartphones or other forms of technology. In actuality, none of the participants required special coaching in the use of the smartphone apps beyond what was planned in the protocol, and weight loss was not associated with comfort using technology. Thus, the frequency of in-person contact should be reduced in future studies using this approach. While contact with a human interventionist may improve outcomes in electronically-delivered weight loss treatments, randomized clinical trials are needed to identify the optimal rate of contact that balances weight loss outcomes with interventionist time and cost.

Limitations and Future Directions

The small, homogenous, sample was a limitation of this study, as was the lack of a control group or comparison condition. It is also important to acknowledge that providing a smartphone to 16/20 participants may have positively influenced retention and adherence to the self-monitoring protocol. Lastly, participants were not followed after 24 weeks of treatment, and the long-term effects of the treatment are unknown. Despite these limitations, this study was important because it was one of the first to test a sophisticated smartphone-based system for BWL delivery, with very favorable weight loss outcomes, and very high rates of compliance with the self-monitoring protocol. Future research should be conducted to test this novel treatment in a larger randomized controlled trial.

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Conflicts of Interest

Conflicts of Interest: None declared.

Multimedia Appendix 1

Example intervention video available within the Health-E-Call smartphone application.

[MOV File, 118B - mhealth_v1i1e3_app1.mov]

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Abbreviations

BMI: body mass index
BWL: behavioral weigh loss treatment
DPP: Diabetes Prevention Program
LookAHEAD: Action for Health in Diabetes
WCDRC: Weight Control and Diabetes Research Center

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Original Paper

Development of a Theoretically Driven mHealth Text Messaging Application for Sustaining Recent Weight Loss

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Abstract

Background: Mobile phone short message service (SMS) text messaging, has the potential to serve as an intervention medium to promote sustainability of weight loss that can be easily and affordably used by clinicians and consumers.

Objective: To develop theoretically driven weight loss sustaining text messages and pilot an mHealth SMS text messaging intervention to promote sustaining recent weight loss in order to understand optimal frequency and timing of message delivery, and for feasibility and usability testing. Results from the pilot study were used to design and construct a patient privacy compliant automated SMS application to deliver weight loss sustaining messages.

Methods: We first conducted a pilot study in which participants (N=16) received a daily SMS text message for one month following a structured weight loss program. Messages were developed from diet and exercise guidelines. Following the intervention, interviews were conducted and self-reported weight was collected via SMS text messaging.

Results: All participants (N=16) were capable of sending and receiving SMS text messages. During the phone interview at 1 month post-baseline and at 3 months post-baseline, 13/14 (93%) of participants who completed the study reported their weight via SMS. At 3 months post-baseline, 79% (11/14) participants sustained or continued to lose weight. Participants (13/14, 93%) were favorable toward the messages and the majority (10/14, 71%) felt they were useful in helping them sustain weight loss. All 14 participants who completed the interview thought SMS was a favorable communication medium and was useful to receive short relevant messages promptly and directly. All participants read the messages when they knew they arrived and most (11/14, 79%) read the messages at the time of delivery. All participants felt that at least one daily message is needed to sustain weight loss behaviors and that they should be delivered in the morning. Results were then used to develop the SMS text messaging application.

Conclusions: Study results demonstrated the feasibility of developing weight loss SMS text messages, and the development of an mHealth SMS text messaging application. SMS text messaging was perceived as an appropriate and accepted tool to deliver health promotion content.

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KEYWORDS

mHealth; short message service; SMS; text messaging; weight loss maintenance

Introduction

Background

Nearly two-thirds of the American population is overweight (body mass index, BMI>25), of which one-third has obesity (BMI>30). Obesity is associated with multiple chronic illnesses [1] and represents a significant cost to the United States health care system [2,3]. Though people are often successful at initial weight loss, only 1 in 6 people successfully sustain weight loss over 12 months [4,5]. The rate of weight gain is highest immediately after cessation of a structured weight loss program [6]. This relapse in weight regain is attributable to a failure to maintain regular physical activity [7-9], follow a low-calorie diet [7], and monitor body weight [8,10,11]. Thus, effective interventions are needed that can follow a structured weight loss program that are accessible, affordable, and use well-accepted treatment strategies that promote sustainability and maintenance of weight loss [3,12].

Mobile phone short message service (SMS) text messaging, has the potential to serve as an intervention medium to promote sustainability of weight loss that can be easily and affordably used by clinicians and consumers. Due to widespread use and low cost of SMS text messaging, this technology pervades all age groups [13-15], many cultures [16], and socioeconomic backgrounds [14,15]. This technology allows reach across geographic boundaries and reaches people directly where they are located. Thus, it is increasingly accepted and used as a mode for health behavior change interventions rather than mediums such as the Internet or traditional telephone [17]. As of 2011, 83% of American's own a cell phone and over 73% of those use SMS text messaging [18]. Thus, no other medium exists that can reach people as quickly and personally as SMS text messaging.

Preliminary studies suggested that SMS text messaging is an affordable mobile health (mHealth) intervention tool, and has positive short-term behavioral and clinical outcomes when compared to usual care [17,19-30] and that once a day may be appropriate to help motivate people to engage in weight loss behaviors without creating substantial burden [31]. However, a review of the literature [31] indicated that SMS text messaging as an intervention medium for weight loss is in its infancy. Furthermore, a recent study by Shapiro et al [32] showed that weight loss text messages had no effect on weight loss over 12 months but had positive effects on weight loss behaviors (eg, adequate exercise and a healthy diet) over 12 months. Though frequency and timing of messages for weight loss initiation is reported, optimal frequency and timing of following recent weight loss is still unknown.

Therefore, an intervention using text messaging was developed to help motivate people to continue their weight loss behaviors within the first month of completing a structured weight loss program. The goal was to design an intervention that would help people to stay motivated and prevent weight regain. However, 3 important aspects need to be researched effectively before we can use text messaging as a tool for sustaining weight loss. These aspects include content, frequency, and timing of the messages.

Theoretical Frameworks

Research has demonstrated that interventions intended to change unhealthy behaviors are more likely to elicit positive changes and benefit individuals and communities if they are guided by theories of behavior change [33]. However, many theory-guided interventions that generated positive rates of initial change failed to facilitate long-term maintenance [10,34-36]. The dominant health behavior change models are successful at guiding interventions that create short-term behavior change but do little to improve sustained behavior change [36]. These models rely on the premise that the strategies people use to initiate a behavior change are the same as those used with maintenance. This is at odds with research that has demonstrated successful rates of initiation do not translate into maintenance [37,38]. Even among intervention strategies that increase the intensity or frequency of a treatment, thus delaying relapse, long-term sustainability and maintenance was not substantially improved [39-41]. Therefore, it is assumed that there are psychological differences in the processes of initiation and maintenance.

To develop an intervention to focus on sustaining weight loss following initiation and completion of a structure weight loss program, Rothman's Behavior Change Process [42] (Figure 1) was used as a guiding framework to focus specifically on continuing weight loss behaviors following an initial change. This framework focuses on transitioning from unhealthy behaviors to healthy behaviors through a 4-step process. The first step is an initial change, where for example, people with obesity begin an exercise program and healthy eating. This is followed by a sustained or continued response where people must overcome challenges and barriers to continuing the new exercise and diet behaviors. Ultimately, people move from the sustained response to a state of maintenance and then habit, where they have integrated the weight loss behaviors into their daily lives. However, for complex behaviors such as weight loss, the transition from continued response to maintenance is challenging [10,34,35]. People often relapse, revert back to their old behaviors and regain lost weight [4,5], particularly within the first month of a structured weight loss program [6].

Due to the obesity epidemic the United States faces, obesity reduction is in critical need of research on sustainability and maintenance strategies. However, different processes govern weight loss initiation versus sustainability [36,42-45]. Emerging research has suggested interventions target and frame messages about how people reach goals in their life, such as sustained weight loss, through either a prevention or promotion focus; this is known as regulatory focus theory [46]. This may be beneficial by motivating people to self-regulate and sustain recent behavioral changes [47] such as weight control [48]. This may be particularly useful at the continued response phase of the behavior change process. The regulatory focus theory argues that there are two distinct strategies that people use to reach a goal [46]. People either promote success (promotion) or prevent failure (prevention) [47]. Although any goal can be pursued with either a promotion or prevention focus, some goals are more compatible with an individual's innate preference of promotion or prevention. When a goal matches a person's innate preference for promotion or prevention, it creates a "fit" [47,49]. Messages that "fit" an individual's regulatory focus resonate more with the individual and are more persuasive [49,50]. Motivational strength is enhanced when goals match a person's regulatory focus [51]. Thus, when a "fit" occurs, people are better able to sustain self-regulation and behaviors that allow them to reach their goals such as physical activity, a healthy diet, and weight monitoring.

We must also identify amount, frequency, and timing of delivery of text messages. In regard to the message frequency, the habituation-tedium theory informs us that message frequency is important for message effectiveness [52]. Repeated exposures to messages lead to familiarity and increased effectiveness [52]. However, too many messages and repetition may lead to tedium, increased boredom, and become burdensome [52]. With regard to content, studies on content inform us that people need information on a healthy diet, exercise, and self-monitoring of weight loss behaviors [7-11].

Figure 1. Rothman's behavior change process [42].

