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Contents

Original Papers

Development and Acceptability of a Co-Produced Online Intervention to Prevent Alcohol Misuse in Adolescents: A Think Aloud Study (e13)
Emma Davies, Jilly Martin, David Foxcroft. . . . 2

Participatory Research as One Piece of the Puzzle: A Systematic Review of Consumer Involvement in Design of Technology-Based Youth Mental Health and Well-Being Interventions (e12)
Simone Orlowski, Sharon Lawn, Anthony Venning, Megan Winsall, Gabrielle Jones, Kaisha Wyld, Raechel Damarell, Gaston Antezana, Geoffrey Schrader, David Smith, Philippa Collin, Niranjan Bidargaddi. . . . 14

Usability Testing of a Complex Clinical Decision Support Tool in the Emergency Department: Lessons Learned (e14)
Anne Press, Lauren McCullagh, Sundas Khan, Andy Schachter, Salvatore Pardo, Thomas McGinn. . . . 34

Assessing the Usability of Six Data Entry Mobile Interfaces for Caregivers: A Randomized Trial (e15)
Frederic Ehrler, Guy Haller, Evelyne Sarrey, Magali Walesa, Rolf Wipfli, Christian Lovis. . . . 46

Original Paper

Development and Acceptability of a Co-Produced Online Intervention to Prevent Alcohol Misuse in Adolescents: A Think Aloud Study

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Abstract

Background: The prototype willingness model (PWM) may offer an appropriate basis for explaining and preventing adolescent alcohol misuse. An intervention was developed using a co-production approach, and consisted of an online quiz featuring 10 questions linked to the PWM.

Objective: This study sought to determine the acceptability and relevance of the intervention content to young people, to incorporate their feedback into a final version.

Methods: A qualitative think aloud study with follow-up semistructured interviews was undertaken with 16 young people aged 11-15 (50%). Transcripts were analyzed using thematic analysis.

Results: The following 3 main themes relating the acceptability of the intervention were identified: “challenging expectations of alcohol education”; “motivations for drinking or not drinking,” and “the inevitability of drinking.” Participants found the intervention appealing because it was counter to their expectations. The content appeared to reflect their experiences of social pressure and drinking encounters. There was evidence that a focus on drinker/nondrinker prototypes was too narrow and that because adolescents perceived drinking as inevitable, it would be challenging to enact any plans to resist pressure to drink.

Conclusions: An online intervention based on the PWM has the potential to engage and interest adolescents. A wide range of alcohol prototypes should be targeted and a focus on short-term harms should ensure that the intervention is credible to young people.

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KEYWORDS

adolescents; alcohol; intervention development; prevention; think aloud

Introduction

Overview

Underage alcohol consumption is higher in the United Kingdom than in other parts of Europe [1] and evidence suggests teenagers aged 11-15 who consume alcohol are at risk of short-term harm [2,3] and later dependence [4]. National surveys suggest that the number of young people in England aged 11-15 who report ever having tried alcohol is falling [5]; however, other evidence suggests that those who do drink tend to consume harmful quantities [6,7]. This evidence points to a need for the development of effective intervention measures to reduce adolescent alcohol misuse and associated harms.

Many interventions aimed at adolescents rely on popular models, such as the theory of planned behavior (TPB) [8], which rest on assumptions of reasoned decision making and

intention-driven behavior. However, there is often a discrepancy between what people intend to do and what they actually do [9,10]. This "intention-behavior gap" is particularly problematic in explaining adolescent health risk behaviors [11]. In support of this, a recent meta-analysis suggested that adult alcohol intentions might be better accounted for by the TPB than adolescent alcohol intentions [12]. This may be because adolescence is characterized by high levels of impulsivity, which is linked to risk-taking behaviors, such as drinking alcohol [13], and tends to peak between the ages of 13 and 19 [14,15]. Drinking at this age tends to occur in social situations where peer influences are strong [16,17] and may provide a challenge to the developing brain [18].

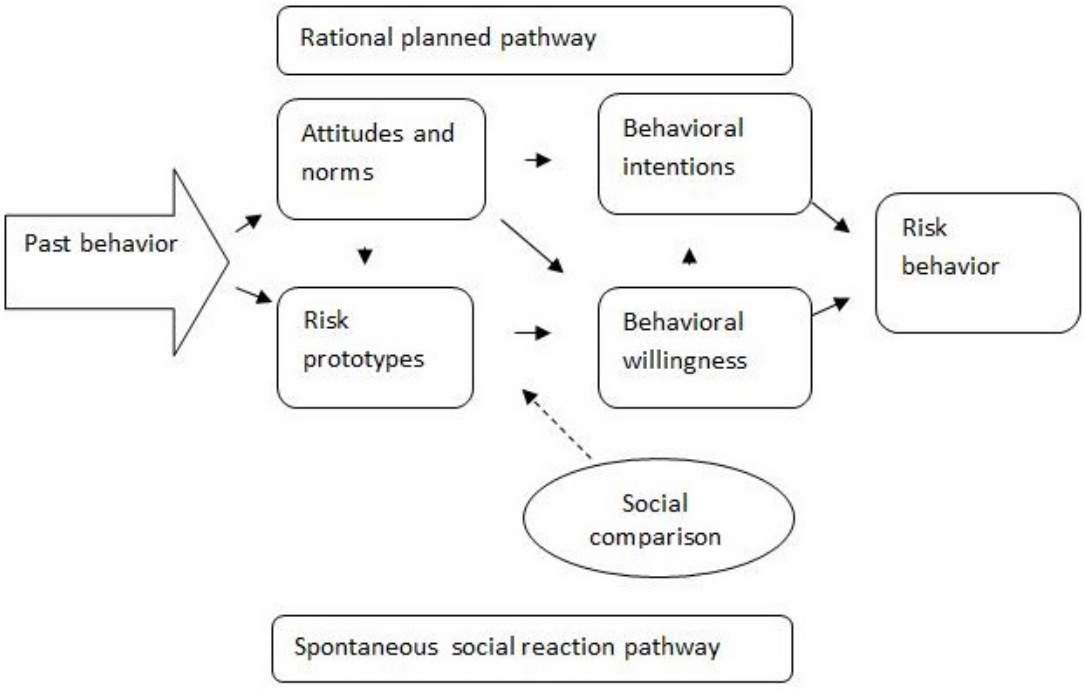
Some evidence suggests that theory-based health behavior change interventions tend to have larger effect sizes than those that are not theory based [19]. However, a recent meta-analysis suggests that some theory-based interventions may fail to appropriately target each construct within the selected theory, and furthermore, not all behavior change techniques (BCTs) are linked to theory [20]. It is therefore essential to identify an appropriate theoretical basis for an intervention to reduce alcohol misuse in adolescents, and to ensure that it is appropriately applied within the intervention.

Prototype Willingness Model

The prototype willingness model (PWM) [21,22] accounts for adolescent health risk taking on the basis that this type of behavior is driven by social reactions to risk-conducive situations, as well as intentions (Figure 1). In common with other dual process models, there are 2 routes to behavior within the PWM: the first, a rational, planned route via intentions, and a second reactive pathway, which is a faster, more spontaneous route, operating outside of conscious control [22]. The spontaneous pathway considers that for young people, risky behaviors tend to occur in a social context and are often unplanned [23]. Within this pathway, the images or "prototypes" that young people have about typical people of their age who drink or abstain from drinking are influential for "willingness" to consume alcohol. This is due to the importance of self-image and social comparison in adolescence [17].

Previous research has shown that the PWM is able to offer a good explanation for risk behaviors, such as alcohol consumption, in young people [24-26]. Studies have also shown that the PWM may offer a suitable basis for an intervention (eg, substance misuse [27] and physical activity [28]). A number of studies have applied this model to alcohol consumption in the United Kingdom, by university students [29] and adolescents aged 16 [30]. However, there is less research that specifically examines the PWM in relation to preventing alcohol misuse in young adolescents, under the age of 16, in the United Kingdom. This study therefore sought to develop an intervention based on the PWM to explore its application to this population.

Figure 1. The prototype willingness model. Adapted from Gerrard et al [28].



Intervention Development

Intervention development has been conceptualized within a number of phases by the Medical Research Council [31]. The "development" phase within this framework covers the important process of identifying the evidence base and ensuring the intervention is clearly linked to theory, a step that is sometimes neglected [32]. To specify a clear pathway through the development phase, we set out a number of steps at the outset of the project, starting with a scoping focus group study and a survey [33,34]. A co-production approach was taken, involving input from adolescents, teachers, and parents as key stakeholders in the intervention at different stages of its development. Co-production aims to acknowledge and empower young people (and other stakeholders) through collaboration in the intervention development process [35].

There were 2 important findings from the focus group study. First, it showed that that young people in the United Kingdom were able to describe drinker and nondrinker prototypes that potentially could be targeted in an intervention. Second, the findings also suggested a distinction between "planned" drinking by older participants (aged 16-17) and "unplanned" drinking in younger participants (aged 11-13) [34]. A survey of 178 adolescents aged 11-17 was then built on these findings by exploring the relationship between prototypes, willingness, intentions, and alcohol consumption. The survey results suggested that young people aged 11-15 were likely to be a more appropriate age group for an intervention targeting prototypes and willingness than those aged 16 or 17. Furthermore, an exploratory factor analysis suggested that targeting prototype characteristics that were related to "sociability" might be an appropriate focus within the intervention [33].

Although there has been a drive in recent years to classify BCTs according to theoretical and behavioral features, at the time of development, no clear BCTs related to the PWM had been specifically defined and agreed. Thus, within the development of this project, we identified techniques used in 8 existing PWM interventions, comparing them with a taxonomy of BCTs [36] and identifying if they adequately reflected the assumed change processes in the PWM. This process was evaluated in a Delphi study, reported elsewhere [37], which resulted in 4 BCTs being identified that were relevant to the social reaction pathway of the PWM. Table 1 presents the identified BCTs and how they relate to the PWM.

Table 1. Logic model to specify behavior change techniques, processes, and outcomes for prototype willingness model intervention in the social reaction pathway.

Input (behavior change technique)	Process in the model	Outcome
Present information on other people's drinking to reduce perception of drinker prototype as the norm to enhance similarity to nondrinker.	Images are often based on misperceptions. Similarity to prototype drinker is strongly related to willingness and drinking.	Drinker prototype similarity decreases. Corrects norm misperception.
Present a positive nondrinker and or negative drinker prototype and enhance similarity to nondrinker.	Target prototype favorability and similarity. Enhance positive features of nondrinker. Present negative image of drinker.	Drinkers and drinking are less favorable and less similar to self. Nondrinkers and nondrinking more favorable and more similar to self.
Teach awareness of social/environmental cues to behavior (that reactive or unplanned is more risky).	Spontaneous influences on behavior may occur when young people do not plan to drink.	Young people are aware of reactive nature of their behavior.
Provide examples of how other young people resist social pressure in social situations.	Reduce unplanned behavior and decrease willingness to drink.	Young people are able to recognize and deal with social pressure themselves.

It is important to ensure that the content and format of an intervention are matched to the preferences of the intended recipients [38]. Discussions from the focus group study suggested that the participants might not be receptive to a classroom intervention delivered by a teacher [34]. Adolescents who attended schools that took part in the focus groups and surveys were consulted in the process of selecting the most appropriate means of delivering the intervention within the classroom. They reported that they preferred to engage with interactive online materials rather than written information. Furthermore, other evidence highlighted the benefits of using computer games to enhance learning within a school context [39] and that online interventions might be a useful means of reaching younger populations [40]. Research with young people suggests a familiarity with using the Internet for schoolwork, and that 46% of young people complete quizzes online [41]. A quiz format was selected as an appropriate mode of delivering the intervention because it required engagement with the content and has been used in other interventions targeting adolescents [42]. At this point, we named the intervention "The Alcohol Smart Quiz" (ASQ) in consultation with adolescents.

The quiz consisted of 10 multiple-choice questions linked to the identified BCTs. In line with previous PWM intervention research [43,44], the information in the quiz was presented as originating from a survey of adolescents who were of the same age as the intended recipients. The answers were provided as explanations from other young people talking about their own experiences. The first 5 questions targeted alcohol prototypes. For example, there were questions that require the participant to select characteristics of the typical drinker or nondrinker who is of the same age as they are. The second 5 questions targeted social pressure and unplanned drinking. This part included questions and answers where young people describe that they resist pressure to drink by making a plan in advance of what they will say if they are in a social situation where alcohol is

present. The quiz materials are available from the main author on request.

Think Aloud

In a think aloud study, participants are required to talk out loud about what they think as they complete a task or a questionnaire. Think aloud interviews have been widely used in psychology as a method of cognitive interviewing [45,46]. For example, French et al [45] used this method to explore what participants understood when reading TPB questionnaires. Think aloud interviews have more recently been used by intervention designers who saw the potential of this method in contributing to an understanding of how users interpret theoretical techniques and relate intervention content to their own experiences [47,48]. This method is also useful for ensuring that the terminology used is understandable to particular samples [47]. It therefore offers an appropriate method of gaining feedback from young people.

The overall aim of this study was to explore adolescent views about the ASQ intervention to determine the acceptability and relevance of the content to young people, and to incorporate their feedback into a final version, as part of the development process.

Methods

Participants

There were 16 participants; 8 boys and 8 girls aged from 11-15 (in year groups 6-11 in the English school system). The participants attended 12 different schools in the South East of England. Interviews were conducted and analyzed until data saturation was reached. Participants were recruited through advertisements to parents and offered a £10 voucher to thank them for taking part. The study received ethical approval from Oxford Brookes University (reference number 120619).

Materials

A paper version of the intervention was constructed using a printed and laminated PowerPoint slide to represent each page of the website. This was presented on a document stand so that participants could flip between pages. A paper version was used so that changes could be made to the content following the study before utilizing funds to build the website. Paper versions of online interventions have been used in similar studies [47]. The pages represented the quiz questions, and answers are presented with pictures of young people of a similar age depicted as giving answers to the questions (see Multimedia Appendix 1). Participants were informed that once the intervention is available online, videos of real people would be used to provide the answers.

Think Aloud Interviews

Interviews took place in a quiet room on university premises and consent was obtained from both the parent and the participant. At the start of the session, the researcher checked the parent had talked about the study to the participant and if they were happy to proceed. The interviewer read out some standardized instructions and demonstrated thinking aloud by completing a similar task, which involved answering questions in a quiz about favorite foods. Participants then worked though each page of the intervention and were prompted to tell the interviewer what they thought of each question. This was followed with some semistructured interview questions to explore factors related to intervention acceptability (Textbox 1). Interviews lasted between 25 and 40 minutes, were audio recorded, and then fully transcribed.

Textbox 1. Semistructured interview schedule of follow-up questions used in think aloud study.

Overall views about the quiz

- What did you think of the quiz?
- Was it easy to understand what you have to do?
- What would you think if you were given this quiz to play at school? At home?
- What improvements could you make?

What did you think about the answers?

- Some of the questions talked about how drinkers and nondrinkers were described—what did you think about the answers?
- What do you think about the answers on peer pressure?
- There were some questions about making plans—what did you think about them?

Learning about alcohol

- What do you think that other people of your age would think about this?
- Is a quiz or a game a good way to find out information about alcohol?
- Have you seen anything similar? Can you tell us about it?
- Are there any other good ways to find out information about alcohol?

Ending questions

- Do you have anything else you would like to add about the materials you have seen, or the topic we have been talking about?

Analysis

Transcripts were subjected to thematic analysis using the stages set out by Braun and Clarke [49]. During familiarization, the transcripts were read and re-read and ideas for codes were noted. An initial set of 36 codes was identified and applied across the dataset. These codes were reviewed during the search for themes resulting in some being merged or renamed. Other codes were combined to form overarching themes relating to the dataset. An initial thematic map consisting of 3 main themes (relating to "expectations about alcohol education," "perceptions of drinking and drinkers," and "experiences with alcohol") was generated. Each theme had a number of related subthemes. This thematic map was developed through testing with the data and discussion between all authors until an agreement was reached on a final set of themes relating to "challenging expectations of alcohol education," "motivations for drinking or not drinking," and "the inevitability of drinking" (Table 2).

Results

Themes and Subthemes

In line with other intervention development research employing the think aloud method [48], this paper focuses on the themes in relation to positive and negative features of the ASQ, because of their implications for intervention development. Supporting quotes for each theme and subtheme are presented using pseudonyms and indicating the sex and age of the participant.

Table 2. Themes and subthemes related to aspects of the acceptability of the Alcohol Smart Quiz identified in analysis of think aloud interviews.

Main theme	Subtheme
Challenging expectations of alcohol education	A different mode of delivery
	This is not "the usual message"
Motivations for drinking or not drinking	Experiences of pressure
	Consequences of drinking
	Perceptions of drinkers
The inevitability of drinking	Normative nature of "drinking as cool"
	Barriers to making plans in the real world

Challenging Expectations of Alcohol Education

Overview

The theme "challenging expectations of alcohol education" encapsulates the participants' responses to the ASQ as something unexpected when compared with their experiences of alcohol education in school, as well as what they had been told by parents and other adults. These expectations appeared to be related to both the format and the content of the intervention.

A Different Mode of Delivery

The online mode of delivery and the quiz format appeared to be well received by the participants in this study. In particular, they liked that it was presented as an online game with interactive features.

> *I like it because, if it is just something written down, then that would be boring, but having it as a game is more interesting.* [Archie, m, 14]

It was also favorably compared with school-based alcohol education, where a teacher might stand up at the front of the class and present information.

> *If you get a teacher to talk to the students about alcohol, then no-one is going to say anything because they are with their friends.* [Lucas, m, 15]

There was also support for using video clips of young people presenting the answers to the quiz once the ASQ had been put on a website because participants felt that people of the same age would be easier to relate to than a teacher. Furthermore, presenting the information as a quiz with a number of possible options appeared to be a positive feature.

> *If you just tell someone a fact, they won't think for themselves, but here if you get it wrong then it makes you think.* [Matthew, m, 13]

This Is Not "the Usual Message"

Intervention content seemed to be different to the information that the participants had expected. They appeared surprised to find out that the number of young people aged 11-15 who reported drinking alcohol has fallen in recent years. This unexpected content may have challenged their preconceptions that "everybody drinks." As this was the first question, it seemed to set the scene that they were not going to hear the usual messages about drinking and that this might be something different.

> *Quite often, in school, you will get told "don't drink, or you will die" sort of thing, which isn't that helpful.* [Kasia, f, 14]

The idea of making plans in advance to deal with a situation also seemed to be unexpected and something that participants found interesting.

