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Contents

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Public Opinions on Using Social Media Content to Identify Users With Depression and Target Mental Health Care Advertising: Mixed Methods Survey

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Abstract

Background: Depression is a common disorder that still remains underdiagnosed and undertreated in the UK National Health Service. Charities and voluntary organizations offer mental health services, but they are still struggling to promote these services to the individuals who need them. By analyzing social media (SM) content using machine learning techniques, it may be possible to identify which SM users are currently experiencing low mood, thus enabling the targeted advertising of mental health services to the individuals who would benefit from them.

Objective: This study aimed to understand SM users' opinions of analysis of SM content for depression and targeted advertising on SM for mental health services.

Methods: A Web-based, mixed methods, cross-sectional survey was administered to SM users aged 16 years or older within the United Kingdom. It asked participants about their demographics, their usage of SM, and their history of depression and presented structured and open-ended questions on views of SM content being analyzed for depression and views on receiving targeted advertising for mental health services.

Results: A total of 183 participants completed the survey, and 114 (62.3%) of them had previously experienced depression. Participants indicated that they posted less during low moods, and they believed that their SM content would not reflect their depression. They could see the possible benefits of identifying depression from SM content but did not believe that the risks to privacy outweighed these benefits. A majority of the participants would not provide consent for such analysis to be conducted on their data and considered it to be intrusive and exposing.

Conclusions: In a climate of distrust of SM platforms' usage of personal data, participants in this survey did not perceive that the benefits of targeting advertisements for mental health services to individuals analyzed as having depression would outweigh the risks to privacy. Future work in this area should proceed with caution and should engage stakeholders at all stages to maximize the transparency and trustworthiness of such research endeavors.

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Introduction

Depression

At any given time, 1 in 6 adults (17%) in Western high-income countries such as England experience a common mental disorder (CMD) such as depression [1]. Depression, alongside other CMDs, accounts for nearly half of all ill health in people younger than 65 years [2,3]. It has a notable impact on both individuals and society; 90% of people who die by suicide have a mental health condition at the time of their death, and the highest rates of suicide are associated with depressive disorders [4]. Depression is also associated with a loss of productivity [5]. Mental illness in England is thought to cost the economy £105.2 billion each year due to factors such as time off work, reduced quality of life, and costs of running services [6]. However, only 1 in 3 adults (37%) aged 16-74 years with depression currently get access to mental health treatment [1].

Underdiagnosis and Undertreatment of Depression

In the United Kingdom, patients usually first seek National Health Service (NHS) health care through their general practitioners (GP) who manage up to 90% of mental health consultations [7]. People with mental health problems can alternatively seek specialized help directly from both NHS services, such as Improving Access to Psychological Therapies and charities. However, there is a geographical variance in the availability of services between regions, and there is still a significant proportion of the UK population who are underdiagnosed and undertreated [8].

Research shows that depression is underdiagnosed in general practice, with less than half of likely cases being recorded in patient notes [9-11]. The diagnosis of depression can be challenging, with some patients presenting with undefined or somatic illness [12]. Those who suffer from depression additionally may not disclose their symptoms to their GP, with common reasons including fear of stigmatization, concerns about privacy regarding medical records being seen by employers, and medication aversion [13]. Even if depression is diagnosed correctly in primary care, it is often undertreated because of the lack of service accessibility and long waiting times. Over 12% of people wait longer than 1 year in the United Kingdom to start nonpharmacological treatment, and 54% of people wait over 3 months [14]. This is in part due to the reductions in the availability of resources dedicated to mental health care as well as the increase in demand for these services, which contributes to the long waiting lists [14]. The impact on patients' quality of life from the underdiagnosis of depression may be considerable, given that mental illness has the same effect on life expectancy as smoking, [2].

Current evidence, therefore, suggests that the needs of patients with depression in the United Kingdom are not being met within the NHS. The gap between diagnosis and treatment of depression could be bridged by charities and third sector organizations, which provide services and treatment to eligible individuals. However, these services are not always publicized widely.

Why Use Social Media?

Social media (SM) offers a promising avenue for targeting information about third sector mental health services to people who need them. SM sites such as Facebook already use algorithms to target advertisement to the most appropriate users, for example, by using search keywords from the history of search engines and links that users have previously clicked on. As machine learning and other computer science techniques have become more advanced, it is increasingly possible to identify or predict specific characteristics, such as mood or depression, of SM users, from the content they post on sites such as Facebook or Twitter [15-18]. This may involve sentiment analysis (the valence of the emotion or mood of their words), analyzing posted images, or recognizing changes in the quantity and frequency of a user's content [19]. Previous research has shown that users disclose depressive symptoms on SM sites such as Facebook [20] and Twitter [21]; in some cases, users disclose enough information for researchers to make a diagnosis of a major depressive episode [20].

Thus, an algorithm could be developed that would identify Facebook users who are experiencing low mood or depression [22]. A mental health charity could then use this algorithm to selectively target the advertisements for its services to the most likely users. Alternatively, pharmaceutical companies could use such technology to target their drugs to the appropriate patient population.

Ethical Issues With Using Machine Learning to Target Advertising for Depression Services

This targeted advertising of mental health services would operate with the intention of promoting help to those who need it, as opposed to marketing goods for financial gain. However, some users of SM may find the notion of profiling their content for their mental health status in a SM forum as unacceptably intrusive. Privacy has been identified as an important concern for population-level SM research, with the association of individuals with a potentially stigmatizing medical condition being an established worry of users [23]. The possibility of breaches in confidentiality, stigmatization, and the consequent modification in SM use due to awareness of this profiling (*known as the Panoptican effect*) are corollaries of such SM analysis, which may cause the public to view it negatively [24]. Chancellor et al established a broad taxonomy of ethical tensions in inferring mental health states from SM, grouping them into issues around ethics committees and the gap of SM research; questions of validity, data, and machine learning; and implications of SM research for key stakeholders [25].

Aims of This Study

Considering the reasons outlined above, the public may have stronger views on the use of targeted advertising for mental health services than for other goods or services. We believe that it is important to understand what SM users think of algorithms for identifying depression from SM content, which would be used for target advertising. Specifically, we seek to understand whether the public is in favor of the analysis of SM content for possible mental health problems.

In this study, members of the public and users of mental health charity services completed an online questionnaire, which aimed to find out the following:

1. Whether SM users feel their posted content reflects their mental health reality.
2. If SM users are largely in favor of:
   - SM content being analyzed for indications of mental health problems and
   - SM content being used to guide targeting of advertising about mental health services.
3. Which aspects of analyzing or targeted advertising make people feel comfortable or uneasy.
4. Whether there are differences of opinion by demographic group.
5. Qualitative reactions to the topic.

Methods

Ethics Statement

This study was reviewed by and received favorable ethical opinion from the Brighton and Sussex Medical School Research Governance and Ethics Committee (*ref ER/BSMS2730/1*).

Study Design

This study is an online open cross-sectional survey designed on Qualtrics.

Participants

Any SM user within the United Kingdom was eligible to complete the survey, with no restrictions on eligibility except that respondents should be aged 16 years or older.

Questionnaire

The questionnaire was developed by authors EF and KC, with comments and suggestions made by all authors. It was developed using an iterative process of item generation, discussion among all authors, and refinement, based on general themes and participant quotes within the relevant literature [17,23,26]. To meet all 5 research objectives, we created questions on the following topics: (1) participant characteristics, (2) participants' SM usage, (3) participants' experience of depression and views on how this influences their SM use, (4) views on the analysis of SM content for depression and targeted advertising for mental health services, and (5) whether participants would support the use of algorithms for identifying depression from their SM content.

The full questionnaire is provided in Multimedia Appendix 1. Questions 1 to 5 captured the demographics and SM usage of the participants. Questions 6 to 11 were simple closed questions that asked the participants how their mood may affect their use of SM. Question 11 and 12 focused on the use of SM and attitudes to privacy. Questions 13 to 15 were generated following review of previous literature on the same topic [17,23,26]. Before these questions, which asked for views on analyzing SM content for targeted advertising, some simple explanatory information was provided about the technical aspects of targeted advertising to ensure that the participants were able to answer these questions. In question 15, we focused

and adapted the themes raised within the literature to generate statements with Likert scale responses, which presented a range of possible reactions to targeted advertising for depression services, with which participants could agree or disagree. We also included open-ended questions (16 to 18) to capture the themes that we may not have addressed within the structured questions. The questionnaire contained a range of multiple-choice questions, matrix tables, and free-text boxes to ensure that a range of both quantitative and qualitative data was generated from the participants across all aspects of the above-mentioned 5 research objectives.

Recruitment and Procedure

The survey was widely advertised on mental health charity websites and SM pages, including Mind, Turning Point, Samaritans, and MQ mental health. It was actively promoted through Facebook, Twitter, and Instagram via paid advertisements and using personal and institutional accounts. Local community groups and mental health support groups on SM sites were also asked to promote the questionnaire. It was disseminated through mailing lists, such as through Brighton and Sussex Universities, and through medical informatics communities, such as the Farr Institute, especially to public panels and interest groups. Due to this method of advertising, it was not possible to estimate response rates to the advertisement for the study. Full study information appeared on the first page of the questionnaire website. Participants were asked to indicate that they had read and understood the information and wished to provide their consent by clicking on a box. Then, the participants completed the questionnaire in their own time. Recruitment was open from February 1, 2018, to October 24, 2018.

Data Analysis

Data were downloaded from Qualtrics into IBM SPSS Statistics version 25.

Quantitative analysis was conducted by the calculation of summary statistics using frequencies and averages. Gender and ethnicity were dichotomized (into male and female, and white and nonwhite, respectively), and comparisons for these variables, as well as previous depression status, were made using a chi-square test.

Free-text answers were downloaded into NVivo version 12 (QSR International Pty Ltd), and qualitative analysis was performed by author KC using thematic analysis according to the 6 phases defined by Braun and Clarke [27]. This was a recursive process, which involved the coding of participants' responses using NVivo and the creation of multiple thematic maps. Codes were aggregated into meaningful groups, and a minimum number of meaningful themes emerged from the data, which best represented the common topics in participants' responses in the most parsimonious way.

Results

Participant Characteristics

In total, 183 full responses were recorded, with participant characteristics shown in Table 1. Participants were spread fairly

evenly across age groups from 16 to 65 years, with 1 respondent aged over 65 years. There was a slight underrepresentation of the younger age groups when compared with the percentage of SM users across the United Kingdom [28]. Twice as many females undertook this survey as compared with males, which may be explained by more females using SM than males [29] and that depression is more prevalent among females [30]. In this sample, 85.3% of the participants were of white ethnicity, which is similar to the population of England and Wales where 86% of the residents are white [31].

Use of Social Media

Facebook, Twitter, and Instagram were the SM platforms most used by participants. Facebook was the most frequented SM site (Table 2).

Participants mostly posted content on Facebook for only their friends to view. Posts regarding personal feelings or asking for support were posted publicly the least. Those who took the survey stated that their posts that were public were largely reserved for impersonal content such as advertising or sharing content from other sources (Table 3).

Table 1. Participant characteristics (N=183).

Characteristics	Values
Age (years), mean (SD)	38 (11.66)
Age groups (years), n (%)	
16-24	24 (13.1)
25-34	50 (27.3)
35-44	51 (27.9)
45-54	38 (20.8)
55-64	19 (10.4)
65+	1 (0.5)
Gender, n (%)	
Female	127 (69.4)
Male	54 (29.5)
Other	2 (1.1)
Ethnicity	
White British	111 (60.7)
Any other white background	45 (24.6)
White and black Caribbean	1 (0.5)
White and black African	2 (1.1)
White and Asian	1 (0.5)
Indian	6 (3.3)
Pakistani	2 (1.1)
Chinese	6 (3.3)
Any other Asian background	5 (2.7)
Arab	3 (1.6)
Any other ethnicity or background not stated	1 (0.5)

Table 2. Use of social media sites and frequency.

Social media sites	Participants using site, n (%)	Frequency of use (% of participants using site), n (%)			
		Many times a day	Once a day	A few times a week	Less than once a week
Facebook	159 (84.6)	103 (64.8)	28 (17.6)	16 (10.1)	12 (7.5)
Twitter	118 (62.8)	49 (41.5)	22 (18.6)	27 (22.9)	20 (16.9)
Tumblr	5 (2.7)	1 (20.0)	0 (0.0)	1 (20.0)	3 (60.0)
Instagram	99 (52.7)	47 (47.5)	20 (20.2)	15 (15.2)	17 (17.2)
Snapchat	44 (23.4)	13 (29.5)	7 (15.9)	6 (13.6)	18 (40.9)
Flickr	10 (5.3)	0 (0.0)	0 (0.0)	0 (0.0)	10 (100.0)
Other	18 (9.6)	2 (11.1)	4 (22.2)	3 (16.7)	9 (50.0)

Table 3. Expected audience for content posted on Facebook. Survey answers for question, "Thinking specifically about Facebook: please select the type of content you post".

Type of content posted on social media	Publicly, n (%)	To friends only, n (%)	To closed groups, n (%)	To open/interest groups, n (%)
Share articles/pictures/quotes from other sources	34 (18.6)	142 (77.6)	4 (2.2)	3 (1.6)
Describe my current life events/share my news	11 (6.0)	161 (88.0)	11 (6.0)	0 (0.0)
Describe my state of mind	21 (11.5)	138 (75.4)	21 (11.5)	3 (1.6)
Ask for advice or support	6 (3.3)	118 (64.5)	53 (29.0)	6 (3.3)
Advertise goods or services/seek goods or services	50 (27.3)	71 (38.8)	36 (19.7)	26 (14.2)
Other—if so, please be specific and tell us the type of content (eg, "Checking in," tagging in memes, sharing own art or pictures, professional content, and sharing political content).	7 (43)	6 (38)	3 (19)	0 (0)

Relationship Between Depression and Use of Social Media

Over half of the participants had experienced depressive symptoms that had made them consider seeking help (62.3% [114/183]; Table 4). This high figure is assumed to be a result of advertising via mental health charities, which gave us access to the above-average number of patients who had experienced depression. In total, 22.7% (40/176) of the participants agreed that their recent low mood would be evident from their SM activity, and most of the participants thought that posted SM content is not reflective of true feelings. As shown in Table 4, three-quarters of participants who answered the question (N=44) stated that they often post less on SM than usual when they are feeling low and only 11% (5/44) post specifically to seek support. Within the same group of participants (N=44), 70% (31/44) agreed that when they are feeling low, they do appreciate getting support from friends on SM.

Table 4. Relationship between depression and use of social media.

Question	Respondents who answered "Yes," n (%)	Total number of respondents per question, n
Have you ever experienced depressive symptoms long or severe enough that you have thought about seeking help?	114 (62.3)	183
If you have experienced low mood in the recent past, do you think this would be evident from your online public social media activity?	40 (22.7)	176
Is your posted social media content reflective of your true state of mind when you are feeling low?	14 (3)	44
How much do you tend to post when your mood is very low?		
More than usual	5 (11)	44
Same as usual	6 (14)	44
Less than usual	33 (75)	44
When you are feeling low, do you appreciate getting support from friends on social media?	31 (71)	44
Do you post on social media specifically to seek support for your low mood?	5 (11)	45

Views and Perceptions Around the Profiling of Social Media for Mental Health

Participants responded to a series of statements using a 5-point Likert scale, with mean responses and standard deviations reported in Table 5 (higher scores equaled a positive agreement). Participants' scores were largely toward the "disagree" end of the scale when they were asked if they would feel comfortable with their Facebook posts being analyzed for target advertising. This was regardless of the type of advertising, although advertising from brands and businesses was viewed least favorably.

As a whole, participants scored more toward the "agree" end of the scale when they were asked about the potential negative *and* positive impacts of the analysis of Facebook content for depression. The negative impacts included stigma, exposure, intrusiveness, and risk to privacy, whereas the more positive impacts included a widening access to services and reaching those who struggle to seek help. On balance, participants did not endorse the idea that the benefit to both individuals and society as a result of this analysis would outweigh the risk to individual privacy (Table 5).

In addition, participants felt uncomfortable with the idea of this analysis happening and felt least comfortable with the idea of a human analyzing their Facebook content for depression, compared with a computer algorithm.

A final question, with a yes/no response, was asked to the participants to ascertain if they supported this analysis and if they would be happy for their own data to be used in this way. In total, 60.0% (96/160) of the participants supported the idea of the use of software to analyze Facebook content for the purpose of improving targeting of charitable mental health care services. However, slightly less than half (43.9%, 69/157) of the participants would give consent for their own SM to be analyzed and even fewer (15.3%, 24/157) participants would be comfortable with this happening to their data without explicit consent (Table 6).

Table 5. Views on analyzing social media for targeting mental health services (5=strongly agree, 3=neutral, and 1=strongly disagree).

Question	Value, mean (SD)
Would you feel comfortable if you discovered that posts on Facebook were being analyzed to target individuals for	
Advertising from brands and businesses	2.44 (1.10)
Health care advice, for example, from the National Health Service	2.76 (1.32)
Mental health care/advice	2.74 (1.34)
Services offered by mental health charities, for example, Samaritans, Mind, or Turning Point	2.79 (1.32)
How much do you agree with the following statements about analyzing Facebook users' content for depression?	
It would increase stigmatisation.	3.10 (1.15)
People might end up being outed as having depression.	3.73 (1.05)
It would make me feel uneasy.	3.69 (1.21)
I would find this intrusive.	3.80 (1.19)
It would increase people's access to mental health services.	3.34 (1.15)
It could identify people who struggle to seek help in real life.	3.58 (1.02)
I would be worried about my privacy if my Facebook was analysed in this way.	3.91 (1.14)
The benefit to society outweighs the risk to my privacy.	2.73 (1.24)
The benefit to individuals outweighs the risk to my privacy.	2.80 (1.26)
I would feel comfortable if	
I knew this was happening.	2.66 (1.31)
I knew a human was analysing my Facebook content for depression.	2.25 (1.22)
A computer algorithm (not a human) was analysing my Facebook content for depression.	2.68 (1.35)

Table 6. Personal views on the use of own social media data for analyzing for depression. Survey answers to the question, "It may be possible using computer programming software, to work out from Facebook content whether a user is depressed or experiencing low mood to provide information about services that may be available. If this technique is shown to work well:".

Question	Participants who answered "Yes," n (%)	Total number of respondents per question, n
In general, I support the idea of the use of this software.	96 (60.0)	160
I would give consent for my Facebook content to be analysed for depression.	69 (43.9)	157
I would be comfortable with my Facebook content being analysed for depression without my explicit consent.	24 (15.3)	157

Differences of Opinion by Demographic Group

The proportions of participants responding positively to the final question were examined by age group, gender, ethnicity, and previous depression status (Table 7). In general, the younger age groups were more supportive of the use of this technology and were more willing to give consent for their own Facebook to be analyzed, although the age group of 55- to 64-year-olds was the group most supportive of this analysis being conducted without explicit consent. In particular, the age group of 16- to 24-year-olds was particularly supportive of this software if they could give their consent to its use, and the age group of 35- to 44-year-olds was the least supportive overall (not examined for statistical significance). A Pearson chi-square test was conducted to determine whether there was a difference in opinion for gender (male and female), ethnicity (white and nonwhite), and previous depression across 3 questions assessing support for the software, willingness to give consent, and whether users felt comfortable with the analysis happening without their consent. No significant results were found.

Table 7. Differences of opinion by demographic group.

Demographics	Percentage of those who support the idea of the use of this software	Percentage of those who would give consent for their Facebook content to be analyzed for depression	Percentage of those who would feel comfortable without explicit consent
Age group (years)			
16-24	85	70	20
25-34	65.1	51.2	22.2
35-44	52.3	31.8	11.4
45-54	60	40	8.57
55-64	38.9	35.3	25
65+	100	100	0
Gender			
Female	58.4	41.1	14.3
Male	63	50	15.9
Other	100	100	100
Ethnicity			
White background	59.1	44.8	14.9
Nonwhite background	65.2	39.1	17.4
Experiences of depression			
Previous depression	58.3	41.2	15.7
No previous depression	65.6	52.5	15.3

Reasons for Responses

Participants' responses to the open-ended questions varied with strong views expressed regarding both the positive and negative aspects of the use of the software. Thematic analysis resulted in 3 themes describing the perceived benefits of the analysis (improvement of services, improvement of diagnosis, and societal benefit) and 3 themes describing concerns (privacy, usefulness, and accuracy of the software).

Benefits

Improvement of Current Mental Health Services by Increasing Access to Resources

A recurring theme was that the use of this software could assist in improving access to mental health services for those who needed them.

Participants mentioned that by providing targeted advertisement, the technology could increase the awareness of services available and, therefore, access to them:

> If people with depression occasionally got targeted ads for e.g. CBT or other therapies they might be more inclined to have a go and potentially seek more help to get better.

> People would be made aware of services available to them. They might realise the difficulties they are facing.

Participants also recognized that provision of resources could be improved by the software through the use of demographic analysis. This could increase access to services by ensuring that the services that are available are appropriate for different members of society:

> Considered at population level, it could provide an overview of the depression and anxiety at a population level, and could be broken down demographically too. This could help provision of resources.

Improvement of Diagnosis

Another key benefit that was raised by the participants was that the software would help improve the diagnosis of depression,

which is vital given that many are undiagnosed for multiple reasons and, therefore, cannot get access to treatment and support [32]:

> I think it could help identify people with mild to moderate depression who are not aware that this is the cause of them struggling with life to offer them support that could improve their wellbeing and quality of life.

Participants suggested that the software would be of particular use in diagnosing those that the system currently misses. Participants recognized that the users of SM may find it more comfortable to post about their feelings than speaking about them in real life, and this could be of use in improving the rates of undiagnosed depression:

> It could help out people who are more introverted and may not speak to other people about how they are feeling.

> It is easy to have depression without identifying it as such. Increased opportunities for diagnosis are therefore a good thing.

> It would be beneficial if it made it easier for people who are struggling had easier access to people who could help them in real life.

Societal Benefits From Advertising

Participants also recognized that targeting advertising already occurs, and some of the participants stated that the use of targeted advertising for the provision of mental health care was preferable to its current use:

> Better than what it's currently used for...

> None - we are all being targeted anyway with everything else, great idea.

Concerns

Privacy

Privacy was a key concern that was identified by a significant majority of respondents. Of particular concern was the potential for the data that were harvested to be exposed to others with untrustworthy motives. Stigmatization and discrimination were explicitly mentioned as worries:

> With the number of data leaks we have by large tech companies, this is a risk too far for many people.

> I don't want people to be profiled, as social media is also a platform for self-expression. This could be used to discriminate against people for health and insurance reasons if the information were identifiable.

> They'll sell the information to anyone, Facebook only exists to make money out of people. This sort of analysis will probably be sold or hacked and would be detrimental, e.g. upsetting the individual and affecting things such as insurance, credit ratings etc.

> In light of recent revelations about the questionable ethics of Facebook I would find it extremely disturbing if they were using my data to carry out "health screening."

Usefulness

Some participants were concerned about how effective the software would actually be. Statements were made by referencing the targeted advertisements that are seen on SM because of the use of cookies and search engine histories:

> I feel like this already happens for advertising, e.g. I see adverts for online counselling if I share that I've been struggling. I don't always appreciate this though, and it can feel intrusive.

A different subtheme identified within the concern about the usefulness of the software was that the analysis was already being done by friends of users on SM sites:

> This is already being done; friends and family already perform this analysis unofficially and take action.

Accuracy of Software

Other participants drew attention to worries regarding the software being oversensitive and potentially labeling those who are not suffering with depression with a diagnosis. It was highlighted that some SM users' posts may contain content that is incorrectly picked up by the machine learning algorithm because of humor or research:

> Sometimes people are joking or being sarcastic on Facebook posts, if a person is not mentally well, they need to speak to someone face to face.