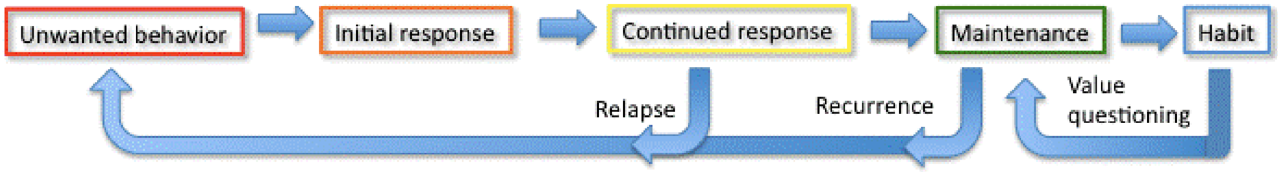
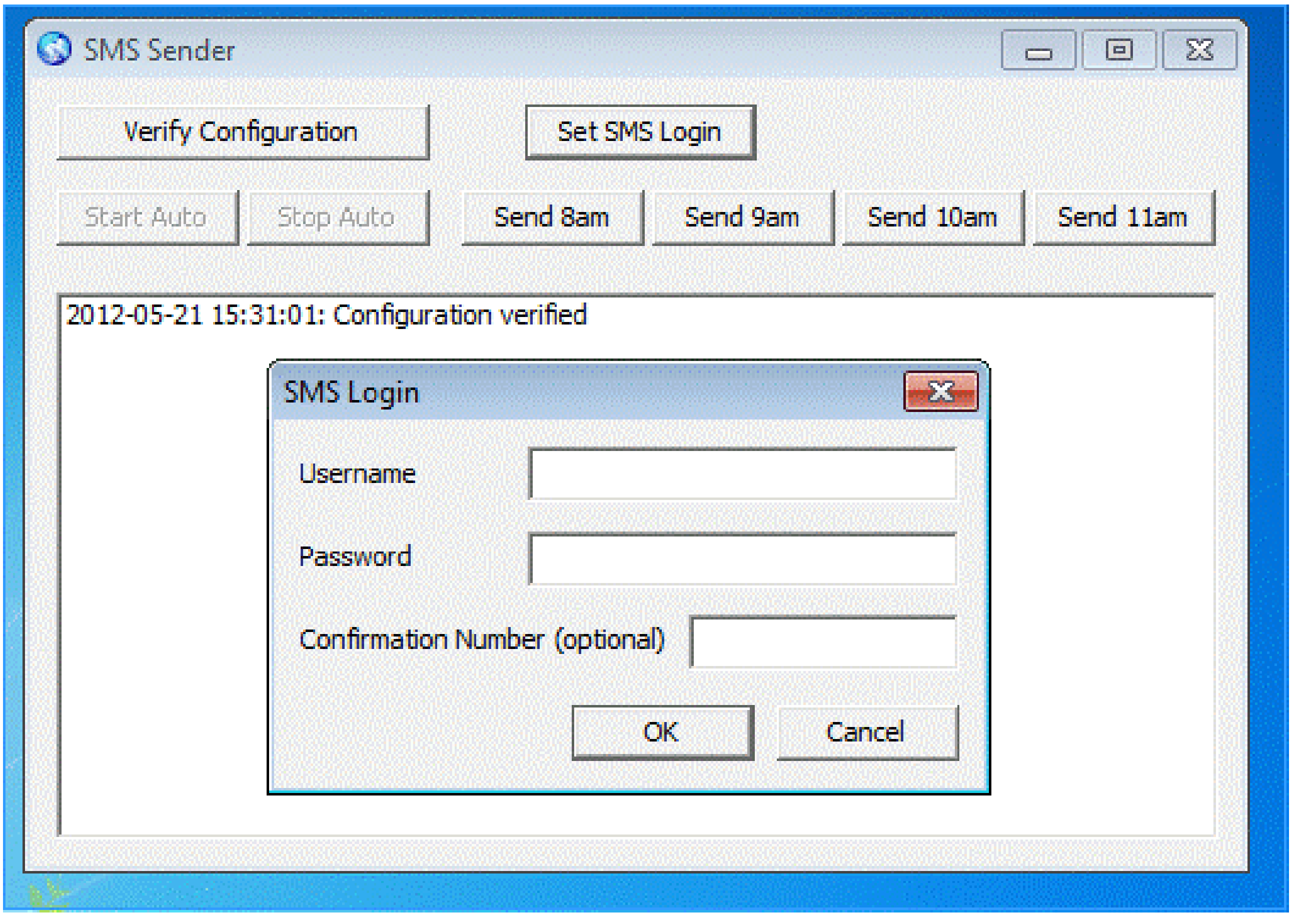


Figure 2. Web application for content management, powered by an SMS gateway–Manual Mode, SMS Login Configuration.



Objectives

The objective of this feasibility and development pilot study involving the use of text messaging was to address 4 aims: (1) to develop promotion and prevention framed weight loss sustaining messages to be delivered via text messaging, (2) to assess participants' perception of the usefulness and attitudes of the text messages, (3) to understand the frequency and timing of message delivery, and (4) to develop an automated intervention to deliver weight loss sustaining messages via SMS text messaging to people with obesity following a structure weight loss program. We will use the results from this development and pilot study for a subsequent randomized controlled trial (RCT). We chose to make an automated program so that message delivery would be consistent and standardized for all participants and could be an efficient tool for clinicians to deliver weight loss messages to ample patients any day and time of the year.

Methods

Message Development

Since many people begin to relapse within the first month of a structured weight loss program [6], we initially created 30 text messages, a month's worth of daily messages on nutrition, exercise, and self-monitoring of weight, diet, and exercise. These are behaviors needed to sustain weight loss activity [7-11,53-55]. Messages were limited to 140 characters, which is less than the standard length of a single text message of 160 characters, to accommodate for limitations of different cell phone models. Message content was derived from current diet and exercise guidelines [56-58], and the Duke University Diet and Fitness Center, a residential weight management program. Nutrition messages focused on strategies to promote fullness, portion control, and to avoid binge eating and trigger foods, planning meals, coping strategies, and monitoring food intake. Exercise messages focused on benefits of exercise, physical activity goals, overcoming barriers, barriers to initiating and maintaining exercise/physical activity, monitoring exercise amount and intensity, and fitness activities. Self-monitoring messages focused on monitoring and recording of weight, food intake, exercise, identifying poor habits, and reviewing progress with weight and behavior patterns over time [59]. We then pilot tested the messages for their usefulness and relevance to people who have recently lost at least 5% of their body weight and are attempting to continue their weight loss behaviors.

We framed each message to a promotion and prevention focus for a total of 60 messages to match the Regulatory Focus Theory (see Table 1). Two expert health psychologists reviewed the messages to verify they were framed appropriately to match a prevention or promotion orientation. The messages were then pilot tested for their usefulness and relevance.

Study Design

Recruitment

With IRB approval, we recruited participants from a residential weight management program in North Carolina known as the Duke Diet and Fitness Center. The Duke Diet and Fitness Center provides a residential weight management program that helps people affected by excess weight and impaired physical fitness achieve better health through weight loss, physical conditioning, and improved self-care habits. Clients enroll in a comprehensive program that provides education, practical behavioral strategies, and ongoing support to make long-term changes. The average participant who attends the Duke Diet and Fitness Center loses on average 5% of their initial body weight.

Eligible participants met the following inclusion criteria: (1) ≥18 years old, (2) able to speak and read English, (3) had completed a comprehensive diet and fitness program, (4) had a BMI≥30 at the start of the diet and fitness program, (5) lost 5% of their body weight by the beginning of the study, (6) had their own mobile phone to personally receive SMS text messaging, (7) physically able to access SMS text messaging on their phone, (8) able to continue physical activity for 3 months, (9) did not have a joint replacement scheduled within 3 months, and (10) were capable of informed consent. Participants were compensated $50 for their participation at study completion.

We recruited participants during a self-management class at the Duke Diet and Fitness Center. Those who met the inclusion criteria and agreed to participate, signed an informed consent, and completed a survey including demographic information and the Regulatory Focus Questionnaire (RFQ) to measure if the participants were innately promotion or prevention focused [60].

Intervention

Following informed consent, we provided participants an orientation to the intervention. Participants received messages (promotion or prevention) that matched with their RFQ results of preference for promotion or prevention. Messages were set in a queue and alternated between nutrition, exercise, and monitoring. We initially tested the frequency and delivery of the text messages and sent them out daily at an arbitrary time, 9:00 AM. We kept a message delivery log and checked it daily to ensure that appropriate daily messages were delivered to participants.

At 1 and 3 months post-baseline, we sent a text message to participants requesting them to self-report their weight. We also sent an email asking participants when they would be available to take part in a phone interview. We followed-up with non-responders with a telephone call. With participants' permission, interviews were recorded and transcribed for analysis.

Measures and Variables

At baseline, we obtained through self-report gender, age, education level, and work status. Height, weight, and BMI were obtained at baseline from participants' medical record. Clinician obtained weights were not possible following completion of the residential weight loss program since participants returned home across the United States. Self-report was deemed as the practical measurement. We used the RFQ [60] to assess innate promotion or prevention preference to reach goals. This measure consists of 11 5-point Likert-type items (5 prevention, 6 promotion), which assesses the history of individuals' success at promotion and prevention tasks over the course of their lives. Scores range from −2 to +2. Positive scores indicate greater previous success in promotion self-regulation. Negative scores indicate greater previous success in prevention self-regulation. This scale has established reliability and validity [60].