> *Things about peer pressure, they just tell you not to give in, but this is something that you could actually do.* [Vicky, f, 13]

There was also information that seemed surprising in some of the questions about making plans to avoid drinking. In particular, most participants were apparently unaware about the amount

of calories in a bottle of wine when this was mentioned in a quiz question about planning to refuse alcohol:

> *I didn't even know you could get calories in a drink!* [Muna, f, 11]

Overall, it appeared that the topics covered in the quiz questions had the potential to capture the participants' attention, in particular because they were in contrast to their expectations.

> *If something surprises you about a subject, then it probably makes you think twice.* [Matthew, m, 13]

Motivations for Drinking or Not Drinking

Overview

The theme "motivations for drinking or not drinking" draws together the complex reasons behind alcohol consumption for the young people in this study. As expected, based on the literature, peer pressure was a common feature of the participants' talk. The consequences of drinking appeared to be described in a negative way, but this did not seem to discourage the participants or their friends. Nondrinkers tended to be described in a negative way.

Experiences of Pressure

A positive feature of the ASQ was that the content of the quiz questions and the scenarios described appeared to relate to the participants' experiences with alcohol and social pressure. Most of the participants reported feeling some pressure in relation to alcohol, as well as smoking. The presence of other people was often acknowledged as a reason for drinking.

> *If there's a lot of people around you and they're all doing it and then they're saying to do it then you are more likely to do it than if you were on your own and there was beer in the fridge.* [Lucas, m, 15]
>
> *If everyone else was doing it then you wouldn't want to be the odd one out.* [Alice, f, 12]

There was also evidence of further distinction evident in the participants' experiences of pressure, which could be either explicit and involve direct coercion

> *Oh that's so stupid and babyish if you don't.* [Emily, f, 12]
>
> *They say "don't be a pussy" and stuff.* [Natalia, f, 14]

Or could be implied pressure

> *When other people start drinking and smoking even if they don't actually pressure you, you will be pressurised even though they are not saying anything to you...because you know at some point you will lose out of the group by not doing the same thing.* [Muna, f, 11]
>
> *If you are at a party and everyone else is doing it, they could be quite persuasive, you would feel boring or antisocial.* [Vicky, f, 13]

This apparent distinction between explicit and implied pressure is important to take into account when describing social pressure to drink with the intervention.

Consequences of Drinking

A number of questions talked about the consequences of drinking, and this was another aspect that appeared to be reflective of participants' experiences. These were mainly the short-term negative outcomes, such as being sick or suffering an injury. Some participants talked about friends who had been to hospital to have their "stomach pumped out" or who had come into contact with the police. Participants appeared to focus on the negative physical or social consequences of drinking alcohol; for example, some participants talked about attending parties and seeing people who had too much to drink:

> *A girl I know didn't eat for three days before the party, she wanted to be skinny or something, yeah she was sick all night long.* [Natalia, f, 14]
>
> *I don't think people know their limits, or when to stop.* [Rachel, f, 15]

Consequences relating to short-term embarrassment also seemed important.

> *Having an embarrassing photo, that's a good answer, because everyone has Facebook now, it is likely that you would do that.* [Chloe, f, 12]

Perceptions of Drinkers

Quiz questions about prototypical nondrinkers described them as sociable, confident, and independent. Participants tended to agree with this answer and some talked about other positive characteristics of nondrinkers in response.

> *Like really cool and strong and you know being able to not drink if lots of people are drinking.* [Emily, f, 12]
>
> *I don't necessarily think they'd use these three words [sociable, confident, independent] they'd use other ones like chilled, relaxed and things like that.* [Lucas, m, 15]

However, there was some evidence within the transcripts that suggested that nondrinkers would be viewed negatively by other people.

> *At parties you know everyone joins in but then there's some people that just decide not to and then they just get sort of judged in a way sometimes cos they are the odd one out.* [Alice, f, 12]

The findings also suggest caution in the way that drinker prototypes are presented. Drinkers appeared to be perceived as cool by many of the participants:

> *There's a system, if someone is not cool, you can't hang out with them if you want to be cool too, and people think the drinkers are cool.* [Jon, m, 11]

However, there appeared to be caveats to this. Heavy drinking and drunkenness tended to be described using negative language.

> *People who have got really drunk at parties, that's not cool, it looks a bit sad.* [Kasia, f, 14]

However, drinking a little was usually described as normal by the older participants.

> *I think it is normal to have a drink, maybe a glass of cider or something, alcohol in moderation is fine.* [Matthew, m, 13]

Other comments revealed that it might be important to tailor drinker and nondrinker descriptions carefully.

> *You can't stereotype people as those who go out and those that stay at home, I am somewhere in between.* [Sam, m, 15]

These quotations suggest that a focus on moderate drinking compared with heavy or binge drinking might be more appropriate for the intervention.

Inevitability of Drinking

Overview

Regardless of the positive response from these participants toward the ASQ, there was a sense of drinking as an inevitable feature of teenage life. The theme "the inevitability of drinking" reflects the findings that alcohol was appeared to be perceived as something "cool," and as such, resisting its draw might be challenging.

Normative Nature of "Drinking as Cool"

The perception of drinking as cool was frequently identified in participants talk about the intervention as they completed the quiz questions, possibly because it was prohibited.

> *I think probably because it's actually not allowed to people like older than about 18 so it's kind of like, to be honest if someone's banned something then it makes it all the more cool if you do it.* [Jon, m, 11]

> *In the shops they have a special section for all of this tobacco and stuff like that so I think that makes it, oh look, I'm special, I'm going here too.* [Muna, f, 11]

It possible that this "coolness" contributed to participants' reasons for trying alcohol for the first time. Although they acknowledged the power of peer pressure, many participants suggested that their reasons for initially trying alcohol were out of curiosity for this "cool" and "forbidden" substance.

> *I wanted to see what it tasted like, I was just really curious cos I mean I'd tried like wine and things from a young age, it tastes horrible, it's like rat poison and suddenly like you try it at about 14 and it's rocket fuel, it's brilliant, and so then you are like oh, damn I want to try all these things, it's like an adventure of discovery.* [Sam, m, 15]

> *I would have thought that quite a lot of people would be peer pressured into it a bit but also that people would be kind of curious.* [Vicky, f, 13]

These comments suggest that it is important to take into account that young adolescents are likely to be curious about alcohol. It may be challenging to alter their perception of it as a "cool thing to do," and so a clear focus on reducing harm appears to be more appropriate than a focus on avoiding alcohol.

Barriers to Making Plans in the Real World

Although the idea of making plans to deal with pressure to drink in social situations was unexpected and positively received, there were many pieces of evidence in the transcripts that indicated participants felt unsure about whether this could really be applied in real life. First, the issue of whether you would actually be able to enact a plan:

> *I think the idea of making a plan is quite a good idea but I think it's a different matter whether you actually stick to the plan...it is quite unlikely that you will actually stick to it in the situation.* [Kasia, f, 14]

Then there was the issue that the situational pressure may prove too powerful

> *Um, if they think it is cool to drink they will laugh at you and won't listen.* [Joe, m, 12]

> *Even if you made a plan in advance, you could still be tempted.* [Alice, f, 12]

Overall, it appears that participants believed formulating plans in advance to deal with social pressure was an interesting concept, but not something that they could realistically enact in a real-life situation. This might be because the social pressure in a given situation would overwhelm any intended plans. Participants came up with a number of alternatives to making plans to avoid alcohol that they thought would be useful for drinking less in alcohol-related scenarios.

> *Maybe if you had like a friend who was like responsible...if you had an older friend then sort of arrange with them saying if I am not there at that time then I'm drunk so come and find me, something like that.* [Vicky, f, 13]

This suggests that it may be possible to encourage young adolescents to focus on plans to avoid harms from drinking, rather than plans to avoid or refuse alcohol.

Discussion

Findings

This paper presented themes and subthemes from the analysis of think aloud interviews with 16 young people. The findings demonstrate that the ASQ had a number of features that demonstrated high levels of acceptability and relevance to the target population. An intervention delivered in schools that is different to what is expected has the potential to capture young people's attention and engage them in the topic. Moreover, because the content of the ASQ related to participants' experiences of drinking and pressure, this has the potential to enhance its credibility. In particular, the focus on short-term potential harms such as social embarrassment and increased calorie consumption reflects genuine concerns.

However, the identified themes also revealed important areas where improvements to the planned intervention should be considered. First, there is a need to consider how to describe alcohol prototypes in the ASQ. Participants disagreed about how they would describe the typical person of the same age as them who drank alcohol. Younger participants described them as "sad" or "stupid" and others who were older described them as "normal." However, the evidence from the transcripts suggested that a "drunk" prototype would be seen as negative. The perception of nondrinkers was also mixed; negative views

were that they were boring or the odd one out. However, some of the participants also said that nondrinkers were sensible or relaxed, which were more positive descriptions. There is little research that explores young adolescents' perceptions of nondrinkers. Research with university students suggests that nondrinkers struggle to be accepted socially, and that a negative perception is normative in the United Kingdom [50]. In our previous focus group study with younger age groups, we found that nondrinkers were perceived as unusual or boring [34].

Second, there was evidence to suggest that although participants were generally positive about the idea of making plans to avoid pressure, they were concerned about whether this would actually be effective in practice. The planning questions in the ASQ were based on implementation intentions, or "if-then" plans [51]. However, it is possible that the plans were not presented in the most optimal manner with the ASQ. They were simply presented as examples and did not explicitly encourage the participants to develop and contemplate their own personal plans.

One way to improve the application of technique in this intervention could be to use volitional help sheets. In a previous study, Arden and Armitage [52] supplied a list of potential situations within which undergraduate students might be tempted to binge drink, together with possible solutions they could use to avoid this behavior. Linking the situations with the solutions created the personal if-then statements, which are central to implementation intentions [51]. Similarly, in another study, students were given options of things that they could say to refuse drinks [53]. The options included saying "no thanks, I do not want to get drunk" or "no thanks, I am watching my weight." Participants were also asked to detail the time and place at which they would enact these plans. These studies were successful in reducing binge drinking in student participants [52,53].

It is possible, therefore, that young people will be able to make successful plans even if they think that it would not work, as long as they could be convinced to do so. Studies that have explored younger adolescents' ability and motivation to make successful plans about alcohol consumption have not been identified. However, a recent study has demonstrated a successful application of implementation intentions to alcohol use with 16-year-old school pupils [54]. Thus, a major improvement to the ASQ would be to provide a range of potential scenarios and refusal options with the quiz questions and to explore the effectiveness of this approach.

Finally, it is important to consider how drinking behavior is perceived by the intended population. Drinking was perceived to be cool because it was forbidden, and therefore, it gave adolescents status among their peers. This supports Crossley's [55] suggestion that risk-taking behaviors symbolize a transgression of social rules and rebellion for young people. Although some participants who had tried alcohol said that they had done so out of curiosity and not because they thought it would make them appear cool, it was clear that this was an important driver in maintaining the behavior. Trying alcohol for the first time was seen as inevitable during the teenage years. Evidence shows that 90% of 15-16-year olds in the United Kingdom have tried alcohol at least once and half have engaged in heavy episodic drinking (>5 drinks) in the last 30 days [1]. Within the ASQ, the quiz questions discuss short-term harms such as being sick, or having an embarrassing photo uploaded to a social media site, which appeared to be in line with participants' concerns. However, further improvements could be made to ensure that the aspects of the ASQ that target prototypes are credible. Because of the inevitability of drinking for these participants, a focus on abstinence and enhancing nondrinker prototypes is probably an unrealistic goal. These findings suggest that in UK adolescents a "nondrinker" prototype target may not be seen as credible. A better focus could perhaps be to look at heavy or binge drinkers compared with moderate drinkers. Some research in the Netherlands identified different dimensions of drinker prototypes such as "tipsy," "moderate," and "heavy" drinkers [56], but this was in an older sample. Within British culture, drinking during the teenage years appears to be seen as part of growing up [34] and once adolescents reach young adulthood, many engage in heavy drinking [57]. Other qualitative research has highlighted the importance of tailoring intervention content to the intended population, suggesting a focus on encouraging young people who drink not to get "too drunk"[38].

Participants in this study described their perception of how peer pressure operates and revealed it to be a complex interplay between perceptions of drinking and the reactions you might receive if you did not drink. There also was a sense of inevitability about pressure to drink, which highlights the importance of this aspect of the intervention.

Study Limitations

Limitations to this study should be taken into account. First, the participants were sampled through convenience, and were self-selected via their parents. Although the sample size is appropriate for this type of study, a wider range of young people may have been able to bring different issues to light in relation to the intervention. Furthermore, it would be useful to explore differences by age and sex in detail, which was not possible with this sample size. Parents were required to bring participants to the university and meet the interviewer leading to a possibility that the participants doubted the anonymity of what they said. In addition, it is important to note the influence of the researcher; participants may have been attempting to provide socially desirable answers. However, all efforts were made to ensure participants were assured of confidentiality, and they were not asked directly to discuss their own drinking behavior. Furthermore, participants' responses to the ASQ were most likely influenced by their previous experiences of alcohol education in school. The think aloud section of the interview always took place first, and thus it is possible that the content of the ASQ influenced the participants' responses to the follow-up questions. Furthermore, their reported attitudes and perceptions may well have been primed by the intervention content. Although we developed the ASQ to be delivered online, for the purposes of illustration, this study used a paper version. This alternative mode of delivery may not reflect the exact findings of our online version of the intervention, designed to enhance its appeal, which will feature videos and interactive content.

This study was conducted in the United Kingdom, where drinking rates among adolescents tend to be higher than in most other European counties and the United States [1]. While this limits the generalizability of the findings, it is important to develop culturally relevant intervention programs as well as to explore the application of popular theories, such as the PWM, across different cultures and contexts.

Implications

The think aloud method meant that the content and format of the planned intervention could be tested with young people to explore their views before a trial. Increasingly, the value of conducting qualitative work before and alongside randomized controlled trials is being acknowledged [38,58,59] and the benefits of co-producing interventions are recognized. Although this method has been used to test other online interventions aimed at adults [47,48,59], no similar studies have been identified that have done so to test an alcohol misuse intervention with adolescents. This study has therefore demonstrated that this method can be used to obtain feedback from this population, and generate detailed discussions on the topic.

In conclusion, there are a number of specific implications of this study for improving the ASQ. The quiz format was well received but the final version should consider how it will be delivered in a classroom setting, to build on the positive features identified by the participants. The findings of this study suggest 3 main areas of focus for improvements.

First, the range of prototypes described in the quiz needs to be widened. Presenting a negative drunk prototype, rather than a negative drinker prototype, may be a more appropriate focus. Second, it is important to enable young people to enact plans to avoid harmful consequences of drinking. Finally, although the intervention does consider the complex perceptions of drinking as cool and how peer pressure affects young people's decisions, it appears that pressure was an inevitable experience for these participants. Further work may be needed to explore the most effective means of delivering credible intervention messages both within the current intervention and more widely within an adolescent population.

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Conflicts of Interest

None declared.

Multimedia Appendix 1

Example screenshots of the Alcohol Smart Quiz intervention used within the think aloud study.

[PDF File (Adobe PDF File), 432KB - humanfactors_v2i2e13_app1.pdf]

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Abbreviations

ASQ: Alcohol Smart Quiz
BCTs: behavior change techniques
PWM: prototype willingness model
TPB: theory of planned behavior

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Original Paper

Participatory Research as One Piece of the Puzzle: A Systematic Review of Consumer Involvement in Design of Technology-Based Youth Mental Health and Well-Being Interventions

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Abstract

Background: Despite the potential of technology-based mental health interventions for young people, limited uptake and/or adherence is a significant challenge. It is thought that involving young people in the development and delivery of services designed for them leads to better engagement. Further research is required to understand the role of participatory approaches in design of technology-based mental health and well-being interventions for youth.

Objective: To investigate consumer involvement processes and associated outcomes from studies using participatory methods in development of technology-based mental health and well-being interventions for youth.

Methods: Fifteen electronic databases, using both resource-specific subject headings and text words, were searched describing 2 broad concepts-participatory research and mental health/illness. Grey literature was accessed via Google Advanced search, and relevant conference Web sites and reference lists were also searched. A first screening of titles/abstracts eliminated irrelevant citations and documents. The remaining citations were screened by a second reviewer. Full text articles were double screened. All projects employing participatory research processes in development and/or design of (ICT/digital) technology-based youth mental health and well-being interventions were included. No date restrictions were applied; English language only. Data on consumer involvement, research and design process, and outcomes were extracted via framework analysis.

Results: A total of 6210 studies were reviewed, 38 full articles retrieved, and 17 included in this study. It was found that consumer participation was predominantly consultative and consumerist in nature and involved design specification and intervention development, and usability/pilot testing. Sustainable participation was difficult to achieve. Projects reported clear dichotomies around designer/researcher and consumer assumptions of effective and acceptable interventions. It was not possible to determine

the impact of participatory research on intervention effectiveness due to lack of outcome data. Planning for or having pre-existing implementation sites assisted implementation. The review also revealed a lack of theory-based design and process evaluation.

Conclusions: Consumer consultations helped shape intervention design. However, with little evidence of outcomes and a lack of implementation following piloting, the value of participatory research remains unclear.

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KEYWORDS

mental health; young people; technology; intervention; participatory; design

Introduction

Technology and Youth Mental Health

More than a quarter of young Australians aged 16-24 years old will experience a mental illness in a 12-month period, with anxiety, substance abuse, and mood disorders the most common [1]. Alarmingly, 3 quarters of first episode mental illness occurs before the age of 25 years [2], and it has been reported that only 30% of these younger people are accessing the professional help that would benefit them [1,3]. With that in mind, technology-based mental health resources and interventions, part of Australia's e-mental health strategy [4], may offer an opportunity to engage the other 70%. The potential of technology, therefore, to increase youth engagement with formal mental health services, particularly in rural and remote contexts where service options can be limited, is yet to be fully realized.

Technology-based mental health care interventions are often cited as methods for providing greater access to and engagement with services [5-7]. A recent review, however, identified only 2 studies that investigated the use of technology to increase engagement with clinical youth mental health services, and a further 3 explored the role of technology as an adjunct to face-to-face therapy [8]. This review detailed promising results and possibilities for the role of technology in creating and augmenting developmentally appropriate and responsive youth mental health services. However, the research included lacked rigor and the dearth of studies highlight the need for more research and development in the field that is guided by an evidence base [8].

Technology-based health interventions commonly suffer from limited uptake and/or adherence [9-13], which may be dependent on methodological issues such as design, particularly how human factors are incorporated [6,12,14]. For example, failing to obtain an in-depth insight into intended consumer behavior and their environments, which is crucial for good design [15]. Guidelines for technology-based mental health design increasingly emphasize the need for formal incorporation of consumer participation into intervention design [6,16-19]. Therefore, engaging young people and their support communities at all stages of development is likely to be crucial in enhancing uptake and adherence of technology-based interventions, particularly those from rural, remote, and disadvantaged communities [20,21].