> In common with many of my friends, I have quite a dark sense of humour and I imagine that my Facebook content might end up flagging concerns incorrectly.

> I am always being targeted for things which I am not interested in because I work with vulnerable young people, and my internet activity often reflects this in terms of the articles I read and content I share/groups I join. This doesn't relate to how I'm feeling, but is research for my work.

Discussion

Summary of Key Findings

We recruited a sample of SM users who were demographically broadly representative of the UK population and who mainly used Facebook, Instagram, and Twitter. Participants expressed opinions regarding the feasibility of using SM data to identify depression, and whether, as users of SM, they would agree to this analysis of their online content.

As many of these participants were recruited through mental health charity channels, we had a higher than usual rate of previous depression in our sample (62.2%, 114/183). Only 22.7% (40/176) of the participants who had experienced depressive symptoms believed that low mood would be evident from their posted SM content, and 32% (14/44) of the participants suggested that their SM content is not reflective of their true state of mind when their mood is low. The majority of the participants suggested that they often post less on SM than usual when they are feeling low. These findings are problematic for the approach of analyzing SM content for depression as they suggest that there may be less data available

for modeling depression than would be assumed if content was posted at the same level as during positive moods. De Choudhury et al [16] suggest that these changes in SM activity could be used as a feature in a predictive model for depression, in conjunction with the analysis of content, but it is not at all clear how predictive a reduction in activity would be, given that such a reduction could be due to any reason. Inkster et al [33] note that depressed users may stop generating content on SM, so additional data sources, such as text messages and sensor data, could be used to continue monitoring individuals [34].

Participants agreed that they would be worried about their privacy if their SM content was being analyzed for depression, and they did not agree that societal benefits outweighed the risk to their privacy. Privacy concerns were also expressed in the open questions, with participants specifically referencing recent scandals about the use of Facebook data, for example, Cambridge Analytica [35]. Participants were worried that the results of this analysis about mental health could be sold or hacked and may subsequently affect the individual's insurance premiums or credit ratings, and they endorsed the statement that such analysis could expose a person as having depression. The analysis was also perceived to be intrusive, and 1 participant suggested that it would be "extremely disturbing" for such health screening to be conducted on the SM content, which is viewed as a platform for self-expression. Interestingly, participants rated feeling least comfortable with a human analyzing their content for depression, although they were still largely negative about a computer algorithm conducting the analysis.

We also asked participants whether they would consent to such analysis of their own data. Although a majority of participants were in favor of the idea of this analysis happening in principle, a minority would give consent for their own data to be used in this way and an even smaller minority would be comfortable with it happening without consent. We did not find any differences in the levels of agreement by gender, ethnicity, or history of depression. This lack of support is of interest, given that the profiling of SM users' demographics and certain content happens without explicit consent already, for targeting advertising within news feeds and across search engines. It suggests that participants may feel qualitatively different about their content being profiled for health status and services compared with advertising for other products. Despite not being in favor of this analysis for their own data, participants could see some benefits in the software being developed, such as identifying and signposting more people to appropriate services and putting current targeted advertising methodologies to a better use.

We have, therefore, identified 3 key issues that weigh with the public when considering the concept of analyzing SM content for signs of depression: (1) that users perceive that the quality of data available may not result in accurate predictions, (2) that they could support the idea of analysis for depression in principle but have key concerns about its safe implementation, and (3) that these concerns center on intrusiveness and risks to privacy. These risks are largely felt to outweigh the benefits of this technology to individuals or society.

Potential Implications for Services

These findings suggest that SM users hold complex and mixed views on the profiling of content for mental health. They can see some benefits but many have lost trust in certain SM platforms as data custodians, and thus, they regard such analysis as unacceptably intrusive. Although certain mental health charities may be keen to embrace such technologies for advertising services, these findings suggest that the climate may not be right for this approach, and it is possible that charities could lose their clients' trust if they go down this route. More work is needed to secure a social license for such use of SM users' data. According to social license theory, which was developed around the ideas of corporate social responsibility by honoring additional safeguards over and above any legal requirements, organizations or corporations may help to engender trust, maintain transparency, and secure societal approval for their activities [36]. Thus, the public looks for a voluntary adherence to the social codes of trustworthy and responsible behavior. When the public is satisfied that the motivations of the organization are trustworthy, their tacit approval can be seen as a "social license" to operate. Previous health data sharing initiatives have collapsed because of failing to secure a social license [37].

Study Strengths and Limitations

A strength of this study was its mixed methods approach, which created structured quantitative data and also allowed participants to express opinions that were not considered in the questionnaire. Our wide range of questions allowed a comprehensive exploration of the particular aspects of SM analysis for depression that made people uneasy. The open questions revealed strong feelings regarding both the advantages and concerns of the use of this type of software in SM and gave us insights into the reasoning behind some of the responses to structured questions.

However, we relied upon a questionnaire that was created for this study and, thus, has not been validated or replicated in other studies. Some of the questions may need further refinement, and it would be valuable to validate our questionnaire against other similar measures available within the field. Furthermore, despite multiple methods of circulation being used, we secured only a small- to medium-sized sample. Although the demographics of our sample reflect UK averages, they may not represent the typical SM user, where younger age groups tend to dominate. We attempted to increase the number of participants from younger age groups by circulating the questionnaire link through youth-focused sites but had limited success. We purposefully advertised our questionnaire to the types of SM users who might be targeted by mental health service advertisement, and thus, we had a high rate of participants with previous depressive symptoms in our sample. Views of our sample may, therefore, not closely reflect the population in general, although it could be argued that they represent a more informed group of SM users and are, thus, richer in information power [38].

A further limitation would be the timing of the survey. It is likely that the perceptions of risk to privacy and intrusiveness of the use of SM data for secondary purposes were particularly

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salient in the wake of the Cambridge Analytica scandal, which was revealed in March 2018, when the survey was open. It would be interesting to repeat the survey at a future date to check if the views expressed are stable over time.

Future Research Directions

Results of this survey suggest a low level of trust in SM platforms to safeguard the users' privacy and a fear that profiling health status among individuals could lead to harms such as discrimination by insurance or other companies. This may be true for many health conditions, not just depression. Our work could, for example, inform teams that are performing the extraction of information on drug side effects from SM, a field which is currently rapidly expanding [39]. Future work should concentrate on understanding and elaborating the levels of trust in SM platforms and assessing how a social license for reusing SM content for research purposes in health can be achieved. Public sector researchers, such as those at universities, who are conducting this type of work should be mindful of the current climate of distrust and work hard to engage stakeholders in all aspects of their research design, data analysis, and implementation.

Conclusions

We have shown that the public holds complex views on their SM content being used for targeting advertising for depression services. Although they support the idea in theory, participants in our sample suggested that their main concerns centered on the risks to privacy and considered that the benefits offered by this analysis did not outweigh the privacy risks. Furthermore, a majority of the participants indicated that they would not consent to their data being used for such analysis. This study focused on depression specifically, but such findings may hold across a number of health conditions, especially if they are stigmatized or public health services for them are lacking. Future work in this field should proceed with caution, given users' current lack of trust in SM platforms, and at a minimum should engage with key stakeholders, such as SM users, at all parts of the research process, to ensure that a social license for research is realized.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Study questionnaire.
[PDF File (Adobe PDF File), 163 KB - mental_v6i11e12942_app1.pdf]

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Abbreviations

CMD: common mental disorder
GP: general practitioner
NHS: National Health Service
SM: social media

<u>Original Paper</u>

Wearable Technology for High-Frequency Cognitive and Mood Assessment in Major Depressive Disorder: Longitudinal Observational Study

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Abstract

Background: Cognitive symptoms are common in major depressive disorder and may help to identify patients who need treatment or who are not experiencing adequate treatment response. Digital tools providing real-time data assessing cognitive function could help support patient treatment and remediation of cognitive and mood symptoms.

Objective: The aim of this study was to examine feasibility and validity of a wearable high-frequency cognitive and mood assessment app over 6 weeks, corresponding to when antidepressant pharmacotherapy begins to show efficacy.

Methods: A total of 30 patients (aged 19-63 years; 19 women) with mild-to-moderate depression participated in the study. The new Cognition Kit app was delivered via the Apple Watch, providing a high-resolution touch screen display for task presentation and logging responses. Cognition was assessed by the n-back task up to 3 times daily and depressed mood by 3 short questions once daily. Adherence was defined as participants completing at least 1 assessment daily. Selected tests sensitive to depression from the Cambridge Neuropsychological Test Automated Battery and validated questionnaires of depression symptom severity were administered on 3 occasions (weeks 1, 3, and 6). Exploratory analyses examined the relationship between mood and cognitive measures acquired in low- and high-frequency assessment.

Results: Adherence was excellent for mood and cognitive assessments (95% and 96%, respectively), did not deteriorate over time, and was not influenced by depression symptom severity or cognitive function at study onset. Analyses examining the relationship between high-frequency cognitive and mood assessment and validated measures showed good correspondence. Daily mood assessments correlated moderately with validated depression questionnaires (r=0.45-0.69 for total daily mood score), and daily cognitive assessments correlated moderately with validated cognitive tests sensitive to depression (r=0.37-0.50 for mean n-back).

Conclusions: This study supports the feasibility and validity of high-frequency assessment of cognition and mood using wearable devices over an extended period in patients with major depressive disorder.

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Introduction

Major depressive disorder (MDD) is characterized by symptoms of low mood, diminished interest and pleasure in daily activities, feelings of worthlessness or guilt, fatigue, sleeping and appetite disturbances, and thoughts of death or suicide. MDD is a leading cause of disease burden and disability worldwide [1,2]. Cognitive symptoms, including difficulty concentrating or making decisions, are features of MDD [3] that may offer a target for intervention [4].

Cognitive symptoms of MDD include deficits in several domains, including processing speed, attention, executive function, learning, and memory [5-7]. Cognitive symptoms are seen in first-episode depression [6,8], persist beyond the symptoms of low mood [9-11], contribute to the risk of relapse [12], and worsen with repeated depressive episodes [13,14].

Cognitive MDD symptoms contribute to disability burden [15]. Poorer memory [15,16], attention, and executive function [17] have been associated with impairment in activities of daily living. Cognitive symptoms have also been associated with poor occupational functioning [18] and unemployment [19], work-related disability, and adverse psychosocial outcomes [20-22]. Longitudinally, improved cognitive function has been associated with higher rates of employment at follow-up in a variety of psychiatric illnesses, including MDD [23]. Treating these symptoms has the potential to improve functional outcomes and quality of life.

Research has highlighted discrepancies between objectively measured cognitive function and patients' self-report from questionnaires, with the latter being affected by depressed mood [15,24,25]. This inconsistency highlights the need for subjective and objective data to be acquired to provide accurate clinical information. A key obstacle is the lack of readily available tools for cognitive assessments outside the clinic. Such tools could support the treatment and remediation of cognitive symptoms associated with MDD.

Mobile digital technologies allow for sampling outside of the clinic and in the patient's home or work environment, providing a shared platform for clinicians and patients to monitor symptoms [26]. In depression, mobile apps have tracked changes in patient-reported mood [27-29] and have been used as part of randomized controlled trials to evaluate treatment efficacy [30]. However, these studies have relied on quantitative self-report or simple sensing and monitoring technologies [26].

This study examined feasibility, that is, viability of brief, high-frequency cognitive and mood assessment over an extended period of time (6 weeks) implemented on an Apple Watch app in individuals with MDD, and validity, defined as agreement between these high-frequency data and validated measures of mood and cognition. Coprimary endpoints were (1) adherence, examined separately for high-frequency cognitive and mood assessment and (2) correlations between daily measures of cognition with traditional full-length cognitive assessments, as specified in study details in the clinical trials registration [31].

The following secondary outcomes were examined, as described in the study analysis plan [32]: (1) the relationship between daily mood measures with full-length validated questionnaires and (2) the reliability of heart rate and activity sensors acquired via the Apple iPhone and Apple Watch (Apple Inc) apps. In addition, exploratory analyses examined the interrelationship of mood and cognitive measures acquired in low- and high-frequency assessment.

Methods

Participants and Recruitment

A recruitment target of 30 was set for this study, commensurate with usual practice for feasibility studies [33]. A sample size of 30 allows estimation of a compliance rate of 80%, with 95% CIs of ±12.8%. This sample size also provides 80% power to detect correlations of r=0.5.

A total of 556 adults underwent an initial screening for eligibility to participate in the study through a patient recruitment company with links to primary care providers and depression patient groups, to identify individuals with depression potentially suitable for the study. In total, 72 individuals were contacted for more detailed medical history information and to complete the Patient Health Questionnaire-9 (PHQ-9) [34] to obtain an index of depression severity. Participant eligibility was determined according to the following inclusion and exclusion criteria before study entry:

Inclusion criteria were primary psychiatric diagnosis of MDD; treated with antidepressant monotherapy; mild-to-moderate depression, defined by PHQ-9 scores between 5 and 15; aged 18 to 65 years; able to read and understand English; and owning their own iPhone.

Exclusion criteria were personal history of other psychiatric disorder (except nonprimary concurrent anxiety); manic or hypomanic episode; mental retardation, organic mental disorders, or mental disorders owing to a general medical condition as defined in the *Diagnostic and Statistical Manual of Mental Disorders 5th Edition*; neurological or neurodegenerative disorder; alcohol or other substance abuse or dependence (excluding nicotine or caffeine); responding only to combination or augmentation therapy in the current episode; hospitalization for MDD in 3 months or suicide attempt in 6 months before screening (or the participant was considered to be at significant risk of suicide or hospitalization); having received any investigational compound within 30 days before screening or 5 half-lives before screening, whichever is longer; concurrent participation in other clinical studies; or participation in 2 or more interventional studies in the year before screening.

In total, 30 of the 72 screened individuals were recruited into the study. Of the remaining screened individuals, 7 were eligible

but not recruited. Others were excluded because of lack of an iPhone (n=4), insufficient time on medication (n=18), lack of antidepressant medication treatment history (n=2), polypharmacy (n=3), other psychiatric diagnosis or neurological condition (n=5), PHQ-9 higher than 15 (n=1), or insufficient information obtained in screening (n=2).

Procedure

The study began with a visit to the study site and a short semistructured interview to explore each participant's expectations and motivations for taking part. Researchers provided study hardware (an Apple Watch Series 2, paired with the participant's own iPhone), presented the tasks, and gave participants the opportunity to practice using the tasks and device and ask questions. Participants were given contact details for the study center, where they could get in touch by email or phone if they experienced technical issues or had questions or concerns regarding their participation. Testing was completed in the subsequent 6 weeks (42 days), corresponding to the time when antidepressant pharmacotherapy shows efficacy in treating the mood symptoms of MDD. Participants were encouraged to respond to cognitive assessment wherever possible but not to worry when individual assessments were missed.

Data collected on the Apple Watch and iPhone were transferred automatically through Wi-Fi or data roaming via the participant's iPhone to a secure data center held on Amazon's Web service. This service provided identity and access control mechanisms to ensure participants (and only participants) had write access, and study managers only had read access. Where data for individual participants were not uploaded for 4 days, the research team made contact to ensure that the study

equipment was working and to gain a better understanding of why assessments were not completed.

Full-length cognitive and validated self-report assessments were completed via a Web-based testing interface. Familiarization with the tests was completed during in-person assessments on the first day of participation. Full assessments were completed on 3 occasions: week 1 (between days 1 and 2), week 3 (days 18-24), and week 6 (days 40-46). Participants were sent a unique link to a secure Web page that delivered the test. On completion of assessment, and when the device established an internet connection, data were transferred to a secure Health Insurance Portability and Accountability Act of 1996 compliant data center in the United States.

The study was completed with a 90-min, semistructured qualitative interview during week 6 at participants' homes. Interviews explored participants' experiences of assessment with the wearable technology, changes in motivation and adherence, and contextual factors that might have contributed to those changes. Study hardware was returned at this time.

Measures

Daily Mobile Digital Assessments

The Apple Watch provides a small touch screen for the presentation of stimuli and collection of participant responses and contains a range of sensors, including accelerometers and heart rate sensor. Participants were asked to wear the watch from 8 am to 10 pm for 6 weeks and to respond to assessment prompts. Additional step count data were acquired via the iPhone. An illustration of mood and cognitive assessment is provided in Figure 1.

Figure 1. Symbol display for n-back (left) and mood assessment questions (right) presented on the Apple Watch. Participants were asked to tap the screen to respond to a match.

High-Frequency Cognitive Assessments

Participants were prompted to complete cognitive assessments 3 times daily (morning, afternoon, and evening). Multiple prompts for cognitive testing were delivered to improve flexibility for participants unable to complete cognitive testing at specific points in the day and to yield data with the potential to examine diurnal changes (not examined in the current report).

Cognitive assessment was completed using a variant of the n-back task, a task which has shown sensitivity to impairments in MDD [35]. This variant was developed for brief high-frequency assessment after initial piloting indicated that a large pool of nonverbalizable stimuli were required to reduce ceiling effects over prolonged testing. A total of 9 symbols, randomly selected from a pool of 227, were presented for 600 ms 1 at a time over 30 trials. Participants were asked to respond when any symbol was the same as the symbol presented 2 trials previously. The primary outcome measure was dprime (the ratio of hits [correct detection of an n-back match] to false alarms [response during no match]). Each full assessment took 30 seconds to complete, after which participants were shown their n-back score.

High-Frequency Mood Assessments

Mood assessment was prompted up to twice daily (afternoon and evening). If participants completed the mood assessment in the afternoon, no prompt was delivered in the evening. Only 1 mood assessment was completed per day as participants were asked to reflect on and respond regarding their experiences over the past day.

Mood was assessed with 2 questions adapted from the PHQ-2, a validated brief form of the PHQ-9, which assesses only low mood and loss of interest or pleasure and is sensitive to depression and suitable for brief assessments [36]. One additional item assessing self-perceived concentration was taken from the Perceived Deficits Questionnaire—Depression (PDQ-D) [37,38], a measure that assesses subjective cognitive dysfunction in depression. Questions were modified from asking about symptom presence over multiple weeks to asking about symptoms over the past day. Wording was also shortened to facilitate presentation on a small screen.

Mood questions were presented in the following manner: *How much have the following problems bothered you over the past day?* Participants rated the following items: (1) lack of interest or pleasure in doing things; (2) feeling down, depressed, or hopeless; and (3) trouble concentrating on things (eg, newspaper, TV). Responses were coded on a 4-point scale of severity of symptoms (1=no problem, 2=slightly, 3=somewhat, 4=greatly). This scale was modified from the 4-point scale of the PHQ-9 to reflect within-day experiences and was kept consistent for the PDQ-D item.

Web-Based Full-Length Assessments

The Cambridge Neuropsychological Test Automated Battery (CANTAB) Connect Web-based testing interface was used to complete full-length cognitive testing and validated questionnaires on 3 occasions (weeks 1, 3, and 6). CANTAB

cognitive assessments have shown sensitivity to a range of cognitive deficits in depression [10].

Cognitive Assessments

1. Spatial working memory (SWM) [39] examined participants' ability to retain and manipulate visuospatial information and to strategize. Between 4 and 8 boxes were presented on the screen. Participants were asked to find tokens in the boxes and move them to a collection area and were instructed that they would not find a token in the same box twice in the same trial. Outcome measures included the following: (1) between errors, the number of times the participant revisited a box in which a token had been found (range of possible scores 0-175); and (2) strategy, the number of unique boxes from which a participant started a new search (range of possible scores 4-28). For both outcomes, lower scores indicated better performance.
2. The CANTAB rapid visual information processing (RVP) [40] test measured sustained attention and processing speed. Digits from 2 to 9 were presented successively at the rate of 100 digits per minute and in pseudorandom order. Participants were asked to respond to target sequences of digits (eg, 2-4-6, 3-5-7, 4-6-8). Two outcome measures were examined: (1) RVP A', a signal detection measure of sensitivity to the target regardless of response tendency (expected range is 0 to 1); and (2) RVP median latency of correct responses (maximum response time allowable 1800 ms).

Validated Questionnaires

1. The PHQ-9 [34] provided an index of depression severity, with higher scores reflecting greater symptom severity.
2. The PDQ-D [37] subscales of attention/concentration and planning/organization were summated to provide an index of participant-perceived cognitive symptoms. Higher scores reflect greater perceived cognitive symptoms.
3. The University of California Los Angeles Loneliness Scale (UCLA-LS) [41] measured subjective feelings of loneliness and social isolation. Higher scores reflect more severe loneliness and social isolation.

Semistructured Interviews

A copy of the discussion guides for semistructured interviews at study onset and end are provided in Multimedia Appendix 1.

Statistical Analysis

High-Frequency Data Preparation and Cleaning

Adherence was assessed separately for cognitive function, mood reports, and activity. Adherence for mood and cognitive assessments was defined in line with methods described in the clinical trials registration [31]: each day was defined as adherent (with participants completing at least 1 full assessment each day) or nonadherent (days with no data). For Apple Watch activity and heart rate measures, nonwearing days (defined as days where <100 steps were recorded [42,43] [n=19 observations] or where heart rate was not recorded [n=6 additional observations]) were excluded from analyses. No

minimum adherence was specified for participants to be included in analyses.

Percentage of adherent days was examined separately for mood, cognitive function, and activity for the duration of the study (defined as percentage of 42 days completed) and calculated for individual study weeks (weeks 1-6). In addition, for cognitive assessments, where responses were prompted 3 times daily, percentage of responses to all possible assessments was examined.

Daily dprime performance was calculated from the mean of all available n-back assessments within each day. Total daily mood was the summation of responses across the 3 questions presented during each assessment. Total step count from the iPhone and the Apple Watch was extracted for each day. Minimum, maximum, and mean daily heart rates for each day were obtained from the Apple Watch.

Summary measures for daily assessments were obtained for total daily mood, daily dprime, average heart rate, and total step count; means of all available daily assessments were calculated across the entire assessment period (6 weeks) and for individual weeks (1-6) to document change over the assessment period. No corrections for missing data and no other adjustments to raw data were made. Normality of all summary measures was assessed with visual examination of the data and with the Shapiro-Wilk test before further analysis.

Web-Based Full-Length Assessments Data Preparation and Cleaning

Absolute scores from validated self-report questionnaires were computed by summating responses within scales and providing summed scores for PHQ-9, PDQ-D, and UCLA-LS at each time point. To reduce multiple comparisons, overall scores from self-report questionnaires and CANTAB cognitive testing were calculated by taking the mean of outcome measures obtained at weeks 1, 3, and 6. This yielded overall means for SWM between errors, SWM strategy, RVP A′, and RVP median latency, as well as for self-report questionnaires (PHQ-9, PDQ-D, and UCLA-LS). Normality of data was assessed with visual examination of the data and with the Shapiro-Wilk test before further analysis.

Adherence Over Time

To examine whether the binary variable of adherence (response vs nonresponse) improved or declined over time, a series of logistic regression mixed models were carried out with study day (days 1–42) as a fixed factor and the participant as a random effect. Logistic regressions were also repeated separately for morning, afternoon, and evening n-back assessments to identify changes in response by time of day over the duration of the study.

Logistic regression models examined whether adherence to cognitive and mood assessments could be predicted by severity of depression symptoms at the onset of the study, as measured by the following covariates: PHQ-9, PDQ-D, and UCLA-LS scores from week 1. These included a covariate-by-day interaction term to examine variation by day. Assumptions of logistic regression models were investigated by examining the distribution and patterns of residuals versus fitted values.

To test whether adherence was associated with cognitive symptoms at study onset, a series of bivariate correlations (Pearson correlations or Spearman rank correlation, as appropriate) were completed. These explored the relationship between overall adherence with CANTAB cognitive measures at week 1. As this was an exploratory study, no corrections for multiple comparisons were made.