We measured feasibility and acceptability at 1 month post-baseline through a semi-structured telephone interview guided by an interview questionnaire. We asked participants how often they read the messages, if there were times when they did not read the messages, and if they encountered technical barriers to assess feasibility and fidelity of the study design and delivery of treatment [61]. We calculated responsiveness and treatment fidelity related to receipt of the messages by how useful and favorable (attitudes) participants felt about the intervention. To assess usefulness, attitudes, and acceptability, participants were asked in the interview how useful they found the text messages, whether they liked the message content, and whether they liked text messaging as an intervention tool for helping to sustain weight loss. In addition, participants were asked if anything occurred during the 90-day study period that may have affected sustaining their weight loss, such as a major life event or participation in other weight loss programs. To assess optimal frequency and timing to deliver the messages, participants were asked their preference about the frequency and timing.

Data Analysis

We calculated demographic variables and change in weight using descriptive statistics with SAS Version 9.3. We analyzed interview data using conventional content analysis, a data reduction technique, to look for recurring themes [62-64] using Microsoft Excel 2007. The analysis was guided by questions we asked in the interviews on perceived usefulness, attitudes [65-67], and experiences [65-67] of the intervention. The content analysis involved dividing text into segments of information and coding them [68]. Inferences were made from the codes and collapsed into themes [69]. A second researcher reviewed approximately half of the interviews. Any disagreements were resolved through discussion and consensus. All codes were agreed upon. Results on perception of the usefulness and attitudes were divided into three categories of negative, positive, and neutral perceptions. Data on the preference for frequency and timing of message delivery were summed.

Table 1. Weight loss sustaining text messages framed to a promotion and prevention focus.[a]

	Promotion	Prevention
1N	Small diet changes add up. Eat breakfast every day. You will eat less during the day and it will help you reach your weight loss goals.	Eat breakfast every day. It will prevent eating more during the day and gaining weight back. Small diet changes add up.
2E	Weigh yourself daily at the same time and on the same scale. This is important. Checking on your progress will help you control your weight.	Check your progress and prevent failure. Weigh yourself daily at the same time and on the same scale. This will help you control your weight.
3M	Exercise regularly. Exercise will maintain a healthy weight, blood pressure, and reduce problems with diabetes.	Prevent diabetes problems, weight gain, and worsening blood pressure. Not exercising affects the body's ability to handle blood sugar.
4N	Sustain your weight loss. Use the "plate method". Fill up ½ your plate with vegetables, ¼ with starch, ¼ with protein.	Avoid eating too many calories. Use the "plate method". Fill up ½ your plate with vegetables, ¼ with starch, ¼ with protein.
5E	Check your food intake. Record everything you eat and portion sizes. Checking increases awareness of what you are eating.	Check your food intake. Avoid falling into the trap of checking only "good days". Record everything you eat and portion sizes.
6M	Count steps to increase the amount you walk. Use your pedometer. Set a goal of adding 150 steps a day up to 5000 steps a day or 2.5 miles.	Don't risk falling off the exercise bandwagon. Count your steps to increase the amount you walk up to 5000 steps a day or 2.5 miles.
7N	Use smaller plates. You will still clean your plate, feel satisfied, and have better portion control.	Prevent over eating. Use smaller plates to avoid filling a larger plate with extra calories.
8E	Keep track of the things that lead to unplanned and overeating.	Prevent yourself from unplanned eating. Keep track of the things that lead to unplanned and overeating.
9M	Activity burns calories and helps maintain weight. Climbing stairs, parking further away, or walking to the office add up quickly to 30 min a day.	Don't let exercise slip away. Small activities such as climbing stairs, parking further away, or walking to the office add up quickly to 30 min a day.
10N	Eat slowly. Put fork down between bites. Check fullness level during meal. When full push your plate away. Satisfaction takes 15-20 min.	Avoid feeling full and giving in to cravings. Eat slowly. Put fork down between bites. Check fullness level. Satisfaction takes 15-20 min.
11M	Keep exercising! After 1 year, dieters who exercise maintain most of their original weight loss.	Steer clear of gaining weight back. Dieters who do not exercise maintain only half of their original weight loss.
12N	Select healthy breakfast cereals. Follow the "5 and 5" rule—5 grams fiber & 5 or less of sugar. Or try heart-healthy oatmeal with honey!	Steer clear of high sugar breakfast cereals. Follow the "5 and 5 rule" —5 grams of fiber and 5 or less grams of sugar.
13E	Monitor your progress and how you are doing. Schedule time to review your progress in your calendar.	Remember not to forget to monitor your progress. Schedule time to review your progress in your calendar.
14M	Exercise helps more than just with weight loss. It helps to decrease high blood pressure, improve diabetes, and decrease cholesterol.	Exercise helps more than just with weight loss. It helps to prevent cancer, diabetes, high blood pressure, and gaining weight back.
15N	Reward yourself. It's OK to have a little sweet foods such as pie, cookies, and candy, and alcohol.	Prevent yourself from overindulging. It's OK to have a little sweet foods such as pie, cookies, and candy, and alcohol.
16M	Cross train. Vary your exercise: walk, bike, elliptical, water /chair aerobics. It will help you stay motivated and have fun!	Prevent boredom, injury, and over training with your exercise. Cross train: walk, bike, elliptical, water/chair aerobics.
17N	Identify and change habits and foods that lead to binges including risky foods kept in the house such as chips or watching TV while eating.	Avoid being tempted by foods and habits that lead to binges. Don't keep risky foods in the house such as chips or watch TV while eating.
18E	Stay on top of how you are doing. Review your monitoring forms to check for patterns. Monitor at least 2-3 times a week.	Prevent yourself from slipping. Pick 2-3 days to monitor and every so often review your monitoring forms to check for patterns.
19M	For general fitness: exercise 30 minutes daily. 8-10 exercises, 8-15 repetitions, 1-3 sets, 30-90 second rest between sets.	Don't exercise too little and stop all together: exercise 30 minutes daily. 8-10 exercises, 8-15 repetitions, 1-3 sets, 30-90 second rest between sets.
20N	Use a grocery list for grocery shopping and only buy planned for items. This will help you buy good healthy foods.	Prevent temptation to buy unhealthy foods. Avoid meal planning or shopping for groceries when you are hungry.
21E	Limit size of portions at mealtimes by measuring planned servings. Keep measuring utensils readily available.	Don't let portion sizes increase in size. Keep measuring utensils readily available and measure planned servings at mealtimes.
22E	Weigh yourself daily. Place the weight on a graph to see trends over time. It is natural to fluctuate daily due to things such as water.	Don't feel surprised and upset when daily weighing. Place the weight on a graph to see trends over time. It is natural to fluctuate daily.
23N	Plan meals in advance to increase self-awareness—3 meals and up to 2 snacks per day going no longer than 4-5 hours between eating.	Plan meals in advance to avoid overeating and being tempted to select poor foods —3 meals, 2 snacks/day no more than 4-5 hrs between eating.

	Promotion	Prevention
24E	Be aware of your blood pressure and monitor it. Check it when and where you can: at home, the doctor's office, blood pressure machine at the drug store, etc.	Prevent or reduce high blood pressure. Keep track of your blood pressure at home, the doctor's office, machine at the drug store, etc.
25M	Stay motivated! At the beginning of the week plan your exercise sessions and treat them like you would any other appointment.	Prevent becoming demotivated. At the start of the week plan exercise sessions and treat them like any other appointment.
26E	Monitor your blood sugar as prescribed and HbA1c every 3-6 months. Keep track of fluctuations and where they are to see how much they are.	Avoid large fluctuations in your blood sugar. Monitor your blood sugar as prescribed and HbA1c every 3-6 months.
27M	When you don't feel like working out, bargain with yourself to exercise for just 10 minutes then see how you feel.	Don't fall into the slippery slope of not feeling like exercising. Contract with yourself to exercise for just 10 min then see how you feel.
28N	Make small changes. Use trade-offs such as: I will have dessert every OTHER night or, I will only eat half of the dessert.	Avoid tempting foods. Use trade-offs such as: I will have dessert every OTHER night or, I will only eat half of the dessert.
29M	Any exercise is better than no exercise. Use a strategy to find a way to get in at least some exercise.	Don't slip into the "I don't have time to exercise" today excuse. Any exercise is better than no exercise.
30N	Use restaurant strategies: 2 vegetable servings, 1 caloric beverage. If calories are listed keep meals below 800.	Don't be tempted to overeat when at restaurants: 2 vegetable servings, 1 caloric beverage, don't arrive hungry. Keep meals below 800 calories.

[a]N=nutrition focus; E=exercise focus; M=monitoring focus

Results

Overview

We enrolled participants (N=16) between September and October 2010. Participants had a mean age of 52.0 (SD 15.5), a mean BMI of 38.1 (SD 7.8), a mean baseline weight of 206.8 pounds (SD 39.8), 81% (13/16) were female, 94% (15/16) were White, and 6% (1/16) was African American. As indicated by the RFQ, 63% (10/16) were innately promotion focused and 37% (6/16) were prevention focused. All participants had a college level education and had previous experience with SMS text messaging technology. Self-reported weight was received from 88% (14/16) of participants via SMS text messaging at 1 and 3 months, and these participants also participated in an individual telephone interview. Weight loss was sustained or continued for 86% (12/14) participants at 1-month post-baseline, and 79% (11/14) participants sustained or continued to lose weight at 3-months post-baseline. The mean change in weight from baseline enrollment to 1 month was −7.4 pounds (SD 8.2) and −13.7 pounds (SD 11.3) at 3 months.