Participatory Research

There is a rich history of participatory research with children and young people in the social sciences [22-25]. Participatory research is conducted in partnership *with* the individuals or community of interest and not *on* them, and in this way differs from traditional research. It purports to increase research relevance and usability through improved context appreciation. Other reported benefits of participatory research include greater stakeholder buy-in and improved efficacy and sustainability of research products (or outcomes) [26-29]. When considering the reported average 17-year gap between publication and translation of findings in health care, it is not surprising that participatory methodologies have gained prominence in the field over the last 20 years [5,28,30,31].

Within mental health design research, common participatory methodologies include community-based participatory research (CBPR), participatory action research (PAR), participatory design (PD), and user-centered design (UCD). PAR aims to develop an egalitarian partnership with a chosen community or group to generate positive, self-identified individual-, group-, and community-level change. While the research goals and associated theories of change may vary, PAR and CBPR are different terms for 1 research methodology underpinned by the same core principles. As such, the terms are used interchangeably in the literature depending on the country of origin [32,33]. PD—borne out of British, North American, and Scandinavian traditions—employs iterative design cycles in which knowledge production and research output(s) are shared by researchers and end-users [34]. Unlike PD, UCD is controlled by the design and research professionals, and participation takes on a strictly consultative role; the project is led, and decisions are made, by "experts" [35]. At the other end of the participatory continuum sits consumer-led research (ie, research initiated and/or controlled by consumers), which has recently taken on new life in the context of social media.

Most research has focused on consumer participation in service delivery, with the literature around participation in intervention design via research projects still developing [36]. It is also less common for the intervention development process to be reported [36]. Boote, Telford, and Cooper [37] argue that consumer involvement in research can be rationalized in 2 ways: (1) empowerment—defined as consumer involvement linked to greater autonomy in decision-making for disempowered/marginalized groups; and (2) consumerism—defined as consumer involvement linked to creating outcomes (eg, products, services or interventions) that generate satisfaction and value-for-money, with consumer input directed at improving efficiency, economy, and effectiveness. Each has different implications for the chosen methodology and role of the consumer.

The Current Review

Given the potential for technology to increase engagement with mental health services, the current review explored the question: "How have participatory methodologies been employed to develop technology-based youth mental health and well-being interventions?"

Youth participation in the development and delivery of mental health services designed to benefit them has received attention and resourcing for some time [38]. On- and offline service-wide youth participation models are well documented and demonstrate a recognition that young people are best placed to judge what works for them given their developmental-specific experience of mental illness [38]. Online services such as Eheadspace [39], beyondblue [40], and ReachOut.com [41] provide examples of youth participation best practice. This review, however, focuses on participatory development of technology-based interventions by research groups, which may include collaboration with services or other health organizations, as compared to youth participation in an existing service. Project teams involved in production and design of technology-based mental health interventions are interdisciplinary and diverse, and their outputs and findings are distributed across multiple channels and fields depending on the discipline focus of the authors. These factors make a review of this kind a complex undertaking. This review has chosen to focus on work titled, indexed, and stored in databases with a mental health focus and, as such, will not have accessed the body of literature that exists in humanities and social sciences databases (particularly around child, youth and consumer rights and youth participation) that are reflective of multiple stakeholder contributions.

Projects that involved consumers in the design and development of interventions spanning the breadth of the mental health intervention spectrum were included to maximize learning opportunities and to gain a broad understanding of participatory processes in this emerging field of research. The aim was to synthesize previous literature and make practical recommendations for mental health technology designers who wish to employ participatory research methods in a youth context. The major concepts under investigation were: (1) the nature of consumer involvement and the participatory process in intervention development; (2) the nature and outcomes of the design process; and (3) the relationship between participatory research and the implementation of research.

By "technology-based" we refer to information and communications technology-based (ICT-based) digital interventions such as health promotion/prevention Web sites, community-focused health promotion/prevention technologies, treatment-focused Web sites/programs/therapies, and other mental health apps, games, and products. The interventions may act as standalone entities or as an adjunct to existing face-to-face treatment or programs. For inclusion in this review, developers need to have adequately defined and documented (ie, via a project report, journal article, conference paper, or thesis) a participatory development/design project.

Methods

Search Strategy

A systematic search strategy was used to identify published and unpublished studies that described participatory research mental health projects. Database search strategies employed both resource-specific subject headings (where available) and keywords describing 2 broad concepts—participatory research and mental health/illness (the emphasis on illness terms reflected the focus on treatment-focused interventions). Keywords were often combined using proximity operators in order to increase search sensitivity (generated by SO, RD, SL, and NB). Comprehensive literature searches were undertaken in the following 15 databases: OvidSP Medline (1946-), PubMed, PsycINFO (1806-), CINAHL, Scopus, Web of Science, Informit (health, social sciences, and science and engineering subsets), arXiv.org, ACM Digital Library, and IEEE Xplore Digital Library. Database searches were limited to studies published in English. The time period for searches was database inception to June 2014. Full search strategies for the OvidSP Medline and PsycINFO databases are provided as Appendix 1.

To identify unpublished studies, 3 simplified versions of the search strategy were used in the Google Advanced search engine and results were restricted to PDF documents. Only the first 100 results for each search variant were reviewed for relevance (ie, total n=300). Web sites of relevant conferences were also checked for additional unpublished papers, including: Participatory Design Conference; Special Interest Group on Computer-Human Interaction; and the Computer-Human Interaction Special Interest Group of the Human Factors and Ergonomics Society of Australia. Reference lists of relevant citations were checked and email contact was made with authors to source additional relevant documentation and current information on the intervention. All searches were conducted in June 2014. EndNote X6 (Thomson Reuters) was used to manage all database citations. A first screening of titles/abstracts by a research assistant (MW) eliminated clearly irrelevant citations/documents based on research method and age group. The remaining citations were screened by a second reviewer (SO). Full text articles were sourced when a decision on relevance could not be made by title or abstract alone.

Inclusion and Exclusion Criteria

All research papers that involved projects judged as having a primary focus on youth mental health and well-being were included in the review, irrespective of whether the mental health focus was related to an existing physical condition. This decision ensured that learnings from the development of interventions spanning the breadth of the health intervention spectrum would inform development of treatment-focused interventions. Specific criteria are outlined below.

Inclusion criteria:

- Mental health or well-being focus (defined in consultation with a multidisciplinary team comprised of clinical mental health, technology and consumer perspectives, and informed by the DSM-V definition of mental disorder) [42]
- English language

- Development and/or design of ICT- or digital technology-based intervention
- Youth-based intervention (or include a youth element)
- Inclusion of participatory research processes or elements thereof

Exclusion criteria:

- Commentaries, opinion pieces, or editorials
- Photovoice studies (judged as a distinct research methodology that does not involve design or development of a technology-based intervention)

Data Collection and Analyses

A multidimensional framework analysis, adapted from research conducted by Oliver et al [43] and Lorenc et al [44], was employed to categorize research. This involved an iterative approach of familiarization with the literature and gradual development of the conceptual framework based on the broad research question. Concepts were drawn from the literature around participatory research and technology-based health intervention design. The outcome criteria were populated by criteria drawn from previous participatory research evaluation and the information needs of the study [28,37,45,46]. Due to the exploratory nature of the review, all levels of evidence were considered. Refer to Textbox 1 for definitions of concepts used and their relationship to the areas of investigation. Each study was evaluated by 2 members of the research team using the definitions in Textbox 1. Discrepancies were discussed and consensus reached. A third member of the team was consulted if required.

Textbox 1. Framework analysis.

Background Information

- Participatory methodology—which participatory methodology underpins the research?
- Project context—who developed the project? Who carried it out? Who funded it?
- Nature of intervention and intended consumers—description of intervention and intended end users.

Nature of Consumer Involvement and the Participatory Process

- Rationale for consumer involvement—empowerment (greater autonomy in decision making for disempowered/marginalized groups) or consumerism (satisfaction and value-for-money, consumer used to improve efficiency, economy and effectiveness) [37].
- Mode of consumer participation—*contractual* (people are contracted into the projects of researchers to take part in enquiries or experiments), *consultative* (people are asked for their opinions and consulted by researchers before interventions are made), *collaborative* (researchers and local people work together on projects designed, initiated and managed by researchers), *collegiate* (researchers and local people work together as colleagues with different skills to offer, in a process of mutual learning where people have control) [46]. Taken from agricultural research, Bigg's [46] modes of participation simplify Arnstein's ladder of citizen participation [47] and were reproduced in Cornwall and Jewkes' paper on participatory research [28].
- Representation (of intended users)—referring to spread of representation from affected interests; including how legitimate the representation was seen to be; the diversity of views not just representatives [45].
- Develop a shared vision and goals—who developed the vision and goals for the project? Did end users have a chance to shape the project in any meaningful way? [45].
- Influence on process (opportunities and quality of involvement)—how and where participants participated in the project (ie, at which stages of the process and in what ways) [45].
- Transparency and quality of decision-making—referring to both internal whereby participants understand how decisions are made; and external; whereby observers can audit the process. Can you determine how and why decisions were made in the project? [45]
- Capacity building and learning for participants—have the participants developed relationships, skills and learning that enable them to take part in future processes or projects? [45].
- Accountability and Legitimacy—referring to whether the representative's core constituencies are satisfied, including expectations. Referring to the outcomes and process are accepted as authoritative and valid (ie, was there any information regarding participant/stakeholder views on participating in the research the research or on the outcome) [45].

Nature and Outcomes of the Design Process

- Theories used to support intervention design—did the author(s) report any specific theories that help guide the intervention development or design?
- Intervention (efficacy)—is there any published work on the efficacy of the intervention?
- Emergent knowledge—referring to the outcome of local knowledge (ie, from end users) on outcome of the research [45].
- Challenges/limitations plus what worked—limitations and strengths of the process

Relationship Between Participatory Research and Implementation

- Champion/leadership—referring to both the internal leadership for the project and champions for the project [45].
- Implementation—was the intended implementation site(s) indicated? Was it integrated into the project?
- Fate of the intervention—was the intervention implemented in practice? (If not, what stage did the project/intervention reach?)

Results

Study Selection

In total, 14,021 citations and Web documents were identified through database searches and open Web searching. Once duplicate citations were removed, 6210 items remained for preliminary assessment of relevance. After title, abstract, and full paper screening, 17 studies were chosen for inclusion in this systematic review (Figure 1 and Table 1). Of these, 1 study reached proposal stage [48], and 1 was designed but not developed [49].

Table 1. The 17 projects included in the literature review.

Project authors (publication year)	Participatory methodology	Project context	Nature of intervention and intended consumers	Fate of intervention
Carroll, Burge, Robertson, and Rosson (2010) [48]	PAR	Proposed intervention design developed by researchers at Pennsylvania State University.	Preventive Intervention: an on- and offline community network health intervention for university students and families with children with autism.	Not designed or developed (project reached proposal stage).
Coyle and Doherty (2009) [7]	UCD/ collaborative design	Project driven by human computer interaction researchers at Trinity College, Dublin.	Treatment Intervention: 3D computer game (Personal Investigator) to support therapists working with adolescents in public clinical mental health services.	Personal Investigator has undergone initial clinical evaluation over 6 months at multiple sites (n=8 mental health clinicians; and n=22 youth, aged 10-16, gender not reported). Indicated that more formal evaluations of the game were under way, no further information beyond time of publication.
Ekberg, Timpka, and Angbratt, et al (2013) [49]	CPBR with PD process for intervention design	Collaboration between university- and government service-based researchers in Sweden. Grant funded by the Research Council for South-East Sweden.	Preventive Intervention: Online health-promoting community (OHPC) aimed at addressing factors that prevent obesity, including mental health, targeting young people aged 15-20.	Email correspondence with first author indicated a pilot of the OHPC was carried out; however, no formal evaluation was written up. The lead author wished to obtain sustainable funding before launching the OHPC and this is yet to be secured.
Elf, Rystedt, Lundin, and Krevers (2012) [50]	PD	PhD project of first author, in Sweden. Funded by The Swedish Institute for Health Science, the University of Gothenburg, and Vinnvård.	Preventive Intervention: Web-based support system (WBSS) for young caregivers (aged 16-25) living close to someone with mental illness.	During Web site development phase, after previous attempts to pass the Web site on, the original Web site (Molnhopp.nu) was partially redesigned and rebuilt on a different platform (Livlinan.org, Lifeline) run by SPIV (a suicide prevention organization) and a volunteer-run local mental health service for ongoing management. The first author published on the relationship between intended (Molnhopp.nu) and real (Livlinan.org) use of the Web site. Intended and real use were weakly related and dependent on context and the needs/interests of users. The original Web site Molnhopp.nu progressed to a randomized controlled trial (RCT) carried out over 8 months (N=241, aged 16-25 years); WBSS (Molnhopp.nu) n=120 (73% female); folder support (containing information on 24 different kinds of available support services in the community or society) n=121. The intention to treat for the primary outcome (stress) showed no significant differences between the Web group and the folder support group. Stress decreased significantly in the folder group.

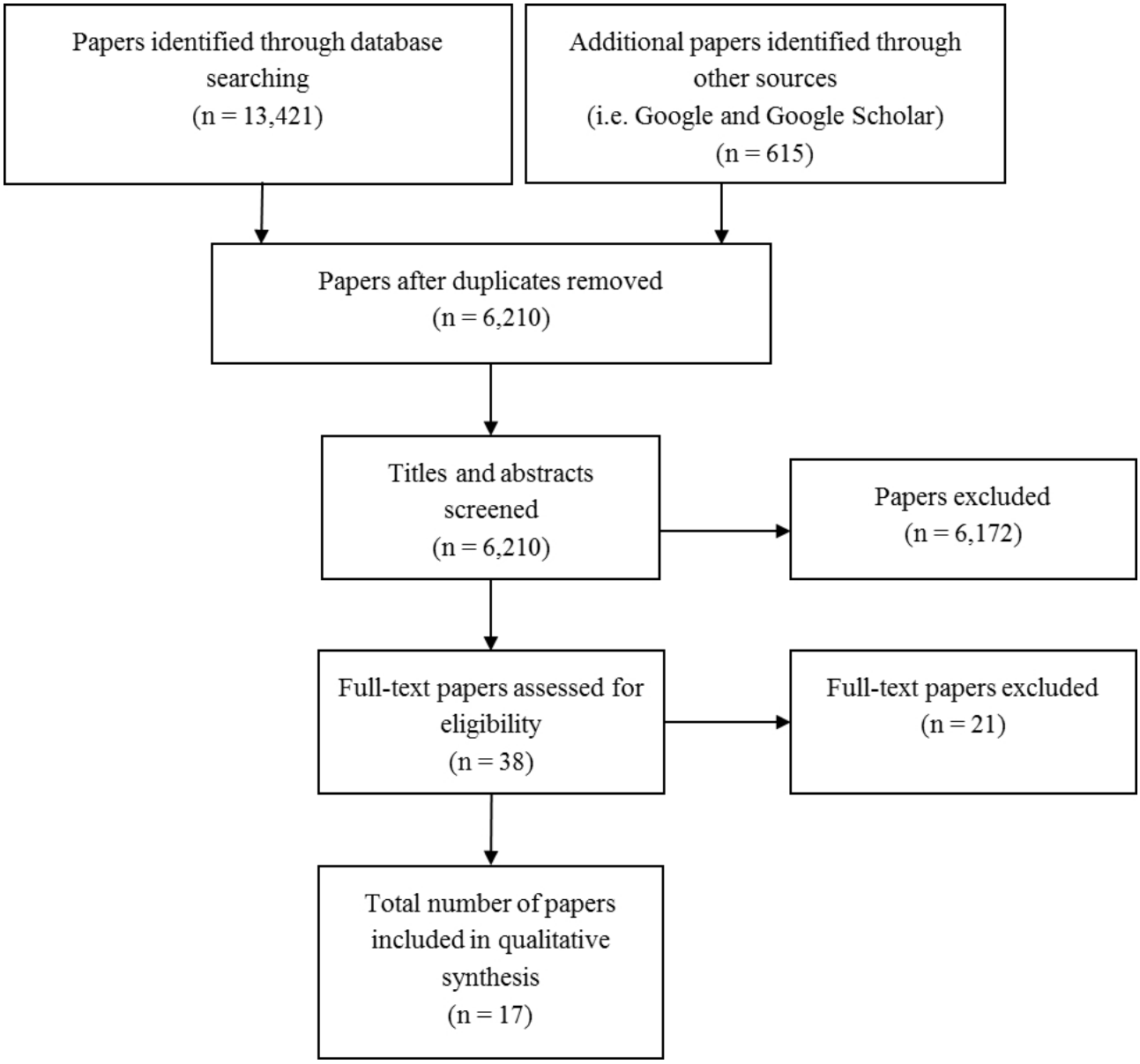
Project authors (publication year)	Participatory methodology	Project context	Nature of intervention and intended consumers	Fate of intervention
Hallett, Brown, Maycock, and Langdon (2007) [51]	PAR	Project driven by a multi-stakeholder participatory action research committee, led by a project officer of the West Australian Aids Council (WAAC) and funded by Healthway (West Australian Health Promotion Foundation).	Preventive Intervention: online, peer-based sexual and mental health promotion (CyberReach) for adult men who have sex with men (MSM) and same sex attracted young people (SSAY). No exact age groups stated, likely to be 14-25 for SSAY and 25+ for MSM.	Stated project objectives met (ie, developing sustainable, transferrable protocols and training, and development of transferrable protocols for peer-based Internet outreach). Paper reports that the piloted intervention became 2 separate services offered by the WAAC: (1) Expanded the existing SSAY to include online outreach and chat; and (2) After a more extensive trial, the MSM service eventually became a national program called "Netreach" offered by the AIDS Councils in Queensland, Victoria, Western Australia, and Tasmania. Netreach primarily provides online chat and support for MSM. Program supported by the Australian Federation of AIDS Organisations and by Gaydar.com.au. No health promotion outcome data available.
Løventoft, Nørregaard, and Frøkjær (2012) [52]	PD with modified form of classic contextual inquiry	University-based research project in Denmark. Project supported by Lundbeck A/S, DIKU, Telenor A/S, HTC Denmark A/S, and PROSA.	Treatment Intervention: mobile phone app aimed at supporting people with depression by assisting with their daily lives. No target age explicitly stated. Youth consumers participating in the study aged 17-24.	Small scale 4-week evaluation of the intervention with participants who assisted with the design process—no further information available on intervention after publication.
Madsen, el Kaliouby, Eckhardt, Hoque, Goodwin, and Picard (2009) [53]	UCD with PD iterative design sessions	Project carried out by MIT Media Lab. Close links with Groden Center and Things That Think Consortium. Funded by National Science Foundation grant (hardware and software prototypes provided by Google and Samsung).	Treatment Intervention: prototype interactive socio-emotional toolkit (iSET) to assist adolescents with autism to improve social interactions (recognition, understanding, and expression of both the user's and others' facial expressions via software and hardware).	At time of publication, the iSET intervention was still under development, no further information is available beyond this date.
Matthews and Doherty (2011) [54]	UCD	Project driven by Human Computer Interaction researchers at Trinity College, Dublin (funding source and trial partners not stated).	Treatment Intervention: a mobile phone and online symptom tracking tool (Mobile Mood Diary) to assist adolescents with depression.	Clinical pilot (n=3 therapist, n=9 clients, mean age = 13.78, SD= 2.63, n=3 males and females, respectively) and n=1 parent, across a range of issues, including depression, mood disorders, self-harm, and anger management. No further information available on intervention after time of publication.