Daily Cognitive Assessment

Cognitive performance on the n-back was modeled using a longitudinal mixed-effects model with daily dprime as response variable, a fixed effect of study day, and a random effect of participant with random intercept and random slope. No covariates were examined. For the fixed-effect part of the model, we compared linear, quadratic, and cubic trends via likelihood ratio test and compared model parameters via maximum likelihood. This allowed the examination of different learning curves on the n-back to identify the best fit for change in performance over time. Each participant's intercept (representing initial level of performance) and slope (representing learning rate) were extracted.

Summary n-back measures (mean, intercept, and slope) were correlated with overall means of CANTAB outcome measures and self-report questionnaires (PHQ-9, PDQ-D, and UCLA-LS). N-back slope was also correlated with the total number of n-back assessments completed over the study period, to examine the effects of practice on learning rate. Pearson or Spearman correlations were performed as appropriate.

Daily Mood Assessment

Multilevel reliability of the 3 mood items was examined using the multilevel.reliability command in the *Psych* package of *R* [44]. The package takes into consideration missing data by including components of variance derived from multilevel mixed modeling and examines multiple sources of variance for each score based on generalizability theory.

Average daily mood was modeled using a longitudinal mixed-effects model with total daily mood as response variable, a fixed effect of study day, and a random effect of participant with random intercept and random slope. No covariates were examined. For the fixed-effect part of the model, linear, quadratic, and cubic trends were compared via likelihood ratio test, and model parameters were compared via maximum likelihood, identifying the best fit for change in mood over time.

Overall means for daily mood assessment from the entire assessment period were correlated with overall means from full-length questionnaires and CANTAB assessments to investigate concurrent validity of daily mood assessments and the relationship between daily mood and full-length cognitive assessments. Parametric or nonparametric correlations were completed as appropriate.

Activity and Heart Rate Data

Total step count from the iPhone and the Apple Watch was extracted for each day. Means were calculated for the duration

of the study (overall means) and for each study week. Minimum, maximum, and average daily heart rates were obtained from the Apple Watch, and the mean daily heart rate was calculated over the study duration (overall mean) and for each study week. The correlation between overall means for steps measured from the iPhone and the Apple Watch was examined.

Ethics Approval

The study was reviewed and approved by the Proportionate Review Sub-Committee of the Wales Research Ethics Committee 6 at Swansea University (REC reference: 17/WA/0042) and performed in accordance with the current version of the Declaration of Helsinki. All participants provided written informed consent before enrollment.

Results

Participants

Of the 37 eligible participants, 30 were enrolled (19 women and 11 men). Participants were aged between 19 and 63 years (mean age 37.2 years; SD 10.4) and had been on their current medication for an average of 9.9 months (range 0.4–94.3 months; SD 9.5). Current medications included serotonin antagonist and reuptake inhibitor (n=1), serotonin and norepinephrine reuptake inhibitors (n=5), selective serotonin reuptake inhibitors (n=20), and tricyclic antidepressants (n=4). Mean depression symptom severity, measured by the PHQ-9, was 9.1 (range 5-15; SD 3.1).

Adherence

Descriptive statistics for adherence across the duration of the study and by study week are shown in Table 1. Full adherence (100%, 42/42 days) was seen in 21 of 30 participants for cognitive assessment, 15 of 30 participants for mood testing, and 13 of 30 participants for activity assessment. Periods of low adherence tended to cluster temporally (Multimedia Appendix 2). Because of a technical issue on the final study day, the evening session was not administered, resulting in lower adherence on day 42. However, logistic mixed modeling showed no deterioration in adherence (ie, responding at least once daily) over time for assessments of mood, cognition, or activity. Logistic regression confirmed that self-reported depressive symptoms, assessed by the PHQ-9, PDQ-D, and UCLA-LS, were not associated with level of adherence in mood or cognitive assessments. Adherence was not significantly correlated with any CANTAB measures at week 1 (maximum rho=0.15; P=.44).

Participants completed a mean of 86.8% of all possible n-back assessments (range 50%-99%, 63-125 of 126 assessments). Rate of responding in the morning (84%) was lower than the afternoon (87%) and evening (89%; χ^2_2=12.9). Furthermore, although adherence (responding at least daily) remained high throughout the duration of the study, logistic regression confirmed modest reductions in individual assessments (morning, afternoon, and evening) over the study duration (morning: fixed-effects estimate=–0.03, P=.02; afternoon: fixed-effects estimate=–0.02, P<.001; evening: fixed-effects estimate=–0.08, P<.001).

Table 1. Percentage adherence for cognitive (n-back) and mood assessments and percentage of watch-wearing days (step count) completed over the duration of the study (overall) and broken down by week (week 1 to week 6). Adherence for cognitive and mood assessments defined as participants completing at least 1 full assessment per day. Watch-wearing days for step count defined as days with a minimum of 100 steps and heart rate recorded.

Measure	Participant adherence (%)						
	Overall	Week 1	Week 2	Week 3	Week 4	Week 5	Week 6
n-back							
Mean (SD)	95.63 (9.28)	94.29 (19.35)	93.33 (18.28)	93.33 (20.8)	99.05 (5.22)	100 (0)	93.81 (17.06)
Range	66.7-100	0-100	28.6-100	14.3-100	71.4-100	100	28.6-100
Mood							
Mean (SD)	94.60 (9.73)	93.81 (19.38)	92.38 (20.46)	92.38 (22.11)	98.57 (5.75)	99.05 (3.63)	91.43 (20.75)
Range	66.7-100	0-100	28.6-100	14.3-100	71.4-100	85.7-100	14.3-100
Step count							
Mean (SD)	90.08 (17.4)	94.54 (14.99)	92.12 (18.15)	92.38 (20.11)	92.38 (19.03)	92.86 (17.09)	85.22 (24.29)
Range	21-100	28-100	14-100	14-100	28-100	28-100	14-100

Daily Cognitive Assessment

Descriptive data for n-back assessments are presented in Table 2. Multilevel analysis of dprime score by study day confirmed a better fit for a cubic term rather than quadratic or linear models (Bayesian information criterion=1298.05; likelihood ratio=10.36; P=.001), indicating an initial rapid improvement in performance followed by a plateau. Model fits for each study participant are shown in Figure 2. Dprime slope showed no significant relationship with the number of n-back assessments completed (rho=–0.02, 95% CIs –0.37 to 0.34; P=.91).

Correlations between task performance metrics from the n-back and overall means from CANTAB cognitive assessments and self-report questionnaires were explored (Table 3). Participants with better performance on CANTAB showed higher intercept and better mean performance on the n-back. Depressive symptoms assessed with the PHQ-9 correlated with mean dprime, and correlations with dprime intercept approached but did not reach statistical significance (P=.06). No significant correlations were seen with PDQ-D or UCLA-LS, or dprime slope.

Table 2. Descriptive data for main outcome variables.

Outcome measure (daily)	Weeks assessed						
	Overall	Week 1	Week 2	Week 3	Week 4	Week 5	Week 6
Daily dprime (n-back)							
Mean (SD)	1.8 (0.53)	1.38 (0.46)	1.72 (0.56)	1.79 (0.51)	1.92 (0.60)	1.97 (0.60)	1.96 (0.58)
Range	0.7-2.8	0.4-2.2	0.6-3.0	0.6-2.84	0.71-3.01	0.84-3.01	0.56-2.88
Total mood score							
Mean (SD)	6.54 (2.41)	6.96 (2.49)	6.75 (2.45)	6.54 (2.26)	6.60 (2.45)	6.15 (2.31)	6.26 (2.41)
Range	3-12	3-12	3-12	3-12	3-12	3-12	3-12
iPhone step count							
Mean (SD)	3762.81 (3168.59)	4124.48 (3610.95)	3605.83 (3207.43)	3961.29 (3282.68)	3751.95 (3305.45)	3404.67 (2438.33)	3745.64 (3053.46)
Range	100-20,183	110-17,529	109-20,183	103-14,470	122-18,393	100-13,548	104-15,485
Apple Watch step count							
Mean (SD)	6429.64 (4242.01)	6778.82 (4294.81)	6607.06 (4093.61)	6542.80 (4699.67)	6106.60 (3980.54)	6072.75 (4124.24)	6487.93 (4223.08)
Range	125-22,360	133-19,560	144-21,533	448-22,360	125-19,808	155-22,130	293-20,049
Heart rate, bpm[a]							
Overall mean (SD)	79.71 (10.47)	78.63 (8.72)	80.76 (11.98)	80.33 (12.87)	79.34 (9.65)	79.50 (8.75)	79.72 (10.17)
Range	60-147	63-116	64-147	60-146	62-140	61-115	61-124

[a]bpm: beats per minute.

Figure 2. Trajectories in n-back performance and mood over time for study participants; each study day is represented on the x-axis. Top: Each dprime (up to 3 daily) is shown on the y-axis (higher scores denote better performance). Bottom: total mood is shown on the y-axis (higher scores denote more depressive symptoms).
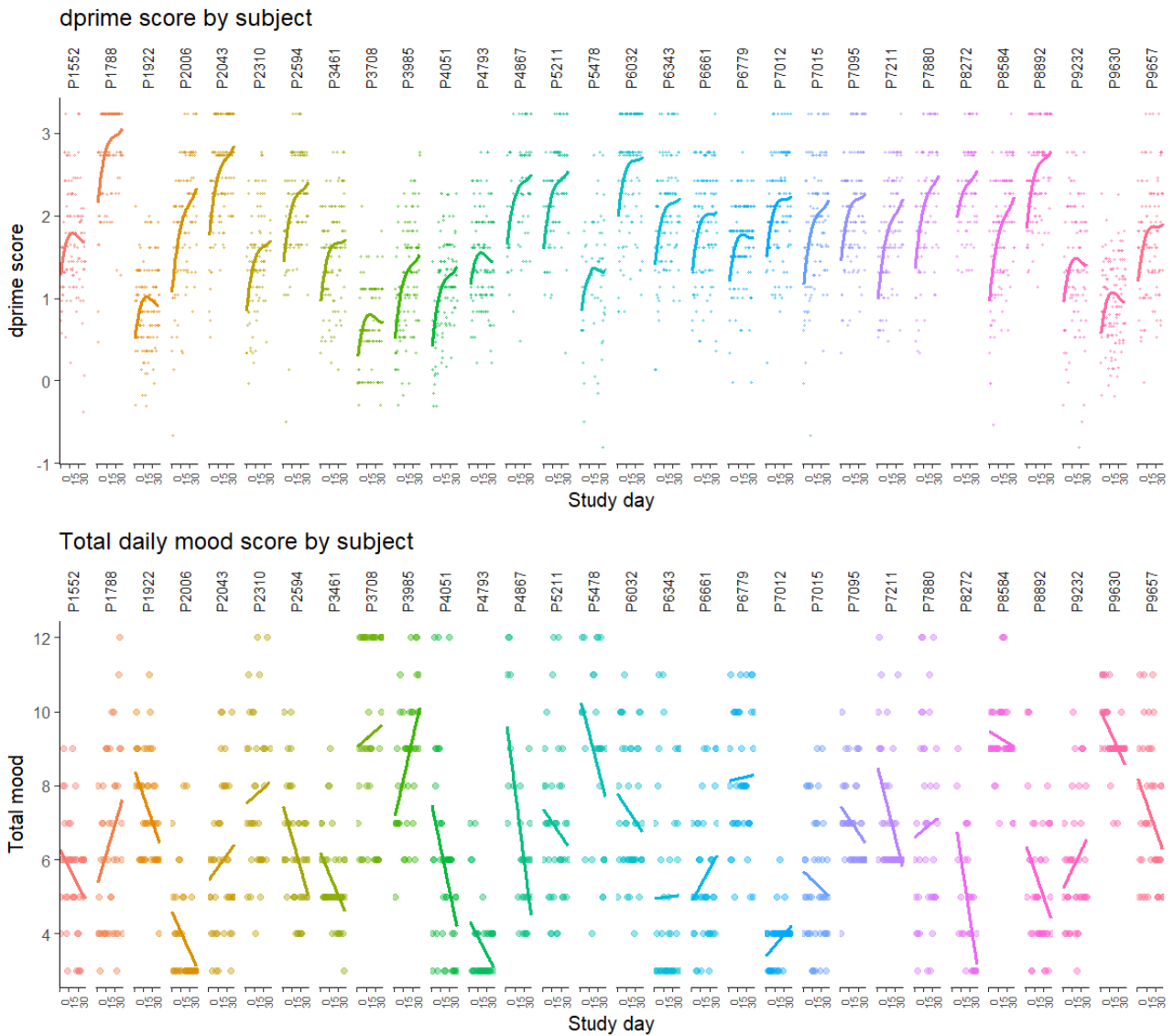
Table 3. Correlation coefficients (95% CIs) for daily cognitive assessments with full-length aggregate Cambridge Neuropsychological Test Automated Battery cognitive assessment outcome measures and full-length aggregate self-report questionnaires.

Outcome measures from full length assessment	n-back performance		
	Mean	Intercept	Slope
SWM[a] between errors	−0.46[b] (−0.70 to −0.11)	−0.51[b] (−0.51 to −0.17)	−0.01 (−0.45 to 0.39)
SWM strategy	−0.37[c] (−0.65 to −0.01)	−0.40[c] (−0.67 to −0.04)	0.05 (−0.34 to 0.46)
RVP[d] A'	0.50[b] (0.17 to 0.73)	0.47[b] (0.12 to 0.71)	0.29 (−0.10 to 0.58)
RVP median latency	−0.42[c] (−0.73 to 0.001)	−0.46[c] (−0.75 to −0.07)	−0.15 (−0.53 to 0.22)
Depressive symptoms (PHQ-9)[e]	−0.38[c] (−0.65 to −0.01)	−0.36 (−0.65 to 0.01)	−0.18 (−0.51 to 0.24)
Cognitive problems (PDQ-D)[f]	−0.25 (−0.57 to 0.12)	−0.27 (−0.58 to 0.11)	0.04 (−0.37 to 0.32)
Loneliness (UCLA-LS)[g]	−0.29 (−0.59 to 0.09)	−0.26 (−0.57 to 0.12)	−0.21 (−0.54 to 0.18)

[a]SWM: spatial working memory.

[b]$P \leq .01$.

[c]$P \leq .05$.

[d]RVP: rapid visual information processing.

[e]PHQ-9: Patient Health Questionnaire-9.

[f]PDQ-D: Perceived Difficulties Questionnaire—Depression.

[g]UCLA-LS: University of California Los Angeles Loneliness Scale.

Daily Mood Assessment

The 3 mood items showed overall good reliability indices, supporting the combined use of the 3 question items. Between-person reliabilities were high (R=0.97 averaged over time and with time nested within individuals), and within-person generalizability was moderate to high (R=0.75 for within-person variation with time nested within individuals).

Descriptive data for total mood are presented in Table 2. Multilevel analysis of total mood by study day confirmed the best fit for a linear model (Bayesian information criterion=73.38; likelihood ratio=6.14; *P*=.01). This model showed a modest overall linear improvement in mood over the course of the study (estimate of fixed effect of study day on mood=−0.0026, *P*=.01). However, there was a great deal of heterogeneity on mood trajectories over the study duration, as shown in model fits for each study participant in Figure 2.

Mean overall scores from daily mood assessments were correlated with full-length self-report questionnaires, showing moderate correlations (Table 4). Self-reported depression (PHQ-9) and cognitive symptoms (PDQ-D) correlated more highly with daily mood assessments than self-reported loneliness as measured by the UCLA-LS.

Significant correlations between dprime mean and intercept were seen for total mood scores, for question items assessing lack of interest, and for low mood (Table 4). Correlations between n-back performance and daily reported cognitive symptoms and all correlations with dprime slope were nonsignificant (*P*=.12-.79). Examining the relationship between daily mood assessment and CANTAB measures, SWM between errors and strategy showed moderate correlations with daily reported mood, whereas correlations with RVP outcome measures were nonsignificant.

Table 4. Correlation coefficients (95% CIs) for daily mood assessments with full-length self-report measures of depression, daily cognitive assessments, and full-length cognitive assessments on Cambridge Neuropsychological Test Automated Battery.

Outcome measures from full length assessments and daily cognitive assessments	Total mood score	Daily question items		
		Low mood (feeling down, depressed, hopeless)	Cognitive symptoms (trouble concentrating on things)	Lack of interest (lack of interest or pleasure)
Depressive symptoms (PHQ-9)[a]	0.69[b] (0.44 to 0.84)	0.56[b] (0.24 to 0.77)	0.69[b] (0.44 to 0.85)	0.70[b] (0.45 to 0.85)
Cognitive problems (PDQ-D)[c]	0.65[b] (0.37 to 0.82)	0.50[b] (0.16 to 0.73)	0.68[b] (0.42 to 0.84)	0.64[b] (0.36 to 0.82)
Loneliness (UCLA-LS)[d]	0.45[e] (0.10 to 0.70)	0.47[b] (0.13 to 0.72)	0.35 (−0.02 to −0.63)	0.45[e] (0.10 to 0.70)
dprime mean	−0.41[e] (−0.67 to −0.06)	−0.36[e] (−0.64 to 0.00)	−0.28 (−0.58 to 0.08)	−0.52[b] (−0.74 to −0.19)
dprime intercept	−0.42[e] (−0.68 to −0.07)	−0.38[e] (−0.65 to −0.03)	−0.29 (−0.59 to 0.08)	−0.52[b] (−0.74 to −0.19)
dprime slope	−0.10 (−0.51 to 0.33)	−0.02 (−0.52 to 0.38)	−0.02 (−0.46 to 0.35)	−0.13 (−0.51 to 0.29)
SWM[f] between errors	0.49[b] (0.15 to 0.73)	0.52[b] (0.19 to 0.74)	0.39[e] (0.03 to 0.66)	0.49[b] (0.15 to 0.73)
SWM strategy	0.44[e] (0.09 to 0.70)	0.43[e] (0.07 to 0.69)	0.41[e] (0.05 to 0.68)	0.41[e] (0.05 to 0.68)
RVP[g] A'	−0.14 (−0.48 to 0.24)	−0.06 (−0.41 to 0.32)	−0.13 (−0.47 to 0.25)	−0.20 (−0.53 to 0.18)
RVP median latency	0.23 (−0.18 to 0.58)	0.27 (−0.09 to 0.57)	0.18 (−0.19 to 0.51)	0.28 (−0.11 to 0.61)

[a]PHQ-9: Patient Health Questionnaire-9.

[b]$P \leq .01$.

[c]PDQ-D: Perceived Difficulties Questionnaire—Depression.

[d]UCLA-LS: University of California Los Angeles Loneliness Scale.

[e]$P \leq .05$.

[f]SWM: spatial working memory.

[g]RVP: rapid visual information processing.

Activity and Heart Rate

Descriptive statistics for step counts and heart rate are presented in Table 2. A moderate correlation was seen between step counts registered on the 2 devices (rho=0.61; 95% CI 0.57-0.65; P<.001), but there were also instances of marked discrepancy (Figure 3). Overall, the Apple Watch provided a higher step count estimate than the iPhone. Measurement issues were noted for heart rate using the Apple Watch, with individual heart rates registered including a minimum of 22 beats per minute, which was not biologically plausible.

Figure 3. Scatter plot of mean daily step count as measured by the Apple Watch vs. the iPhone, and reference line for perfect agreement between devices.
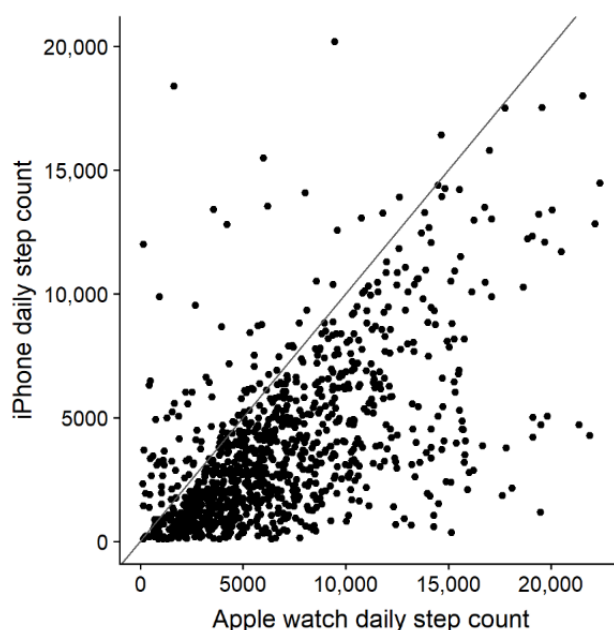
Discussion

Principal Findings

This study demonstrated the feasibility of daily assessments of cognition and mood in mild-to-moderate MDD. The study spanned 6 weeks, corresponding to the time during which response to antidepressant pharmacotherapy efficacy would expect to be demonstrated, indicating that high levels of adherence can be achieved and retained over this time frame.

Exploratory analyses examined the relationship between high-frequency mood and cognitive assessment and validated full-length cognitive assessments and questionnaires. These analyses aimed to establish the degree to which brief frequent assessments capture similar information to validated cognitive assessments and rating scales. Daily mood assessments showed moderate to strong correlations with validated self-report questionnaires of depression, cognitive problems, and loneliness. Correlations were highest for the PHQ-9, a scale designed as both a diagnostic instrument and a severity measure [34], which also showed the highest item overlap with high-frequency assessments. Daily n-back performance correlated moderately with performance on standardized tests of working memory and sustained attention. Findings support the concurrent validity of the measures examined during daily assessments.

Adherence

Adherence, defined as engaging with cognitive and mood assessments at least once daily, was very high (95%-96%), did not deteriorate over time, and was not predicted by depressive symptoms or cognitive function at study onset. These adherence rates, as well as the overall rate of responding to high-frequency assessments in the current study ($\approx$87% for all possible cognitive assessments), are in keeping with previous compliance rates reported in high-frequency assessments in psychopharmacology, around 50% to 90% [45]. However, it is notable that although this study was significantly longer in duration than most previous high-frequency assessment studies, spanning 6 weeks rather than the typical 1- to 2-week duration, the daily frequency of assessment was lower, with most other studies typically sampling 5 to 10 times per day [45]. Previous studies in patients with mood disorders have shown good overall feasibility and acceptability of high-frequency assessments, although there is likely to be an interaction between protocol burden and burden of illness [46]. The brevity of the current protocol in conjunction with the proximity to wearable assessments may have helped to support the high levels of compliance seen here.

Participants reported that completing assessments was easier when study sessions fit into their daily routines, and that periods of high and low mood affected their motivation to complete assessments. Adherence was also affected by technical problems for some participants, and by forgetting to wear the Apple Watch because of low mood or bereavement. Study center support and reminders during nonadherent periods provided a framework to enable participants to maintain a high level of engagement with the study.

Change Over Time

Participants' performance on the n-back improved over time. Overall, mood symptoms showed a modest concurrent improvement, albeit with great heterogeneity in the trajectories observed over the assessment period. Participants were stabilized on monotherapy at the time of assessment, and many had started their current treatment many months before study participation (9.9 months on average). Improvements on the n-back, therefore, likely reflect the influence of practice effects and task specialization. Participants reported continued improvement in task performance as a motivator for engagement. This finding is supported by studies exploring gamification of tasks, where the use of game design elements (eg, points and scoreboards) can improve motivation [47,48].

Importantly, very few participants reached and maintained ceiling levels of performance on the n-back. The symbols presented were designed to be hard to name, and each testing occasion drew 9 items from a stimulus pool of 227 items. Almost all participants felt that the task was challenging yet achievable. Attainability encouraged them to set personal goals to improve or maintain their scores, indicating that striking a balance between difficulty and attainability can promote engagement [49].

Individual learning rates for each participant were reflected in their n-back slope, which did not correlate significantly with either CANTAB cognitive test measures or self-reported mood. This suggests that the capacity to improve performance is not directly affected by either depressive symptoms or cognitive impairment, consistent with research in a previous study showing that practice effects in cognitive tasks were not moderated by depressive symptomatology [50].