Acceptability

Participants reported from the interviews that the intervention was useful, defined as beneficial in helping them sustain weight loss, and were positive towards the text message content and SMS text messaging technology as an intervention medium. Interview themes indicated the participants perceived the intervention as a reinforcement tool, a reminder, a form of social support, and a useful way to receive short relevant messages directly to them.

Perception of the Usefulness of the Text Messages

The messages were perceived as useful in helping 71% (10/14) of the participants to sustain weight loss. Reinforcement and encouragement arose as a theme. One respondent said, "It really helped me. It was like having a pearl [of wisdom]. I liked that they reinforced behaviors". Several participants said that the information helped to reinforce and remind them what behaviors they should be performing to sustain weight loss. For example, one participant stated that the messages "helped get the message home." Participants felt that the message content was appropriate and reflected behaviors they needed to perform to sustain recent weight loss (a healthy diet, physical activity, and monitoring of progress). Twenty-one percent (3/14) of participants noted that they missed the contact of receiving the messages and were disappointed when the study ended.

Some (3/14, 21%) participants enjoyed the messages, but were not sure how much the messages helped them sustain their weight loss. These 3 participants felt that the messages needed to be more motivational and that additional elements such as supportive phone calls, a mentoring program in-person or online, and an online support program with other people who are losing weight should be added to the intervention. One participant said, "Takes more than [a text message] to lose weight." Furthermore, one participant (7%) did not find the messages useful at all. This participant said the messages were annoying and redundant and that she did not enjoy receiving information she already knew.

Attitudes Towards the Text Messages

While 93% (13/14) of the participants were favorable toward the messages, 7% (1/14) was not favorable toward the messages. Participants reported enjoying and receiving "a daily boost of confidence", and that they "always looked forward to it." These messages were also viewed as social support. For example, one participant said, "It says there is somebody out here who cares and is reminding you don't forget. It just starts your morning." Another participant said, "It was like having a buddy," while another said, "It was like someone was over my shoulder. It was like a conscience."

Usefulness and Attitudes Towards SMS text messaging Technology

All participants thought that SMS text messaging was a favorable communication medium and was a useful way to receive messages promptly and directly. As noted by one participant, “I always have my cell phone on me.” Twenty-nine percent (4/14) noted SMS text messaging was useful because they were able to keep the messages on their phone and it was easy to read them multiple times. Fifty percent (7/14) of participants said that they read the messages multiple times, though it is unknown how many this entails. Twenty-nine percent (4/14) of participants said that they preferred SMS text messaging compared to other mediums such as email or telephone because it directly reaches them, is convenient, and is easy to use. However one older participant, > 65 years old, said that she preferred email over SMS text messaging. Twenty-one percent (3/14) said they forwarded and shared the messages with other people who were also trying to lose weight.

Another theme that emerged was that SMS text messaging is a good tool to deliver short relevant messages. Three participants said that they found the SMS text messaging useful because it consisted of small amounts of relevant information. One participant noted “I have the [weight loss program] material to go back and review, but what I am trying to figure out is what the most powerful tool [information] is for me.” This participant said that SMS text messaging made it easy to find the information and it came directly to her.

Fidelity and Message Delivery

All 14 participants said they read the messages when they knew they arrived. Most participants (11/14, 79%) said that they read the messages every morning during the 30 days of message delivery. Several participants (3/14, 21%) did not read the messages every morning. Of these, one said that she was more tied to email and missed some messages coming in because her phone was on silent or she did not notice the message had arrived. Another was on vacation during part of the intervention and did not receive the messages during that time period. Another participant self-reported technical difficulties with her phone and stopped receiving messages after 2 weeks.

All participants (14/14) thought the frequency of receiving a daily message promoted weight loss sustaining behaviors. Participants felt that weight loss is a daily activity and that receiving messages less frequently would be less effective. Several participants (3/14, 21%) expressed that twice a day would still be appropriate and they indicated that a message in the morning and at night would be acceptable. All participants expressed that the best time to deliver daily messages was in the morning around 8:00 AM. This was expressed as an optimal time because it sets a precedent for the day. One participant noted that receiving a message later in the day may not be as effective because they may have already missed exercising or eaten something not on their dietary plan.

Technical issues did arise, such as a non-functioning phone in one participant and a silent mode or delay in checking the messages by two others. No participants had problems responding their self-reported weight via text message.

Lessons Learned

This pilot study provided the following lessons learned for the development of an automated text message intervention for sustaining weight loss to be used in a future planned RCT. These included the following:

1. Participants want at least one daily message.
2. Messages should be delivered at 8:00 AM in a participant’s respective time zone.
3. To avoid splitting on some cell phones messages should not be beyond 140 characters.
4. Participants’ phone numbers are considered personal identifiable information (PII) and must be used with a secure system.

Application Development

The Web application for content management, powered by an SMS text messaging gateway, was written in C++, using the Microsoft Visual C++ 2010 compiler. Three code libraries were used: the Microsoft Visual C++ runtime (for basic computer services), Microsoft Foundation Classes (for user interface services), and libcurl (for secure hypertext transfer protocol secure, HTTPS, data transmission services).

The application read a database of configuration information and subject information. Configuration information consisted of the text messages for each planned intervention group and the login information for the HTTPS-based SMS text messaging service. Subject information consisted of each participant’s telephone number, time zone, intervention start date, and intervention group.

The database was in the form of 5 text files on a secure file server. Three files held the list of messages for each intervention group, with one message on each line: arm1.txt, arm2.txt, and control.txt. One file held login information for the HTTPS-based SMS text messaging service, with the account name and password on separate lines, obfuscated by a simple encoding: login.txt. This file optionally held a confirmation number, where a text message confirming successful message delivery was sent. The final file held subject information in a comma-separated value (CSV) format: subjects.txt.

The application also wrote logs of its activity. The database of logs consisted of text files stored on the same secure server as the configuration and subject data. Each log file was named by the date of activity described within the file. The location of the secure file server was stored in a file, SMS text messaging.ini, placed in the same directory as the application itself. If this was not specified, the application defaulted to its own directory.

The application had two modes of use: manual and automatic. Manual mode was for initial setup, testing, and error recovery. Automatic mode was for regular use throughout the course of the trial. Manual functions included SMS text messaging service login configuration, configuration verification, and message sending. Automatic functions were configuration verification and message sending.

The SMS text messaging login configuration function allowed the user to specify the account name and password for the HTTPS-based SMS text messaging service. The user could also specify the confirmation number where a text message confirming successful message delivery was sent. Figure 1 shows this manual function.

Configuration verification read all of the configuration data and confirmed that there were no obvious errors. Configuration verification checked that the lists of text messages for each intervention group each contained 30 messages. Configuration verification checked that the SMS text messaging service login information was present. Finally, it checked that the subject information list was present and formatted correctly. Configuration verification had the option to be triggered manually through the user interface, and was done automatically every time text messages were sent, whether manually or automatically.

Because the intervention specified that each participant receive a text message at 8:00 AM local time, message sending in the application worked by processing the subjects in batches based on time zone. This processing was triggered manually by pressing a button in the user interface, or triggered automatically by setting the computer to run the application as a scheduled task, with an appropriate command-line option.

The application assumed that all subjects were in the continental United States, and therefore had 4 options for sending a batch of messages. The application named the batches using the time (specifically Eastern time zone). Thus, if a batch was sent to the Eastern Time zone at 8:00 AM, it was named "8am," and the 8:00 AM batch sent to the Pacific time zone was named "11am." When processing of a batch began, the application went through the following steps:

1. Verified the configuration
2. Read the subject information and gathered the batch of subjects that were in the current time zone
3. Using the subject start date and the current date, calculated which day of the intervention each subject was on, discarding subjects whose intervention had not started yet, or whose intervention was over
4. Logged in to the HTTPS-based SMS text messaging service
5. For each subject in the batch:
    - Selected the appropriate text message using the subject's calculated intervention day and intervention group the subject was in (for a planned future RCT)
    - Sent the selected text message to the subject's phone number
6. If the application was running in automatic mode, and the batch was the first batch of the day (8:00 AM batch), sent a confirmation text message to a confirmation phone number

If an error occurred at any step, the error was logged. Processing continued as much as was possible, including the text confirmation message in the final step. If errors prevented the sending of any messages, the confirmation text message included this information. If a failure occurred during automatic processing, we launched the application in manual mode to identify and fix any configuration errors and attempted to send the message again.

Automatic mode was configured with help from the operating system. For this trial, four Windows Scheduled Tasks were set up, one for each time zone. The tasks were configured to run daily at 8:00 AM, 9:00 AM, 10:00 AM, and 11:00 AM Each task launched the application with a command line option that instructed the application to automatically send the batch of messages for that particular time, like so:

- 8:00 AM: SMS text messaging.exe /run8
- 9:00 AM: SMS text messaging.exe /run9
- 10:00 AM: SMS text messaging.exe /run10
- 11:00 AM: SMS text messaging.exe /run11

The service was set up to "Run As" a user with access to the secure file server, which stored the configuration, subject, and log files. This allowed the service to run daily and send all necessary messages without regular manual intervention.

Patient Privacy Considerations

Patient privacy was a major consideration in the design and development of the application. When designing IT applications such as this, data encryption must be written into the software development. Data are transmitted to participants from a secure server, which reads PII (telephone numbers) and then transmits data to a personal phone through a secure communication protocol HTTPS to a SMS text messaging gateway. HTTPS provides authentication of a third-party SMS text messaging service that this application used to transmit the text messages. This was critical to provide assurance that the application communicated precisely with the website it intended to and ensured the communicated content (eg, PII telephone numbers) were not read by any unintended third parties. mHealth interventions may often times use a third party to transmit SMS text messaging, video messages, voice messages, or other data onto an app. It is imperative that PII is limited regarding what is transmitted and that these third party companies or services also have privacy agreements.