Project authors (publication year)	Participatory methodology	Project context	Nature of intervention and intended consumers	Fate of intervention
Mazzone, Read, and Beale (2008) [55]	UCD with PD	PhD study of first author who was the design researcher in a multidisciplinary research team. UK university-based project led by researchers in developmental psychology and computing. Overall project, joint collaboration between a team of psychologists, interaction designers, and developers. Funded by the HEFCE's Strategic Development Urban Regeneration Fund, devoted to a consortium of universities in the UK, with additional funding from Esmee Fairburn Foundation.	Treatment Intervention: e-learning product to improve teenagers' emotional intelligence for pupils (aged 12-15 years old) taken out of mainstream schooling due to behavioral issues (participating consumers were recruited from Pupil Referral Units).	Intervention (Uthink) implemented in Flash by a graphic designer. Uthink evaluation: N=84 (youth aged 14-16, n=72 males, n=12 females), no control group. Significant changes in a number of socio-emotional skills, including stress management, adaptability, and the ability to appreciate relationships between environmental cues and emotions. Participants demonstrated experiencing more care and guidance within friendships and less conflict. Reduced delinquent behavior and a desire to be increasingly challenged in school was also demonstrated. Correspondence with project leads indicated that the game is freely available at the Uthink Web site and is currently being used by schools in Lancashire, England, and is recommended by the Lancashire County Council for use in high schools.
Moen and Smørdal (2012) [56]	Action research with PD workshops	University-hospital collaboration in Norway. Funded by Centre for Rare Disorders and the IT department at Oslo University Hospital. Exploratory study.	Preventive Intervention: wiki-like site offering information, strategies, and support for people (and their families) living with anorectal anomaly focused on "living well." Indicated all ages were being targeted, but email correspondence with first author indicated a significant youth component.	Email correspondence with the first author indicates there is no outcome paper for the intervention due to employment changes for key contributors. Piloting was undertaken but was challenging due to technical and interoperability problems and lack of professional and organizational support.
Monshat, Vella-Brodrick, Burns, and Herman (2012) [57]	Participatory research	Researcher-led via Orygen Youth Health Research Centre. Funding: K.M. Australian National Health and Medical Research Council (NHMRC) Public Health Postgraduate Scholarship, J.B. Victorian Health Promotion Foundation (VicHealth) Fellowship, and H.H. NHMRC Practitioner Fellowship.	Preventive Intervention: online mindfulness therapy program (mindfulness awareness training and education (MATE)) targeted at young people aged 14-25.	Pilot testing: (n=11 young people, aged 16-24, gender not reported) evaluated the 6-week MATE program. Focus group (n=7) and interview (n=5) data. No further information available.

Project authors (publication year)	Participatory methodology	Project context	Nature of intervention and intended consumers	Fate of intervention
Lakey (2014) [58]	Participatory research	Project driven and funded by the National Health Service Greater Glasgow and Clyde as part of their strategic direction for Child and Youth Mental Health. The Greater Glasgow & Clyde NHS, Mental Health Foundation, Snook, and Young Scot were commissioned to carry out project in partnership. Outcome of project is to provide a basis for discussion with stakeholders in the board area to translate findings.	Preventive Intervention: Aimed at exploring the potential of the Internet, social media, and mobile technologies in promoting better mental health and well-being for young people. Multiple planned outputs. Produced digital postcards that act as a guide to staying safe and well online for young people aged 15-21.	Project supported the development of youth-generated ideas for digital interventions to promote youth mental health and well-being. Animated GIFs (youth guide) developed but not available to the public yet. The project also developed other health service/resource design briefs. Work officially launched by Health Board on March 28, 2014. Project opened up connections with innovators across the UK who are willing to collaborate and develop it further. Email correspondence with project lead: project is close to gaining confirmation of funding that will allow development and delivery of recommendations from the project's first phase.
Owens, Farrand, Darvill, Emmens, Hewis, and Aitken (2011) [36]	Participatory research	Collaboration between university and government service researchers and representatives in the UK. Funded by the National Institute for Health Research.	Treatment Intervention: text-messaging intervention to reduce self-harm for all ages.	Exploratory trial in progress at time of publication. No further information available.
Schmidt (2009) [59]	PAR	Source document was author's master's thesis. Youth Voices for Change (YVC) project was a subset of a larger research project (Healthy Youth/Healthy Region) that investigated connections between youth well-being and regional prosperity in the Sacramento, California, region in the US. Participating agencies: The Center for Regional Change at the University of California Davis (UC Davis) in collaboration with other project centers in UC Davis and the West Sacramento Youth Resource Coalition (WSYRC), which led the project. Funding from Sierra Health Foundation and The California Endowment.	Preventive Intervention: Google map (containing youth-produced videos and photos relating the built environment and well-being—eg, favorite, challenge, and adjust places in the community) and project Web page (the project produced other outputs but they were not technology-based). The overall aim was to investigate links between the built environment and youth well-being.	Media products presented at the planned youth community event. Qualitative data (interviews and surveys) indicated that the media products created for the event were perceived as successful by both the youth and the attendees (in terms of overall satisfaction, learning about the community, inspiring discussion, understanding people in the community and its diversity). At time of writing, the thesis indicates that the videos (and other project outputs) were being used by youth groups involved in the project, the Sactown Heroes, to promote their ideas and profile within the community (no clear idea how). The current utilization status of the Google Map is unknown as it was transferred from the project Web page (which was discontinued) and placed on a community Web site. The WSYRC is using the output and connections made as a result of the YVC project to develop a sustainability plan for the Sactown Heroes group as other funding comes to an end.

Project authors (publication year)	Participatory methodology	Project context	Nature of intervention and intended consumers	Fate of intervention
Stewart, Riecken, Scott, Tanaka, and Riecken (2008) [60]	PAR, youth participation model	Collaboration between university-based researchers and Canadian indigenous youth.	Preventive Intervention: Canadian indigenous youth developed artistic educational videos to address self-identified health concerns. For use in the local and other communities (aimed at high school and university students). Key research question: how can creating videos contribute to expanding health literacy?	Student videos presented at planned showcase event at the end of the school term to an audience of peers, friends, family, and community members. No information as to whether the videos have been used in other communities/contexts as planned.
Valaitis, O'Mara, and Bezaire (2007) [61]	PD	Campus-community partnership between researchers at McMaster University and the local government health unit in Ontario, Canada (rural context). Funded by Health Canada's Drug Strategy Community Initiatives Fund.	Preventive Intervention: rural youth (aged 14-24) developed a Web site aimed at meeting their specific health promotion needs (with moderated peer support) with a broad aim to address problematic alcohol use. The project also aimed to provide an opportunity and skills for local youth at-risk to develop and implement the health promotion Web site.	No peer reviewed papers published for this study. Project report: the Web site was evaluated over 8 months (2006-2007). No outcome data available on ability of Web site to meet identified health promotion needs. The Youth Spark Web site was functional and updated until late 2014, when it was converted to a Facebook page.
Wadley, Lederman, Gleeson, and Alvarez-Jimenez (2013) [62]	PD	Research project that involved collaboration between universities (from human-computer interaction and clinical backgrounds) and a research supportive youth mental health clinic in Australia. Supported by Victorian Government, University of Melbourne, Telstra Foundation, IBES, the Telematics Trust, and the Helen Macpherson Trust.	Treatment Intervention: online therapy involving psycho-education, peer-to-peer social interaction, advice, and moderation from mental health practitioners for young people with psychosis aged 15-25.	Completed a 4-week safety and acceptability trial (n=20 clients, n=3 clinicians, age and gender not reported). Results of pilot testing results secured funding for a 4-year RCT. Email correspondence with first author indicates that the intervention is in the first year of a RCT—no final outcomes available.

Figure 1. The multiple stages through which studies were selected for inclusion using the PRISMA flow diagram.



Characteristics of the Included Studies

Of the 17 projects included in the review, included treatment-focused interventions [7,36,52-55,62]. The remaining 10 were preventive interventions [48-51,56-61]. UCD [7,53-55], PD [50,52,61,62], and PAR [48,51,59,60] were the most common methodologies used (4 projects each). PD provided the sub-framework for an iterative design process in a further 4 projects [49,53,55,56]. UCD or PD methodologies tended to scaffold development of treatment-focused interventions. Three projects were based in the US and Australia, respectively, and 2 each in Ireland, Sweden, England, and Canada. The final 3 were based in Denmark, Norway, and Scotland. The age range of youth involved was 10-26 years old; 5 studies did not report age, 9 did not report gender. Besides age, no other socio-demographic variables were reported.

Nature of Consumer Involvement and the Participatory Process

Most projects (11 of the 17) involved young people (and other relevant stakeholders) for principally consumerist purposes [7,48,49,51-55,57,58,62]; that is, to create usable, effective, and efficient interventions. A further 2 reported elements of both empowerment and consumerism [36,50]. No projects actively involved youth consumers in the project planning stage, with project aims and goals unreflective of their input.

Overall, consumers were involved in a combination of 3 main stages of research: (1) Needs analysis/design specification; (2) Intervention design/prototyping and development; and (3) Usability and pilot testing. Two projects involved consumers in all 3 stages [52,61]. Projects commonly included consumers, who were most often youth and mental health clinicians (rarely family or caregivers), in the needs analysis/design specification stage [7,49,50,52,54,56,58,61,62]. Some projects entered this stage with a predetermined intervention in mind [49,50,52,54,61], while others operated with a looser set of

intended outcomes [7,56,58,62]. Four projects involved consumers in the intervention design/prototyping and development stage [36,52,58,61]. In other projects, consumer involvement involved consulting to refine an existing intervention [51,57] or solely usability and pilot testing [53,55]. The community-based projects of Schmidt [59] and Stewart et al [60] developed community health education tools. They involved consumers at all stages of the project besides initial project planning.

Youth participation was variable, both across and within projects. Overall, 70% of projects reported predominantly consultative consumer involvement [7,49-57,62] and the remaining projects were collaborative in nature [36,58-61]. The projects, therefore, sat in the middle of Biggs' modes of participation [46]. Youth involvement was consultative in 6 of 7 treatment-focused projects [7,52-55,62], and 4 of these projects involved mental health clinicians as part of the research team [7,54,55,62]. Projects that developed treatment-focused interventions generally involved the most limited forms of consumer input. The highest level of youth participation was evident in the prevention-intervention projects, particularly Lakey, Stewart et al, Valaitis et al, and Schmidt [58-61].

Families, caregivers, and intended implementation-site representatives were under-represented in the projects. Of the 16 carried out, 7 projects clearly identified the intended implementation site and included representatives in the design phase [7,49,51,57,58,61,62]. The Stewart et al [60] and Schmidt [59] projects developed community-education focused interventions with local community representatives; however, it was unclear how widely their products were intended for distribution and thus the specific implementation site(s).

Overall, it was difficult to gain insight into consumers' views on their participation in the projects (process evaluation) and their outputs (evaluation of the intervention). Three projects involved consumer evaluation of their experience of research [59-61]. These evaluations suggested a general trend toward perceived legitimacy and accountability of the research process and its outputs, but they also served to highlight the different expectations regarding process and outcomes between project/research leads and consumers. Other projects reported informal and anecdotal consumer support for the research process [51,55-57]. In some cases, pilot and small-scale clinical evaluation data were reported [7,51,52,54,57,61,62].

In line with the consumerist rationale for most projects, deliberate capacity building and learning for consumers was limited; only 5 projects involved significant opportunities for this [51,58-61]. These involved development of preventive interventions.

Consumer involvement was seen as crucial to intervention design and development in most projects; emergent knowledge was evident in all project outputs and each made explicit reference to value of consumer involvement in intervention development. Projects reported clear dichotomies around designer/researcher assumptions of effective and acceptable interventions and those of the intended consumer. These differences were present in intervention premise and content [50], and mode of delivery and characteristics/components [52,56,62]. Projects reported compromises between the perspectives, which were evident in the designs. Consumer consultations in the needs analysis/design specification stage were used to underpin and inform intervention design [7,49,50,52,54,56,58,61,62]. Consumers also played a role in tailoring and contextualizing interventions [7,53-55].

Eleven of the 15 completed projects reported challenges with consumer recruitment, capacity, commitment, and reliability [7,36,50-52,54,55,58,59,61,62]. Cited reasons included lack of access to the target consumer group, consumer personal circumstances and/or condition-related factors, and the busy lives of youth. All projects aiming to develop treatment-focused mental health interventions found recruitment and ongoing participation of intended youth consumers difficult to achieve; however, youth consumer attrition during intervention design and development was not specific to development of treatment-focused interventions [50,59,61].

Nature and Outcomes of the Design Process

Three projects used heuristic guidelines to support intervention design [7,54,62]. Monshat et al [57] was guided by constructs of the Technology Acceptance Model (TAM) [64]. Overall, 4 projects reported use of technology frameworks or theory to guide intervention development [7,54,57,62]. Valaitis et al [61] used logic models to support major project decisions, including those specifically related to intervention design, such as the prototyping process, as well as techniques from scenario-based design [63,65]. Ekberg et al [49] employed design rationales and design space analysis, which detail reasons for and justification of design decisions, to guide development of their intervention [66]. Eight of 17 studies utilized PD methodology or principles to guide intervention development [49,50,52,53,55,56,61,62]. Nine projects mentioned the broad theories (including psychological, health, education, group, empowerment, and cultural) on which the intervention or project were based [6,36,48,51,54-56,60,61] (the details of 2 were found in project reports provided by the authors, not in the published articles [51,61]).

A structured design process, with activities able to scaffold consumer input through the design stages, was seen to be effective in a third of completed projects [49,52,55,58,61]. Use of scenario-based design—which included techniques such as storyboarding, personas [63,65], think-aloud techniques [67,68], and varied methods for capturing user experience and knowledge—was seen to assist the design process. Inspiration/idea progression and prototyping was facilitated by appropriate planning and resourcing with respect to design activities and the space in which they were conducted.

Project flexibility and responsiveness, including the ability to adapt to changing resources, priorities, work styles/preferences, output standards, and deadlines, was often built into design and was a common thread throughout projects that reported high levels of consumer involvement and influence [36,51,59,61]. Projects led by nontechnical researchers also reported the need for integration of technical expertise at all stages of intervention design and development [36,49,61]. A professional appearance of the final intervention product was also seen as important by youth consumers in a number of projects [49,50,62].

In addition, balancing consumer requirements with what was possible technically, ethically, and practically (ie, time and resource, both financial and human, restrictions) was highlighted in 3 projects [49,50,56]. Of particular concern were social and consumer self-authoring components of interventions, privacy, confidentiality, clinical risk, and authenticity of information. Formal outcome data was available for 2 projects [50,55].

Relationship Between Participatory Research and Implementation

While leadership was not always clearly defined, most projects were researcher-led. Interdisciplinary project teams were common, including researchers or professionals with various combinations of mental health and technology domain expertise. Often, however, 1 discipline had overall responsibility for the project.

Five projects [36,51,58,59,61] reported existing relationships with outside champions who were linked to implementation sites or organizations capable of progressing the project beyond the intervention development stage. In 2 projects, Hallett et al [51] and Valaitis et al [61], project and governance plans were designed such that implementation of the intervention was integrated and a further 4 studies reported established links with intended intervention sites [55,57,58,62]. Stewart et al [60] and Schmidt [59] integrated community-based dissemination of outputs into their project plans. Many projects were, however, exploratory and involved development of technology-based interventions with a limited evidence base.

With the information available at the time of writing, 5 projects had extended beyond the intervention design, development, and pilot stage [50,51,55,61,62]. It is unclear the extent to which outputs from the 2 community-based projects [59,60] were used in a health promotion or prevention capacity beyond the life of the project.

Eleven projects utilized existing relationships and networks to assist with recruitment of target consumers [36,49-51,53,55-59,62]. The benefits of accessing consumers through existing networks was often noted; in particular, this made a significant difference in recruiting consumers with lived experience of mental illness for studies developing treatment-focused mental health interventions [36,53,55,62].

Discussion

Nature of Consumer Involvement and the Participatory Process

A strong history of youth participation in mental health research and service development exists, rooted in the empowerment of young people to address service quality and access issues [38]. In contrast, the projects included in this review generally involved consumers for consumerist intentions and in a consultative capacity. This represents a departure from the traditional empowerment and emancipatory rationales for participatory research demonstrated in a minority of projects in this review [36,50,56,59-61]. These increasingly consumerist underpinnings have implications for why and how consumers are asked to participate in research and the degree of mutual benefit that is possible, desired, and ethical.

Eight of the 17 projects explicitly reported using PD methodology or methods to guide intervention development, and others used PD-related design techniques such as user journeys, personas, and workshops. PD originated in the 1970s from a Scandinavian tradition of empowering workers to exercise control over the role of technology in their workplace [69]. Increasingly, however, the application of PD as a methodology or collection of techniques/methods has moved into design underpinned by consumerist principles that emphasize usability, effectiveness, and acceptability of the product [5,19]. This shift was embodied in several projects in this review [49,52,53,55,58,62]. Participatory methodologies with consumerist underpinnings tend to seek information and understanding through consultation and, thus, support a more passive role of the consumer in the research.

In attempting to assess perceived accountability and the legitimacy of the research process and outputs in the studies reviewed, it became clear that researchers are not in the practice of evaluating and reporting on the consumers' participation experience. This is not only a missed opportunity for consumers to collect data in order to reflect on and learn from their experience of research, but it represents an invaluable source of data from which other projects wishing to conduct participatory intervention design and development could benefit. Email correspondence with 1 author of the studies reviewed revealed that the intervention did not progress any further from the design stage due to possible consumer dissatisfaction with the design, despite the intervention being designed and developed in collaboration with them. This highlights the need for formal assessment of consumer perceptions of accountability and legitimacy of the intervention. Existing literature notes the value derived by researchers and consumers in building in evaluation/reflection cycles, particularly for promoting the dialogue, critical reflection, and trust that are crucial components of high-quality participatory research [23].