Association Between Measures

The n-back paradigm is commonly used alongside functional neuroimaging, where it activates a network of frontoparietal areas [51]. Research suggests that n-back is not simply a measure of working memory capacity but depends on functions such as updating, inhibition, and attention [52]. Consistent with this suggestion, n-back mean and intercept correlated with full-length CANTAB cognitive tests of attention and working memory, supporting the use of n-back performance as a sensitive but nonspecific marker of cognitive function.

The trajectory of moods reported by patients during the course of the study was highly heterogeneous, showing no clear relationship with change in cognitive performance (Figure 2). However, we observed a significant association between aggregate daily mood measures with cognitive measures from CANTAB and n-back task performance (mean and intercept).

Relationship With Full-Length Assessments

The relationship between self-report questionnaires and high-frequency assessments of symptoms has been examined in a number of clinical conditions. Although in some cases the correlations are good [53], there can be a mismatch, with questionnaires relying on retrospective recall tending to overstate the severity and frequency of symptoms [54]. Retrospective recall shows distortion in favor of more salient or unique events

at the expense of the more mundane [54], and depression is associated with negative biases in recollection during periods of low mood [55]. High-frequency assessment may be particularly useful in patients with MDD for ensuring accurate recording of the course of their illness and treatment response.

In this study, correlations between daily measures and validated self-report questionnaires were moderate to high. Discrepancies between objectively and subjectively assessed cognitive function have been reported before, with the latter being affected by depressed mood [15,24,25]. Our results confirm this association. PDQ-D scores were correlated with daily mood assessments but not with cognitive performance, indicating that self-reported cognitive function cannot substitute for objective assessments.

Limitations

As our study focused on patients with mild-to-moderate MDD who volunteered for participation, it is unclear whether results would generalize to patients with different severity or to those who are less motivated. In addition, assessment using a small touch screen may not be feasible for patients with visual impairments or those requiring a larger typeface.

Step counts collected via the Apple Watch and the iPhone were discrepant, which could be accounted for by differences in wearing patterns but undermines the reliability of activity data from either device. Measurement issues with heart rate data may reflect that the equipment was not of medical grade, or occasions when the Apple Watch was not fitted sufficiently tightly for reliable measures to be obtained. Although the wearable nature and ease of use of the technology allow for data to be collected over longer periods of time, our findings indicate that caution is required when this equipment is used to examine heart rate in scientific research. Variable accuracy for wrist-worn heart rate monitors, including the Apple Watch, compared with electrocardiogram measurement has also been noted previously in brief comparisons of bouts of exercise [56].

Conclusions

This study supports the feasibility and validity of high-frequency assessment on wearable devices to assess cognitive function and mood in patients with MDD. The study spanned 6 weeks, indicating that high levels of adherence can be achieved and retained over this time frame. Our study suggests that these methods can be used to monitor cognitive function and mood symptoms after the initiation of treatment for depression.

Multimedia Appendix 1
Discussion guides for semistructured interviews at study onset and end.
[PDF File (Adobe PDF File), 309 KB - mental_v6i11e12814_app1.pdf]

Multimedia Appendix 2
Periods of adherence for cognition, mood, and activity assessment.
[PPTX File , 1552 KB - mental_v6i11e12814_app2.pptx]

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Abbreviations

CANTAB: Cambridge Automated Neuropsychological Test Battery
MDD: major depressive disorder
PDQ-D: Perceived Difficulties Questionnaire in Depression
PHQ-9: Patient Health Questionnaire-9
RVP: rapid visual information processing
SWM: spatial working memory
UCLA-LS: University of California Los Angeles Loneliness Scale

Original Paper

Predictors of the Number of Installs in Psychiatry Smartphone Apps: Systematic Search on App Stores and Content Analysis

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Abstract

Background: Mental health is integral to our salubrity, but mental disorders are very debilitating and common. Therefore, it is critical to provide accessible, timely, and inexpensive mental care. This can be done through mobile health (mHealth), namely, mobile medical apps, which are gaining popularity among clinicians and patients. mHealth is a fast-paced field, and there is significant variation in the number of installs among psychiatry apps. However, the factors that influence psychiatry app installs have yet to be studied.

Objective: This study aimed to identify predictors of the number of app installs in psychiatry.

Methods: A literature review identified which factors influence app installs. Psychiatry apps available in the Google Play Store were reviewed, and publicly available data were collected. A multivariate ordinal logistic regression analysis was performed to evaluate the effect of said factors on the number of installs.

Results: Our search identified 128 psychiatry apps: 2.3% (3/128) had never been installed, approximately half (53.1%, 68/128) had less than 500 installs, and only 0.8% (1/128) had over 10,000,000 installs. A multivariate logistic regression analysis identified that apps with a lower price ($P<.001$), a higher rating ($P<.001$), optional in-app purchases ($P<.001$), and age restriction ($P=.04$) had a higher number of installs. The involvement of a psychiatrist or other health care professional (HCP) had no statistically significant influence on the number of installs. Only data from the Google Play Store and the developers' websites were available for analysis, and the depth of involvement of HCPs was impossible to document.

Conclusions: Psychiatry apps with a lower price, optional in-app purchases, age restriction, and a higher rating are expected to have a higher number of installs. Unlike other medical fields, in this study, the explicit participation of psychiatrists in app development was not a significant predictor of the number of installs. Research is needed to identify other factors that may influence the number of installs, as that can help mHealth app development.

Introduction

Background

Mental health is integral to our salubrity, as reflected in the definition of health by the World Health Organization (WHO): "Health is a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity" [1]. Mental disorders are very common, and studies have estimated that the cumulative global impact of mental disorders in terms of lost economic output amounted to US $16.3 billion between 2011 and 2030 [2]. Therefore, it is critical to provide accessible, timely, and inexpensive mental care [2], and this

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can be done with the help of information technology, such as mobile health (mHealth), "the delivery of healthcare services via mobile communication devices" [3].

An increasingly popular expression of mHealth is through smartphone apps: the global mHealth apps market, which is dominated by Apple App Store and Google Play Store, was valued at approximately US $8.0 billion in 2018 and is expected to have a compound annual growth rate of around 38.3% between 2019 and 2025, generating US $111.1 billion by 2025 [4]. To use an app from these stores, you have to install it, which requires downloading it and then running it on your device. However, there is no publicly available information in the Apple iOS App Store about the number of downloads of each app. Therefore, we focused our study on the apps available on the Google Play Store. Although the exact number of installs is not publicly available, each app in the Google Play Store is classified with a level of installs (described in detail in the Methods section), ranging from level 0 (ie, no installs) to level 19 (ie, between 1,000,000,000 and 5,000,000,000 installs).

Studies in economics (for generic, not health care–related apps) have identified several factors that positively affect the number of app installs, including lower price, higher number of user reviews and rating, and availability in both platforms (ie, Apple App Store and Google Play Store) [5,6]. A previous study in mHealth observed that cheaper apps with in-app purchases and higher user ratings and number of written reviews are more

likely to have more downloads [7]. Furthermore, in a study of mHealth in urology, the participation of health care professionals (HCPs) in app development enhanced the apps' probability of having a greater number of installs [7]. Other factors that have been associated with the number of app downloads are app size, the textual and visual description (ie, screenshots) of the app in the online store, updates, and age-restricted content [8-12].
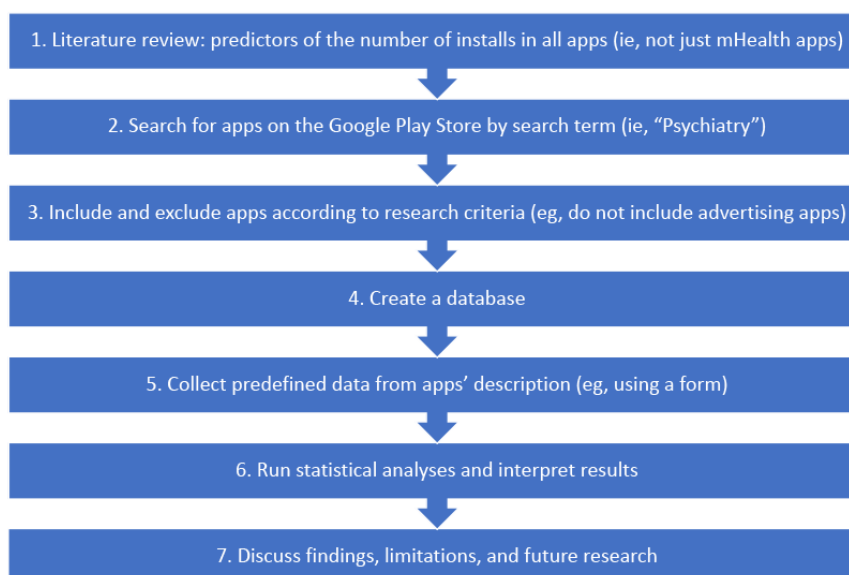
Objectives

Successful mHealth clinical implementations have been demonstrated in several mental conditions, such as anxiety, bipolar disease, depression, posttraumatic stress disorder, and schizophrenia [13-17]. However, although mental health apps can be used for self-monitoring, counseling, clinical practice support, and telemedicine, there are varying levels of adoption by users, as demonstrated by the discrepancy in the number of app installs in published articles [18-21]. However, to our knowledge, the factors that influence the number of installs of psychiatry apps have not been analyzed. Therefore, we aimed to identify predictors of the number of installs in psychiatry apps.

Methods

Study Outline and Research Procedure

A flow diagram with the process used in this study is represented in Figure 1.

Figure 1. Study outline and research procedure. mHealth: mobile health.

1. Literature review: predictors of the number of installs in all apps (ie, not just mHealth apps)

2. Search for apps on the Google Play Store by search term (ie, "Psychiatry")

3. Include and exclude apps according to research criteria (eg, do not include advertising apps)

4. Create a database

5. Collect predefined data from apps' description (eg, using a form)

6. Run statistical analyses and interpret results

7. Discuss findings, limitations, and future research

Search Strategy

A literature search using the search terms "Psychiatry," "smartphone," "tablet," "Android," "application," "app," "mHealth," "installs," "level," "downloads," "success," "predictors," "factors," "determinants," and "demand" was conducted using the PubMed, Google Scholar, Scopus, and

Web of Science databases to find all the literature related to mHealth and psychiatry apps' downloads up to May 1, 2019. Subsequently, the bibliography of the included articles was reviewed with the aim of locating relevant studies.

Simultaneously, a review of available psychiatry apps in the Google Play Store was conducted: all apps retrieved with the search term "Psychiatry" in their metadata (ie, the title,

description, keywords, or version history) were examined. As some predictors (eg, app rating) or the dependent variable (ie, number of installs) might change, we decided to capture all the available Google Play Store data in a single day (April 9, 2019) as a snapshot. Only psychiatry-specific apps were included in this study; consequently, generic apps (ie, with content directed at several specialties, eg, a physiology book), ludic games (ie, nontherapeutical), and advertising apps (ie, related to a pharmaceutical product or a private office) were excluded.

Although the exact number of downloads is not explicit on Google Play Store, each individual app has a *level of installs*. Google Play Store publishes the amount of downloads an app has in incremental brackets: 0 (ie, no installs), 1 to 5, 5 to 10, 10 to 50, 50 to 100, 100 to 500, 500 to 1000, 1000 to 5000, 5000 to 10,000, 10,000 to 50,000, 50,000 to 100,000, 100,000 to 500,000, 500,000 to 1,000,000, 1,000,000 to 5,000,000, 5,000,000 to 10,000,000, 10,000,000 to 50,000,000, 50,000,000 to 100,000,000, 100,000,000 to 500,000,000, 500,000,000 to 1,000,000,000, and 1,000,000,000 to 5,000,000,000 installs. As there is no public information regarding the number of app installs for each individual app in the Apple App Store, this study only included apps available on Google Play Store.

Predictor Variables for the Number of Installs

On the basis of previous economic studies of app demand that determined which factors influence *generic* (ie, not health care specific) app installs, 2 reviewers (MP and NA) recorded all available information for each app according to 14 predetermined variables: (1) number of installs, the dependent variable; (2) number of written user reviews; (3) price in US dollars; (4) average user rating (number of stars from 1 to 5);

(5) app size (in megabytes); (6) number of screenshots (ie, an actual app image that showcases its features and functionality); (7) length of app description (number of characters in the app description not including spaces); (8) app availability in the Apple App Store (ie, whether the app is also available for iOS smartphones or tablets); (9) new versions available (ie, whether the app has been updated since launch); (10) absence of age restriction (ie, defined by the developer as having content appropriate for all ages); (11) availability of in-app purchases (ie, the opportunity to buy extra content); (12) participation of a psychiatrist (ie, psychiatrist or psychiatry association); (13) participation of another HCP (ie, other medical doctors, pharmacists, or nurses); (14) no HCP (ie, no explicit mention of an HCP). The identification of HCP participation was based on an examination of the app description or its website and was only considered to be present when explicitly mentioned. These variables are listed in Table 1. The list of predictors is presented as a form in Multimedia Appendix 1. Apps were not downloaded.

The 2 reviewers gathered data about the level of installs based on the classification system used by Google in the Play Store (Table 1). At the time of review (April 9, 2019), no psychiatry app had been installed over 50,000,000 times.

Statistical Analyses

Analyses were performed using SPSS v20 (IBM Statistics). $P<.05$ was considered statistically significant in all analyses. Descriptive analyses were conducted, and a multivariate ordinal logistic regression analysis was performed to identify the factors predicting the number of installs for each app.

Table 1. The variables included in the model and their annotations.

Variables	Description
Level of installs[a]	
Level 0	no installs
Level 1	1-5 installs
Level 2	6-10 installs
Level 3	11-50 installs
Level 4	51-100 installs
Level 5	101-500 installs
Level 6	501-1000 installs
Level 7	1001-5000 installs
Level 8	5001-10,000 installs
Level 9	10,001-50,000 installs
Level 10	50,001-100,000 installs
Level 11	100,001-500,000 installs
Level 12	500,001-1,000,000 installs
Level 13	1,000,001-5,000,000 installs
Level 14	5,000,001-10,000,000 installs
Level 15	10,000,001-50,000,000 installs
Number of reviews	Number of reviews in the Google Play Store
Actual price	Actual price of the app in US dollars
Average user rating	User evaluation on a scale from 1 to 5 stars
App size	App file size in megabytes
No age restriction[b]	
0	Age restriction
1	No age restriction (ie, appropriate for all ages)
Number of screenshots	Number of screenshots in the Google Play Store
Length of description	Number of characters (without spaces) in the textual app description in the Google Play Store
Availability in the Apple App Store[c]	
0	Not available
1	Available
Version	
0	One version
1	New version exists
In-app purchases	
0	No in-app purchase
1	In-app purchase available
Psychiatrist participation	
0	Other
1	Psychiatrist- or psychiatry association
HCP[d] participation other than psychiatrist	
0	Other
1	Other HCPs, pharmacists, and nurses

Variables	Description
No HCP participation	
0	Other
1	No HCP mentioned

[a]The exact number of installs is not available from the Google Play Store. We categorized it according to the system used by Google in the Play Store.

[b]Apps without age-restricted content.

[c]Available on the Apple App Store.

[d]HCP: health care professional.

Results

Descriptive Statistics

The PubMed search identified 1 study on the predictors of downloads in mHealth smartphone apps, but it did not reveal any studies on the predictors of the number of installs for psychiatry apps, suggesting that this is the first study of its kind. However, studies in economics were found on Google Scholar, which determined the predictors of downloads for generic apps and were tested in this study.

We performed a search on the Google Play Store on the April 9, 2019. A total of 250 Android apps contained the term "Psychiatry" in their metadata. Among them, 122 apps were excluded: 119 were generic apps (ie, not designed specifically for psychiatry, eg, "Medicine: diagnosis, clinical cases, Tumor Node Metastasis, International Classification of Diseases") and 3 were just for making appointments or advertisement (eg, "Shantvan Clinic").

Of the 128 included apps (Multimedia Appendix 2), 72.7% (93/128) were free. Of the paid apps, the prices ranged from US $2.99 (several apps) to US $209.99 ("Principles and Practice of Geriatric Psychiatry 3"), with a median price of US $26.39. The average app rating was less than 3 stars (average 2.76), and 83.6% (107/128) apps had no written review at the time of the study. On average, each app had 8.87 screenshots, and the length of the description varied from 75 to 3456 characters (without spaces; Table 2).

Table 2. Summary of descriptive statistics for continuous variables.

Variables	Mean (SD)	Range	Median
Number of reviews	2739.05 (27,958.02)	0-314,639.00	0
Actual price in US dollars			
All apps	11.04 (29.22)	0-209.99	0
Paid apps	40.39 (44.37)	2.99-209.99	26.39
Average user rating	2.76 (2.07)	0-5	3.85
App size	11.96 (18.03)	0.29-141	6.55
Number of screenshots	8.87 (5.73)	2-24	8
Length of description	1253.23 (822.42)	75-3456	1301.50

Figure 2 shows the number of apps in each level of installs and HCP participation (ie, psychiatrists or psychiatry association, other HCP, or no HCP at all). There was a wide variation in HCP participation in each level of downloads, ranging from 0% (0/3) in apps without any download to 100% (6/6) in all apps with more than 500,000 installs, which included levels 12 (ie, between 500,001 and 1,000,000 installs), 13 (ie, between 1,000,001 and 5,000,000), and 15 (ie, between 10,000,001 and 50,000,000 installs).

Figure 2. Number of apps per level of installs and health care professional participation.
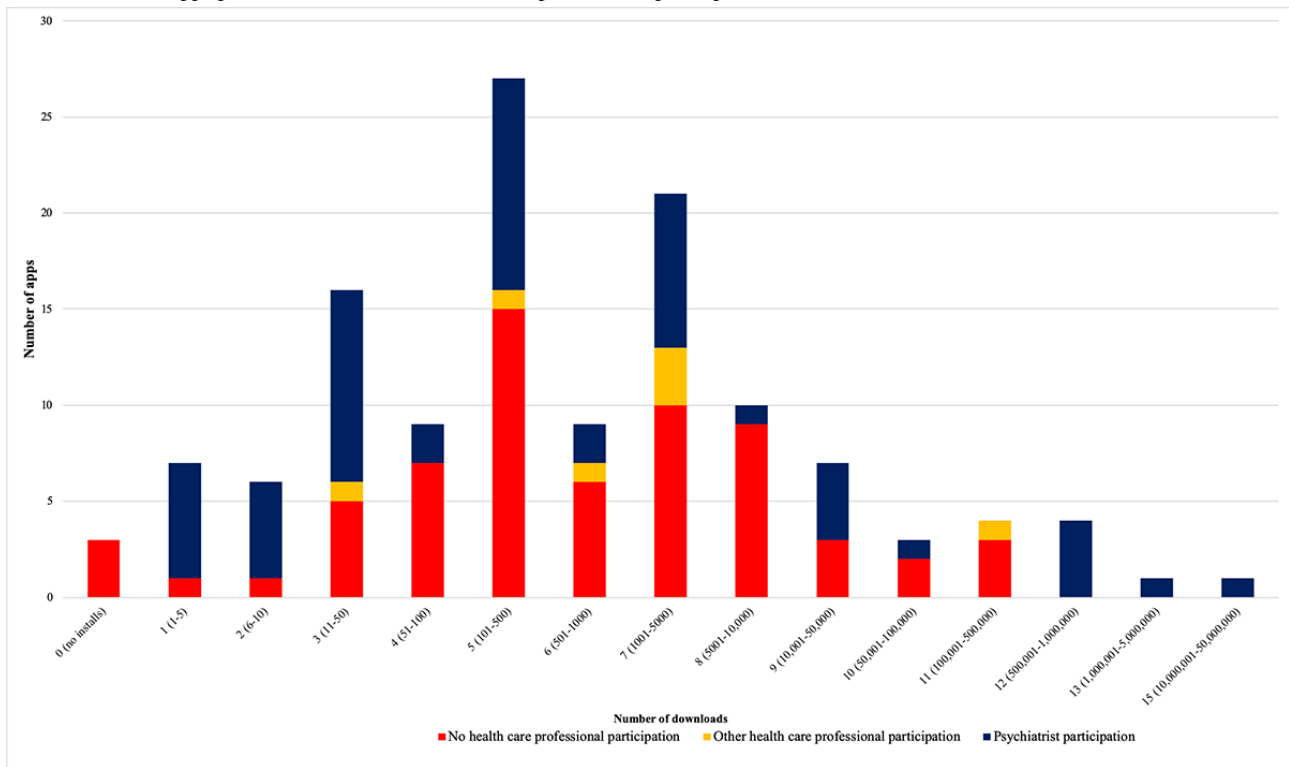
Although 0.8% (1/128) of the apps had between 10,000,000 and 50,000,000 installs, approximately half 53.1% (68/128) had less than 500 and 2.3% (3/128) had never been installed (Table 3).

Less than half of the apps 43.8% (56/128) were developed with psychiatrists' input, and other HCPs were involved in development of 5.5% (7/128) of the apps; 50.8% (65/128) of the apps had no documented HCP involvement. Furthermore, 95.3% (122/128) of the apps had no age restriction. Only 21.9% (28/128) had in-app purchases (Table 3).

Table 3. Frequencies for the categorical and binary variables (N=128).

Variables	Frequency (%)	Cumulative percentage (%)
Level of installs		
Level 0: no installs	3 (2.3)	2.3
Level 1: 1-5 installs	7 (5.5)	7.8
Level 2: 6-10 installs	6 (4.7)	12.5
Level 3: 11-50 installs	16 (12.5)	25.0
Level 4: 51-100 install	9 (7.0)	32.0
Level 5: 101-500 installs	27 (21.1)	53.1
Level 6: 501-1000 installs	9 (7.0)	60.2
Level 7: 1001-5000 installs	21 (16.4)	76.6
Level 8: 5001-10,000 installs	10 (7.8)	84.4
Level 9: 10,001-50,000 installs	7 (5.5)	89.8
Level 10: 50,001-100,000 installs	3 (2.3)	92.2
Level 11: 100,001-500,000 installs	4 (3.1)	95.3
Level 12: 500,001-1,000,000 installs	4 (3.1)	98.4
Level 13: 1,000,001-5,000,000 installs	1 (0.8)	99.2
Level 14: 5,000,001-10,000,000 installs	0 (0)	99.2
Level 15: 10,000,001-50,000,000 installs	1 (0.8)	100.0
No age restriction		
Age restriction	6 (4.7)	4.7
No age restriction	122 (95.3)	100.0
Availability in Apple App Store		
Not available	83 (64.8)	64.8
Available	45 (35.2)	100.0
Version		
Only 1 version	29 (22.7)	22.7
More than 1 version exists	99 (77.3)	100.0
In-app purchases		
No in-app purchase	100 (78.1)	78.1
In-app purchase available	28 (21.9)	100.0
Psychiatrist participation		
Other	72 (56.3)	56.3
Psychiatrist- or psychiatry association	56 (43.8)	100.0
Other HCP[a] participation		
Other	121 (94.5)	94.5
Other HCPs, pharmacists, and nurses	7 (5.5)	100.0
No HCP participation		
Other	63 (49.2)	49.2
No HCP mentioned	65 (50.8)	100.0

[a]HCP: health care professional.

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A Multivariate Logistic Regression Analysis

A multivariate logistic regression analysis revealed the factors that influence the number of installs among psychiatry apps (Table 4).

Cheaper apps (*P*<.001), apps with higher user rating (*P*<.001), and apps with available in-app purchases (*P*<.001) were significantly associated with app installs. Moreover, apps with age restriction were more likely to have a greater number of installs than apps without age restriction.

Although only apps with HCP participation had more than 500,000 installs (ie, levels 12-15), the explicit involvement of a psychiatrist or another HCP in the development of the app was not statistically significantly associated with the number of app installs. All other evaluated factors (ie, number of reviews, app size, number of screenshots, length of description, availability in the Apple App Store, and new published versions) were also not statistically significant predictors.