Nevertheless, cell phones are often shared and other people can read information transmitted to participants. This is particularly true for SMS text messaging where user authentication is not available for an individual message at this time beyond having a password protected cell phone. Furthermore, SMS text messaging is fundamentally a non-encrypted communications protocol. Thus, we must be careful and aware of the sensitivity of the delivered content.

Discussion

Principal Findings

These results suggest that it was feasible to develop and deliver promotion and prevention framed weight loss sustaining messages via SMS text messaging to people who have recently completed a structured weight loss program and are in the continued response phase of the behavior change process. Most participants (11/16, 79%) sustained or continued to lose weight at 3 months post-baseline and had a mean change in weight from baseline enrollment to 3 months of −13.7 pounds (SD 11.3). Many participants felt that the messages helped them stay motivated. Several participants expressed that they felt they had a companion with the daily messages and that it was important to receive daily reminders. Of the 3 participants who had a neutral perception and the one who had a negative perception of the intervention, all indicated they would have preferred the messages to either be more motivational or have additional components such as a telephone element or online discussion group. All 3 continued to lose weight at month 3.

All participants were positive about the SMS text messaging delivery method. Participants expressed favorability towards SMS text messaging because messages were delivered directly to them. Most of the participants read the messages every day; however some technical issues did arise.

In regard to the message frequency, the habituation-tedium theory suggests that message frequency is important for message effectiveness [52]. Repeated exposures to messages lead to familiarity and increased effectiveness. However, too many messages and repetition may lead to tedium, increased boredom, and become burdensome. Thus, it is imperative that optimal frequency of message delivery be determined prior to testing an effectiveness trial. Previous studies report a daily text message had a positive clinical effect on behavior [24,27,70] and a review of the literature on SMS text messaging weight loss interventions indicated that once a day might be appropriate to help motivate people to engage in weight loss behaviors without creating substantial burden [31]. Results from suggest that once a day was deemed as the most appropriate message frequency and 8:00 AM as the best delivery time. However because weight loss is a continuous process, several participants indicated that receiving messages twice a day, preferably at morning and night would be beneficial. In relation to the habituation-tedium theory, more than twice a day would be considered burdensome and create tedium, while fewer than once a day would not be effective and fail to reach habituation. Thus, the ideal frequency for message effectiveness was at least once a day and no more than two times a day. SMS text messaging also emerged as an appropriate medium to collect self-report data on weight.

As stage 2 of Meaningful Use is upon us, the Center for Medicare and Medicaid Services guidelines call on providers and researchers to determine whether personally identifiable health data is secure in storage, with the goal of encouraging providers to encrypt data when it's transmitted to mobile devices. In the design of our SMS text messaging intervention, we specifically took strides to ensure that data would be stored on a secure server and would transmit data securely to a third party SMS text messaging service. When selecting a third party service it is crucial that one is used in which privacy rules are in place and data security is robust.

Limitations

This feasibility and development pilot study was limited in sample size, and the majority of participants were from a more affluent and educated background, mostly White non-Hispanic, and not representative of the general US population. Furthermore, the study relied on self-report of weight. Because scales can vary, baseline report of weight at the Duke Diet and Fitness Center may differ from the self-report of weight that participants take at home. Nevertheless, the accuracy of self-reported weight has been demonstrated in Internet-based weight loss treatment programs and has shown to be comparable to observed weight [71]. In addition, participants who left the residential weight loss program did not return to the program for follow-up weights. Thus, the self-reporting of weight reflects a more realistic application and evaluation. Though we asked participants if they read every message, we did not inquire if participants read the words when the messages arrived. Furthermore, we did not assess the effects of the message framing in this pilot study. Despite the limitations, the results from this pilot study were useful and helped guide the development of an evidence-based and theoretically driven SMS text messaging intervention.

Implications for Clinical Practice

SMS text messaging interventions have the potential to be easy-to-use tools that clinicians and consumers can use to help manage chronic conditions and sustain healthy behaviors. Because text messaging is such a ubiquitous medium of communication, it can allow providers to easily reach and deliver care directly to their patients. One can envision this SMS text messaging intervention being leveraged in primary care clinics and weight loss specific centers as a way to extend care affordably. Tools such as this could also easily be leveraged for many other self-managed chronic diseases such as diabetes, hypertension, and glaucoma.

Conclusions

As a pilot study of a larger weight loss sustaining RCT intervention, results from this pilot study provide valuable insights on development of weight loss text messages, frequency, timing, and the development of an automated mHealth text messages intervention. Consistent with the literature [17,28,31], SMS text messaging was an appropriate and accepted tool to deliver health promotion content. Our next steps using the message content, information on frequency and timing, and application developed in this study, are to assess the effects of these weight loss-sustaining messages and the intervention on sustaining weight loss and preventing relapse. We will also examine the differential effects of framed weight loss messages on sustaining weight loss in a RCT at the Duke Diet and Fitness Center.

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Conflicts of Interest

Conflicts of Interest: None declared.

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Abbreviations

BMI: body mass index
CSV: comma-separated value
HTTPS: hypertext transfer protocol secure
PII: personal identifiable information
RCT: randomized controlled trial
RFQ: Regulatory Focus Questionnaire
SMS: short message service

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Original Paper

“Let’s get Wasted!” and Other Apps: Characteristics, Acceptability, and Use of Alcohol-Related Smartphone Applications

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Abstract

Background: Smartphone applications (“apps”) offer a number of possibilities for health promotion activities. However, young people may also be exposed to apps with incorrect or poor quality information, since, like the Internet, apps are mostly unregulated. Little is known about the quality of alcohol-related apps or what influence they may have on young people’s behavior.

Objective: To critically review popular alcohol-related smartphone apps and to explore young people’s opinions of these apps, their acceptability, and use for alcohol-related health promotion.

Methods: First, a content analysis of 500 smartphone apps available via Apple iTunes and Android Google Play stores was conducted. Second, all available blood alcohol concentration (BAC) apps were tested against four individual case profiles of known BAC from a previous study. Third, two focus group discussions explored how young people use alcohol-related apps, particularly BAC apps.

Results: 384 apps were included; 50% (192) were entertainment apps, 39% (148) were BAC apps, and 11% (44) were health promotion and/or stop drinking–related apps. When testing the BAC apps, there was wide variation in results, with apps tending to overestimate BAC scores compared with recorded scores. Participants were skeptical of the accuracy of BAC apps, and there was an overall concern that these apps would be used as a form of entertainment, further encouraging young people to drink, rather than reduce their drinking and risk taking.

Conclusions: The majority of popular alcohol-related apps encouraged alcohol consumption. Apps estimating blood alcohol concentration were widely available but were highly unreliable. Health departments and prominent health organizations need to endorse alcohol smartphone apps that are accurate and evidence-based to give specific apps credibility in the ever-expanding market of unregulated apps.

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KEYWORDS

alcohol drinking; young adult; mobile phone; applications

Introduction

Excessive alcohol use is a major public health problem that stems partly from a social and cultural acceptance of alcohol consumption [1] despite the harms of excessive drinking being widely understood [2]. Social acceptability is exacerbated by the prevalence of alcohol marketing and promotion; young people are particularly vulnerable to regular exposure to alcohol marketing through the mass media [3]. Evidence suggests that exposure to alcohol advertisement campaigns is associated with an earlier onset of drinking and an increased level of consumption [4-6]. As well as traditional forms of advertisement, such as television and print, alcohol is increasingly being promoted through digital platforms such as social media (eg, Facebook, Twitter) [3].

Young people are prolific users of digital technologies [7]. Smartphones have revolutionized mobile communication technology by offering users Internet access and computerized functions on their mobile phones. Smartphones allow users to download applications ("apps")—programs that are designed specifically for smartphone operating systems. In 2012, Apple reported that over 25 billion apps had been downloaded from its Apple iTunes store, and Google Play (Android's app store) reached 15 billion downloads [8,9].

While recent evidence suggests smartphone apps offer a number of possibilities for health promotion activities [10-13], young people may also be exposed to apps with incorrect or poor quality information, since, like the Internet, apps are mostly unregulated. Little is known about the quality of alcohol-related apps or what influence they may have on young people's behavior. A comprehensive literature search identified only one published study investigating alcohol-related apps available in the Apple iTunes store. This study analyzed available apps that addressed alcohol use, treatment, and recovery and found that while a number of apps encouraged alcohol use, few addressed behavior change; this study did not look in detail at the use or acceptability of alcohol-related apps [14]. Studies of apps in other health areas have also identified apps providing health information of varying accuracy to users [12,13,15,16]. The purpose of the current study is to review the most popular alcohol-related smartphone apps and to explore young people's opinions of these apps.

Methods

Phase 1: Descriptive Analysis of Smartphone Apps

The first phase of the three-phased mixed method approach involved a content analysis of smartphone apps. The term "alcohol" was used to search Apple iTunes and Android Google Play stores in April 2012 using the stores' default search algorithms. The top 250 apps from each store were included. The following data were extracted for each app from the stores: category as defined by the app store (eg, medical, education, entertainment, health and fitness, lifestyle), ranking (position in search results), user star rating (eg, the average number of stars given to apps by users), cost, and seller name.