While it has been reported that participatory research can enhance recruitment rates [70,71], this review highlights the consumer access, recruitment, and participation challenges faced by projects aiming to develop mental health and well-being interventions, particularly those with a treatment focus that target involvement of consumers with lived experience of mental illness. Those individuals who identify as struggling with mental illness still face stigma and privacy concerns, which restrict use of common recruitment methods such as advertising [62]. Even projects that reported collaboration with mental health services or access to those with lived experience of mental illness noted ongoing participation difficulties with maintaining consumer participation throughout the intervention design and development process [36,62].

Collaborating with existing groups of young people such as schools and youth groups [49,53,55,58-60] or organizations with a strong track record of engagement and outreach with the target consumers [51,56,57] represented a recruitment starting point for multiple projects. However, they too still reported struggling with ongoing participation difficulties. These

recruitment concerns are not surprising considering the move into more consumerist-based projects that tend to be less integrated into communities than traditional participatory research.

Personal capacity, reliability, and attrition of consumers, particularly in the treatment-focused intervention development projects, must also be considered [36,50,52,55,61,62]. Todays' young people contend with a myriad of demands on their time, and projects included in this review experienced this in the form of participant nonattendance, unreliability, and dropout. This effect may be amplified when the youth consumer is currently living with a mental illness. Consumers may also face financial or transport [62] barriers in attending planned project activities that may be related to their age and/or health status. Broadly speaking, participatory research that involves consumers, particularly those who are members of minority or vulnerable populations, carries with it particular ethical considerations that require careful and sensitive negotiation and practical restrictions [72-75]. This is best exemplified in the Løventoft et al project [52], which reported moving from egalitarian principles of PD to a designer-led user-centered approach due to challenges with consumer engagement, retention, and capacity.

The projects with the most extensive youth consumer participation were those in which young people were involved in design and development of health prevention interventions, as exemplified in Stewart et al [60], Valaitis et al [61], Lakey [58], and Schmidt [59]. This nonclinical consumer group is far easier to access and does not have the same privacy, stigma, and personal capacity concerns facing the clinical youth consumers.

Despite this, many studies reported successful participatory research with youth consumers from a range of backgrounds. Participation is greatly assisted by links to existing consumer groups. Integration into the community of interest, via sustained partnerships between academic and nonacademic partners, is a hallmark of participatory research and has previously been shown to enhance recruitment capacity [70,71]. Beyond this, future research projects would be well advised to plan for attrition; both with respect to an ongoing recruitment source and development of materials that can be provided to consumers for seamless integration into the project whenever they choose to engage or reengage. As borne out in this review, participation can and will fluctuate throughout the project and must be planned for and communicated to consumers [59].

Flexibility and open-mindedness, embodied by a willingness to work with a non-static group of consumers and to renegotiate the time, length, style, and content of planned interactions, was repeatedly noted by the projects included in this review [36,51,55,61]. Owens et al [36] in particular highlights the flexibility required by a project when working in an egalitarian manner with consumers. Their intervention became more complex than planned and required extra time and resources to create. Increased cost in terms of necessary resources, time and expertise associated with participatory research [29], along with the need for flexibility in terms of role division, project structure(s), timeframes, and even communication methods have been noted elsewhere [23].

In working with adolescents with behavioral problems, Mazzone et al [55] recommend small groups and many short activities with simple tasks and objectives. They also endorse building in praise and a sense of ownership when working with all youth consumers (see also Dold et al [73]). A structured design process that scaffolds consumers throughout was also found to be effective [49,52,55,58,61]. Given the probable lack of technical and design knowledge of the average consumer (via techniques like storyboarding, think-aloud techniques, and scenario-based design), scaffolding the design process appears to be an important consideration for researchers.

Planning for and understanding consumer expectations of participation in research, along with their self-perceptions as mental health consumers, matters [73]. Given the limited data available regarding consumer experience of research, building reflection and evaluation into research plans should be a focus for future research projects. Ideally, projects wishing to collaborate with youth mental health consumers require committed, youth-supportive research leadership and a process that is well-resourced and supported. Previous research suggests that projects that are age and developmentally appropriate and incorporate meaningful, individualized, empowering, and capacity-building elements improve consumer output and buy-in [59,73,76], which has obvious implications for improving the current recruitment and participation issues.

Recognizing that issues of power and agency are embedded in participatory research with young people, it is important to achieve best practice [23]. When researchers adopt the mind-set that "young people are creative agents who bring about change" [23], participatory research can represent an important opportunity for young people to be recognized and contribute meaningfully.

Nature and Outcomes of the Design Process

Most studies indicated that consumer participation was integral to good intervention design and development [7,36,49-51,53-56,58,60-62]. Accessing consumers' implicit domain knowledge was the cornerstone of producing relevant, accessible, and usable interventions and output, which is consistent with prior reviews of participatory research [71,77].

Consumer involvement was associated with flexibility, responsiveness, human-centeredness, and adaptability in design. For example, in their online adaptation of peer-based health promotion for adult men who have sex with men and same sex attracted young people, Hallett et al [51] engaged peer volunteers to develop and pilot the intervention. This allowed the project to be responsive and to adapt the intervention and its evaluation as needed. The peer volunteers provided important information regarding online etiquette and technical proficiency, and during piloting facilitated access to clients and development of rapport and credibility through use of shared language and cultural understandings.

Consumer collaboration significantly altered Owen et al's [36] text-based self-harm prevention intervention from the original design brief. Researchers originally planned for a replication study in which generic texts were sent at predetermined, high-risk times; the co-design process resulted in a more flexible

and human-centered design involving client self-authored texts accessible on demand. Authors noted that the final form and function of the intervention would not have been possible without consumer input.

Successful outcomes require researchers to balance consumer requirements against those of other stakeholders, such as funders and implementation sites, while managing time, resourcing, and ethical considerations. This difficult task requires careful negotiation along with clear and ongoing communication [36,49,50,55,56].

This is best exemplified by analysis of (1) an exit focus group with youth consumers; and (2) youth consumer-designer/researcher email conversations throughout the Elf et al [50] project. Analysis revealed that, as the project progressed, the mind-set of the researcher/designers changed from exploration of ideas with consumers to concrete production of output. This shift in priorities was attributed to increasing pressure around resources (eg, human, financial, time), and delivering technical components on time became the priority over implementing consumer ideas/suggestions.

Theory to Support Intervention Design

Consistent with prior literature, limited application of theory to guide technology development was evident [17]. As a result, researchers are not maximizing the potential uptake, efficacy, and impact of their interventions. Three projects [7,54,62] used heuristic guidelines to support technology-based intervention design and development. The guidelines emphasize design for outcomes, with mental health professionals, within a UCD framework [6,18]. Consideration of clinical validity, therapist and client usability, along with intervention acceptability, access, engagement, adaptability, and sustainability are also highlighted. Monshat et al [57] was guided by constructs from TAM [64]. Beyond this, theory or models with the ability to explain consumer interaction with the technology were absent.

While the literature is still developing, the behavioral intervention technology model [17] is an example of a model to guide the conceptual and technical architecture of behavior-changing eHealth and mHealth interventions—where eHealth is defined as “internet or other electronic media to disseminate health related information or services” [78] and mHealth as “medical and public health practice supported by mobile devices, such as mobile phones, patient monitoring devices, PDAs, and other wireless devices” [79]. The model guides researchers through development of clinical and usage aims, choice of technical elements and characteristics, and development of the intended workflow associated with the intervention. It assists in translating intervention aims into intervention elements and characteristics [17].

eHealth participatory design best practice advocates for intended users as co-designers and partners in *all* phases of research, along with intervention evaluation criteria that balances youth relevance, meaning, and engagement with existing evidence [19]. This type of theoretical integration is sorely needed in a field constrained by issues with uptake, adherence, and engagement [9-13,17]. Furthermore, persuasive features that “reinforce, change, or shape attitudes or behaviors or both without using coercion or deception” [80] and consumer motivation have had limited application in participatory technology-based mental health intervention design and, therefore, represents a focus of inquiry for future projects [10,14,81,82].

Planning for uptake and established connections with intervention sites were common to projects that successfully implemented their interventions or secured future funding [51,55,58,61,62]. Few projects reported evidence of inclusion of representatives from intended implementation sites in design and development of their interventions, even when accounting for the exploratory nature of some of the projects. A narrow definition of *consumer* may have led to limited representation of intervention site stakeholders in the intervention design phase.

Researchers need to be designing with an implementation site in mind and integrating influential system and organization level representatives into the process. In the case of treatment-focused interventions, mental health teams exist within larger systems that play an important role in acceptance and adoption of new interventions. Intimate knowledge of, and a strong working relationship with, the implementation sites of interest must be a priority of designer-researchers. Wolbling et al [83] argues that “ground-breaking ideas that arise within an existing organization that are not consistent with their values, routines, and overall strategy will be more difficult, if not impossible, to implement.” This assertion has clear implications for a research team wishing to implement new interventions from the outside. Organizational factors such as workplace ICT culture and policy and availability of resources have shown to be facilitators of uptake of ICT in health care [8]. Whilst Coyle et al [6] and Doherty et al [18] account for individual therapist considerations in their heuristic guidelines, they fail to account for organizational and system level factors that can impact on intervention uptake and impact.

Designing with target consumers is crucial. The most commonly reported barriers to uptake of ICT in health care are design and technology concerns including lack of clinical relevance or impracticality; in addition lack of clinician time and perceived ICT skills are frequently reported barriers. On the flip side, facilitators of ICT uptake include system usefulness and functionality, clinical relevance and ease of use [8,84]. This research indicates a clear role for application of theory to guide design and systematic consideration of human factors.

Limitations

A limitation of this review was the broad inclusion criteria. This is particularly evident with respect to the Schmidt [59] project, which developed community health education outputs to explore youth conceptions of the relationship between the built environment and well-being. Whether these outputs can be categorized as interventions is debatable given the limited detail reported on the project. Despite the fact that youth participation was identifiable in the Owens et al [36] paper, it did not have an exclusive youth focus. It was chosen for inclusion due to the nature of the project and its value in contributing to the aims of the review. In addition, the screening process may have benefited from involvement of a second reviewer to double screen. Evaluation of consumer representation was deemed too

complex and broad to explore fully within this review beyond the description provided in the results table (Table 1). Finally, while every reasonable effort was made to find all relevant citations, the broad terminology used to describe the research in question may have resulted in some studies being overlooked, particularly where participatory processes may have been described in the methods sections of papers and not noted in the keywords, title, or abstract. Furthermore, the broad research field means the publication of some studies may not have been amenable to the titles, search terms, and databases that were used to construct this study and answer the research question. Moreover, participatory approaches are used in service settings but not always evaluated with the findings published and as such this work was not represented in the review. This review highlights the need for more research, evaluation, and publication on the use and outcomes of participatory approaches in the design and delivery of technology-based youth mental health services and interventions. The Young and Well Cooperative Research Centre (CRC) [85] is an initiative that prioritizes this connection and creates the required space for the corresponding evidence base to be built.

Given the nascent stage of this field of research and the corresponding exploratory aims of this review, the broad nature of the search terms and studies included facilitated a wide-ranging description and analysis of participatory design and development of technology-based youth mental health and well-being interventions. This ensured that insights and learnings from the breadth of the mental health intervention spectrum were incorporated. The heterogeneous nature of the projects included, however, prevented the number of specific comparisons that could be made between similar projects and intervention types. We also wish to acknowledge that analysis and results of this review attempted to define and summarize a diverse and often ill-defined research field, and in doing so may have inadvertently oversimplified the practical application of participatory intervention design. Finally, in a rapidly evolving field, the search cutoff date meant that highly relevant recent projects found in conference abstracts were not included in the review.

Conclusions

The current review found limited evidence that consumer consultations lead to routine uptake of interventions in practice; that is, consumer participation does not act as a default implementation or uptake strategy. Overall, strategies aimed at increasing uptake of technology in health care practice are not well understood or reported. A consumerist rationale, which prioritizes acceptability and usability of the intervention, has characterized most projects in this field. It was clear that consumer involvement shaped intervention design in ways that were reported as beneficial by the designers/researchers. While consumer consultations were associated with flexibility, responsiveness, human-centeredness, and adaptability in design, it was not possible to determine the impact of this on intervention effectiveness due to lack of outcome data. The implications for why and how consumers are asked to participate in this field of research and the degree of mutual benefit that is possible, desired, and ethical requires rigorous examination. Participatory intervention design projects are advised to develop flexible and well-resourced project plans, which integrate theory and implementation within the design and make space for reflection, evaluation, and publication of consumer experience of research.

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Conflicts of Interest

None declared.

Multimedia Appendix 1

Systematic review search strategy.

[PDF File (Adobe PDF File), 501KB - humanfactors_v2i2e12_app1.pdf]

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Abbreviations

ICT: information and communications technology
iSET: interactive socio-emotional toolkit
CBPR: community based participatory research
CRC: Cooperative Research Centre
MSM: men who have sex with men
NHMRC: National Health and Medical Research Council
OHPC: online health-promoting community
PAR: participatory action research
PD: participatory design
RCT: randomized controlled trial
SSAY: same sex attracted young people
TAM: technology acceptance model
UCD: user-centered design
WAAC: West Australian Aids Council
WBSS: Web-based support system
YVC: Youth Voices for Change

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Original Paper

Usability Testing of a Complex Clinical Decision Support Tool in the Emergency Department: Lessons Learned

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Abstract

Background: As the electronic health record (EHR) becomes the preferred documentation tool across medical practices, health care organizations are pushing for clinical decision support systems (CDSS) to help bring clinical decision support (CDS) tools to the forefront of patient-physician interactions. A CDSS is integrated into the EHR and allows physicians to easily utilize CDS tools. However, often CDSS are integrated into the EHR without an initial phase of usability testing, resulting in poor adoption rates. Usability testing is important because it evaluates a CDSS by testing it on actual users. This paper outlines the usability phase of a study, which will test the impact of integration of the Wells CDSS for pulmonary embolism (PE) diagnosis into a large urban emergency department, where workflow is often chaotic and high stakes decisions are frequently made. We hypothesize that conducting usability testing prior to integration of the Wells score into an emergency room EHR will result in increased adoption rates by physicians.

Objective: The objective of the study was to conduct usability testing for the integration of the Wells clinical prediction rule into a tertiary care center's emergency department EHR.

Methods: We conducted usability testing of a CDS tool in the emergency department EHR. The CDS tool consisted of the Wells rule for PE in the form of a calculator and was triggered off computed tomography (CT) orders or patients' chief complaint. The study was conducted at a tertiary hospital in Queens, New York. There were seven residents that were recruited and participated in two phases of usability testing. The usability testing employed a "think aloud" method and "near-live" clinical simulation, where care providers interacted with standardized patients enacting a clinical scenario. Both phases were audiotaped, video-taped, and had screen-capture software activated for onscreen recordings.

Results: Phase I: Data from the "think-aloud" phase of the study showed an overall positive outlook on the Wells tool in assessing a patient for a PE diagnosis. Subjects described the tool as "well-organized" and "better than clinical judgment". Changes were made to improve tool placement into the EHR to make it optimal for decision-making, auto-populating boxes, and minimizing click fatigue. Phase II: After incorporating the changes noted in Phase 1, the participants noted tool improvements. There was less toggling between screens, they had all the clinical information required to complete the tool, and were able to complete the patient visit efficiently. However, an optimal location for triggering the tool remained controversial.

Conclusions: This study successfully combined "think-aloud" protocol analysis with "near-live" clinical simulations in a usability evaluation of a CDS tool that will be implemented into the emergency room environment. Both methods proved useful in the assessment of the CDS tool and allowed us to refine tool usability and workflow.

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KEYWORDS

clinical decision support; emergency department; usability testing; clinical prediction rules; Wells criteria; pulmonary embolism

Introduction

Usability Test for a Clinical Decision Support Tool

Clinical decision support (CDS) tools for pulmonary embolism (PE) diagnosis have been designed and implemented over the past several years with limited success [1]. Tools have been designed to alert physicians during the order entry section of the electronic health record (EHR). However, physicians either dismissed or were noncompliant with the PE CDS tool [1]. With more flexibility in EHR off-the-shelf technology, we sought to design and test a CDS tool that would fit seamlessly within the emergency department environment. This paper highlights the usability testing conducted prior to integration of the Wells score into the emergency room EHR.

Clinical Decision Support

A physician's ability to determine a patient's risk of disease can sometimes be unclear and can make clinical decisions difficult. CDS tools help providers in their decision making process. These tools have been on the rise in recent years due to their ability to bring evidence-based medicine to point of care. A CDS system (CDSS) is a CDS that is integrated into the EHR and allows physicians to easily utilize the tool effectively. The CDSS incorporates individual patient data, a rule engine, and a medical knowledge base to produce a patient-specific assessment or recommendation of a management plan [2,3].

Clinical prediction rules (CPRs) are a type of CDS tool that quantifies the effect an individual patient's characteristics have toward their diagnosis, prognosis, or likely response to treatment [4]. These characteristics are based on various components of the history, physical examination, and basic laboratory results. CPRs use evidence to guide clinical management by allowing physicians to identify a patient's individual risk of a certain disease based on their personal risk factors. CPRs attempt to standardize, simplify, and increase the accuracy of clinicians' diagnostic and prognostic assessments [5]. There are numerous CPRs in the literature, but those with the highest level of evidence are those that are validated in numerous external environments and hold true in numerous clinical scenarios [4].

A common difficulty with CDS tools is trigger fatigue, when users begin to ignore or override the triggered tool due to a high frequency of alerts [6]. Successful workflow integration depends on careful consideration of what timing in the patient interaction the CDS is "triggered". For example, in a prior study implementing a pneumonia CPR tool into an ambulatory primary care environment, four key triggering points were identified: chief complaint, encounter diagnosis, orders, and diagnosis/order combinations [7]. This capacity to customize triggers to reflect real-world provider habits was a driver of the high adoption rates of the tool. This is why proper trigger placement is so important when designing a CDS tool. For this reason, finding an optimal trigger location for the tool was emphasized in our initial usability testing protocols.