The Nagelkerke R^2 statistic, which measures the strength of the association between the dependent variable and the predictor variables, was moderate.

Table 4. Multivariate ordinal logistic regression analysis.

Variables[a,b]	Estimates[c]	SE	*P* value	95% CI
Other health care professionals' participation	−0.186	0.741	.80	−1.64 to 1.27
Psychiatrist participation	−0.583	0.451	.19	1.47 to 0.3
Number of reviews	0.000089	0.000059	.13	−0.000027 to 0.0002
Actual price in US dollars	−0.031	0.008	<.001	−0.05 to −0.01
Average user rating	0.631	0.099	<.001	0.44 to 0.83
App size	−0.002	0.013	.86	0.03 to 0.02
No age restriction	−1.722	0.829	.04	3.35 to −0.097
Number of screenshots	0.014	0.031	.64	0.05 to 0.08
Length of description	0.0001	0.0002	.63	−0.0003 to 0.001
Availability in the Apple App Store	0.517	0.417	.22	−0.3 to 1.33
Version	0.536	0.425	.21	−0.297 to 1.37
In-app purchases	1.67	0.459	<.001	0.77 to 2.57
Nagelkerke R^2	—[d]	—	.62	—

[a]The dependent variable is the level of installs.

[b]The reference level for HCP participation is *No HCP participation*.

[c]Estimates are the ordered log-odds regression coefficients, and they show the relative magnitude (ie, relative impact of the factor) and direction (ie, positive or negative) of impact of the listed variables on the level of installs.

[d]Not applicable.

Discussion

Principal Findings

This study is innovative in psychiatry because it shows that a lower price, optional in-app purchases, age restriction, and a higher rating positively influence the number of app installs. This is in line with studies in economics that identified predictors of the number of downloads in non-mHealth apps: lower price, available in-app purchases, smaller app size, more textual and visual descriptions, and version updates [5,6,8-12].

Although a lower price has been identified as a significant predictor of downloads, and it has been shown that the possibility of in-app purchases can positively affect a user's decision to download the app, some users opt to pay upfront for a more complete app, whereas others only download free apps, even if they have limited features [6].

Online word of mouth (ie, online exchange of opinions) influences ecommerce sales, including smartphone apps [9].

Online word of mouth has 2 main features: volume (the amount of word of mouth that generates the cognitive consequence of awareness) and valence (whether it is positive or negative that produces the cognitive consequence of attitude). In commercial app stores (ie, Apple App Store and Google Play Store), user rating and reviews may be perceived as reflecting previous users' experience: the number of reviews as the volume and the user rating as the valence, although it has been shown that there is no correlation between mental app ratings and the apps' quality of information or adherence to best practice guidelines [6,10,14]. Moreover, because most mHealth apps are available on commercial stores, the decision to download an app can be influenced by the apps' information (eg, title, description, developer, and screenshots). In addition, having the same app available on the 2 most popular mHealth app platforms (ie, Apple App Store and Google Play Store) may raise awareness about it, thereby influencing the number of downloads [6].

HCP participation can be a proxy of scientific integrity, and it has been hypothesized that establishing scientific evidence for commercial mHealth apps can promote their adoption in health

care practice and improve clinical outcomes [22]. Moreover, a study in mHealth identified HCP participation as a significant predictor of download of urology apps [23]. However, in our Android Play Store psychiatry-specific sample, although an HCP was documented in all apps that had more than 500,000 installs, the explicit participation of psychiatrists in app development was not a significant predictor of the number of installs. Moreover, only half of the apps had explicit scientific expert input, and when HCP participation was mentioned, there was no objective method to measure the extent of that involvement or a guaranteed method to assess if it was actually true. Potentially, this can be resolved by requiring mHealth apps to have a detailed disclosure form (eg, similar to scientific publications) or by implementing an independent certification of HCP participation. This would be beneficial toward the functional certification and content regulation of mHealth apps.

As mHealth apps are becoming increasingly popular, for both professionals and patients, the lack of evidence to recommend a specific mental mHealth app in favor of another becomes a pressing issue, and several pitfalls have been identified, such as outdated information or misinformation, often created by lay people, with disregard for usability and scientific evidence [24-27]. Moreover, warnings have been issued because of subpar safety, inadequate privacy policies, questionable content, and even dangerous nature of mental health apps [28-30].

To address these problems, it has been suggested that HCPs should have a pivotal position in the development, review, and recommendation of mHealth apps [27]. This can either be done individually or through scientific societies, which could coordinate this effort. A pragmatic stance has been taken by the American Psychiatric Association (APA), which devised a step-by-step App Evaluation Model [31] in which psychiatrists are advised the following:

1. To begin by collecting background information on the app (eg, who is the developer and what is the business model)
2. To exclude risk, privacy, and security issues (eg, does the app have a privacy policy, which personal data are collected, and are the data available to any third party)
3. To evaluate the evidence (eg, is there peer-reviewed, published evidence about the app or the science behind it)
4. To evaluate how easy is it to use (ie, evaluate its usability)
5. Assess interoperability (ie, how easy is it to share the data in the app with other health care software).

The APA's step-wise approach is built so that if, for example, there are privacy concerns, the app is considered dangerous and therefore excluded without having to evaluate other factors [31]. By taking an active role in mHealth, HCPs can safeguard the apps' up-to-date scientific evidence and, concurrently, promote user safety and privacy. This is in line with the WHO's Mental Health Action Plan 2013-2020: promote mental well-being; prevent mental disorders; provide care; enhance recovery; promote human rights; and reduce the mortality, morbidity, and disability in people with mental disorders [1].

Limitations

This study has limitations, in addition to the impossibility of controlling all factors (either mathematically or not measurable) that may influence the number of installs in the real world. Our study sample was restricted to the Google Play Store because Apple does not publish an individual app's number of downloads. Instead, Apple lists the *Top 200 Medical Apps*, ranked by a undisclosed proprietary algorithm, which prevents further analysis from being performed as there was no way of inferring the number of installs from the position within that list. Furthermore, at the time of the review, there were no psychiatry apps in that *Top 200 Medical Apps* list. Moreover, our search was performed in the US store, which may not be representative of other locations. Identifying psychiatry apps on Google Play Store is dependent on Google's search algorithm and is not straightforward. Therefore, to avoid entropy, we decided to perform a search using just the term "Psychiatry." Future research might determine the predictors of the number of installs for specific mental health keywords (eg, "anxiety," "depression," or "schizophrenia").

Conclusions

Mental health apps can be used by patients and HCPs in a myriad of contexts, from academic research to clinical practice. Our study shows that psychiatry apps with a lower price, optional in-app purchases, age restriction, and a higher rating are expected to have a higher number of installs. Research is needed to identify other factors that may influence the number of installs, as that can help mHealth app development.

Conflicts of Interest

None declared.

Multimedia Appendix 1
List of predictors.
[XLSX File (Microsoft Excel File), 12 KB - mental_v6i11e15064_app1.xlsx]

Multimedia Appendix 2
List of included apps.
[PDF File (Adobe PDF File), 113 KB - mental_v6i11e15064_app2.pdf]

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Abbreviations

APA: American Psychiatric Association
HCP: health care professional
mHealth: mobile health
WHO: World Health Organization

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Original Paper

Acceptance and Expectations of Medical Experts, Students, and Patients Toward Electronic Mental Health Apps: Cross-Sectional Quantitative and Qualitative Survey Study

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Abstract

Background: The acceptability of electronic mental (e-mental) health apps has already been studied. However, the attitudes of medical experts, students, and patients taking into account their knowledge of and previous experiences with e-mental health apps have not been investigated.

Objective: The aim of this study was to explore the attitudes, expectations, and concerns of medical experts, including physicians, psychotherapists and nursing staff, students of medicine or psychology, and patients toward e-mental health apps when considering their knowledge of and former experiences with e-mental health apps.

Methods: This cross-sectional quantitative and qualitative survey was based on a self-developed questionnaire. A total of 269 participants were included (104 experts, 80 students, and 85 patients), and 124 eligible participants answered a paper version and 145 answered an identical online version of the questionnaire. The measures focused on existing knowledge of and experiences with e-mental health apps, followed by a question on whether electronic health development was generally accepted or disliked. Further, we asked about the expectations for an ideal e-mental health app and possible concerns felt by the participants. All items were either presented on a 5-point Likert scale or as multiple-choice questions. Additionally, 4 items were presented as open text fields.

Results: Although 33.7% (35/104) of the experts, 15.0% (12/80) of the students, and 41.2% (35/85) of the patients knew at least one e-mental health app, few had already tried one (9/104 experts [8.7%], 1/80 students [1.3%], 22/85 patients [25.9%]). There were more advocates than skeptics in each group (advocates: 71/104 experts [68.3%], 50/80 students [62.5%], 46/85 patients [54.1%]; skeptics: 31/104 experts [29.8%], 20/80 students [25.0%], 26/85 patients [30.6%]). The experts, in particular, believed, that e-mental health apps will gain importance in the future (mean 1.08, SD 0.68; 95% CI 0.94-1.21). When asked about potential risks, all groups reported slight concerns regarding data security (mean 0.85, SD 1.09; 95% CI 0.72-0.98). Patient age was associated with several attitudes toward e-mental health apps (future expectations: r=–0.31, P=.005; total risk score: r=0.22, P=.05). Attitudes toward e-mental health apps correlated negatively with the professional experience of the experts ($r_s(94)$=–0.23, P=.03).

Conclusions: As opposed to patients, medical experts and students lack knowledge of and experience with e-mental health apps. If present, the experiences were assessed positively. However, experts show a more open-minded attitude with less fear of risks. Although some risks were perceived regarding data security, the attitudes and expectations of all groups were rather positive. Older patients and medical experts with long professional experience tend to express more skepticism.

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Introduction

Background

Smartphone apps for mental disorders, so called electronic mental (e-mental) health apps, have the potential to deliver immediate therapeutic help for various illnesses like substance abuse, bipolar disorders, depression, anxiety, psychosis, and even suicide [1]. They offer support at any time and place and provide context-aware interventions and real-time feedback. A recent review found 165 primary research studies on smartphone interventions for mental health in 2017-2018, and much evidence has been provided according to the effectiveness of these interventions [2]. In particular, patients suffering from depression benefit from e-mental health apps [3], and some clinical experts have welcomed this development to empower patients toward improved care [4].

Nevertheless, e-mental health apps available in the app stores of the market leaders Google and Apple are rarely clinically validated, and only a few are registered under the European Regulation on medical devices [5]. Thus, it is hardly surprising that there is criticism about the potential adverse effects such as low quality of therapeutic content or replacement of health care contacts [6]. In fact, the real-world user engagement of e-mental health apps beyond the clinical setting is rather low. There is a high attrition rate due to drop outs after a few days or weeks of use [7]. Recently, Fleming and Bavin [8] showed that the completion or sustained use of these programs varied from 0.5% to 28.6% [8]. One of the reasons for this gap between clinical trials and real-world engagement lies in different target populations of trials and people using apps in the real world [9]. However, some authors found that low usability, concerns about privacy, and a lack of trust prevent potential users to create the necessary confidence in e-mental health apps [10].

To bridge this gap and make clinically valid, effective interventions available to the broad public, a deeper understanding of the attitudes of all stakeholders is necessary. These are first and foremost patients in clinical and outpatient settings, medical experts who are in close contact with the psychotherapeutic process (such as physicians, psychological and medical psychotherapists, and nursing staff) and finally, future professionals who are current students of medicine or psychology.

Attitudes of Patients

Previous studies on attitudes toward e-mental health apps observed that the majority of the participants prefer face-to-face therapy over Web-based interventions. Interestingly, anonymity is the least important concern for rejecting e-mental health apps, while helpfulness, credibility, and accessibility are more important [11]. Research on privacy concerns reveals an inconsistent picture: The intention of patients to share personal health information with health care providers, in general, is highly influenced by privacy concerns [12]. This may result in a lower willingness to trust e-mental health apps, which of course implies sharing intimate experiences with software of unknown origin. In qualitative interviews, patients have expressed concerns about becoming dependent on apps or of losing social support [13].

Despite many doubts, patients also see advantages in using apps targeting mental disorders. These possibilities range from the acquisition of new skills, social connectedness, and feelings of a "safety netting" [13] to a deeper understanding of personal mood and triggers of their mental health problems [14] and even alarm functions and reminders for clinical appointments for patients with psychosis [15]. Internet interventions, in general, were rated as helpful, while guided programs or videoconferencing were preferred over unguided self-help programs [16]. Recent results show that especially patients with negative care experiences tend to prefer electronic health (eHealth) services, in particular, those with lower educational levels [17].

The relationship with physicians also seems to play a role in the acceptance of e-mental health apps for patients. A strong "doctor-related locus of control" has been negatively associated with the intention to use e-mental health apps [18]. Similarly, the willingness of patients to use e-mental health apps and programs depends to a high degree on their acceptance by the respective clinician [19] and even on the awareness of experts in teaching related topics to their medical students [20].

Attitudes of Medical Experts

Physicians in Germany show a positive attitude toward future eHealth developments, in general; nonetheless, some voice concerns about immature technology and neglected privacy [21]. However, only half of the established physicians in Germany feel adequately informed about these developments [22].

What expectations of and knowledge about e-mental health apps do physicians really have? A glance at topics in American mental health–related conferences in 2013-2015 shows that only 0.3% of the sessions addressed e-mental health apps [20]. This number, of course, may be higher today. A closer look reveals the underlying divided opinions of medical experts about digital health interventions. On the one hand, mental health care staff fear that internet-based services could replace face-to-face support. On the other hand, access to helpful information at any time and place, the possibility to express oneself in forums, and the incorporation of psychoeducational material is perceived as a great asset. Finally, internet-based services have been seen to possibly lower the threshold to initiate psychotherapy [23]. One

recent study, which specifically investigated the attitudes of physicians and psychotherapists, showed that experts doubt the possibility of effective treatment via the internet, but they regard telemedicine as a possible potential supplement to conventional face-to-face therapy [24]. A direct comparison of the attitudes of patients with depression and psychotherapists found more negative attitudes among psychotherapists than patients. Similarly, patients in clinical settings seemed to be more skeptical than patients recruited via the internet [25].

Missing Aspects

Three important aspects of attitudes toward e-mental health are missing in the studies highlighted above. First, the opinion of the future medical experts, that is, students of medicine or psychology, has not been studied. Apart from the integration of eHealth topics in single universities in the medical curriculum [26,27] and the willingness to use mental health apps by students themselves [28,29], data on the attitudes of students toward the topic are limited.

Second, the attitudes and expectations of the nursing staff, who are in close contact with patients who have used mental health apps or plan to do so, need to be considered. A study that inquired about their views on eHealth development, in general, not specific to e-mental health apps, reported that staff fear a loss of quality in social interaction caused by care robots while benefiting from process improvements due to digital documentation systems [22]. However, their opinions specifically about e-mental health apps are missing.

Third, and probably most important, none of the studies have asked the participants about their previous knowledge and personal experiences with e-mental health apps. It is conceivable that this contributes to the insights delivered by the research on user engagement mentioned in the beginning. Despite a growing amount of evidence-based interventions available on e-mental health apps, the dropout rates are high. This has been explained by poor usability, lack of trust, and concerns about missing data security [10]. The following question arises: Have the reservations about these tools increased or decreased depending on existing knowledge and personal experiences with e-mental health apps?

In this study, we have integrated these missing aspects in our research design to contribute to a deeper understanding of the barriers and facilitators of real-world engagement of e-mental health apps.

Objective

This study investigated the attitudes, expectations, and concerns toward e-mental health apps of physicians, psychological psychotherapists, psychotherapists in training, nurses, students of medicine or psychology, and patients with relevant support needs who could be prospective users of e-mental health apps.

The main objectives were based on the following research questions: How many e-mental health apps do the participants know of? How many have they tried and what were their experiences? Are e-mental health apps accepted or disliked, and for what reasons? What expectations do these groups have and what risks do they see?

Finally, the study also reports on the possible determinants of attitudes like age and sex of all groups as well as the number of years of professional experience of the medical experts.

Methods

Study Design

We conducted a cross-sectional quantitative and qualitative study using a questionnaire that was designed for the purpose of this survey. Data were collected between September 2017 and June 2018. The questionnaire was distributed either as a Web-based version via the online tool SoSci Survey [30] or in a paper-pencil version. We obtained a sample of 269 participants; 124 eligible participants answered the paper version and 145 answered the online version.

The study "Acceptance and expectations of experts, students and patients according to health apps for mental disorders" was registered in the German Clinical Trials Register (DRKS00013095).

Target Population and Recruitment

This study focused on physicians in the disciplines of General Medicine, Internal Medicine, Psychosomatics, Psychiatry, or Psychotherapy as well as psychological psychotherapists, trainee psychotherapists and nurses, students of medicine or psychology, and patients with a psychosomatic disorder.

Recruitment was performed with postings and mail distribution services to medical experts and students within the University Hospital of Heidelberg's Department of Internal Medicine and Psychosomatics in the Medical Faculty and in the Psychological Institute of the University of Heidelberg. More than 120 patients of the inpatient and outpatient services in the Department of Internal Medicine were approached with the paper-pencil version. Further participants were recruited via the internet. We wrote more than 800 personalized emails to physicians and psychotherapists published by the Association of Statutory Health Insurance Physicians. Further, students and patients received an invitation via Facebook, XING, LinkedIn, SurveyCircle, deutsche depressionsliga, and Diskussionsforum Depression. All groups and forums gave their consent in advance. Patients were excluded if they stated that they did not have a mental disorder or another disease that affects mental health (in the Web version only). No reward was given for participation in the study.

Ethical approval was obtained by the Ethics Commission of the Medical Faculty of Heidelberg (S336-2017) prior to data collection.

Sample Description

We collected 285 completed questionnaires. We then excluded 16 questionnaires; in one case, we received no informed consent, and 15 participants did not fulfill the inclusion criteria.

The sample consisted of 269 participants aged between 18 and 77 years (mean 37.39 years, SD 14.14 years). The demographic characteristics of the sample are presented in Table 1. Nearly two-thirds were female (173/269 [64.3%]). The sample comprised 104 medical experts, 80 students, and 85 patients.

The questionnaire was filled in by 43 physicians, 33 psychological psychotherapists, 16 psychotherapists in training, and 13 nurses. As one physician was also a psychotherapist in training, there were 104 experts in total. Of the 80 students, 54 were students of medicine and 28 were students of psychology (two of them studied both). Finally, 41 patients were recruited from the University Hospital of Heidelberg (Internal Medicine), and 44 patients were recruited via the internet.

Table 1. Descriptive statistics of the study sample (N=269).

Characteristics	Participants, n (%)
Age (years), mean (SD)	37.39 (14.14)
Sex	
Female	173 (64.31)
Male	96 (35.69)
Other	0 (0)
Nationality	
German	251 (93.31)
Other	18 (0.69)
Family status	
Single	158 (58.74)
Married	86 (31.97)
Separated	4 (1.49)
Divorced	14 (5.20)
Widowed	1 (0.37)
Other	5 (1.86)
Missing	1 (0.37)
Profession (experts)[a]	
General medical practitioner	7 (6.73)
Specialist in internal medicine	23 (22.12)
Specialist in psychosomatics	12 (11.54)
Specialist in psychiatry	9 (8.65)
Specialist in psychotherapy	6 (5.77)
Physician (total)	43 (41.35)
Psychological psychotherapist	33 (31.73)
Psychotherapist in training	16 (15.38)
Nurse	13 (12.50)
Experts (total)	104 (100)
Subject (students)[a]	
Medicine	54 (67.50)
Psychology	28 (35.00)
Students (total)	80 (100)
Patients	
Patient of the University Hospital Heidelberg	41 (48.24)
Patient recruited via the internet	44 (51.76)
Patients (total)	85 (100)
Education (patients)[a]	
Still in school	1 (1.18)
Secondary school	13 (15.29)
Secondary high school	24 (28.24)
Higher school certificate	26 (30.59)
Study exam	18 (21.18)

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Characteristics	Participants, n (%)
Other	3 (3.53)

[a]Multiple choice possible.

Measures

We developed a 10-minute, structured questionnaire that consisted of two major parts: The first section was titled "Demographics" and contained nine items; the second section was titled "Attitudes towards e-mental health apps" and contained 25 items. We distributed three versions of the questionnaire to the various target groups: medical experts, students, and patients. The versions differed slightly regarding the first part.

The sociodemographic data obtained were age, sex, nationality, marital status, socioeconomic status, and either profession or study subject. The medical experts were further asked to state their professional experience in years.

The items of the section "Attitudes towards e-mental health apps," the results of which are reported in this article, are listed in Table 2 and sorted by issues in the same order presented in the questionnaire.

The first part of the section "Attitudes towards e-mental health apps" addressed individual knowledge and prior experiences with the most common e-mental health apps at the time of the survey. If present, the experiences could be rated with a 5-point Likert scale from "negative" to "positive." After that, the questions asked for attitudes toward e-mental health apps, in general. The participants were asked to choose one option of five statements, from "I am concerned about the development" to "I think, there's great potential in the development." A further item asked for the participant's opinion about whether e-mental health apps will gain importance in the future, with a 5-point Likert scale ranging from "no" to "yes."

The next section of the questionnaire asked for expectations toward an ideal e-mental health app in eight statements (ie, "Privacy should be respected" or "The design should be appealing"). Another part asked for four different risks referring to no helpfulness, harmfulness to health, loss of social contacts, and lack of data security. In this section, the Cronbach alpha was .56 as well. Both parts, expectations and risks, were presented as a 5-point Likert scale from "not important" to "very important" and "no risk" to "high risk," respectively.

Additionally, four items were presented as open-text fields in order to give the participants the opportunity to express their opinions in a more detailed way.

Table 2. Items of the section "Attitudes towards e-mental health apps" sorted by issues.

Issue and item	Type
Knowledge	
Which of the following apps do you know? (list)	Multiple choice
Experiences	
Which of the following apps did you already try? (list)	Multiple choice
How do you rate your experiences?	5-point Likert scale[a]
Attitudes (1)	
What do you think in general of e-mental health apps?	Rank order (ordinal)
Attitudes (2)	
Do you think, that e-mental health apps will gain importance in the future?	5-point Likert scale[a]
Positive aspects	
Which positive aspects do you see regarding e-mental health apps?	Open-text field
Expectations toward an ideal e-mental health app	
What functions or properties would you like to have in an ideal e-mental health app? (8 sub items)	5-point Likert scale[a]
Further functions or properties	Open-text field
Negative aspects	
What would stop you from using an e-mental health app?	Open-text field
Risks	
What risks do you see in e-mental health apps? (4 sub items)	5-point Likert scale[a]
Further risks	Open-text field

[a]Range: –2 to +2.

Statistical Analysis

Data analysis was conducted using SPSS Statistics (version 24; IBM Corp, Armonk, New York) [31]. The data of the three groups were recorded simultaneously and analyzed for group differences. The preliminary exploration of the descriptive statistics was performed by calculating frequencies, means and SDs, and reporting 95% CIs. The range of all continuous items was coded from –2 to +2.

We explored differences between the three groups in attitudes by using the Pearson chi-square tests for attitudes rated on an ordinal scale and by using a 1-way analysis of variance (ANOVA) for attitudes rated on a 5-point Likert scale. In case of variance homogeneity, we calculated post-hoc tests according to Scheffé; if variance homogeneity was missing, we chose Dunnett-T3 due to its ability to discover even small differences among groups [32].

To explore the expectations toward an ideal e-mental health app, we carried out descriptive measures and an additional factor analysis (root cause analysis) in order to identify main components of the expectations toward an ideal e-mental health app and conducted a further ANOVA with the factors. The Cronbach alpha was calculated to assess the internal consistency of this section. It was rather low with an α=.56, which could be due to the heterogeneity of the concept [33].

The risks seen by the three groups were calculated via descriptive measures and an ANOVA. Additionally, we calculated a total risk score by averaging the four risks.