A coding scheme was developed that categorized the framing, focus, purpose, consequences, attitude, and recommendations of each app. This coding scheme was developed specifically for this study, using a recent study on media reporting of illicit drugs as a template [17].

Each app was downloaded to a smartphone and reviewed by a researcher (EW) between July and November 2012; 20% of apps were reviewed by a second researcher (ML) to check for coding consistency; 9% had a coding discrepancy.

Apps were classified according to their overall purpose: those that calculated a score for the amount of alcohol in the blood or breath were classified as "Blood Alcohol Concentration (BAC) apps", apps that provided health information or supported reducing drinking were classified as "health promotion or antidrinking apps", and all other apps, including drinking games, cocktail recipes, and bar-finders, were classified as "entertainment apps".

Phase 2: Testing of BAC Apps

The second phase of the study involved testing the accuracy of BAC apps with reference to the Australian legal limit for driving (0.05% BAC). Apps were tested using data collected from a prior field-based study conducted in Melbourne. The Patron Offending and Intoxication in Night-Time Entertainment Districts (POINTED) study aimed to measure drinking practices of patrons in entertainment precincts across five Australian cities and included BAC collection [18]. Data from four randomly selected POINTED participants (including gender, age, number of drinks consumed, and hours spent drinking) were entered into each app to calculate a blood alcohol reading. Participants' height and weight were not recorded as part of the POINTED study, so these were estimated using average values for an Australian male or female at that age [18,19]. Scores from each app were recorded and compared to the actual measured scores for each participant from the field-based study when a standardized Breathalyzer was used.

Descriptive analysis was conducted and 95% confidence intervals were determined using Stata 11.

Phase 3: Focus Group Discussions With Young Smartphone Users

The third phase of the study was informed by the content analysis of smartphone apps and the testing of the accuracy of BAC apps. Two focus group discussions explored how young people engage with alcohol-related apps. Approval was granted by the Alfred Hospital Human Research Ethics Committee.

Participants were recruited from a cohort of festival attendees involved in a previous study about risk-taking behavior [20] who had agreed to be contacted for involvement in further research. Participants could also refer friends to participate. All participants were aged between 18 and 30 years old, drank alcohol at least occasionally, had their own smartphone, and provided written consent to participate. Participants were provided with refreshments during the focus group and reimbursed AU$40 for their time and travel costs.

Two focus groups were conducted, with a total of 12 participants (5 males and 7 females). Focus groups were held in a private meeting room at an urban Melbourne site with 2 researchers present and lasted between 60 and 90 minutes.

A focus group schedule was developed to explore participants' opinions of alcohol-related apps and what, if any, impact they believed the apps would have on young people's behavior. Participants were asked about previous use of apps and their opinions of these apps in general. Participants were asked to test a selection of BAC apps identified in Phase 1 of the study (by entering details such as their gender, age, and number of drinks typically consumed) and to then reflect on their usability, trustworthiness, accuracy, and how they believed they would be received by other young people. Finally, they were asked whether they thought an alcohol health promotion app would be an effective way of engaging with young people about risky drinking behavior and if so, what sort of information would be useful to them in an app.

Focus groups were audio recorded and transcribed. Interview transcripts were managed using NVivo 10 and were analyzed thematically.

Results

Descriptive Analysis of Smartphone Apps

Of the 500 alcohol-related apps, 36 were considered not relevant (ie, they did not have an alcohol focus), 52 were no longer available to download or were not compatible with the study phones, and 28 were duplicates. Of the 384 remaining apps, entertainment apps were the most common (50%, n=192), followed by BAC apps (39%, n=148), and health promotion and/or stop drinking–related apps (11%, n=44) (Table 1). Of the 192 entertainment apps, 67 (35%) were drinking games, 60 (31%) were drink-making recipes, 17 (9%) were bottle shop/bar finder apps, 13 (7%) were brewing or collectors tools, and the remaining 35 (18%) included alcohol-related jokes, brand-specific apps, other entertainment (eg, ringtones), or hangover advice. Of the 43 health promotion and/or stop drinking–related apps, 23 (53%) had a health promotion/information focus (eg, provided information on the effects of alcohol on the body, outlined alcohol laws, or described detoxing) and 20 (47%) were hypnosis or motivational apps to help with stopping drinking. The hypnosis apps used audio recordings to encourage the user to relax while simultaneously delivering persuasive antidrinking messages. Screenshots of some example apps (Let’s Get WASTED! by DDW!; Blood Alcohol Calculator by CITYJAMS; Drink Thin by 2099, LLC; and Alcohol Liver Disease by EXPANDED APPS, INC) from each category are shown in Figures 1-4.

Table 1. Description of alcohol-related apps.

Variable		Blood alcohol concentration (BAC)	Health promotion	Entertainment	Total
Number of apps, n (%)		148 (39)	44 (11)	192 (50)	384 (100)
Store					
	Android	100 (68)	32 (73)	75 (39)	207 (54)
	Apple	48 (32)	12 (27)	117 (61)	177 (46)
Attitude towards alcohol					
	Positive	10 (7)	1 (2)	86 (45)	97 (25)
	Negative	2 (1)	34 (78)	4 (2)	40 (10)
	Neutral	136 (92)	9 (20)	102 (53)	247 (65)
Cost of app					
	Free	104 (70)	19 (43)	130 (68)	253 (66)
	< $1	23 (16)	9 (21)	34 (18)	66 (17)
	≥ $1	21 (14)	16 (36)	28 (14)	65 (17)
App store category					
	Entertainment	31 (21)	1 (2)	39 (20)	71 (18)
	Games	0 (0)	0 (0)	20 (10)	20 (5)
	Health and Fitness	46 (31)	14 (32)	9 (5)	69 (18)
	Lifestyle	36 (24)	11 (25)	67 (35)	114 (59)
	Medical	5 (3)	9 (15)	1 (1)	15 (4)
	Tools	6 (4)	0 (0)	1 (1)	7 (2)
	Utilities	10 (7)	1 (2)	4 (2)	14 (4)
User star rating					
	Unrated	37 (25)	23 (53)	71 (37)	128 (33)
	1-3	57 (39)	6 (14)	58 (30)	124 (32)
	4-5	54 (36)	15 (34)	63 (33)	132 (34)

Entertainment apps were more likely to be on Apple (61%) than Android (39%); BAC apps were more likely to be on Android (68%) than Apple (32%). Most apps on Android were free to download (64%), whereas 65% of Apple apps had a cost associated with downloading. While it was not possible to determine the country of origin for most apps, the most common country of origin identified was the United States (9%).

The most common negative alcohol-related consequence mentioned was physical health (9% of all apps), followed by mental health (8%), crime (4%), and social consequences (3%). Other negative consequences described in the apps were weight gain, death, road trauma, reputation, and financial. The most common positive consequence mentioned for drinking alcohol was the social aspect (12%), followed by taste (8%). Recommendations were rarely expressed by apps, but the most frequent were to not drink (3%), to reduce drinking (2%), and to wait before driving (2%). Twenty-nine per cent (n=111) of all apps and 46% of BAC apps (n=68) had disclaimers generally stating that the app was for entertainment purposes only or that the information provided was an approximation only. See Table 2.

Table 2. Data extracted from each app.

Variable		Description
All apps		
	Country of origin	Free text (if known)
	Main focus (only those classified as "alcohol" were reviewed further)	Alcohol; Duplicate (of an already reviewed app); Unavailable (or could not be downloaded); Other (Other classified as apps that merely mentioned alcohol in their content but did not have an alcohol focus)
	Alcohol type	Beer; Wine; Spirits; General; Non-specific; Other
	Presence of any disclaimer	Free text
	Purpose of app	Alcohol brand specific; Alcohol health promotion info; Alcohol health service info; Alcohol-related jokes; Alcohol-related facts; Alcohol units consumption tracker; Blood alcohol content calculator; Brewing or collection tool; Drink-making recipes; Drinking games; Stop drinking tool; Alcohol health promotion information; Find bar/bottle shop; Other advice (eg, legal); Hangover advice
	Negative consequences	Criminal; Death; Dependence; Financial; Hangover; Physical; Mental; Violence; Sexual; Road Trauma; Other
	Positive consequences	Fun; Taste; Social; Health; Other
	Overall attitude to alcohol	Positive; Negative; Neutral
	Recommendations	Don't drink; Reduce drinking; Don't drive; Wait before driving
BAC apps		
	Variable input	Gender; Age; Weight; Hours; Number of drinks; Physical activity; Food and Water; Other
	Drink measurement	By alcohol volume; By alcohol content and volume; By unspecified "standard drink"; By specified "standard drink"; By type and volume of drink; By unspecified "Number of drinks"

Figure 1. Let's Get Wasted! screenshots showing the way that data are entered and interpreted in the entertainment app.