Clinical Decision Support and Pulmonary Embolism

Emergency medicine physicians across the nation are being asked to improve their resource utilization, while competing with a low tolerance for missed diagnoses. This conflict of interest contributes to emergency department (ED) overcrowding, delay in diagnosis, and unnecessary exposure to radiation. EDs across the nation are backed-up with low risk PE patients waiting for unnecessary computed tomography (CT) scans, while high-risk patients, in need of urgent diagnosis are waiting in the same line. PE patient morbidity and mortality can be improved by timely diagnosis and treatment [8]. However, since PE is a condition with major repercussions and can be difficult to diagnose, providers often overestimate patient risk and order unnecessary tests [9]. Furthermore, these tests are labor intensive and expensive for patients. Studies show that 80%-90% of PE work-ups are negative and costs per case diagnosed are unduly high [10].

A CPR that is extremely well studied is the Wells score criteria, which enables a physician to predict a patient's risk of having a PE. The rule has been extensively validated in multiple settings [11-13] and has the potential to rule out 70%-80% of patients without further testing [14,15]. It considers several criteria based on history and physical examination to estimate the patient's pretest probability of PE as low, moderate, or high.

Despite successful validation of the Wells score criteria; there has been very limited success with implementation of the rule at the point of care, resulting in underutilization [16-18]. Multiple studies have found that the use of a CDS tool for the evaluation of a suspected PE, in the ED, is associated with an improved yield of positive CT scans [1,19,20]. However, the CDS tool was also found to be extremely time consuming and a hindrance to the physician's workflow, leading to poor acceptance rates by emergency physicians. This led to increased ordering of CT scans and decreased the effects of the tool overall [1]. These findings emphasize the importance of implementation of the Wells criteria in a way that will gain maximum acceptance by treating physicians.

Usability Testing

Formal usability testing has begun to be considered critical to the EHR adoption and implementation lifecycle [21]. This is because usability testing allows for the optimization of a tool prior to its integration into the clinical workflow environment. This is especially true in the ED where efficiency is vital.

A recent study emphasized the success of a novel approach to usability testing that combined a "think-aloud" protocol with "near-live" simulations [22]. Combining the two methodologies allowed for quick assessment of user preference and impact on user workflow.

"Think-aloud" protocols require users to verbalize their thought process while interacting with a new CDSS tools. For example, specifying why they are clicking on a specific part of the tool and explaining why it is (or is not) helpful. This type of usability testing was specifically well suited for our purpose, due to its

ability to identify barriers to adoption and surface level usability issues [23-25]. However, this protocol is limited by its ability to identify real-time hindrances within the CDSS tool.

Therefore, we combined this methodology with a "near-live" analysis following the adjustments identified through the first phase of testing. "Near-live" testing allows for a more fluid environment in order to identify further real-life barriers. Historically, "near-live" testing has been used in the engineering world to identify the most effective ways to apply new technologies. However, more recently, it has been documented as a successful methodology for implementing CDSS tools into Health Informatics Systems [26,27]. During simulations, each participant completes a mock scenario with a standardized patient. In this case, each provider interviewed two patients with varying risk categories (ie, low, intermediate, and high) for a PE. We hypothesized that combining these two unique usability methodologies would allow for optimal insight into the most efficient mechanism of integration of the PE CDSS tool into the EHR.

Methods

Usability Testing

We conducted two rounds of usability testing to identify the optimal way in which to integrate a PE tool into the EHR. This study was the first phase of a larger study looking at the implementation of the Wells CPR in the EHR through a randomized controlled trial. The study took place with emergency room physicians and residents at a large tertiary hospital in Queens, New York. There were four providers that participated during the first phase of the study, and three providers that participated in the second phase of the study. The number of participants involved was based on observations from previous studies where a saturation of feedback was identified at approximately four participants. Therefore, we aimed to recruit approximately four participants in both rounds of testing. A prototype of the EHR was created for the two rounds of usability testing in the Innovation Lab at the Center of Learning and Innovation. Usability data was used to refine and create a production tool. Usability data was used to refine and create a production tool. The PE tool was built as an active CDSS tool that could be triggered by the user during a typical workflow using two different approaches, including patient chief complaint and order entry, the former being upstream versus the latter more downstream (Figures 1 and 2 show this). The subjects reviewed two versions of each case; one with the tool popping up at the initial visit through the nurses triage note and the second trigger at the order entry. If the CDS tool were "triggered" by the triage nurse, the tool would be present when the physician clicked on the name of the patient. Conversely, following an order entry workflow, the CDS tool appeared when the physician ordered any test that is used to diagnose PE. This included a D-dimer test, CT chest, computed tomography angiography (CTA), ventilation/perfusion scan, and/or a lower extremity Doppler examination. After the tool was triggered, the physician had the ability to complete the Wells score CDSS. After completion, the tool calculated the patient's risk for PE and an explanation of the most appropriate next step(s) in the management of the patient appeared at the bottom of the screen. At this point the physician was linked to a bundled order set and automatic documentation of the tool's use. The automatic documentation within the functionality of the tool was used in order to incentivize use. This research study received approval from the North Shore-LIJ Institutional Review Board.

Figure 1. CDS tool; order entry workflow. PE: pulmonary embolism, ER: emergency room, CT: computed tomography, VQ: ventilation/perfusion, LE: lower extremity, HPI: history of present illness, CDS: clinical decision support, DVT: deep vein thrombosis, SOB: shortness of breath, ROS: review of symptoms, D-dimer: Fibrin split product, MD: medical doctor.

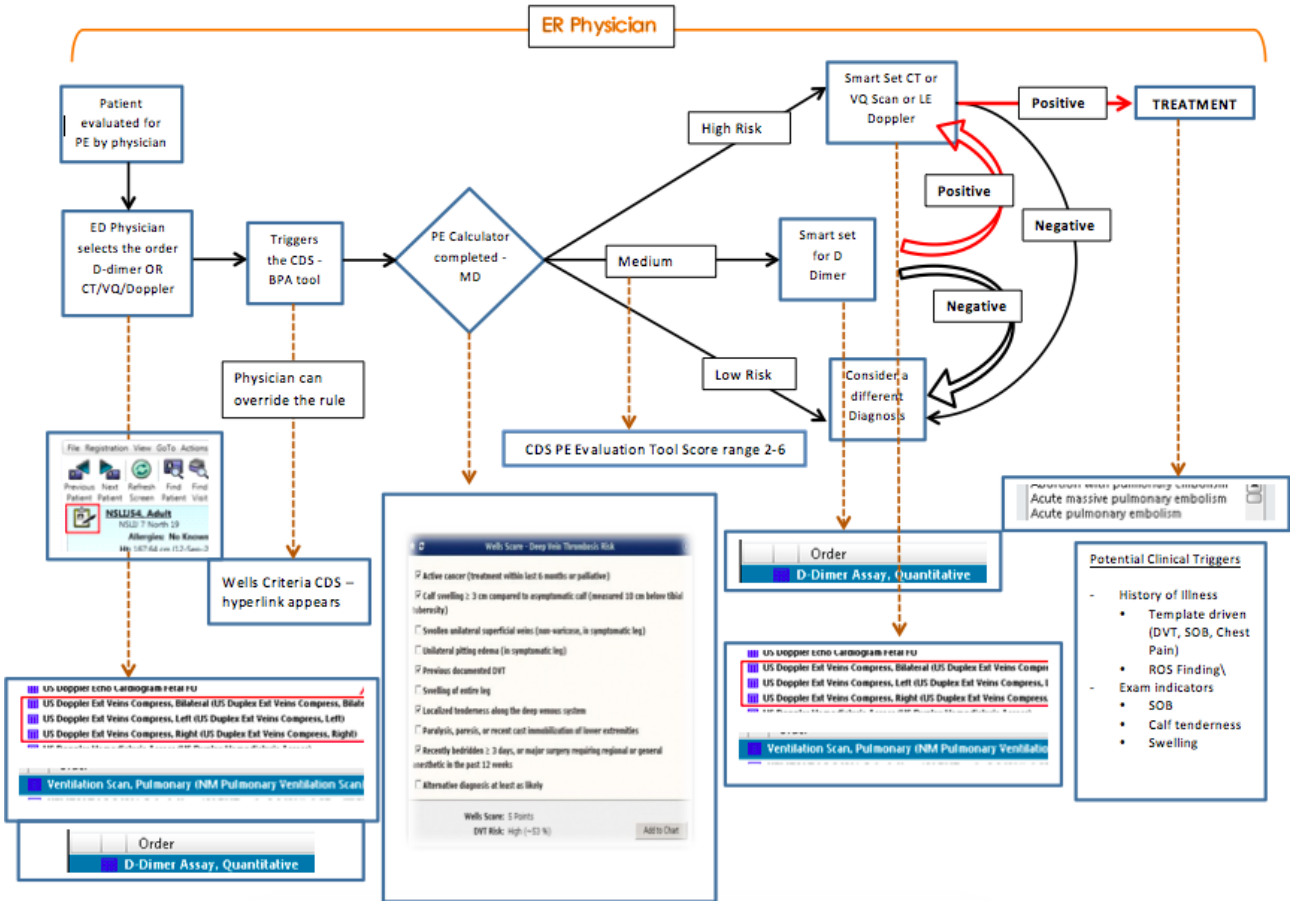
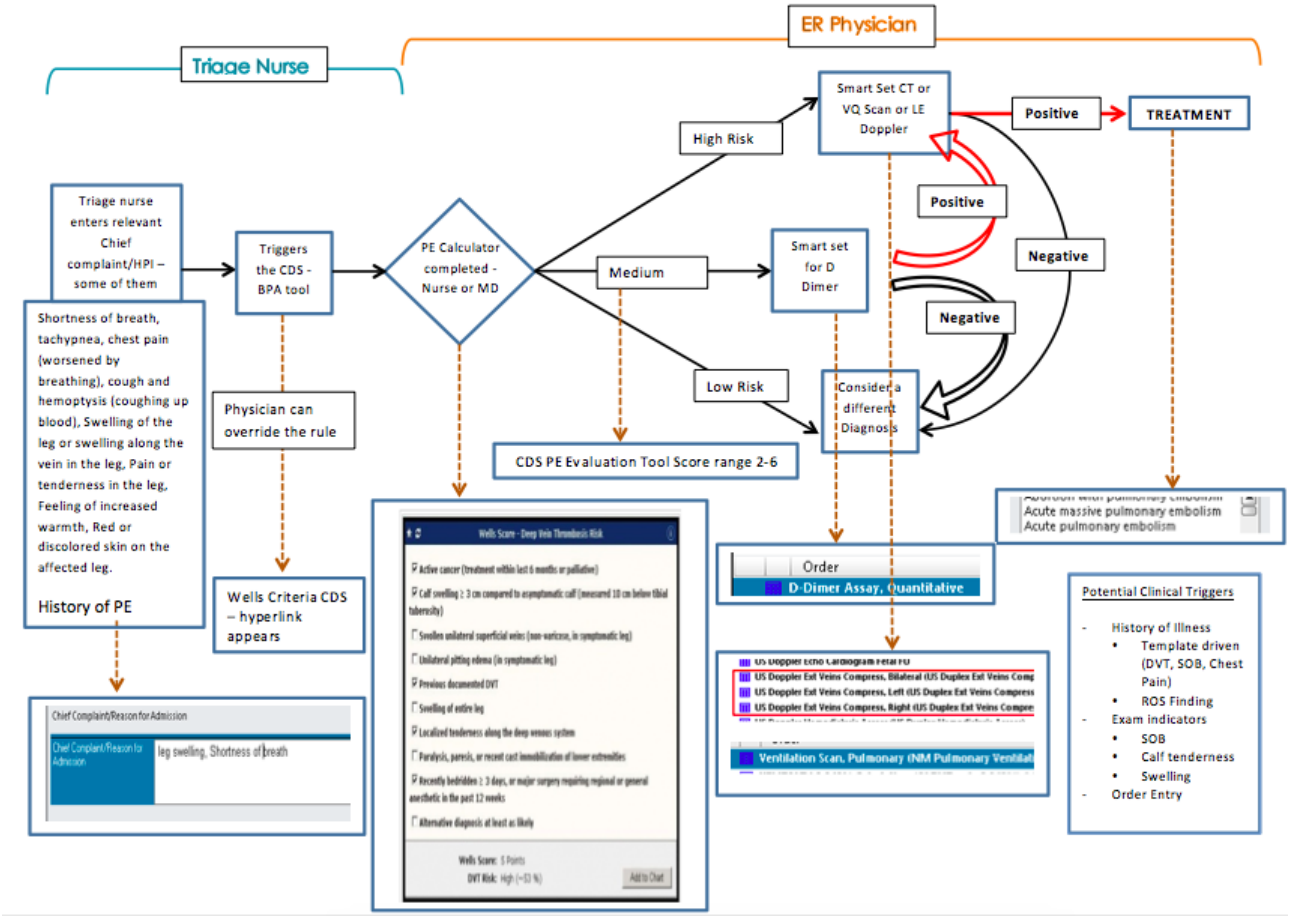


Figure 2. CDS tool; triage nurse workflow. PE: pulmonary embolism, ER: emergency room, CT: computed tomography, VQ: ventilation/perfusion, LE: lower extremity, HPI: history of present illness, CDS: clinical decision support, DVT: deep vein thrombosis, SOB: shortness of breath, ROS: review of symptoms, D-dimer: Fibrin split product, MD: medical doctor.



Phase I

Subjects

The four residents who participated in the "think-aloud" phase of usability testing were emergency room residents. Subjects were selected from volunteers to form a convenience sample. Each participant had similar training experience and familiarity with the EHR, ranging between one to three years.

Procedure

The usability session was conducted at the usability clinic that is associated with our health care system at the Center for Learning and Innovation. Each subject was given thirty minutes to complete four paper cases. The subjects each had two unique cases that had a different level of PE patient risk, varying from low to high. The subjects reviewed two versions of each case; one with the tool popping up at the initial visit through the nurses triage note and the second trigger at the order entry when a CT chest or CTA was ordered.

The subjects were instructed to read each case and enter patient data, develop a progress note, and complete the Wells CPR when it appeared. Using "think aloud" and thematic protocol analysis procedures, scripted simulations of patient encounters with 4 emergency medicine providers were observed and analyzed. Providers were instructed to follow "think-aloud" protocols throughout, which call for them to verbalize all thoughts as they interacted with the mock EHR. The "think-aloud" approach is particularly well suited for studies exploring adoption and implementation issues associated with use of CDS, since it can integrate qualitative and quantitative analyses of provider-decision support interactions.

Data Analysis

We collected audio and video recordings of provider's reactions to the CDS by encouraging them to vocalize their behaviors and thought processes. In addition, all computer screens during the interaction were captured as movie files using the screen recording software. In order to identify how each subject was interacting with the two different CDS tools and how it impacted their workflow, coders grouped facilitators and barriers of each component of the tool. Coders were given a streamlined matrix, training on what to look for, and were instructed to compare and combine thematic codes. For this study, thematic analysis was used in order not only to understand the effectiveness and efficiency of the tool, but also to understand the impact of the tool on the user's workflow. Following this first phase, we went back through an iterative process of editing the CDS tool from the "think-aloud" feedback.

At the end of the scenario, the subjects were asked for their overall opinion of the tool and it's positive qualities versus areas for improvement.

Phase II

Subjects

The three physicians who participated in the "near-live" clinical scenarios were emergency room residents.

Procedure

During *Phase II*, three subjects were assigned two cases each with forty minutes to complete both cases. Each provider interviewed two patients with varying risk categories (ie, low, intermediate, and high). Standardized patients in a mock clinical environment acted out the cases. The patient name, vital signs, medications, history, and chief complaint were all preentered into the EHR. Prior to the start of each case scenario, subjects were instructed that patient information for each case was available in the chart and were asked to conduct the visit as they would in their usual practice environment. Subjects received no navigational guidance from the research staff. Similar to *Phase I*, all of the scenarios were audio and video recorded and all the computer screens were captured.

Data Analysis

Similar to *Phase I*, audio and video recordings of the subjects were collected. There were two independent coders that reviewed the screen recordings to capture the timing of specific actions during each encounter. External usability experts reviewed the video, and coding of facilitators and barriers was preformed. Outcomes were measured by rates of positive/negative, overall subjective comments, and functionality of the tool.

Results

Phase I

There were four coding categories that were identified in the first phase of this study: trigger point, calculator, efficiency, and visibility. For trigger point, the subjects felt that the upstream trigger was more effective than a downstream one due to their decision-making process. They felt that if the tool was only triggered by an order entry, their management plan was less likely to change. On the contrary, if the tool was triggered purely on chief complaint, the subjects were more likely to use the tool in order to make their decision. However, a challenge to the upstream trigger point was the lack of all available data in order to complete the tool at that point. When it came to the calculator code, the subjects identified the tool as easy to use and well organized. Furthermore, they felt that in the intermediate cases, when PE diagnosis was unclear, it was better than clinical judgment. The efficacy was determined as being helpful. The visibility of the tool made it clear that there needed to be an option to have the tool on the sidebar of the EHR in order to make it easily identifiable (Table 1).

Table 1. Phase I usability coding results.

Code		Example	How it was addressed
CPR component	Trigger point	Pros • Trigger in the beginning helped to frame thoughts around PE diagnosis. Cons • Downstream trigger, at order entry, was less helpful due to lack of influence in clinical decision making. • Not enough information was attained prior to upstream trigger, which made it hard to complete at that time.	Upstream trigger was further analyzed.
	Calculator	Pros • Easy to use and well organized. • Wells criteria is well verified and very respected. Cons • Too many "clicks" results in "click-fatigue".	Employed information technology, IT, to assist with the auto-populating of boxes.
Usability	Efficiency	Pros • Easy to use. • Good idea to have a tool. • The tool is helpful. Cons • It will not trump clinical judgment. • Need to ensure that it will be applied to the right subset of patients.	Need to streamline triggering process to ensure tool is being applied to the necessary population of patients.
	Visibility	• Lack of clarity as to where the tool could be found and when it would initiate.	An option to find the Wells score in the side panel, as a stand-alone tool, is needed.
General comments	Positive comments	• Well-organized tool. • Easy to use.	The organizational structure of the tool was well received and should be further analyzed in the second round of testing.
	Negative comments	• There should be an organized place to place comments and justify a subjects' clinical thought process.	Option needed for a text box to appear, where any further comments and/or reasoning can be explained.

The Matrix Data

The matrix data from *Phase I* displayed a general agreement between the severity identified by clinical judgment and the tool. Subjects commented that the tool was most useful in the first set of cases that were identified as low or intermediate risk, when the patient diagnosis was uncertain. This tool was less helpful with high-risk cases since a CT scan to rule out PE was clearly necessary. For the second phase of the study, we modified the census trigger to account for patient assessment and auto-populated information from the past medical history to address the EHR clicking fatigue that was verbalized in the first part of the study.