Looking for possible determinants of attitudes, expectations, and risks, we calculated correlations for age and professional experience of the experts. When appropriate, we calculated Pearson correlations (r) and Spearman rank correlations (r_s). We looked for sex differences by calculating the Mann-Whitney U tests or an ANOVA, depending on the scale levels of the items.

The qualitative data in open-text fields were analyzed manually by building inductive categories and taking into account the recommendations of content analysis and its possible quantification of categories following Mayring [34].

Results

Knowledge and Previous Experiences With Electronic Mental Health Apps

Of a short list of common e-mental health apps, 33.7% (35/104) of the experts and 15.0% (12/80) of the students indicated that they knew at least one of the apps (Table 3). The percentage of experts and students who had already tried one e-mental health app was 8.7% (9/104) and 1.3% (1/80), respectively. In the group of the patients, 41.2% (35/85) knew at least one app and 25.9% (22/85) had at least tried one app. The patients who had already tried at least one app were patients of the University Hospital of Heidelberg in three cases, and the other 19 were recruited via the internet.

When prior experiences with an e-mental health app were present, they were evaluated as positive. The nine experts who stated to already have experiences with an app rated the experiences with a mean of 1.22 (SD 0.44, 95% CI 0.88-1.56). The 22 patients rated their experiences with a mean of 1.18 (SD 0.96, 95% CI 0.76-1.61).

Table 3. Results for the question, "Which of the following apps do you know?"

App	Experts (n=54), n	Students (n=16), n	Patients (n=58), n	Total (N=128), n (%)
ARYA	2	1	4	7 (5.47)
DepressionsCoach (TK)	14	4	9	27 (21.0)
Deprexis24	16	0	3	19 (14.84)
Human Progress	0	3	2	5 (3.91)
Meplus	0	0	1	1 (0.78)
Minddistrict	2	0	2	4 (3.13)
Moodgym	5	0	4	9 (7.03)
Moodpath	1	2	11	14 (10.94)
MyTherapy	2	4	7	13 (10.16)
Novego	0	0	1	1 (0.78)
Selfapy	5	2	3	10 (7.81)
Others	7	0	11	18 (14.10)

Attitudes Toward Electronic Mental Health Apps

Quantitative Results

There were more proponents than skeptics against e-mental health apps (Table 4): 28.6% answered skeptically by choosing one of the first two options (31/104 [29.8%] experts, 20/80 [25.0%] students, 26/85 [30.6%] patients), 62.1% showed positive attitudes by choosing one of the last two options (71/104 [68.3%] experts, 50/80 [62.5%] students, 46/85 [54.1%] patients), and 7.4% were neutral (1/104 [1.0%] experts, 10/80 [12.5%] students, 9/85 [10.6%] patients). Experts expressed significantly more positive attitudes than skepticism compared with students and patients. The differences were significant (χ^2_3=11.45, n=184, P=.01 [experts vs students]; χ^2_3=12.19,

n=189, P=.01 [experts vs patients]), but not for students compared with patients.

Patients of the clinic expressed skepticism (15/41 [36.6%]), positive attitudes (18/41 [43.9%]), and neutral attitudes (4/41 [9.8%]; missing: 4/41 [9.8%]), while patients recruited via the internet answered skeptically (11/44 [25.0%]), positively (28/44 [63.6%]), and neutrally (5/44 [11.4%]). This difference was not significant (χ^2_3=6.80, n=85, P=.08).

The three groups differed in their opinion about whether e-mental health apps will gain importance in the future ($F_{2,263}$=7.64, P=.001). The experts believed this (mean 1.08, SD 0.68, 95% CI 0.94-1.21), while students and patients did not share this attitude (students: mean 0.79, SD 0.85, 95% CI 0.60-0.98; patients: mean 0.60, SD 0.99, 95% CI 0.39-0.82). There was a significant difference between experts and patients (Dunnett-T3: M_{diff} [mean difference]=0.48, SE 0.13, P=.001, 95% CI 0.17-0.78) and between experts and students (M_{diff}=0.29, SE 0.12, P=.04, 95% CI 0.01-0.57) but not between students and patients (M_{diff}=0.19, SE 0.14, P=.49, 95% CI –0.53 to 0.16).

Table 4. Results for the question, "What do you think in general of e-mental health apps?"

Response	Experts (n=104), n	Students (n=80), n	Patients (n=85), n	Total (N=269), n (%)
I think, there's great potential in the development.	22	15	16	53 (19.70)
I'm basically in favour of the development.	49	35	30	114 (42.38)
I'm in favour of the development of health apps, but not for mental disorders.	1	10	9	20 (7.43)
I am sceptical about the development.	25	16	24	65 (24.16)
I am concerned about the development.	6	4	2	12 (4.46)
Not answered	1	0	4	5 (1.86)

Qualitative Remarks

Many participants (n=199) took the opportunity to comment by answering the question: "Which positive aspects do you see regarding e-mental health apps?" These data were analyzed using content analysis by building inductive categories as described above. The most frequent category of answers was that an e-mental health app may deliver low-threshold access to psychotherapy. This view was shared by 70 participants (experts: 36, students: 21, patients: 13). Further, 53 statements expressed the belief that such an app improved everyday support (experts: 23, students: 9, patients: 21), and 50 remarks referred to improved self-management with such apps (experts: 23, students: 13, patients: 14). Finally, 23 statements mentioned the possibility of documentation/monitoring of therapeutic progress (experts: 7, students: 6, patients: 10). In particular, the experts believed that an e-mental health app had a good chance to improve psychoeducation (22 remarks in total; experts: 16, students: 5, patients: 1).

Expectations

Quantitative Results

The highest rated expectation toward an ideal e-mental health app was "privacy should be respected" with a mean score of 1.85 (SD 0.59, 95% CI 1.78-1.93). The lowest rated item was "it should be changeable and adaptable by me" with a mean of 0.66 (SD 1.14, 95% CI 0.52-0.80). All results are presented in detail in Table 5.

By principal component analysis, three dimensions could be extracted from the initial eight items: transparency, costs, and design/customizability; these accounted for 55.1% of the variance (Table 6). A subsequent ANOVA showed that the groups differ in their expectations ($F_{2,261}$=3.28, P=.04). The experts attached more importance to transparency than the patients (Scheffé: M_{diff}=0.38, SE 0.15, P=.04, 95% CI 0.01-0.74), while the latter put more emphasis on costs compared to the experts (M_{diff}=0.59, SE 0.14, P<.001, 95% CI 0.23-0.94) and design/customizability compared to the experts (M_{diff}=0.45, SE 0.15, P=.01, 95% CI 0.09-0.81). All other comparisons were without significant differences.

Table 5. Results for the question, "What functions or properties would you expect in an ideal e-mental health app?" (for all: min=–2, max=2).

Item	Participants (N=269), n (%)	Mean (SD)	95% CI
It should be changeable and adaptable by me.	267 (99.26)	0.66 (1.14)	0.52-0.80
It should not cost much.	266 (98.88)	1.05 (1.06)	0.92-1.18
It should be covered by the health insurance.	266 (98.88)	0.67 (1.20)	0.52-0.81
The purpose of the exercises should be clear and concise.	267 (98.26)	1.61 (0.68)	1.53-1.69
It should be clear who designed the app.	268 (99.63)	1.04 (1.14)	0.90-1.18
There should be scientific evidence of efficacy.	268 (99.63)	1.21 (0.92)	1.10-1.32
The design should be appealing.	268 (99.63)	1.13 (0.91)	1.02-1.24
Privacy should be respected.	268 (99.63)	1.85 (0.59)	1.78-1.93

Table 6. Matrix of components after varimax-rotation (the rotation is converged in 5 iterations; method of extraction: main component analysis).

Component	Transparency	Costs	Design/customizability
It should be clear who designed the app.	0.72	–0.17	–0.08
There should be scientific evidence of efficacy.	0.70	0.03	0.03
Privacy should be respected.	0.62	0.16	0.10
The purpose of the exercises should be clear and concise.	0.54	0.40	0.12
It should be covered by the health insurance.	0.11	0.71	0.25
It should not cost much.	–0.05	0.79	–0.18
The design should be appealing.	0.42	0.26	–0.56
It should be changeable and adaptable by me.	0.25	0.18	0.77
Eigenvalue	2.18	1.22	1.01
Percentage of total variance	27.27	15.25	12.56
Total variance	—[a]	—[a]	55.09[b]

[a]Not applicable.

[b]Deviations due to rounding.

Qualitative Remarks

The quantitative results are supported by a closer look at the statements made in open-text fields: Of the 19 statements in total, those referring to usability and customizability were nearly all expressed by students and patients (usability: experts: 1, students: 4, patients: 1; customizability: experts: 0, students: 0, patients: 2). The remarks of the experts in contrast referred to an improved risk management and possibilities for the patients to get in contact with a psychotherapist (risk management: experts: 3, students: 1, patients: 1; contact: experts: 2, students: 0, patients: 1).

Risks

All groups had concerns regarding the lack of data protection (mean 0.85, SD 1.09, 95% CI 0.72-0.98). All results are presented in Table 7. An ANOVA showed that there were no differences between the groups except in one item: "The exercises don't help." Students and patients showed significantly more concerns than experts ($F_{2,261}$=6.03, P=.003; students vs experts: M_{diff}=0.48, SE 0.15, P=.004, 95% CI 0.13-0.83; patients vs experts: M_{diff}=0.42, SE 0.16, P=.003, 95% CI 0.04-0.81).

The mean total score of all four risks was 0.11 (SD 0.74, 95% CI 0.02-0.19). There was no significant result after comparison of the three groups via an ANOVA ($F_{2,261}$=0.28, P=.76).

Table 7. Results for the question, "What risks do you see in e-mental health apps?" (for all: min=–2, max=2).

Item	Participants, n (%)	Mean (SD)	95% CI
The exercises don't help.			
Experts	103 (99.04)	–0.01 (1.04)	–0.21 to 0.19
Students	79 (98.75)	0.47 (0.92)	0.26 to 0.67
Patients	82 (96.47)	0.41 (1.12)	0.17 to 0.66
Total	264 (98.14)	0.27 (1.05)	0.14 to 0.39
The exercises are harmful for the health.			
Experts	103 (99.04)	–0.50 (0.96)	–0.68 to –0.31
Students	79 (98.75)	–0.46 (0.95)	–0.67 to –0.24
Patients	81 (95.29)	–0.47 (1.21)	–0.74 to –0.20
Total	263 (97.77)	–0.48 (1.03)	–0.60 to –0.35
By using such apps social contacts get lost.			
Experts	104 (100.00)	–0.16 (1.32)	–0.42 to 0.09
Students	79 (98.75)	–0.25 (1.21)	–0.53 to 0.02
Patients	83 (97.65)	–0.31 (1.42)	–0.62 to 0.00
Total	266 (98.88)	–0.24 (1.32)	–0.40 to –0.08
The data are not protected.			
Experts	104 (100.00)	0.91 (1.04)	0.71 to 1.12
Students	79 (98.75)	0.73 (1.11)	0.49 to 0.98
Patients	83 (97.65)	0.88 (1.13)	0.63 to 1.13
Total	266 (98.88)	0.85 (1.09)	0.72 to 0.98

Qualitative Remarks

The item "What would stop you from using an e-mental health app?" received 69 comments; all three groups expressed the fear that the development of e-mental health apps could promote a tendency toward the "transparent patient" caused by a missing protection of privacy. Missing scientific background of an e-mental health app was named as the second most frequent barrier (31 comments) followed by the fear of replacement of real-life psychotherapy (25 comments). Another question for specific risks demonstrated that some of the experts and patients (n=7 in total) expressed their concerns that an e-mental health app could become a substitute for real-life psychotherapy. Finally, 8 participants stated that the patient is left alone without a feedback by using e-mental health apps. Another participant, a patient, wrote: "One is reminded of the illness. Every day."

Possible Determinants of Attitudes, Expectations, and Risks

Age

There was no significant correlation between age and general attitudes toward e-mental health apps. We found a slight but nonsignificant negative correlation of general attitudes with the age of the experts (r_s(103)=–0.17, P=.09; students: r_s(80)=–0.16, P=.15; patients: r_s(81)=–0.07, P=.53).

The expectation that e-mental health apps will gain importance in the future correlated negatively with the age of the patients

(r=–0.31, P-.005; experts: r=–0.19, P=.05; students: r=–0.01, P=.95).

The expectations toward an ideal e-mental health app were not related to the age of the participants, except in the factor transparency in the group of the patients: The older the patient, the more emphasis he or she put on the opinion that an ideal e-mental health app should be transparent (ie, clear who designed the app, scientific evidence, etc) with a highly significant association (r=.35, P=.002; experts: r=–0.01, P=.88; students: r=–0.02, P=.87).

In the group of patients, age also correlated positively with the total risk score (r=0.22, P=.05; experts: r=0.17, P=.09; students: r=–0.03, P=.81).

Professional Experience of the Experts

The professional experience of the experts ranged between 1 and 33 years (physicians: mean 14, SD 10; psychological psychotherapists: mean 17, SD 10; psychological psychotherapists in training: mean 3, SD 2; nurses: mean 18, SD 10).

Regarding the attitudes toward e-mental health apps, there was a significant negative correlation with the professional experience of the experts (r_s(94)=–0.23, P=.03). The longer a medical expert had already practiced his or her profession, the lower was the acceptance of e-mental health apps, in general. The opinion that e-mental health apps will gain importance in

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the future also correlated negatively with the years of professional experience ($r=-0.23$, $P=.03$).

The professional experience of the medical experts did not correlate with expectations toward an ideal e-mental health app (transparency: $r=0.07$, $P=.50$; costs: $r=-0.18$, $P=.09$; design/customizability: $r=-0.13$, $P=.21$).

There was a significant positive correlation between professional experience and the total risk score ($r=0.21$, $P=.04$).

Sex

We found no differences in sex regarding general attitudes (experts: $U_{48,55}=519.5$, $P=.57$; students: $U_{27,53}=561.0$, $P=.10$; patients: $U_{18,63}=519.5$, $P=.57$) or the expectation of the role of e-mental health apps in the future (experts: $F_{1,101}=0.25$, $P=.62$; students: $F_{1,78}=1.07$, $P=.30$; patients: $F_{1,81}=1.39$, $P=.24$).

Discussion

Principal Findings

This study investigated the attitudes, expectations, and concerns toward e-mental health apps of medical experts, students of medicine or psychology, and patients. A special interest was to explore the role of previous knowledge of and former experiences with e-mental health apps made by the participants. Do these factors help reduce reservations about the utility of these tools, and thus, in the long term, increase user engagement? The results showed that in spite of a moderate knowledge of e-mental health apps, there was very little experience with these apps, especially in the group of medical experts and students who will be the future experts. However, a distinct group of patients were already in touch with e-mental health apps; they were not patients of the clinics but patients who joined the study via the internet and had self-reported mental health problems. If present, the personal experiences were rated positively. Trial of an e-mental health app led to a decrease in the reservations about the issue. However, the number of those patients who had personal experiences was too low to allow for conclusions based on further statistics.

In general, the highest acceptance of the development of e-mental health apps was expressed by the medical experts. They more often expected a growing importance of the topic in the future than students and patients. They recognized that online interventions could reduce the threshold to psychotherapy and deliver potentially useful psychoeducation for patients.

When asked for the possible risks, all groups reported concerns regarding data security. The experts were less worried about a potential risk of ineffective interventions. This risk was considered more likely by students and patients. Current medical and psychological experts may trust the state of the development more than others. Yet, the results show that experts especially express their wish to be informed about scientific evidence, purpose, and the developers of apps, which was summarized in the factor "transparency" in this study. From the patient's perspective, financial aspects and customizability were more relevant.

Regarding the topic e-mental health apps, which is very close to technical innovations, in general, one could expect a strong moderating role of the factor age. In fact, March et al [18] showed earlier that this is only the case for therapist-assisted e-mental health services, but not for self-help interventions. In our results, age, as a determinant for expectations or perceived risks, was only found in the group of the patients (aged 18-77 years). In the group of the experts, the years of professional experience (range: 1-33 years) could explain more than age: The higher the experience, the lower was the acceptance of e-mental health apps, in general, and the expectation that e-mental health apps will gain importance in the future.

Implications and Recommendations

The implications of the results should be reflected separately for the three groups investigated.

A closer look at the attitudes of medical experts reveals that psychotherapists, especially in the surveys of Schröder et al [25] and Tonn et al [24], expressed more critical opinions (in both cases, toward internet interventions, in general) than they did in our study. However, the often-reported fear of therapists of being replaced by internet-based therapy [8] could not be confirmed in our study. Maybe our results help explain the concerns in a more subtle way. Looking at the qualitative remarks of the experts, many therapists do not fear losing their patients to the internet, but the therapeutic relationship could be missing for the patients, which is not the same. The importance of the therapeutic relationship is well investigated and documented [35-37], and the focus of further research should lie on the question of how responsibilities of experts change with parallel therapeutic offers via an app. Some of their patients may rely on possible untrustworthy content of semiprofessional apps, which may be potentially harmful [23]. In this context, we recommend increasing the awareness of changing professional roles by promoting vivid discussions about e-mental health topics via conferences. As reported in the introduction, there is a current lack of exchange on the topic [20], especially among experienced by senior medical experts. Regarding these new responsibilities due to technical innovations, experts should have access to guidelines in order to assess the quality of e-mental health apps, as the German Federal Chamber of Psychotherapists already requires [38].

The implications have a direct impact on the role of the future experts—the students of medicine or psychology. Although some of them are already in touch with e-mental health apps for their own use, as indicated by studies conducted in the United States [29], students expressed little knowledge and experiences in our study. Regarding the still-growing market of e-mental health apps, assessing the seriousness and scientific evidence of these apps should become part of the curricula. There are only a few years left until today's students will have to be able to make reasoned decisions and assess the circumstances when confronted with patients who want to use an e-mental health app or already did and were confused by them.

In this study, patients were the group with the largest amount of knowledge and the widest experience with e-mental health apps. There is a certain group of patients who act autonomously

and care for its own recovery and self-management. This goes along with the observation that by being digital, patients increasingly gain independence [39]. Similar to our work, Schröder et al [25] reported that patients in nonclinical settings showed more positive attitudes toward internet interventions than clinical patients [25]. In our study, we found a similar, but not statistically significant, tendency. Recent results show that patients with negative care experiences tend to prefer eHealth services; this is especially true for those patients with a lower educational level [17]. March et al [18] reported that the willingness to use internet-based mental health services depends on the individual diagnosis. Patients with depression are more likely to prefer these services than patients with anxiety [18].

Based on these results, we recommend a personalized approach. Patients in clinical settings may need encouragement to try an established, validated e-mental health app (eg, for self-management of symptoms during after-care). Patients with negative prior care experiences or fear of clinical settings are difficult to be reached directly. For them, established standards for the development of e-mental health apps are highly needed. These implications support the recommendations referring to the expanded responsibilities of the experts and the future experts, as discussed above.

Study Limitations

As part of our study, we presented the participants with a short list of current programs and apps. This list could be complemented manually by the participants, and many of them took advantage of this possibility. Nevertheless, the development of e-mental health apps is a rapidly changing market, and the results may soon become obsolete.

Furthermore, the willingness to respond to a questionnaire with a focus on e-mental health apps depends to a high degree on an affinity to the internet or technology-related topics. This may be one reason for the positive responses toward the future of e-mental health apps. In particular, patients in the clinic who refused to take part in the study told us that they were not used to smartphone technology at all and that they did not feel competent enough to complete the questionnaire. A similar effect might exist in case of the experts contacted via email.

Another limitation lies within the group of the patients. Less than one half of these patients could be recruited in the Department of Internal Medicine of the University Hospital of Heidelberg. The remainder was found in self-help groups and forums on the internet and they were, not surprisingly, more in touch with the e-mental health app topic than the patients of the clinic. A bigger survey with a more representative sample of patients, also including outpatient services, would reveal a broader insight into the perspective of the patients. Further, some of the online patients may be medical experts or students as well, which was not asked explicitly.

We did not ask for the type of mental disorder of the patients, because patients of the psychosomatic departments often suffer from somatic diseases, which are accompanied by mental strains. Asking for a specific diagnosis would have raised the threshold for taking part in this survey. Further studies should focus on a more differentiated picture of the different types of mental disorders.

Finally, more research is necessary on the role of previous experiences with health care providers and the specific diagnosis of the patients as determinants of attitudes toward e-mental health apps.

Conclusions

This study revealed a lack of knowledge and experience of e-mental health apps in experts, students of medicine and psychology, as well as in patients. Even though some concerns were expressed regarding the potential negligence of private data protection, the attitudes and expectations of the target groups were rather positive. This was associated with a younger age of the patients and less professional experience of the medical experts. In consideration of a growing market with professional and semi-professional offers in the app stores, a deeper understanding and awareness of experts and students is an urgent necessity.

Conflicts of Interest

None declared.

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Abbreviations

ANOVA: analysis of variance
eHealth: electronic health
e-mental: electronic mental
SELFPASS: Self-administered Psycho Therapy SystemS

Original Paper

Patient Privacy Perspectives on Health Information Exchange in a Mental Health Context: Qualitative Study

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Abstract

Background: The privacy of patients with mental health conditions is prominent in health information exchange (HIE) discussions, given that their potentially sensitive personal health information (PHI) may be electronically shared for various health care purposes. Currently, the patient privacy perspective in the mental health context is not well understood because of the paucity of in-depth patient privacy research; however, the evidence suggests that patient privacy perspectives are more nuanced than what has been assumed in the academic and health care community.

Objective: This study aimed to generate an understanding on how patients with mental health conditions feel about privacy in the context of HIE in Canada. This study also sought to identify the factors underpinning their privacy perspectives and explored how their perspectives influenced their attitudes toward HIE.

Methods: Semistructured interviews were conducted with patients at a Canadian academic hospital for addictions and mental health. Guided by the Antecedent-Privacy Concern-Outcome macro-model, interview transcripts underwent deductive and inductive thematic analyses.

Results: We interviewed 14 participants. Their privacy concerns varied, depending on the participant's privacy experiences and health care perceptions. Media reports of privacy breaches and hackers had little impact on participants' privacy concerns because of a fatalistic belief that privacy breaches are a reality in the digital age. Rather, direct observations and experiences with the mistreatment of PHI in health care settings caused concern. Decisions to trust others with PHI depended on past experiences with the individual (or institution) and health care needs. Participants had little knowledge of patient privacy rights and legislation but were willing to participate in HIE because of perceived individual and societal benefits.

Conclusions: This study introduces evidence that patients with mental health conditions would support HIE. Participants were pragmatic, supporting HIE because they wanted the best care possible. They also understood that their PHI was critical in supporting the single-payer Canadian health care system. Participant health care experiences informed their privacy perspectives, trust, and PHI sharing attitudes—all accentuating the importance of the patient experience in building trust in HIE. Their lack of knowledge about patient rights and PHI uses highlights the degree of trust they have in the health care system to protect their privacy. These findings suggest that the patient privacy discourse should extend beyond the oft-cited barrier of patient privacy concerns to include discussions about building trust, communicating the benefits of HIE, and improving patient experiences. Although our findings are in the Canadian context, this study highlights the importance of engaging patients in privacy policy discussions, regardless of jurisdiction, to ensure their nuanced perspectives are reflected in policy decisions on their PHI.

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Introduction

Privacy and Health Information Exchange

Privacy and trust are critical for patients with mental health conditions. Effective therapeutic patient-provider relationships require patient candor and trust that health care providers will protect patient privacy (or confidentiality) [1,2]. Mental health records often contain sensitive information, including intimate revelations or references to stigmatic medical conditions [3]. As such, people with mental health conditions may be concerned about the disclosure of this sensitive personal health information (PHI). Fear of the stigma and discrimination may cause them to withhold information from health care providers or avoid seeking care altogether—which can be detrimental to patient care [4]. A recent meta-analysis [5] found fear of stigma had a small- to moderate-sized negative effect on health-seeking behavior, and concerns with PHI disclosure was the most commonly reported reason for health care avoidance. For this reason, mental health care and mental health records have historically been isolated from other medical care to protect patient privacy [6,7].