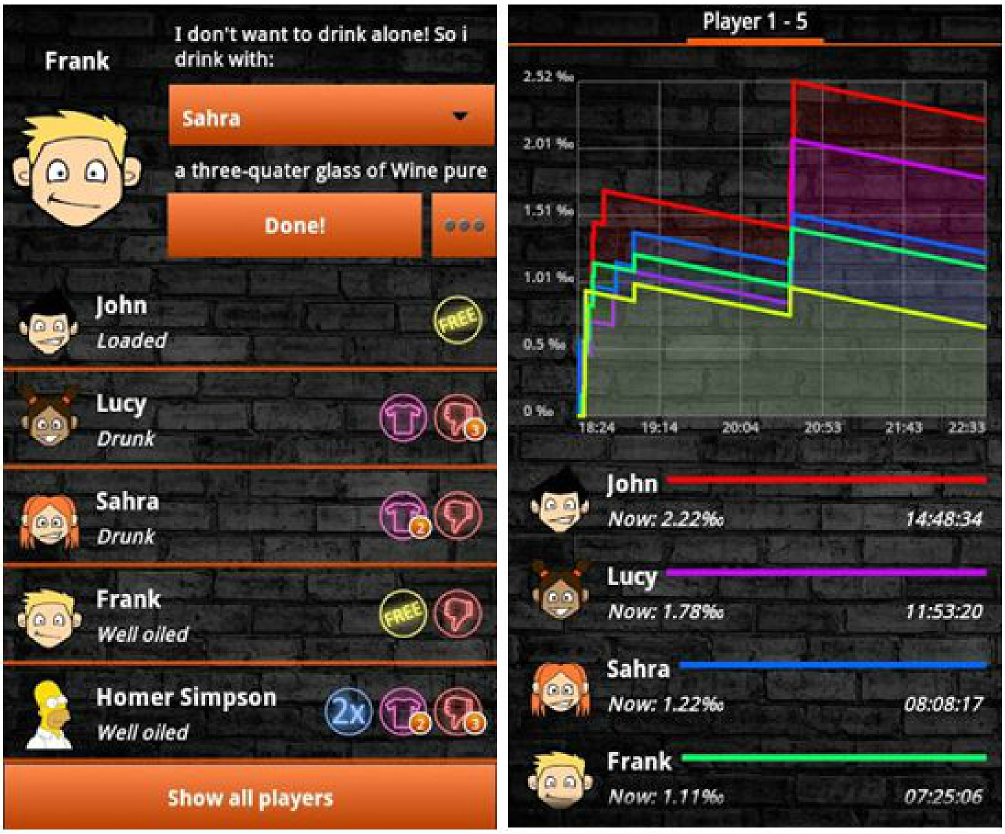

Figure 2. BAC screenshots showing a list from which users choose their drink and its alcohol content and how the BAC score is presented to users.

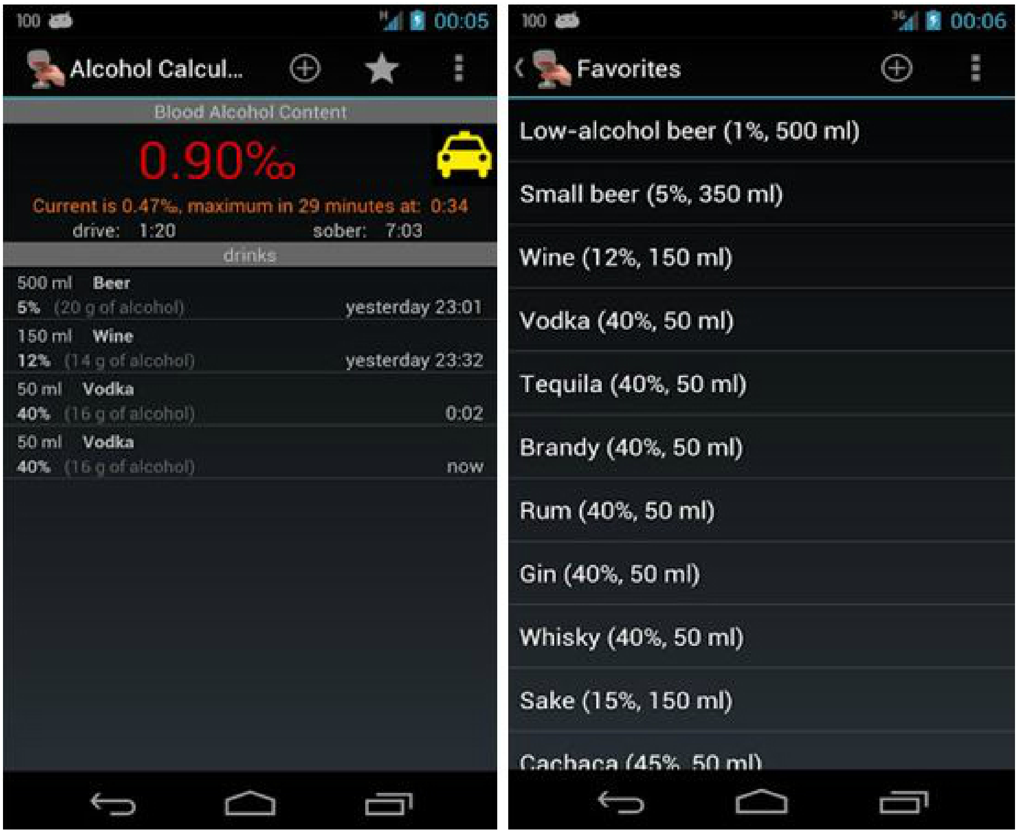

Figure 3. Drink Thin screenshots demonstrate the quality of information provided from an app categorized as a health promotion app.

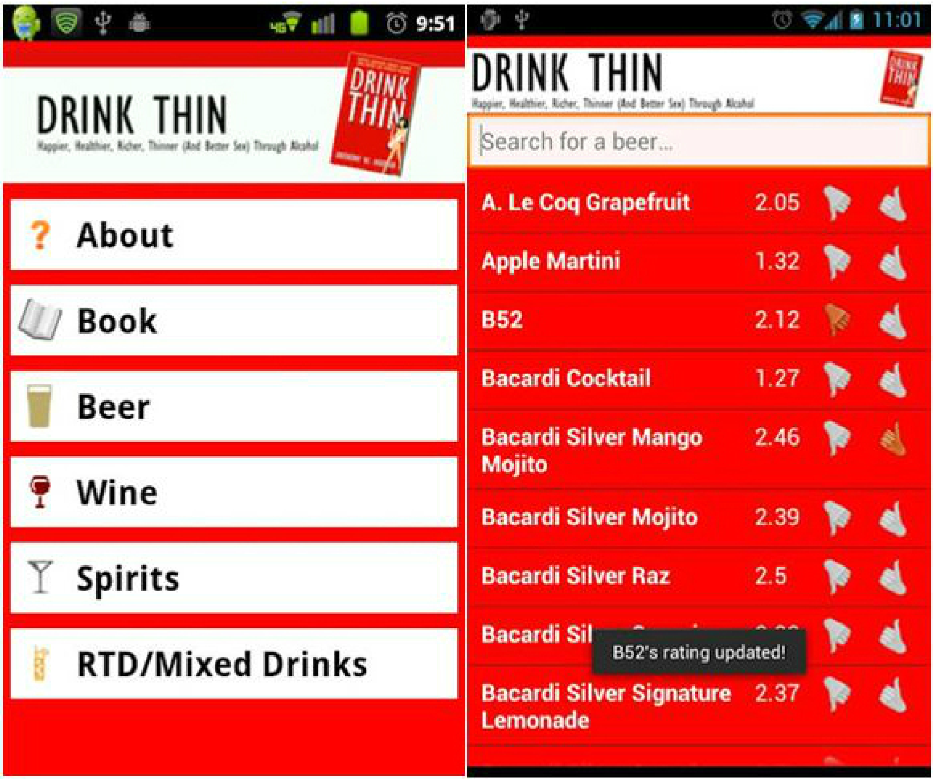

Figure 4. Screenshots from the Alcohol Liver Disease app demonstrating the content presented in health promotion apps.

Testing of BAC Apps

A total of 98 BAC apps were used to test scenarios; 50 BAC apps were not included due to being a duplicate, unavailable, or not operational. Variables required to produce a reading varied across apps: 94% of all apps required gender, weight, and number of drinks. In addition, 68% required length of drinking session, 15% required age, 7% required information about food or water consumption, and four apps asked about recent physical exercise. Forty per cent of BAC apps measured drinks consumed by alcohol content and volume (eg, one 100 mL drink with 10% alcohol content), 31% by unspecified “number of drinks”, 19% by type and volume of drink (eg, two glasses of beer), and 14% by “standard drinks”. Fifteen apps purported to estimate BAC using a fingerprint scanner or asked users to blow air on the phone.

When entering the profile information extracted from the POINTED study, we found that different BAC apps gave a very wide range of BAC results (Table 3); this is likely due to different algorithms being used [21]. For example for Profile 1, BAC estimates ranged between 0.001 and 0.91. Most overestimated the BAC for each scenario. For example, Profile 1 involved an 18-year old male who reported having five standard drinks over a 2-hour period. In the field, this participant recorded a BAC of 0.03; when this information was entered into the BAC apps used, a mean BAC score of 0.148 (95% CI 0.118-0.178) was produced. Eighty-nine per cent of apps gave Profile 1 a higher BAC than the calibrated Breathalyzer. BAC apps that collected more data showed greater accuracy—in Profile 1, apps that required gender, weight, and number of drinks had a mean BAC score of 0.59 (SD 1.7), whereas those that required these inputs and hours of drinking had a mean BAC score of 0.30 (SD 0.32).

Table 3. Blood alcohol content calculator app scores using four profiles from the POINTED study.