Phase II

Similar to *Phase I*, the usability matrix during *Phase II* testing revealed an agreement between the clinical decision making of the physician and the tool when the patient was identified to be either high or low risk. However, if the patient was in the intermediary level, participants tended to overclassify them as high risk. This caused them to order a CT angiogram; at odds with the suggestion of the tool, which identified a D-dimer study as the best next step in diagnosis (Table 2). Similarly, residents identified the tool as useful in low and intermediary cases of PE, due to the uncertainty in these cases. For high-risk patients, they felt they did not need this tool. For this reason, they expressed a desire for a large dismiss button that would allow them to leave the tool incomplete if they chose to do so. Furthermore, they expressed a desire to have the tool as a "suggested next step", as opposed to mandatory guidelines. Given these stipulations, if triggered at the right point in time, the participants stated they were likely to use the tool in their clinical environment.

Table 2. Phase II usability matrix results

Risk level	Participant 1	Participant 2	Participant 3
High		Agreed with: risk-assessment and order set.	Agreed with: risk-assessment and order set.
Intermediate	Disagreed with: 1.)Assessment. 2.)Order set.	Disagreed with: 1.)Assessment. 2.)Order set.	
Low	Agreed with: risk-assessment and order set.		Agreed with: risk-assessment and order set.

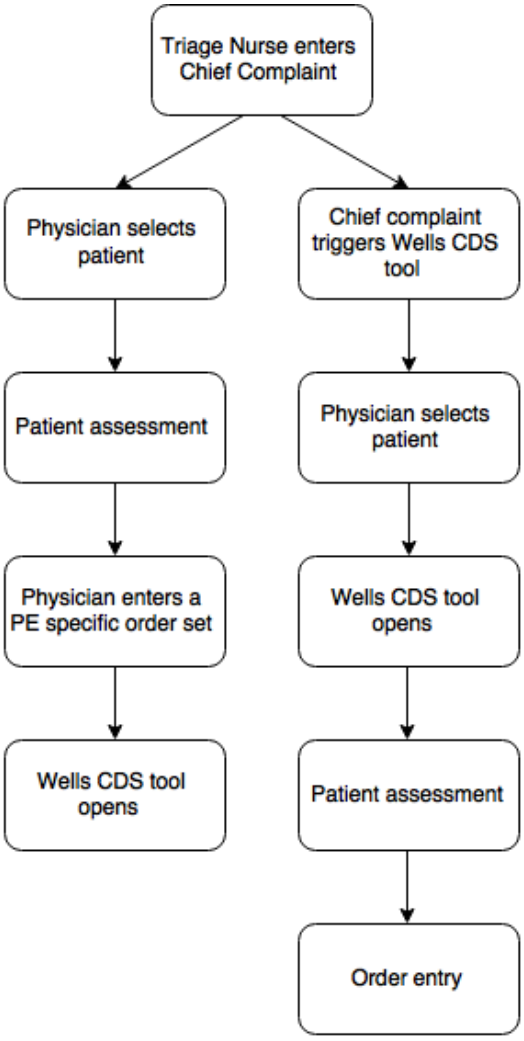
After Phase I

Following *Phase I,* we considered several options within the EHR to house the PE assessment tool based on discussions with the internal informatics team, provider familiarity, and provider workflow. In addition, we looked at different components of the tool depending on different work trigger locations. The different trigger locations included were based on workflow analysis; one trigger was placed after initial assessment, and one trigger was placed upon the ED physician order entry. As a result, the team was able to analyze the differences in provider workflow based upon trigger position. However, the lack of standardized workflow that the subjects used made identification of a perfect trigger point location extremely difficult. We found a unique set of workflow limitations and opportunities that apply specifically to ER physicians. For example, the physician workflow can vary significantly for the same diagnosis. A patient may initially have typical presenting symptoms for a PE (leg swelling, shortness of breath, malignancy), which would make the triage nurse an appropriate sentinel for triggering a tool (the nurse would alert the physician through the EHR to fill out the checklist when seeing the patient). Alternatively, the patient's presentation may initially be subtler, which would result in clinical suspicion of PE not arising until well after the physician has examined the patient. In this scenario, one could envision triggering the tool while the physician was entering his history and physical examination of the patient into the EHR (Figure 3 shows this). We also observed various different workflows, with some of the subjects looking at the computer first and some going straight to the patient to review the chief complaint and history of present illness.

Therefore, an ideal trigger point that the participants could use was not easily identified. It was clear that an effective trigger point for this tool would need to occur before order onset, but an ideal time was not as clear. This is due to the fast-paced and unpredictable nature of the ED patient flow. If the trigger is placed during ordering, the physician has already chosen the best course of action, has likely informed the patient of their decision, and is less likely to change their management of the patient. However, it was also clear that an upstream trigger point was likely to be too far removed from the physician's clinical thinking and workflow, and may cause "trigger fatigue".

The refinements following the first round of usability testing included modification of census trigger to account for patient assessment and the ability to auto-populate from past medical history to address EHR clicking fatigue. From this round, we noted that providers did not use the tool until after they looked at the patient, and in most instances, they had already made a clinical decision before they saw the PE tool.

Figure 3. Upstream versus downstream trigger locations. PE: pulmonary embolism, CDS: clinical decision support.



Discussion

Principal Findings

In both phases of our study, we identified a strong desire for the CDS tool and received positive feedback on the usefulness of the tool itself. Subjects responded that they felt the tool was helpful, organized, and did not trump clinical judgment. However, each round of testing identified clear barriers to integration and areas for improvement. We improved the tool by auto-populating information from the past medical history and identifying ordering bundles to incentivize use. The lack of standardized workflow that the subjects used made identification of a perfect trigger point location extremely difficult, which reinforced the theme to have two trigger locations: one upstream and one downstream to compare the effects on clinical decision making. Our study further demonstrates that usability testing for implementation of CDS tools into the emergency room environment is essential due to the unique challenges that arise.

Although numerous well-validated CPRs exist, few studies have reported significant adoption rates of CPR tools in real-time clinical interactions. A way to address this issue is by integrating CDS tools into the EHR. However, a lack of usability testing prior to their use can result in poor integration within an established clinical workflow [28]. Therefore, studies have begun to focus on usability testing of CDSS tools. Specifically, prior studies have focused on the role of usability testing in the primary care outpatient setting. For example, one recent study looked at the integration of an outpatient CDSS tool based on the Walsh rule for streptococcal pharyngitis and the Heckerling rule for pneumonia. This study resulted in a successful increase in adoption rates of the EHR CDS tool to 62.8%, as opposed to the average figure of 10%-20%, due to the usability testing employed prior to integration [5]. Conversely, studies attempting to integrate the Wells CDSS tool into the ED EHR have failed to lead to successful adoption rates [1,19,20]. This was due to a lack of focus on usability testing prior to the integration of the tool.

Due to this gap in literature, we applied the same usability methodology previously applied to the outpatient setting to the emergency room, where the workflow is often chaotic and high stake decisions are often made. This paper summarized the methods and results of the usability testing that we conducted. We hypothesize that conducting usability testing prior to the integration of the PE CDS will increase adoption rates of the tool.

The most important limitation was our ability to simulate a real emergency environment in the simulation center that we have

created. However, we instructed subjects to document their encounter and make use of the EHR mirroring the way in which they would do so in their normal clinical environment. Another limitation was the lack of malleability of our EHR system and lag in real-time implementation of subjects' suggestions due to the technical difficulties in doing so. During the study, we worked closely with an information technology (IT) team to resolve usability issues that we identified during both rounds of usability testing. However, due to the lack of malleability of the EHR system, there were specific elements of the tool that could not be transferred from the prototype EHR to the EHR system utilized by the health care system. An example of this is automatic documentation of the utilization of the tool. An EHR, which is more easily manipulated, would be ideal for this type of study.

Conclusions

This study employed usability testing methodology to analyze the integration of a Wells PE calculator into the emergency room EHR. The first round of testing employed a "think-aloud" approach, which identified numerous opportunities for optimization. By implementing these suggestions into the second round of testing, we were able to increase the usability of the tool. By using a "near-live" approach, we were also able to further identify specific workflow barriers that we were unable to identify in the first round of testing. For example, a desire for a large dismiss button that would allow them to leave the tool incomplete if they chose to do so. Furthermore, they expressed a desire to have the tool as a "suggested next step", as opposed to mandatory guidelines. Using this methodology in the integration of CDS tools into the ED, we believe we identified bridges that will allow for more seamless integration and adaptation by physicians. The next step in this study is a system wide roll out of the tool in a tertiary care environment.

Acknowledgments

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Conflicts of Interest

None declared.

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Abbreviations

CDS: clinical decision support
CDSS: clinical decision support system
CPR: clinical prediction rule
CT: computed tomography
CTA: computed tomography angiography
ED: emergency department
EHR: electronic health record
IT: information technology
PE: pulmonary embolism

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Original Paper

Assessing the Usability of Six Data Entry Mobile Interfaces for Caregivers: A Randomized Trial

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Abstract

Background: There is an increased demand in hospitals for tools, such as dedicated mobile device apps, that enable the recording of clinical information in an electronic format at the patient's bedside. Although the human-machine interface design on mobile devices strongly influences the accuracy and effectiveness of data recording, there is still a lack of evidence as to which interface design offers the best guarantee for ease of use and quality of recording. Therefore, interfaces need to be assessed both for usability and reliability because recording errors can seriously impact the overall level of quality of the data and affect the care provided.

Objective: In this randomized crossover trial, we formally compared 6 handheld device interfaces for both speed of data entry and accuracy of recorded information. Three types of numerical data commonly recorded at the patient's bedside were used to evaluate the interfaces.

Methods: In total, 150 health care professionals from the University Hospitals of Geneva volunteered to record a series of randomly generated data on each of the 6 interfaces provided on a smartphone. The interfaces were presented in a randomized order as part of fully automated data entry scenarios. During the data entry process, accuracy and effectiveness were automatically recorded by the software.

Results: Various types of errors occurred, which ranged from 0.7% for the most reliable design to 18.5% for the least reliable one. The length of time needed for data recording ranged from 2.81 sec to 14.68 sec, depending on the interface. The numeric keyboard interface delivered the best performance for pulse data entry with a mean time of 3.08 sec (SD 0.06) and an accuracy of 99.3%.

Conclusions: Our study highlights the critical impact the choice of an interface can have on the quality of recorded data. Selecting an interface should be driven less by the needs of specific end-user groups or the necessity to facilitate the developer's task (eg, by opting for default solutions provided by commercial platforms) than by the level of speed and accuracy an interface can provide for recording information. An important effort must be made to properly validate mobile device interfaces intended for use in the clinical setting. In this regard, our study identified the numeric keyboard, among the proposed designs, as the most accurate

interface for entering specific numerical values. This is an important step toward providing clearer guidelines on which interface to choose for the appropriate use of handheld device interfaces in the health care setting.

(JMIR Human Factors 2015;2(2):e15) doi:10.2196/humanfactors.4093

KEYWORDS

data collection; mobile applications; computers, handheld; user-computer interface; vital signs; patient safety

Introduction

Electronic data collection and recording in the health care setting is performed increasingly at the patient's bedside. Data (eg, medical prescriptions, medical summary reports, or daily recordings of body temperature, respiratory or cardiac frequency) can easily be collected on portable computers. Such devices have the advantage of being easy to store, manipulate, and use in emergency departments, outpatient clinics, or other crowded areas. Among the portable devices on offer, tablets and smartphones are becoming increasingly popular due to their handiness and resemblance to traditional paper-and-pencil data collection interfaces [1-3]. They also offer the advantage of providing apps designed especially for handheld devices, such as drug dosage calculators, electronic pharmacopeias, textbooks, or medical literature databases [1,4-7].

In the health care setting, many usability problems contribute to medical errors [8], of which those related to data entry are a major source. The quality of recorded information is of utmost importance because the life of a patient can easily be put at risk by the improper recording of a drug dosage or the incorrect labeling of a physiological or biological value [9-11]. Accuracy in the process of data recording can be significantly influenced by the design of an interface or by factors related to the type of data to be recorded, such as a number's length, type, magnitude or frequency, and even font appearance [12]. This has already been demonstrated for specific entry devices, such as infusion pumps [12-14], and in the context of medical prescriptions [8]. The limited size and tactile interaction paradigm of handheld devices compared to traditional laptops has further emphasized the risk of increased errors in data entry [3].

The influence that specific characteristics of handheld devices can have on human-machine interactions has already been studied [15-27]. Earlier works investigated the impact of limited display size on users' performances for tasks such as browsing, information retrieval, readability, or target selection [15-19]. These studies showed that the size of a mobile screen has no major impact on the user's comprehension of the information displayed. However, a correlation was found between the ease of reading and the size of the screen. In this context, Duchnicky and Kolers [20] found that it takes users up to 25% longer to read a given text on a small-width display than on a regular desktop screen width. This was confirmed by another study by Resiel and Shneiderman [21] who reported that reading on a 22-line display compared with a 60-line display resulted in a 15% decrease in the speed of reading. The same is true for information retrieval; studies have indicated that information retrieval tasks are harder to perform on small screen devices [22]. Moreover, users are more likely to perform incorrect choices when selecting from possible links and waste more time carrying out additional scrolling type activities [23,24]. Screen size also influences the quality of information input. Most studies assessing users' performance have confirmed that data input accuracy can be impacted by keyboard size or character setting, but also by other factors, such as a user's finger size [25-27]. Generally, a familiar disposition of the display and large keyboards improve user performance.

All these tend to demonstrate that it is crucial to take into account screen size specificity in the design of mobile device interfaces. Therefore, we assessed 6 tactile interfaces representing many of the common interfaces used on tablet PC and smartphones as interfaces built based on user requirements.

Methods

In order to identify the most suitable interface for the effective and reliable recording of numerical data on handheld devices, we performed a crossover randomized trial assessing 6 handheld interfaces designed according to 6 paradigms ranging from commercially available solutions to experimental designs. Each participant had to record several vital numerical signs on each interface. The interfaces were provided automatically in a random order.

Participants

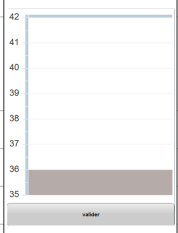
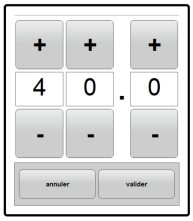
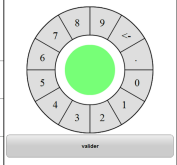
A sample most representative of health care professionals likely to collect, record, or use clinical data as part of their daily activity was recruited within the University Hospitals of Geneva, Switzerland. Recruitment was carried out following approval of the project by the "Commission cantonale d'éthique de la recherche," the University hospitals' human research and ethics committee. Previously published research on similar research questions were able to demonstrate significant differences between data entry interfaces with 30 participants involved [13]. However, because we were able to recruit among a large number of caregivers and had no prerequisites as to participants' characteristics, we relied on a convenience sampling approach. In total, 150 hospital workers selected across 5 categories of professionals were recruited: nurses, assistant nurses, midwives, physicians, and administrative staff. Participation was on a voluntary basis and there was no exclusion criterion.

Instruments

To test the 6 interfaces, we used a common commercially available smartphone, the Samsung Galaxy Note, which has a 5.3-inch screen with a resolution of 1280×800 pixels. This type of smartphone is representative of contemporary smartphones. It is also characterized by a high level of flexibility, which reduces to the minimum the design constraints set by human-machine interfaces. The 6 interfaces that were tested were designed to represent the most complete range of options

man-machine computer interfaces can offer (Figure 1). Four of the interfaces were chosen among existing interface design frameworks. The numeric keypad interface was chosen because it is recognized as being a being very effective at reducing the number of entry errors [13]. The stepper and wheel interfaces were chosen because they are commonly available on 2 major commercial smartphone operating systems, Android and iOS. Finally, the character recognition interface was chosen because it was among the first interfaces proposed for touchscreen devices, such as the PalmPilot. The last two options were developed by two distinct expert committees based on end-user requirements for recording interfaces. The first committee included caregivers who designed a dynamic chart (named "column") aimed at facilitating the identification of vital sign trends. The second committee included computer scientists at the hospital who developed a fast data entry system (the "circle") built on an interaction principle similar to the SwiftKey keyboard. The interfaces were implemented by the research team and installed on all devices provided to participants. Experimental designs were previously extensively tested by volunteers to ensure usability of the recording interfaces.

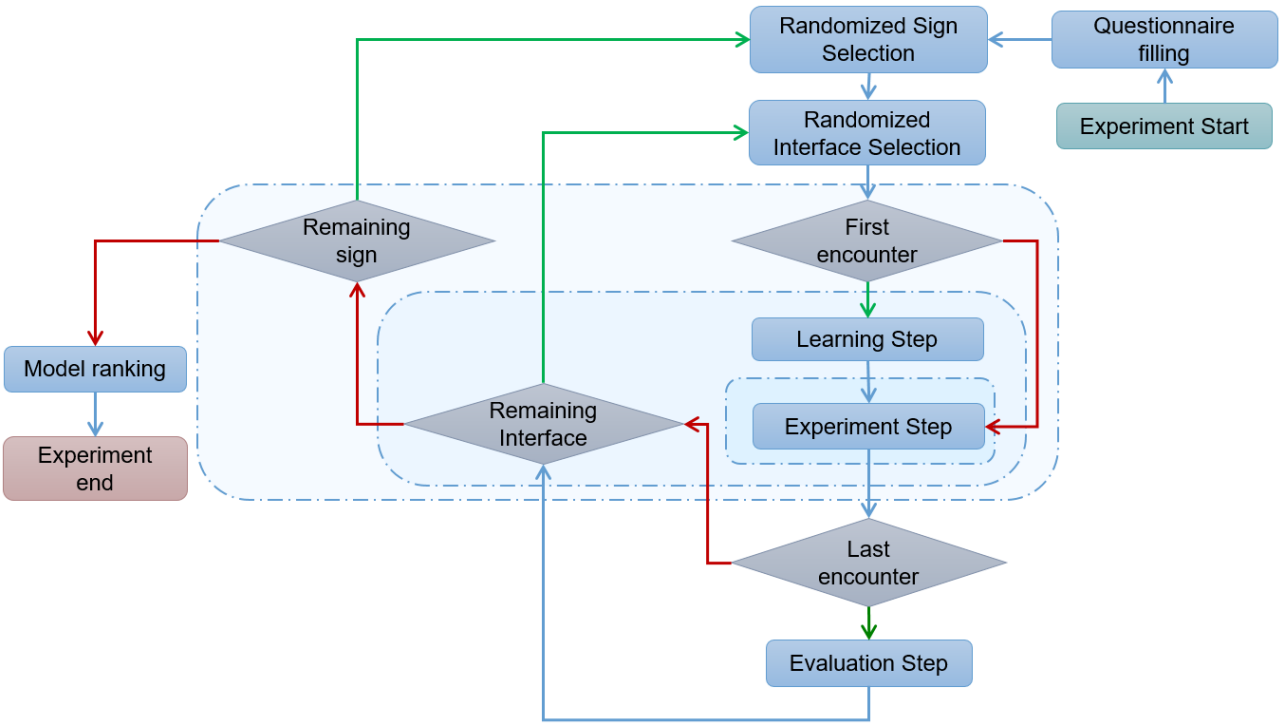
Figure 1. Description of the six data entry interfaces.