Patient privacy is an issue that has come to the forefront in discussions about health information exchange (HIE) [8]. In this paper, HIE refers to the process where PHI is electronically shared between health care providers, patients, and other health care stakeholders through interoperable health information technology (HIT) [9,10]. HIE can provide HIT users with the best information possible for 3 common uses: clinical care [11], patient access and management of their PHI (ie, patient-mediated exchange) [11-13], and research and health system planning [14-17]. Internationally, there is consensus that HIE can improve health care quality, safety, and efficiency [18,19].

In recognition of the transformative potential of HIE, Canadian federal and provincial or territorial governments have made significant investment into the creation of interoperable HIT (ie, electronic health records [EHRs]) to enable HIE to support their single-payer, publicly funded *universal* health care system—an institution rooted in the Canadian identity [19,20]. Despite the strong interest, the adoption of HIE in Canada has been slow [21]. Privacy is an oft-identified adoption barrier, as the seamless flow of PHI creates challenges to protecting patient privacy [8,16,22]. Much of the privacy debate centers around whether HIE would raise patient privacy concerns, erode trust in patient-provider relationships, and cause adverse health care behaviors [23-27].

Privacy Perspectives of Patients with Mental Health Conditions

From a mental health perspective, there are divergent views on the appropriate use of mental health records and its inclusion in HIE [28-30]. These debates have overshadowed the value of HIE. For instance, the inclusion of psychiatric notes in the EHR were found to reduce hospital readmission rates for psychiatric

patients [31]. HIT supporting patient-mediated exchange of PHI via a mental health care patient portal could improve patient activation, patient recovery, and appointment attendance [32]. Finally, population-based research using large databases has been an effective tool in battling the stigmatization of mental health disorders. Evidence generated from research has been used to raise awareness of the societal burden of mental health, identify gaps in treatment efficacy and effectiveness, and increase access to mental health care through more efficient utilization of health care resources [33].

The balance between protecting patient privacy and providing optimal care is value-laden, requiring careful consideration of all stakeholder perspectives. Unfortunately, the patient perspective is often based on conjecture, reflecting the values and norms of the academic and health care community [34]. Sometimes patient privacy needs are overestimated [35-37]. A 2018 systematic review found the patient privacy perspective was more nuanced and context dependent than what was suggested [38]. An emerging stream of research suggests that patient-perceived benefits can offset the postulated impact of privacy concerns [39-48]. This privacy trade-off is known as the privacy calculus—a cognitive risk-benefit analysis used to determine their information sharing behavior [49]. There is evidence of this trade-off for patients with sensitive PHI [45-48] but not specifically in the mental health context [38]. With policy makers trying to overcome the challenges of HIT for mental health [50], we need a better understanding of the patient privacy perspective to ensure patient-centered policy decisions are made [51,52]. The aim of this study was to generate insights on how patients with mental health conditions feel about privacy in the context of HIE.

Methods

Theoretical Framework

This study is a part of a larger project aimed at adapting the Antecedent-Privacy Concern-Outcome (APCO) macro-model [53] for use in health informatics research. The APCO is a high-level process model that delineates how antecedents contribute to privacy concern and how concerns can impact information sharing behaviors. *Behavioral reaction* is the most prominent outcome, as it represents an individual's intention to use a Web-based service or technology. *Regulation* and *trust* are proposed to have reciprocal relationships with *privacy concern*, acting as both antecedents and outcomes. The privacy calculus is included as *perceived risk* and *perceived benefit*. An adapted APCO model (Figure 1) was used as the framework for this study [38]. Its constructs (herein *italicized*) are presented and defined in Table 1.

With the dearth of in-depth and qualitative patient privacy research in mental health [38], this study was conducted to bridge this evidence gap. The objective of this study was to understand how patients with mental health conditions feel

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about privacy as it relates to their PHI and its uses facilitated through HIE (ie, clinical use, secondary use, and patient-mediated exchange). This study also sought to identify the factors underpinning their privacy perspectives and explore how their perspectives influence their willingness to electronically share PHI through HIE. Using the APCO as a guiding framework, we asked the following questions:

- How do patients feel about the privacy of their PHI (privacy concern)?

- What are the reasons for their privacy perspective (APCO antecedents)?

- Who do patients trust with their PHI (trust)? Why?

- What is the role of privacy policies and regulations (regulations) in the patient privacy perspective?

- What do patients know about their PHI rights and the legislated PHI uses (regulations)? How do they feel about them?

- How do patients feel about the various uses of PHI via HIE (behavioral reaction)?

Figure 1. Adapted Antecedent-Privacy Concern-Outcome model. Dotted arrows indicate tenuous relationships between constructs (ie, has not been confirmed through repeated studies).
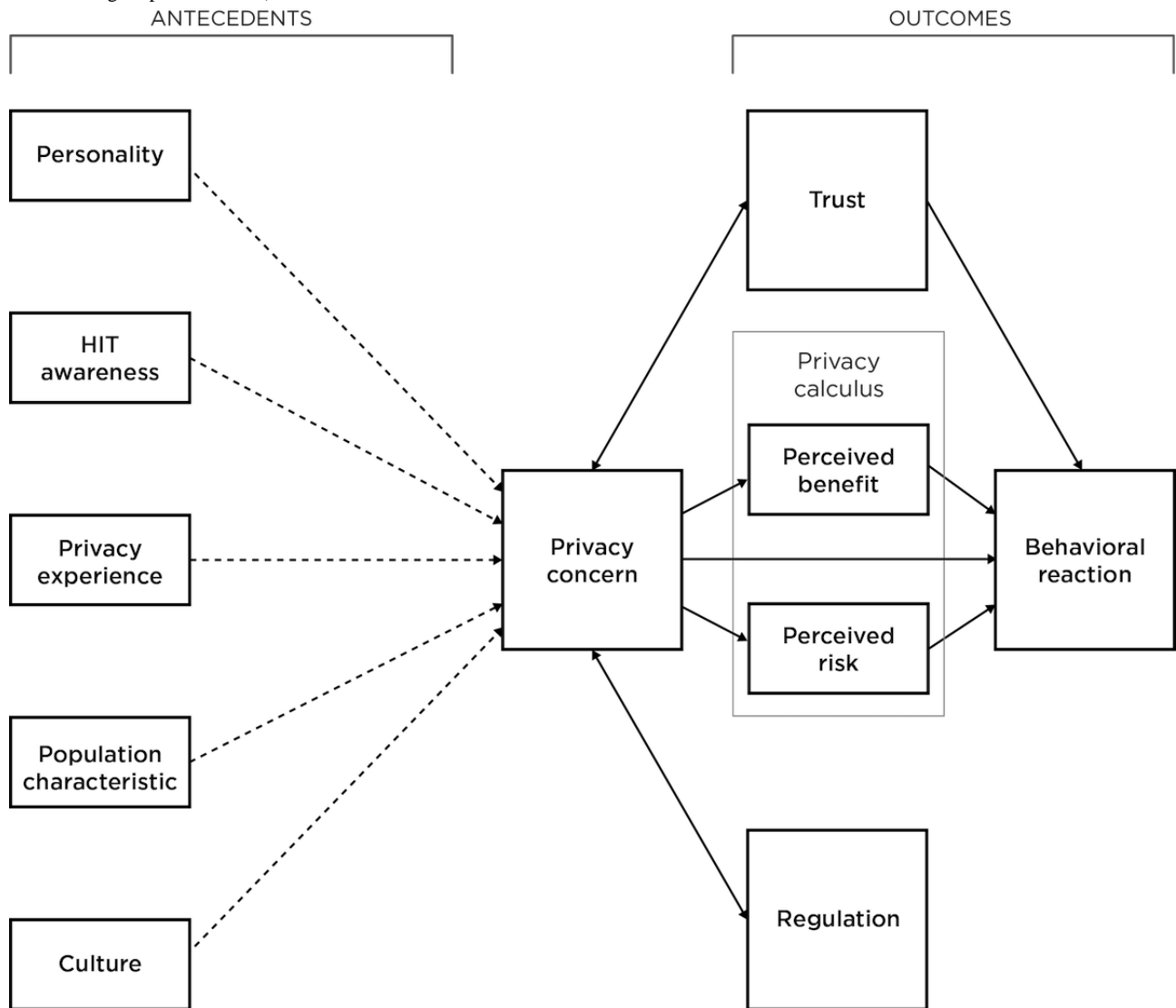
Table 1. Adapted Antecedent-Privacy Concern-Outcome construct definitions.

Antecedent-Privacy Concern-Outcome domain and construct	Definition
Privacy concern	An individual's beliefs, attitudes, and concerns about the electronic sharing of their PHI[a]
Antecedent	
Privacy experience	The extent to which individuals have been exposed to or been a victim of information abuses
HIT[b] awareness	The extent to which individuals have been exposed to or have knowledge of HIT
Population characteristic	The differences based on the shared characteristics of a population (eg, age, gender, income, education, etc)
Personality	An individual's psychological characteristics, patterns of thinking, feeling, and behaving
Culture	The attitudes, customs, and beliefs that distinguish one group of people from another
Outcome	
Perceived benefit	The degree to which an individual believes that the electronic sharing of their PHI can help themselves and others
Perceived risk	The degree to which an individual believes that the electronic sharing of their PHI will result in a loss or harm
Behavioral reaction	An individual's intention to electronically share their PHI or use HIT
Antecedent and outcome	
Trust	An individual's willingness to become vulnerable to the actions of another party
Regulation	An individual's knowledge of and attitudes toward the privacy safeguards and use of their electronic PHI

[a]PHI: personal health information.

[b]HIT: health information technology.

Recruitment

This study was conducted at the Centre for Addiction and Mental Health (CAMH)—Canada's largest academic health sciences center for mental health. Through consultation with the CAMH leadership, we recruited patients receiving acute care and structured treatments from 2 main programs at CAMH: Mood and Anxiety and Addiction Medicine Services. Together, these programs serve CAMH patients with depression; bipolar disorder; anxiety disorders; obsessive-compulsive disorders; and drug, alcohol, gambling, and other addiction issues, accounting for approximately 15,000 patients of the 37,065 unique CAMH patients.

To be eligible for this study, participants had to be receiving care at one of the CAMH programs, English-speaking, ≥18 years, and able to provide written informed consent. Participants were offered a Can $10 coffee gift card and reimbursed for public transportation costs. Research ethics approval (CAMH 067-2015) was acquired before recruitment. Potential participants were invited to participate through clinician referral, advertisements at participating clinics, and the CAMH research study website. Participants were also recruited at the end of patient group meetings, where CAMH researchers were scheduled to provide a 1-min description about their study. The clinicians prefaced and emphasized that the research was independent to treatment program and that participation was voluntary, having no bearing on the care they receive at CAMH. Interested patients could approach the researcher for more information about the study or sign up after the meeting. The lead author (NS) recruited participants from these meetings and

introduced the study as a part of his PhD thesis on understanding patient views on privacy.

A maximum variation purposive sampling strategy was employed to identify cross-cutting themes derived from a diverse range of perspectives [54]. This strategy requires the researcher to first identify relevant diversity characteristics as criteria and then choose participants that meet these criteria to provide maximum variation in the data collected [55]. Participants were asked to fill out a preinterview screening questionnaire (Multimedia Appendix 1) and were included or excluded serially, with each included participant contributing a unique background to the study [56]. Variation was sought across the following *population characteristics*: treatment program, years at CAMH, and self-reported health status (Health Utility Index Mark III [57]). A trusting disposition scale [58] was also used to assess an individual's general propensity to trust others (ie, *personality*). Trusting disposition is based on their willingness to give people a chance until proven wrong (ie, trusting stance) and general belief that people generally act with benevolence, integrity, and competence (ie, faith in humanity). Given the challenges of recruiting participants from this population, especially individuals with distrusting dispositions, participant interview responses regarding to trust (or distrust) was used in conjunction with the trusting disposition scale to ensure the study included a diversity of views on trust.

Recruitment continued until theoretical saturation was achieved (April to June 2017). Saturation was defined as the point where the interviews yielded no new data or themes. An a priori thematic saturation approach was undertaken to exemplify a

theory (ie, ACPO) based on its predetermined theoretical constructs [59].

Data Collection

One-on-one interviews were conducted in-person at CAMH sites, each lasting approximately 45 min. A semistructured interview format was selected for the interviews to allow the interviewer (NS) to diverge and pursue ideas in more depth when necessary [60]. Informed consent was collected before the interviews. NS introduced himself as a PhD candidate, affiliated with CAMH as a research trainee and disclosed that he had no involvement in the delivery of patient care. Participants were reassured that participation was independent from the care they receive at CAMH, and their individual responses would only be accessed by the research team for data analysis. They were also informed that the interviews would be audio recorded for transcription, and field notes would be taken throughout and after the interviews.

An interview guide (Multimedia Appendix 2) was developed by the research team and focused on the patient perspectives on *privacy concern, trust, regulation, and behavioral reaction*. Each section began with a broad question and narrowed down to focus on the *why*, allowing latent concepts to emerge through participant responses [61]. For this reason, specific questions related to privacy antecedents and privacy calculus were not included in the interview guide. The section on regulation also included an educational component where participants were asked broad questions about their views on *regulation* and what they knew about their patient rights and legislated PHI uses. They were then briefed on the provisions pertaining to their rights (ie, access records, request audit, and request consent directives) and permitted PHI uses (ie, use in provision of care, health system planning, and research ethics board [REB]–approved research). With this context, we then asked participants who they trusted with their PHI (*trust*) and whether they were willing to electronically share their PHI (ie, HIE) for provision of care, health system planning, REB-approved research, and patient-mediated exchange (*behavioral reaction*).

Data Analysis

The data analysis was conducted independently by 2 authors (NS and LS). At various points throughout the process, the authors compared their analysis and resolved any disagreements through discussion. NVivo 9 (QSR International) qualitative analysis software was used to code and organize the data.

A thematic analysis of the data was conducted in 2 phases using the framework method [62] and Braun and Clarke framework (Figure 2) [63,64]. The framework method [62] was used in the first phase to *chart* the data to the APCO. The data were deductively analyzed using the APCO constructs as predefined codes [65]. Open coding was used when data did not fit the predefined codes, and themes were inductively generated. This allowed for the extension of the APCO by uncovering health care–specific concepts (or constructs) not captured in the original model [62,66,67]. The Braun and Clarke thematic analysis framework [63,64] was used in the second phase to inductively analyze the data collated within each construct. After achieving consensus between the 2 authors, a final report was drafted where selected extracts relating to the analysis and the research questions were highlighted. This report was circulated to participants via email for member checking to ensure the accuracy and credibility of the reported results [68]. We did not receive any conflicting or discrepant feedback from the participants. As such, the findings were finalized and reported in this paper.

Figure 2. Approach to data analysis. APCO: Antecedent-Privacy Concern-Outcome.
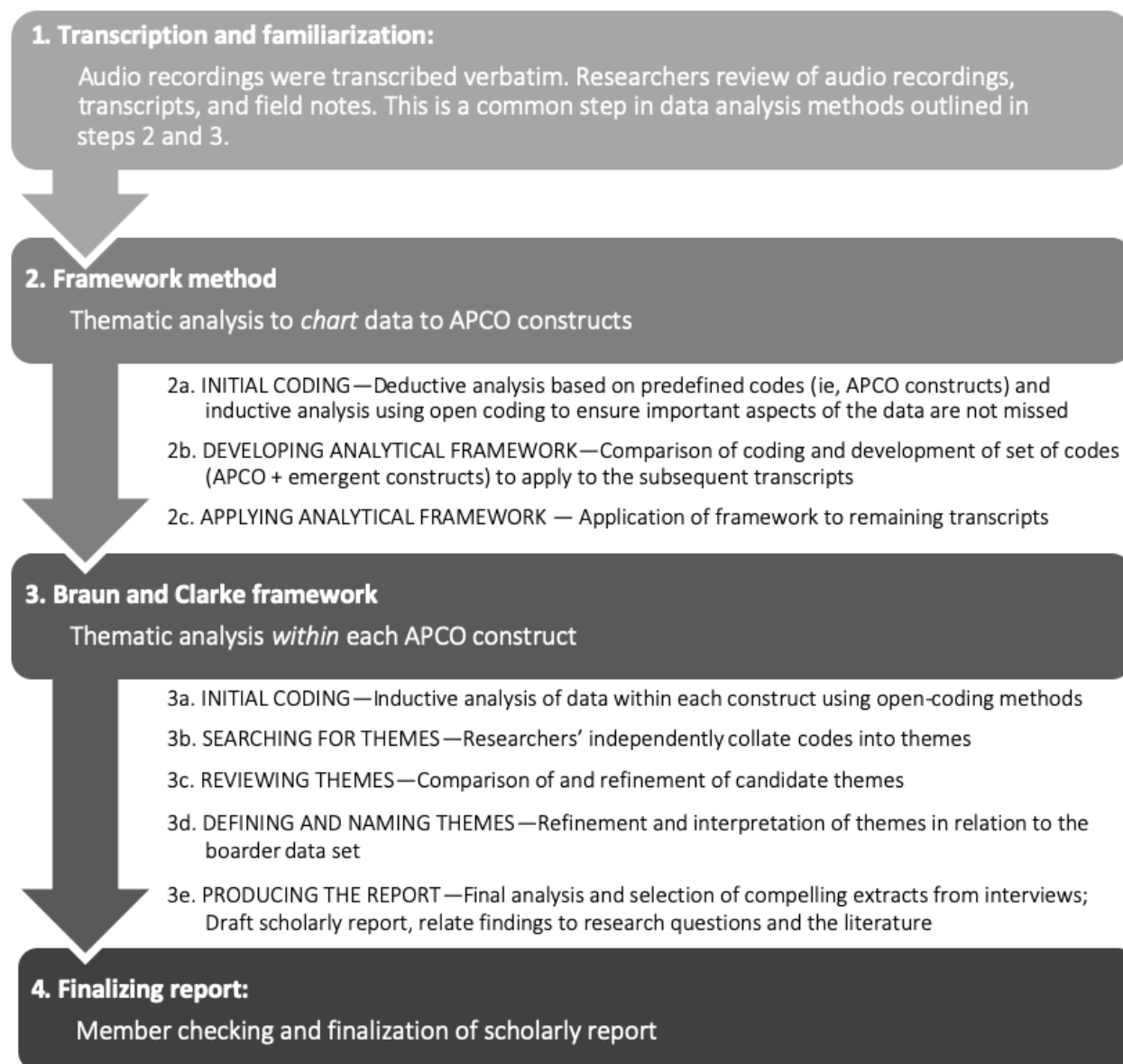
Results

Participant Characteristics

A total of 47 patients inquired about the study, of which 21 patients completed the preinterview questionnaire. On the basis of their questionnaire responses, 4 participants were excluded from the study because they did not add heterogeneity on the trusting dispositions subscales and did not report any patient characteristics unique to the sample. In total, 17 unique participants were included in the study; however, 3 participants were not interviewed as they were lost to follow-up. The characteristics of the 14 participants are reported in Table 2. Most participants were daily internet users and used the internet for health-related purposes. Participants generally had a trusting disposition. All participants trusted in the competence of others, and only 1 participant did not have a trusting stance.

Table 2. Participant characteristics.

Characteristics	Number of participants (n)
CAMH[a] program	
Addiction Medicine Services	6
Mood & Anxiety Services	8
Both	1
Years at CAMH	
<1	7
>1	7
Gender	
Male	7
Female	7
Other options[b]	0
Age (years)	
18-34	3
35-44	5
45-64	5
>65	1
Self-rated health status	
Poor	0
Fair	5
Good	8
Very good	1
Excellent	0
Internet use	
At least once a day	13
At least once a week	1
At least once a month	0
Less than once a month	0
Trusting disposition	
Trust	10
Neutral	2
Distrust	2
Integrity	
Trust	9
Neutral	4
Distrust	1
Competence	
Trust	14
Neutral	0
Distrust	0
Trusting stance	
Trust	13

Characteristics	Number of participants (n)
Neutral	0
Distrust	1
Type of internet use	
Health-related uses	11
Search for health info	7
Use of health information technology[c]	4
Email health care provider	2
Personal	10
Information seeking	9
Entertainment	8
Tasks and services	8
Purchasing	6

[a]CAMH: Centre for Addiction and Mental Health.

[b]Other options provided included the following: trans-sexual, transgendered, gender-queer, 2-spirit, female-to-male, male-to-female, intersex, unsure, questioning, prefer not to answer, other (please specify).

[c]Access their lab results, manage their health records or clinical appointments, or file insurance claims.

Patient Privacy Perspective (Privacy Concern)

Privacy was defined by some as having some control over who could access their information. Others equated privacy with confidentiality (eg, need to *protect* and limit *access* to other parties). Privacy was also normative, described as how people and PHI should be treated by using terms such as *respect, trust, appreciating, understanding*, and *honesty*.

There was an agreement that privacy was important in health care—often referring to privacy as a patient right. Privacy is especially important because of the stigma associated with mental health. Without privacy, discrimination may *hamper their ability to do [things]* and *prevent them from living a fulfilled life*. A *professional patient* shared his experiences:

> I've had HIV since the '90s and that was a concern... that information getting out in the early days because it was the plague and you're a social leper. Now mental health is that [way]. They're just labeled as crazy. [INT10]

Participants were divided on whether they had privacy concerns with HIE. Although they were quick to discuss their perceived risks (ie, hackers, unauthorized access by employers, and insurance companies), it did not appear to be of *particular* concern to some. Most participants discussed past *privacy experience* as their reason for concern.