Variable	Profile 1	Profile 2	Profile 3	Profile 4
Profile characteristics				
Sex[a]	male	female	female	male
Age[a]	18	23	19	39
Estimated weight, kg	70	60	58	82
Length of drinking session, hrs[a]	2	4	1	4
Type of drinks consumed[a]	white spirits	wine + cider	punch	dark spirits
Number of standard drinks[a]	5	16	6	7
Recorded BAC[a]	0.03	0.05	0.08	0.11
App testing				
Number of apps entered into[b]	98	96	95	93
Mean BAC [c]	0.148	0.648	0.220	0.163
95% confidence intervals[c]	0.118-0.178	0.359-0.937	0.186-0.254	0.129-0.197
Median BAC [c]	0.102	0.405	0.19	0.122
Minimum [c]	0.001	0.04	0.0002	0.0002
Maximum [c]	0.91	13.476	1.0179	0.85
Standard deviation	0.149	1.426	0.165	0.164
Apps giving score higher than calibrated Breathalyzer[a], n (%)	87 (88.8)	90 (93.8)	81 (85.3)	49 (52.7)
Apps giving score over the legal driving limit [d], n (%)	83 (89.2)	90 (98.9)	84 (93.3)	76 (86.4)

[a]Information self-reported in a Melbourne field-based study. BAC calculated by a calibrated Breathalyzer.

[b]Number of BAC apps varies for each profile as some apps had restrictions on how they could be used. For example, if you first entered your profile as a male, you were unable to change the profile to be female; multiple users could not use the app at the same time due to a time delay.

[c]Data calculated by BAC apps.

[d]Limit for legal driving in Australia is 0.05.

Focus Group Discussions With Young Smartphone Users

Health and Alcohol-Related App Use Among Focus Group Participants

Focus group participants generally had experience using health-related apps, with exercise apps such as tracking your run/cycle and gym workout being the most popular. Many participants had also used alcohol-related apps, all of which fell into the entertainment category (including bar trackers, bottle shop finders, drinking games, "happy hour" finders, and cocktail recipe apps). No participants reported personal use of BAC apps, although when prompted, 2 participants reported that they had seen them used by friends.

Utility of BAC Apps

Young people generally viewed BAC apps as games or forms of entertainment rather than as health promotion or education tools. One suggested that these apps would encourage competition between friends and possibly encourage them to get drunk: "If I had one of them, I'd be with my mates and it would be like 'who can get the highest score?' You'd just get smashed!" Participants were, however, receptive to the idea of alcohol-related apps and felt that they could serve a variety of useful purposes, such as preplanning for a night out or informing decisions about whether it was safe to drive. One participant commented: "If you're just using it to see if you can drive or not, which means that you won't be that drunk, and you kind of have the capacity to put it all in accurately enough to get a good idea of whether or not you should be driving—that's good."

Despite this, issues of trust and skepticism were raised by participants. Participants recognized that the apps were not necessarily accurate, noting that "there are so many confounders...like it's not just weight and height." The difficulties of accurately monitoring alcohol consumption were also noted: "It's hard for it to be completely accurate, unless you're tracking 'I had this and it has this much alcohol in it, and I've had this and it has this much alcohol in it', because no one measures standard drinks when you're out." Furthermore, some participants were wary of the potential negative effects, where people would intentionally drive because of app results, even when they knew they should not. One participant described an experience where a friend had used a BAC app and then driven home: "It was so bad." Another participant stated: "People would just use it as a way to justify their actions."

The overall concern among participants was that BAC apps would encourage young people to drink, rather than reduce their drinking. One participant stated: "I think it's a bit dangerous, as afterwards it gives you your blood alcohol content, you can drink more and it tells you how much more you can drink, until you can drive so that's wrong. If you follow that, you're in trouble." Some were concerned that the information provided would mislead young people, as highlighted when one participant stated: "If you're using it and you have a low blood alcohol, and you're already pretty drunk, you'd be like, 'I've got low blood alcohol. I can just keep drinking' or 'I can drive home'…If it's inaccurate, it can just be really dangerous."

When testing BAC apps, participants generally thought apps that were preprogrammed with type of drink (eg, beer/wine) were easier to use than those asking for a specific volume or percentage of alcohol. Some found the apps difficult to use because of imperial rather than metric measurement, the detail of information required, or the layout of the app. One participant commented: "We couldn't figure out how to end the drinking session [in the app]. And we're sober and trying to figure out how to use the app and so what are you going to do when you're already drinking?!"

Suggestions for Future Health Promotion Apps

Safety while drinking alcohol was the key concern among focus group participants, and apps were identified as being able to play an important role in promoting this. One participant stated, "It's just about keeping safe while you're drunk" and another suggested that an app that was like "a little book of how to get out of drunken situations" could be helpful. Participants identified that an app offering essential services to young people "when you're panicked" is what is needed. Apps that could provide information on "where good spots are to get cabs" or in situations where "friends have had too much to drink…and you don't know what to do" would be useful. Sexual health information, referrals to appropriate health services, and hangover advice were also areas of interest for a new health promotion app. One participant thought an app that had both a benefit to people while drinking as well as a longer-term benefit, such as an app that told you to "keep drinking water—don't be hung over in the morning", would be of interest. Participants felt there was a need for such an app as this kind of information is not provided at school, and an Internet connection is often not reliable when in a nightclub so having an app that does not rely on the Internet ensures people have the information with them.

Discussion

Principal Findings

To date, only one other study has been published that explored alcohol-related apps [14]; the current study is the first study to our knowledge to critically review alcohol-related apps on both Android's Google Play and Apple's iTunes stores. This is also the first study to specifically study the accuracy of BAC apps and to explore their use and acceptability among young people. Our study found that half of alcohol-related apps reviewed were classified as entertainment apps that endorsed drinking, 30% were BAC apps, and a minority (11%) were classified as health promotion apps.

Testing BAC apps suggested that these apps not only overestimated BAC level but also provided an extremely wide variation in scores. This could be because apps did not collect all the necessary data to accurately calculate a BAC level, such as height, age, and hours spent drinking, or because their method of calculation was flawed. Alcohol consumption was also not collected in a standardized manner. BAC apps that collected more data displayed greater accuracy and consistency in their scores. Some apps did not even collect data but simply provided a random BAC when users blew air onto the smartphone. Reassuringly, participants in the focus group discussions were skeptical of these apps, recognizing the number of variables that could affect their accuracy, including their own self-reporting of number of “standard drinks” consumed. Current literature suggests that the accuracy of self-reporting alcohol consumption depends on the social context in which it occurs [22,23]. Participants agreed that peer pressure would often prevent accurate or sensible use of these apps and could further fuel heavy drinking among some groups.

Worryingly, many BAC apps gave a specific time at which users were able to resume driving after a drinking session. While participants thought this was useful for planning their night out, they also identified that BAC apps failed to recognize variations between countries; it was often unclear in which country apps were developed and therefore the legal limit being referenced. Many users may have their provisional license and according to Australian law must have a BAC of 0.0% when driving [24]; hence, following the advice of these apps would potentially lead to breaking the law. Another factor influencing the accuracy of the information produced was how data were entered; participants found some apps difficult to use, such as when entering the alcohol volume consumed. Many BAC apps (54%) also had no disclaimer warning that they may not be valid or reliable. This may increase the risk of users perceiving the output to be accurate.

Entertainment apps including drink recipes, drinking games, and bar finders dominated the app stores and were the only type of app previously used by participants. Given this, it is reasonable to assume young people are more likely to download apps that encourage drinking rather than apps designed to reduce drinking and/or harm. This has also been noted as an issue in tobacco use; in a recent review of tobacco apps, researchers found that 107 pro-smoking apps were very popular, having been downloaded by over 6 million users [15]. Research has shown that drinking games encourage excessive alcohol consumption and are associated with several negative alcohol-related consequences [25]. Only 44 health promotion apps were reviewed as part of this study. Of concern is that some of these apps gave the impression of promoting health messages when in fact they were inaccurate in content. Some were categorized as “Medical” or “Health & Fitness” apps in the app stores, reinforcing their false legitimacy to users. For example, the app named “Drink Thin” (Figure 3) was categorized as a “Health & Fitness” app, despite promoting health and weight loss through drinking *more* alcohol. Poor categorization of apps, particularly of those wrongly claiming to provide legitimate health messages, was also noted by researchers investigating the pro-smoking apps [15].

Limitations

This study had limitations. First, participants in the focus groups were a small sample with relatively homogenous characteristics and so may not represent the views of all young people. Second, the accuracy of data from the POINTED study may be subject to social desirability or recall bias, as all data, excluding the BAC score, were self-reported [18]. Finally, using the term “alcohol” to search app stores for alcohol-related apps may have limited our search but was justified given this was a pilot project and the large number of apps retrieved using one search term; multiple terms such as “drinking” could be explored in future research.

Conclusion

In 2012, the number of people downloading health-related apps reached 247 million [26]. Smartphone apps are clearly growing in popularity and will play a key role in the future of health promotion initiatives. Studies have proven the effectiveness of using mobile phones in health promotion [10,20], and smartphone apps are shown to be effective in managing people suffering from long-term illnesses and alcohol dependence by offering support, resources, and information [27]. Health departments and prominent health organizations need to move with the current climate and endorse quality, evidence-based apps to give specific apps credibility in an ever-expanding, unregulated market, as is being done by the Australian Drug Foundation [28]. Apps developed by health professionals need to be innovative, useful, desirable, and fun in order to compete with apps encouraging unhealthy behaviors. While young people in our study displayed skepticism about the quality and accuracy of apps, emphasis should be placed on raising awareness of fraudulent or inaccurate apps. App stores could also play an important role in regulating the quality of available apps, by ensuring all apps have an appropriate disclaimer and/or age limit and are categorized appropriately.

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Conflicts of Interest

Conflicts of Interest: None declared.

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Abbreviations

BAC: blood alcohol concentration
POINTED: Patron Offending and Intoxication in Night-Time Entertainment Districts

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