	**Name:** Numeric keypad **Description:** Most common method for data entry on calculators, computer keyboards and mobile phones. In order to record a number, the user presses in a sequential order on the different digits before validating the overall recording. **Minimum number of actions:** 1 per digit **Selection mechanism:** Deterministic **Design source:** literature **Influencing factors on usability:** buttons size and position		**Name:** Column model **Description:** To select a value, the user puts his finger in the middle of the screen, next to the wanted number that appears in full characters on the screen. If the displayed number is incorrect, the user can move his fingers upwards or downwards until the exact wanted value is displayed. **Minimum number of actions:** 1 per number **Selection mechanism:** Nondeterministic **Design source:** caregivers design **Influencing factor on usability:** Unknown
	**Name:** Numeric stepper **Description:** The user presses the "plus" button to increment higher values on the central counter or presses the "minus" button to decrement the counter towards lower values. **Minimum number of actions:** Sum of the digit **Selection mechanism:** Deterministic **Design source:** Android™ OS widget **Influencing factors on usability:** Independent selection of single digit versus selection of the whole number		**Name:** Circle model **Description:** To perform data recording, the user puts his finger on one of the digit of the circle. He validates his selection by moving his finger back to the center of the circle. He can slide his finger again to select the next digit and validate his choice using the same process. **Minimum number of actions:** 1 per digit **Selection mechanism:** Deterministic **Design source:** computer scientist design **Influencing factors on usability:** Unknown
	**Name:** Numeric wheeler **Description:** Selection of values to be recorded is performed by a swipe of the user's finger in the upper or lower direction of the wheel. The speed at which the swipe is performed influences the speed at which numbers will change. **Minimum number of actions:** 1 per number **Selection mechanism:** Nondeterministic **Design source:** IOS™ widget **Influencing factors on usability:** Independent selection of single digit versus selection of the whole number. Velocity of the wheel		**Name:** Character recognition model **Description:** The closest to the traditional pencil-paper data recording process. Numbers are directly drawn on the screen and a character recognition software transforms the drawing into a number that is then displayed on the screen **Minimum number of actions:** 1 per digit **Selection mechanism:** Nondeterministic **Design source:** palm OS widget **Influencing factors on usability:** Performance of the character recognition algorithm

Study Procedure and Data Collection

The trial was designed to minimize interaction biases. Based on a set of possible problems identified in a pilot phase, standardized procedures were defined so that any problem (eg, a system crash) would by default always be handled in a similar way. Each session of the trial took place in a controlled environment where participants could perform the test without any interruption or other disturbance. Before beginning the trial, each participant was shortly briefed on the study purpose and overall procedure. Participants were also informed that there was no time constraint for entering the displayed numbers. Each participant was then provided with a smartphone. Because the study procedure and instructions were available on each device and the entire study process was regulated by a computer program, there was no need for further interaction with the research team. Although the experiment took place in a controlled environment, participants were asked to use only one hand to hold the device to simulate the real-life bedside recording procedure as closely as possible (see Multimedia Appendix 1 for the CONSORT checklist filled for this study).

Figure 2. Data recording process.



Participants were first asked to read the instructions of the experiment that were displayed on the smartphone. A short questionnaire then popped up on the screen asking for details on participants' demographics and computer literacy. Following these steps, the actual trial phase began. Each participant was requested to enter data on all 6 interfaces. The sequence in which interfaces came up was automatically computed and randomly defined for each participant. The procedure was the same for each interface: participants were first able to practice the procedure before entering the data to be recorded. For each interface design, participants were asked to enter 3 types of physiological measures (body temperature, respiratory rate, pulse rate) that were displayed at the top of the screen. We chose these 3 vital signs from among the most frequently collected signs during patient follow-up that could be described using a single numerical value. For this reason, measurements such as blood pressure (composed of 2 values) were discarded as were other types of data, such as dates or time, which we considered would require other types of dedicated entry interfaces. When entering a number, participants could correct it as many times as they wanted before validating it. The computer program randomly generated the type of physiological data to be recorded and a value to be entered. During the training period, participants had to record 2 physiological values with the interface displayed on the screen. Users could not skip this step and had to continue the selection process until they succeeded. This is the only time users were allowed to request external assistance if they did not understand how to use the interface. Once the 2 physiological values were successfully recorded, the testing process started and participants were asked to record 3 random values for each possible interface-sign combination. Data for pulse, respiratory rate, and body temperature were given a predefined range of recordable values (Table 1).

Table 1. Range of recordable values.

Sign	Range	Decimal	Number of possible values
Pulse	30-170	No	140
Body temperature	36-41	Yes	50
Respiratory rate	3-20	No	17

The task was repeated until 3 values were recorded for each of the 3 physiological signs in each of the 6 interfaces. Altogether, this totaled 54 data entries for each participant.

Measured Variables

All variables needed for assessing the performance of each participant were recorded automatically on the smartphone. Among the variables that were measured were the number of actions performed by the participant, the number of corrections made, and the time until data entry validation. Data could be exported in a comma separated value file. Accuracy was measured by comparing the values participants were requested to enter as they appeared on the top of the smartphone's screen with the ones actually entered by each participant. Success or failure outcomes were then summed and reported as a proportion of the maximum possible score for each category of data entry. Effectiveness was assessed by measuring the time used to record each of the values.

Analysis

Descriptive summary statistics of continuous variables included means (SD), or medians with ranges, depending on their distribution. Continuous variables were compared using the paired Student *t* test or the Wilcoxon signed rank test if not normally distributed. For categorical variables, we used frequencies and proportions. Participants' satisfaction was assessed using the Friedman 2-way ANOVA test. After adjusting for age and familiarity of use of computers or smartphones, possible associations between the data entry time for each type of variable and the type of interface used or the sequence of data entry were examined using multilevel linear models. The same was done to evaluate the number of errors and corrections associated with each interface, this time using multilevel mixed logistic models. To obtain a normal distribution of the dependent variable, we used the log of speed of data entry. Interfaces were nested within the type of data entry, which were themselves nested within the coder.

A *P* value <.05 was considered statistically significant. We performed all analyses using the statistical package Stata version 12.

Results

Only 4 participants failed to complete the test due to technical problems or professional emergency causing them to leave the study before its completion. These incomplete records were removed from the study analysis. Demographics for the remaining 146 participants could be summarized as follows: mean age of participants was 43.6 years (SD 10.2) with two-thirds (64.4%, 94/146) younger than age 46 years. Most of participants enrolled in the study (92.5%, 135/146) were right-handed and nearly all (95.9%, 140/146) possessed a personal computer, although only 61.0% (89/146) already owned a smartphone. Most (75.3%, 110/146) were caregivers; the remaining 24.7% (36/146) were recruited among administrative personnel or computer scientists classified as "other participants." Study participant characteristics are detailed in Table 2.

The time needed to enter values with the different interfaces differed depending on the type of vital sign recorded (Table 3). In most cases, it took less time to enter pulse than body temperature values, and even less time to enter respiratory rates (except for the wheel mode). The results provided in Table 3 show that the speed of data entry was also influenced by the type of interface used. Differences were statistically significant (*P*<.001). The fastest interface for data entry was the numeric keyboard, with a mean entry speed ranging from 2.81 (SD 0.06) to 4.34 (SD 0.08) seconds depending on the type of variable recorded. This was significantly quicker than the stepper (mean 4.31, SD 0.11 seconds to mean 7.23, SD 0.36 seconds), the wheeler (mean 5.13, SD 0.14 seconds to mean 8.35, SD 0.21 seconds), and the circle (mean 4.45, SD 0.01 seconds to mean 9.38, SD 0.28 seconds) models. Finally, the less efficient interfaces were the column (mean 5.25, SD 0.16 seconds to mean 10.49, SD 0.45 seconds) and character recognition (mean 6.32, SD 0.24 seconds to mean 14.68, SD 0.64 seconds) models.

Table 4 shows data entry accuracy for the different interfaces. The numeric keyboard was the most accurate interface (96.3%-99.3% accuracy). It was followed by the stepper (97.9%-98.4% accuracy) and the wheel (95.4%-98.6% accuracy). Other interfaces were associated with more data recording errors. The other interfaces yielded levels of accuracy ranging from 93.2% to 94.3% for the column model, 88.6% and 96.1% for the circle, and 81.5% to 86.8% for the character recognition interface.

Among the tested interfaces, the numeric keyboard achieved the highest level of accuracy for recording pulse data. When looking at the mean scores of all 3 measures, the overall performance of the numeric keyboard was comparable to that of the stepper and wheel models. With regard to speed of data entry, the numeric keyboard scored the highest, with results at least 1.5 times faster than all other interfaces regardless of the type of variable recorded. Interfaces built based on a participative design, such as the circle or column, were associated with additional errors. Character recognition was found to be the most inaccurate and slowest interface for clinical data recording (Table 5).

Discussion

These study results can be explained by several factors. First, the selection mechanism used to enter values into the system was the most influential factor for determining speed of data entry. With a deterministic selection mechanism, such as the keyboard, the actions performed by users are transformed unambiguously into the associated outcome. This differs from a nondeterministic selection mechanism, such as character recognition, where there is no guarantee that the action of the user is transformed into the desired outcome. The interfaces with such nondeterministic selection mechanisms require some level of expertise and training to perform accurate actions that can be transcribed by the system into the desired outcome. The number "1" could, for instance, be at misinterpreted as a "7" and therefore require additional time to be corrected. The second parameter influencing the speed of data entry is the number of actions required to record it. In this regard, the stepper is not as fast as the keyboard because it requires more actions to enter a given numerical value.

An analysis of the error rate enabled us to classify the interfaces into 2 main categories: those yielding a level of accuracy greater than 95% (numeric keyboard, stepper, and wheel) and those yielding levels less than 95% (character recognition, circle, and columns). Interfaces offering no immediate feedback and those where it was difficult to modify recordings (character recognition, wheel) were associated with a significantly increased risk of recording errors.

Table 2. Participant characteristics (N=146).

Participant characteristics	n (%)
Age (years)	
22-34	42 (28.8)
35-45	52 (35.6)
≥46	52 (35.6)
Gender	
Female	96 (65.7)
Male	50 (34.3)
Hand preference	
Left-handed	11 (7.5)
Right-handed	135 (92.5)
Profession	
Assistant nurse	4 (2.7)
Nurse	76 (52.2)
Administrative	19 (13.0)
Midwife	11 (7.5)
Physician	19 (13.0)
Other	17 (11.6)
Has a computer	
No	6 (4.1)
Yes	140 (95.9)
Has a smartphone	
No	57 (39.0)
Yes	89 (61.0)
Frequency of vital sign recording	
Never	45 (30.8)
Monthly	12 (8.2)
Every day	89 (61.0)

Table 3. Mean time to enter 3 variables for each interface-sign combination.

Data type	Interface entry time (sec), mean (SD)						*P*
	Character recognition	Circle	Columns	Numeric keyboard	Stepper	Wheel	
Pulse	10.50 (0.44)	6.27 (0.14)	10.06 (0.34)	3.08 (0.06)	6.53 (0.36)	8.35 (0.21)	<.001
Body temperature	14.68 (0.64)	9.38 (0.28)	10.49 (0.45)	4.34 (0.08)	7.23 (0·18)	7.22 (0.19)	<.001
Respiratory rate	6.32 (0.24)	4.45 (0.01)	5.25 (0.16)	2.81 (0.06)	4.31 (0.11)	5.13 (0.14)	<.001

Table 4. Correct data entries for the 3 variables on each of the 6 interfaces.

Data type	Correct data entries, n (%)						*P*
	Character recognition	Circle	Columns	Numeric keyboard	Stepper	Wheel	
Pulse	372 (84.9)	421 (96.1)	413 (94.3)	435 (99.3)	431 (98.4)	432 (98.6)	<.001
Body temperature	357 (81.5)	388 (88.6)	412 (94.1)	425 (97.0)	431 (98.4)	427 (97.5)	<.001
Respiratory rate	380 (86.8)	413 (94.3)	408 (93.2)	422 (96.3)	429 (97.9)	418 (95.4)	<.001

Table 5. Data entry speed and accuracy for different interface characteristics.

Interface characteristics	Mean time (sec)	Mean accuracy, %	Minimum number of actions measured	Selection	Design source
Numeric keyboard	3.41	97.5	1 per digit	Deterministic	Literature
Stepper	6.02	98.2	Sum of the digits	Deterministic	Android OS
Circle	6.7	93	1 per digit	Deterministic	Computer scientists
Wheeler	6.9	97.2	1 per number	Nondeterministic	iOS
Columns	8·6	93.9	1 per number	Nondeterministic	Caregivers
Character recognition	10.5	84.4	1 per digit	Nondeterministic	Palm OS

Our results are in line with other research findings [13,28,29]. A study comparing 5 number entry interfaces for an infusion pump [13] showed lower error rates and speed of data entry when entering values on a number pad rather than a stepper. In a study evaluating data recording accuracy of a keyboard for electronic health recording systems compared with handwritten medical paper records, authors found that 25.6% of vital signs had one or more errors when documented on paper medical records compared to 14.9% errors when documented in an electronic format [28]. This confirms the improved accuracy of a keyboard compared to handwriting, as used in character recognition interfaces. Another study by Wager et al [29] compared error rates for 4 different types of entry devices (paper, computer on wheel, tablet, and direct feed from the monitoring system). Although no details were provided about the interfaces used, the error rate associated with a keyboard on a tablet was 5.6%, on average, similar to our study findings.

There are several limitations to our study. The first is the lack of exact knowledge about the prior level of familiarity users had for each of the 6 interfaces. However, one can reasonably assume that the novel interfaces implemented for the study were unknown to all users, whereas numeric keyboard and character recognition interfaces were probably familiar to computer and mobile phone users. Our study sample was mostly composed of the latter (see Table 2). In order to minimize this bias, we included a training session for each interface in our protocol. It is unclear whether this was sufficient to ensure a similar level of mastery for all categories of interfaces, but this limited the risk of variability due to insufficient training rather than to a true difference between interfaces [30,31].

A second limitation is the unknown influence of the original parameters set into the system on study outcomes [32,33]. Indeed, there are many factors that can influence the data entry process. For instance, the size of the keyboard buttons is known to influence a user's performance during data entry [27,34]. On infusion pumps, such factors can generate up to 28 different implementations of the data entry interface [13]. In their study, Cauchi et al [35] confirmed that these parameters not only influence data entry performance, but also the severity/degree of recording errors. Likewise, the character recognition algorithm can facilitate or complicate user inputs [36]. Therefore, if our results show clear and statistically sound differences in interface usability and accuracy, other studies analyzing the same interfaces but using different settings may show different results.

Third, despite explicitly instructing participants to act as they would normally during the trial session, while at the same time forbidding observers to intervene after the testing phase, it cannot be excluded that external observers may have had an influence on participants' behavior. For example, participants may have improved or modified an aspect of their behavior in response to the context in which they were acting rather than in response to the type of device used. This is known as the "Hawthorne effect" [37].

Fourth, the experimental setting cannot be considered as an ecologically valid one because the experiment took place in a controlled environment. Although we attempted to minimize this limitation by asking users to carry the device in only one hand, the fact that the numbers to enter were provided directly on the smartphone did not reflect real-life situations, where numbers are more likely to be read from another source. We chose this method of data delivery to exclude errors that might otherwise arise when transcribing data from one place to another [38].

Fifth, the purely quantitative approach adopted in our study cannot provide explanations as to why variations exist across different interfaces and what the implications are for the design and evaluation of mobile data entry tools. To clearly answer these questions, a more qualitative methodology needs to be adopted, such as the one used by Kushniruk et al [8] in their analysis of the relationship between usability problems and prescription errors in handheld applications.

Finally, it is also worth pointing out that evaluating failure based on a binary measure does not make it possible to evaluate the type and potential severity of an error. Indeed, studies such as those carried out by Wiseman et al [39] or Oladimeji et al [13,40] reported up to 7 classes of errors. Due to this limitation, our results do not highlight the fact that interfaces that enable each digit to be chosen independently are much more likely to create errors of higher magnitude and usually critical in a clinical context [12,41,42].

Although there is a marked increase in use of handheld devices in the health care environment, not all interfaces are adapted to specific constraints, such as smaller, interactive tactile screens. The possibility of recording clinical information on mobile devices opens the door to many questions. Interfaces set on these devices are usually complex to use. In his study, Howard [43] showed that this complexity could be explained by 4 reasons: intricacy, equivalence, omniscience, and commitment. To account for these different aspects, the design of a new

interface should evaluate each parameter separately for effectiveness and accuracy before combining parameters into a more complex design. Moreover, the identification of the most appropriate handheld user interface to record numerical data in an electronic format is only one of the many aspects that need to be investigated. Further aspects, such as the manipulation of text data or the recording of graphical data, need to be analyzed also.

Recording information in real time on handheld devices at the patient's bedside is increasingly becoming the standard of care in many health care settings. These devices offer improved portability and flexibility compared to desktop computers. The ease and accuracy with which data can be recorded in such settings will determine the choice of the most appropriate human-machine interface. Although a lot of work has been done on physical keyboards by engineers and ergonomists to improve the reliability and efficiency of data recording, a lot of work still has to be done for handheld devices. Our study shows that among the interface designs we selected, the keyboard reached the highest level of speed and accuracy when recording pulse data. The stepper and wheeler interfaces demonstrated similar accuracy, whereas the numeric keyboard remained by far the quickest interface for tactile interaction. Whether this conclusion will remain valid when using other interface parameters remains to be tested; however, the need for more in-depth evaluation of novel interfaces has clearly been demonstrated.

Although some interface designs may, at first sight, appear promising, only formal and rigorous assessments in randomized trials will enable the identification of the most accurate and usable interfaces for data recording in the clinical setting. As the new generation of handheld devices progressively replaces traditional computers, future developments to find the most appropriate human-machine interface should not only be based on designer or user committee inputs, but also on advice from other fields, such as experts in ergonomics.

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Conflicts of Interest

The authors are owners or developers of the software used in this study.

Multimedia Appendix 1

CONSORT checklist.

[PDF File (Adobe PDF File), 897KB - humanfactors_v2i2e15_app1.pdf]

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