Past privacy incidents or negative experiences with family, friends, colleagues, and acquaintances were reasons why some participants were cautious about discussing their mental health with other people. A participant provided the following account:

> I have, not real concerns... I've got reservations. Since I had one negative experience... [T]he insurance company sent my medical records, all of them [since birth], because of the consent form that I signed—not just for that particular incident with the bipolar

> illness—were sent to my president... [T]hat individual decided, "I don't want a nutcase for a VP" and did everything possible to make me quit, but I didn't... [W]e had a long time in court, and I won. It was 100% undoubtedly proven in court. [INT4]

Although many participants did not have past privacy incidents, a number of them brought up the frequent media reports about high-profile organizations being hacked, incidents at local hospitals, lost computers and Universal Serial Bus drives, and improper disposal of *obsolete computers*. Despite this heightened awareness, it was not a direct concern for most participants as they saw hacking as a new reality in the digital world—people with *nefarious intentions* will find a way to gain access to PHI regardless of the protective measures undertaken. This fatalistic view was described by a participant:

> ...it's happening all the time now... like I said before, you hope that it won't happen, but it could happen and that's just, I hate to say it, something you just have to get used to. (laughs) Convenience opens those doors for... breaches and things like that. [INT9]

Privacy experiences within a health care setting appeared to have a more direct impact on privacy concern. Positive experiences with doctors and health care institutions handling information reassured participants that their privacy was taken seriously. In a few cases, their doctor's candor and outlook on EHRs were able to quell their concerns:

> [E]very two-three months [you hear] about something that's been hacked... On the other hand, I'm impressed with the way my doctors handle the information. Though Dr [C] says that... some things were faster with paper. But on the whole, you know, they can access information, they can do drug interactions, they can look up history, that you know, they can give out information among themselves. It's very good. [INT2]

Negative health care experiences were reasons for concern. Some participants recalled incidents where patient data were visibly out in the open, openly discussed in waiting areas, or given to the wrong person. A participant shared her experiences as a patient and as clinician-researcher working at a different hospital:

> [T]hat's mostly a systemic failure. There are other people like I described, like my former supervisors that, you know, are clearly flagrantly violating like privacy laws as well as just sort of, I don't know, the social contract. [INT14]

The longitudinal content in the EHR was also a reason for concern for some participants. They discussed instances where they were treated differently or judged by health care providers because of what was in their records. A couple participants felt that past diagnosis, which they believe to be less relevant in the present, could still be used against them. A participant shared this concern:

> Privacy is huge for me. I'm a pretty private person. I didn't realize... [that]as an inpatient, every single thing that you do and that you say, it gets... [charted] right into the, I guess now, the computer system... and it's all in there for, I guess forever for them to see... [T]hey bring it to the future where you've grown from that experience and they hold over your head for, you know, two, three years later. If you go to hearings or review boards, they bring the past with you. What they have written... in the system. [INT13]

Trusting Beliefs (Trust)

Trust was described as a mutual understanding earned and maintained through interpersonal relationships over time. Many spoke about trust in terms of a principal-agent relationship, where there is an element of *faith*, *reliance*, or *confidence* that a trustee will *do the right thing*, act with the trustor's *best interests*, or deliver on some *expected outcome* that *was agreed upon*. Participants cited confidential relationships with health care providers and institutions as examples of trust:

> I don't think you can legislate trust. I don't think you can write trust down in the same way you can privacy. Trust is, I think, more of an interpersonal, uh, concept. [INT14]

Participants relied on common heuristics when deciding to trust individuals with PHI. First, they would share their PHI if they were *actively seeking* something or if sharing *served a purpose*. Sometimes, PHI sharing was *out of necessity* to gain access to mental health services or receive the proper care. A participant recalled:

> I have been holding back some information... I mean, not anymore, but yes [it] just kind of reached a point where—I needed help (humph). [INT8]

Later in the interview, they commented that it was *"not a benefit to say, 'No, you can't have access to, you know, all of the previous stuff.' It's kind of self-defeating."*

Another common heuristic was credentials (ie, degrees, affiliations, and professional college memberships). Credentials

meant that an individual has reached a certain level of competence or was *bound by a set of standards* or *code of ethics*. A participant's comment best represented the role of credentials:

> [T]he degree to which I believe it will be kept private and secure [depends on] the credentials of the people involved. I would trust like a doctor, like a Doctor of Medicine or a doctor of psychiatric medicine or a counselor, more than I might trust, say, a life coach. They're trying to do similar tasks to some degree, but a life coach, for example, may not have the same training, same experience, and may not be licensed in the same manner. [It's like] listening to a doctor versus listening to someone on the internet. [INT6]

Relationship-specific heuristics, such as reputation, familiarity, closeness, and history were considered when sharing PHI. Many stated the positive reputation of CAMH gave them confidence in their services. Some participants discussed how trust in health care providers was established over time and with repeated positive experiences:

> [T]he head pharmacist, he's been working with me for the last like 25, 30 years and I always refer him to the pharmacist at whatever hospital I'm at, I just say, "Talk to Henry, he knows everything." [INT1]

These heuristics also apply to personal relationships. For instance, a participant (INT9) identified their mom, sister, and 2 best friends as the only people they would trust with PHI because of their history. They were confident that these individuals could *keep a secret* and *would not use it against* the individual. In addition, the information recipient needed to be open-minded to struggles of living with mental health conditions. Participants shared how poor attitudes or *bedside manner* might have a detrimental effect on their trust. A participant was hesitant to share with those who did not understand their chronic pain and mental health issues because of the past judgement they received from their family and others, including health care providers:

> [there's a] lack of understanding of why, why aren't I doing more or, or why, why is it that I have been struggling for all of these years... so people don't associate that with, uh, chronic health issues, whether that's mental or physical and even less when you're "passing as" [a nondisabled person]. [INT12]

Sometimes, the decision to share PHI was *instinctual* or based on a *good vibe from the person*. Participants also attributed their trust and privacy views to their personalities (eg, *a private person*, an *open book*, or *not having that magical trust*). Trust also reflected the participant's views on humanity. Generally, participants believed that people are well intentioned and are trying their best. For this reason, participants did not conflate past mishaps or non-PHI–related mistakes with trust in their health care providers. There was a belief that breaches occur because a small segment of the population is *malicious* or negligent with patient privacy. A few participants provided commentary on why profit-driven entities (eg, pharmaceutical industry) cannot be trusted. When asked what corporations and controversial entities can do to rebuild trust, most believed that these entities need to become transparent about their motives

for how PHI would be used and what is being done to ensure its security.

Privacy Policy and Legislation (Regulation)

Laws were seen as a form of accountability for those who handled their PHI, serving as a deterrent for improper access or unauthorized disclosure. Without laws, participants would only seek care in urgent and emergency situations. Despite the importance of law, participants had a *vague understanding* of the legislated patient privacy rights and PHI uses:

> *This is sort of tied into why I'm interested in this. Because one of my emergency visits a few years ago, they ended up suspending my driver's license for health issues (laughs). And it all kind of happened without me knowing, until I get a letter in the mail from the [Ministry of Transportation] saying "Your license has been suspended." They didn't even tell me in the hospital... so it's kinda tied into stuff like that... Should police get access to it?... Yes or no, and then when and why?* [INT3]

Much of their knowledge of privacy laws and policies came from instances where they exercised certain rights. Some rights, such as the right to access their PHI, to request an audit of who accessed their PHI, and ability to place blocks on certain parts of their PHI, were interesting to participants as they felt it would have helped them in the past and could be useful in the future. Most participants *suspected* or *assumed* that PHI was used by the government for health systems planning and REB-approved research but were unfamiliar of the protective measures taken for these data (ie, prescribed entities, deidentification, and aggregation).

Participants felt reassured that much thought went into law development; however, it did not change how they felt about their PHI privacy. Some reflected on their experiences dealing with bureaucracy when exercising their rights, as a participant (INT4) noted, "that is the law, but it doesn't work that way." Others reiterated the fatalistic belief, bringing up examples of PHI snooping of local public figures by privacy-trained health care professionals. To them, laws can only do so much as there will always be a *snoopy sally*.

Participants generally felt the government and health care institutions were responsible in protecting their privacy by establishing the privacy laws (or policies), oversight, and enforcement of those laws. Many also felt that anyone handling PHI should be responsible. A few participants accepted responsibility for themselves, explaining they should be cautious when disclosing information; however, the responsibility shifts to the health care provider once the information is disclosed. A participant quipped:

> *Well once you give them [your PHI], I don't know if there's a lot the patient can really do. Um, supposed to stay 'til the office closes to make sure they lo-, shut down the computer, or that its password protected?... or to make sure if they still use old paper files. Is the, is the file room locked at night? (laughs) Is there, is there a good lock on the door? Or no windows, and*

> *do they have bars on the windows?... So yeah, I think it's mostly up to the organization.* [INT3]

When asked what could be done to ease any concerns about the electronic sharing of PHI, many felt there was a need for more effective communication of privacy laws, recommending patient-accessible documents, such as a *top-ten list* or a *bill of rights*. Suggestions on content include simple communication (eg, "your privacy is ensured" and announcements of privacy certifications and accreditation), lists of PHI uses and protections, and a guide on how to exercise privacy rights. Some participants also suggested more active dissemination approaches, such as greater prominence on institutional websites, news features (eg, television, Web, and newspaper), and town hall meetings.

Health Information Exchange Attitudes (Behavioral Reactions)

Participants were willing to allow their PHI to be used for clinical use, patient-mediated exchange, health service planning, and REB-approved research. A few participants voiced preferences on who could access their records and whether consent should be required; however, they were still supportive as they saw utility in the exchanges. Participants were aware of the wide range of potential benefits of PHI use. They quickly rationalized how each case could be beneficial. The *privacy calculus* was discussed in a few interviews, where *the advantages outweigh the disadvantages*; however, participants discussed the benefits and seldom discussed the risks.

Sharing PHI for clinical use was seen as advantageous, as complete information was required for the *best care possible*. Many discussed the importance of complete medical history in emergency situations and mental health crises where they were *not in a 100% sound state* or lacked capacity to discuss their medical histories. Even in nonemergency situations, clinician access to complete records can take the *stress off the patient* to remember everything or have to repeat *the same story*. They believed there would always be *gaps* in their memories regardless of how organized they are with their records.

Overall, patient-mediated exchange was thought to be a good idea but not necessarily for everyone. Some were amused by the idea and were curious to try it out. Others indicated they already used patient portals or were invited to register for access. Having access was seen by many as a way for them to review and keep track of their records, help them better understand their health, or become *partners in their care*. A few felt that having access to their PHI was a form of patient accountability, as it would allow them to refer to documentation about decisions made, ensure their PHI is accurately recorded and mistake-free, and identify which health care professionals have accessed their PHI (if possible).

Participants supported HIE for health system planning and REB-approved research, where PHI was deidentified or aggregated. There was a sense of altruism when it came to using PHI for health system planning, as it was a way for participants to *give back*, contribute to a *greater good, or* help fix a *fractured system*. They explained the government needed *reliable numbers* to address health care issues (ie, underfunded and understaffed

programs, wait times, budget constraints, and access to mental health care) and plan for a more efficient or effective system. Similarly, REB-approved research was seen as beneficial and essential in finding new or better treatments, medications, and cures. The *professional patient* reflected on his medical history:

> *I was part of the early days of HIV. And [those] days are guinea pigs for drugs. So perhaps if, um, more information we share, more things would have come out...now that there's electronic data that's able to be shared, things are shared quicker. Who knows what advances in research would happen.* [INT10]

Discussion

Principal Findings

We conducted this study to begin bridging the patient privacy evidence gap in mental health HIE [38]. This study sought to understand the privacy perspectives (*privacy concern*) of patients with mental health conditions and explore the interplay of their perspectives with the antecedents and outcomes delineated in the APCO (ie, *trust, regulation, and behavioral reaction*). Through inductive and deductive analysis, this study introduces evidence on the context-dependency on the patient privacy perspective on mental health HIE. Although all participants agreed on the fundamental importance of privacy in health care, especially in mental health care, the degree of concern expressed in the interviews varied. Privacy concerns commonly stemmed from negative health care privacy experiences and negative health care perceptions based on their patient experience, whereas other privacy antecedents were infrequently discussed.

Privacy experience is a construct seldom explored in HIE patient privacy research [38]. In our findings, *privacy experience* was the only antecedent that consistently identified in the data. Although many participants were concerned about increasing occurrences of privacy breaches as reported in the press, it was not a direct concern because of their fatalistic privacy view—a belief that that breaches are a reality in our digital society, and all they could do is trust those involved will do their best to protect patient privacy. Conversely, direct experiences or observations of lack of privacy vigilance within a health care setting left a lasting impression on participants. Poor patient experiences unrelated to privacy also had the effect of leaving participants with a negative perception of the health care environment. As such, health care perceptions should be included as a construct in future adaptations of the APCO, as it was a cross-cutting theme across *privacy concern, trust, regulation,* and *behavioral reaction*.

Participants used credentials and relationship-specific heuristics to determine their comfort in sharing about their mental health with others (*trust*). They generally trusted that health care professionals and institutions would protect the privacy of any information shared in receiving care. This degree of trust is accentuated by a lack of knowledge about the legislated PHI uses (*regulation*), especially when juxtaposed with the high importance they placed on law. There was a passive acceptance that legislative and institutional safeguards would ensure those working with PHI are properly trained and accountable to their conduct. Whether privacy related or not, poor patient

experiences (eg, bureaucracy and bedside manner) caused skepticism about the effectiveness of the legislative and institutional safeguards protecting their privacy. This is consistent with other studies, where patient perceptions of quality of care, patient-physician relationship, and trust in health care providers have strong associations with perceptions of privacy and PHI sharing attitudes [38,69-71].

Despite the varying perspectives on privacy and trust, participants were pragmatic about HIE and its potential PHI uses (ie, *behavioral reaction*), recognizing the best care required the best information possible. Some participants reflected on their experiences in accessing and receiving mental health care or perceptions about the health care system, acknowledging that sharing PHI is necessary to improve treatments and health care policy decisions through research and analytics. The patient-mediated exchange was novel to some participants; however, they understood the value of accessing and managing their records and agreed that interested patients should have the option to do so. These individual and societal benefits of HIE were the primary focus in most responses to *behavioral reaction* questions, whereas the risks of HIE were seldom discussed. As suggested earlier, participant-*perceived risks* might have been muted by their fatalistic privacy views. Receiving the best care possible may also supersede the need for their personal risk assessment [72].

Echoing past policy recommendations [39,73-77], participants suggested the following as the first steps in fostering trust: transparent communication of the value of interoperable HIT, PHI uses, protective measures, and patient privacy rights. In addition to public education, patient engagement is essential to its success [78-80]. Patient feedback is critical in the highly debated topic of consent [81-84]. Surprisingly, consent was rarely mentioned by participants, especially as studies found patients wanted granular control of their PHI [85,86]. Their passive acceptance and pragmatic views suggest that contextual integrity may be a viable alternative approach to the consent. Contextual integrity assumes the act of sharing information is only an issue when shared outside the boundaries of socially acceptable contextual norms (ie, *norms of appropriateness* and *norms of flow*) [87,88]. These contextual norms provide a technology-agnostic standard to evaluate the acceptability of new HIT, as they capture the patients' perspectives with respect to information flow. Patient engagement and deliberation on PHI privacy will be required to establish these norms [89].

Finally, understanding the patient health care perceptions can provide privacy and HIT policy and decision makers with insights on where health care system exceeds or fails to meet their privacy expectations. These insights inform how the health care environment, processes, and delivery can be redesigned to foster greater patient trust and mitigate their concerns. Addressing privacy concerns in a way that is vigilant and sensitive to the health care environment can improve patient views on privacy and patient satisfaction [90]. These improvements will require a strong commitment to making major administrative, philosophical, and operational changes that respect both patient privacy and satisfaction.

Limitations

This study contributes to the understanding of the privacy perspectives of patients with mental health conditions or sensitive PHI—an area where there is a dearth of research. Limitations on the sample and study context should be considered when interpreting the findings. First, the challenges of recruiting patients in a mental health setting may have limited the sample size; however, studies have shown that data saturation can be achieved with sample sizes anywhere from 12 to 17 participants [91,92]. Our findings may not reflect the views of the broader mental health population, including patients receiving care in other CAMH programs and services. Although we employed a maximum variation sampling strategy, the findings are not intended to be generalizable nor numerically representative; rather, this sampling strategy is intended to highlight diversity in responses [93].

The results of this study may reflect the views of patients with more trusting dispositions, as there was difficulty identifying participants with distrusting stances. Given distrust is a predisposing factor of health care avoidance [94], those receiving care may be more trusting or become more trusting because of their positive experiences at CAMH. As CAMH is an academic hospital, participants may be more familiar with the health care system and how their PHI is used for health system analytics and research. Moreover, these findings pertain to the Canadian context and may not be applicable to other countries. In Canada, the *universal health care* system is a part of the national identity [20], which may influence participant awareness or understanding of its sustainability. Canadians may have a more favorable health care perceptions and views of HIE, which could positively bias their *behavioral reaction*.

The use of a proxy measure for achieving maximum variation in trusting disposition should be considered. As observed in the interviews, the degree in which participants trusted others with their PHI varied from trusting no one to trusting everyone bound by privacy law. These differences in responses in the interviews indicated variation was achieved with trust. These differences also suggest the trusting disposition scale may not have been appropriate for this study, as it was rigorously validated in a nonhealth care context (ie, electronic commerce) [58]. The role of trust in patient participation in research may be another explanation for the difficulty in recruiting distrusting participants. Using trust as a parameter for variation may introduce self-selection bias, as trusting patients may be more willing to participate in research [95-97]. As the trusting disposition scale was related to participants' *personality*, the observer bias (ie, Hawthorne effect) should also be considered [98]. Participants in active care may not be fully candid with their views on how their PHI is being handled, given the research team's affiliation with CAMH. Efforts were made at every step of this study to ensure that the patients understood that the study is independent to the care they received and their individual responses would remain anonymous.

Finally, the privacy perspectives in this study includes those who work in health care or research. Although their views may include professional insights on PHI privacy, being a patient does not preclude privacy experiences from other facets of life as delineated in the APCO. The findings reported here represent views echoed by other participants and were identified through thematic analysis.

Conclusions

Through their first-hand accounts, this study introduces evidence that patients with mental health conditions support HIE in Canada, where the benefits to their health was compelling enough to overcome privacy concerns over the risks associated with sharing their PHI. Patients saw the societal value of sharing their potentially stigmatizing PHI to support the single-payer universal Canadian health care system. Their fatalistic view on digital information underscores the importance of trust in the patient privacy discussion. Although these findings are within the Canadian context, this study highlights how engaging patients can illuminate the nuances to the patient privacy perspective that are often lost in mental health privacy conjecture. The nuances associated with trust and the patient experience are seldom explored in the HIE privacy discourse; however, these are critical in reassuring patients that the health care system prioritizes patient privacy in providing the best care possible. With many innovative and transformative PHI uses on the horizon, it is imperative that health care systems globally engage patients to ensure that patient-centric privacy policy decisions about PHI are made and are reflective of the nuanced views of the patients.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Pre-interview questionnaire.
[PDF File (Adobe PDF File), 49 KB - mental_v6i11e13306_app1.pdf]

Multimedia Appendix 2
Interview Guide.

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[PDF File (Adobe PDF File), 62 KB - mental_v6i11e13306_app2.pdf]

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       [Medline: 24275499]

Abbreviations

APCO: Antecedent-Privacy Concern-Outcome
CAMH: Centre for Addiction and Mental Health
EHR: electronic health record
HIE: health information exchange
HIT: health information technology
PHI: personal health information
REB: research ethics board

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Original Paper

Determinant Factors of Public Acceptance of Stress Management Apps: Survey Study

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Abstract

Background: Chronic stress is a major public health concern. Mobile health (mHealth) apps can help promote coping skills in daily life and prevent stress-related issues. However, little is known about the determinant factors of public acceptance of stress management in relation to preferences for psychological services.

Objective: The aim of this survey study was to (1) assess determinant factors of public acceptance (behavioral use intention) of stress management apps based on an adapted and extended version of the Unified Theory of Acceptance and Use of Technology (UTAUT) model and (2) explore preferences for mHealth apps compared with other mental health services.

Methods: Using convenience sampling, participants completed a multiscale 54-item Web-based survey. Based on significant correlations with acceptance, hierarchical stepwise regression analysis was performed within three blocks: (1) background and stress-related control variables, (2) beliefs and attitudes toward using mHealth, and (3) the core UTAUT determinants. The preference for mHealth apps in comparison with nine other mental health services (operationalized as readiness to use) was analyzed using paired t tests.

Results: Of 141 participants, nearly half (69/141, 48.9%) indicated prior mHealth use. Acceptance of stress coping apps was moderate (mean 3.10, SD 1.03, range 1-5). Hierarchical stepwise regression including four of 11 variables (R^2=.62; P=.01, f^2=1.63) identified positive attitudes toward using mHealth for stress coping (beta=0.69, P<.001, 46% R^2 increase above block 1, f^2=0.85), skepticism/perceived risks (beta=–0.14, P=.01, f^2=0.16), and stress symptoms (beta=0.12, P=.03, f^2=0.14) as significant predictors of acceptance. UTAUT determinants added no predictive contribution beyond attitudes (all P>.05, R^2 increase of 1%), whereas post hoc analysis showed significant R^2 increases of attitudes and skepticism/perceived risks beyond UTAUT determinants (all P<.001, R^2 increase of 13%). The readiness to use apps was equivalent to or significantly higher than most service types, but lower than information websites.

Conclusions: Attitudes may be at least as predictive for the acceptance of stress management apps as for more elaborated outcome beliefs. Efforts aimed at improving the public adoption of mHealth could put more emphasis on the pleasant aspects of app use, address misconceptions, offer stress screening tools on health websites, and increase options to try high-quality apps.

KEYWORDS

Introduction

Background

Chronic stress represents a tremendous health risk [1-3] and is a key contributor to the global burden of mental illness, which results in high economic costs on a societal level [4]. Therefore, from a public health perspective, it is vital to invest in the prevention of stress-related health problems. In this paper, stress is to be understood according to the Transactional Stress Model by Lazarus and Folkman [5], according to which subjective stress and coping appraisals caused by an event can result in further problem-focused or emotion-focused coping strategies.

These strategies are the centerpiece of efficacious cognitive behavioral and multimodal stress management interventions, which are commonly provided in group settings [6]. Beyond group interventions, e-mental health services that can be delivered via mHealth apps may increase public access to interventions for the prevention of mental health problems [7]. Utilization rates in target groups in the field of workplace health promotion may also increase [8-10] by providing effective occupational e-mental health interventions for employees [11-13].

Meta-analyses have demonstrated that high-quality mental health apps are efficacious in reducing the symptoms of anxiety [14], depression [15], and stress [16]. There are evidence-based digital stress management programs for nonclinical target groups, such as employees (eg, GET.ON [17-20]) and university students (eg, StudiCare [21-23]).

Common content or behavior change techniques of available stress management apps involve problem-focused strategies, such as time management, goal setting, and planning social support. Emotion-focused strategies often include relaxation techniques, such as breathing exercises, mindfulness, or meditation and autogenic training [24].

Although more than 10,000 mental health apps are publicly available, very few have been evaluated scientifically [25]. Health policy is necessary to ensure the structural requirements for the dissemination of high-quality, safe, and effective apps. To date, only a few stand-alone mHealth apps have been evaluated in randomized controlled trials (RCTs) and meet the criteria for becoming prescribable in medical contexts [26].

In 2018, the German National Association of Statutory Health Insurance Funds made it possible to cover the costs of certified digital self-help programs for insured persons [27]. Furthermore, with the recently passed draft of the Digital Healthcare Act (Digitale-Versorgung-Gesetz [28]), the German Federal Ministry of Health set the course for the prescription of quality-approved mHealth apps.

Despite increasing efforts to promote the diffusion of e-mental health worldwide, there is a remarkable discrepancy between the interest in and real-world uptake of mental health apps [29,30]. A comprehensive understanding of user characteristics, as described in the behavior change model for internet interventions [31] (eg, demographic and health-related variables as well as attitudes and beliefs), represents an essential first step to create persuasive digital interventions [31-33].

Assessment of the Acceptance of Stress Management Apps

Hennemann et al [34] acknowledged the confounding with intervention satisfaction as a major methodological weakness of the commonly practiced retrospective assessment of acceptance of e-mental health services, which does not allow for exploring genuine attitudes or reasons for use or nonuse.

Predictive models of acceptance of information technology, such as the Unified Theory of Acceptance and Use of Technology (UTAUT) [35], operationalize acceptance as the strength of one's behavioral intention to use a novel technology [36-38].

Given that the assessment of technology acceptance is in many ways context-sensitive [34], the operationalization of UTAUT predictors has to be adapted to the respective type or purpose of the intervention [39], health outcome, or target population [40]. A growing body of research has used the UTAUT framework to investigate eHealth acceptance in various contexts, such as disease management apps for chronic illness [41,42] and Web-based interventions for depression [43,44], chronic pain [45], and occupational stress [34,46]. A low-to-moderate acceptance was indicated across all studies.

In view of our scope on mHealth for health promotion and stress reduction, we expected a moderate or slightly higher acceptance of mHealth for stress coping in a sample of internet users compared with surveys of patients in health care settings.

Determinants of the Acceptance of Stress Management Apps

According to the generic UTAUT model, performance expectancy (eg, perceived usefulness), effort expectancy (eg, ease of use), and social influence (eg, subjective norm) are predictors of the intention to use an innovative technology, whereas facilitating conditions (eg, perceived behavioral control) and behavioral intention are hypothesized as direct determinants of actual use [35].

Generally, most research on the UTAUT model point to performance expectancy as the strongest driver of technology acceptance across different contexts and innovations [47-49], including eHealth services [34,46,50-52].

Beyond core UTAUT determinants, several additional predictors of technology acceptance have been suggested, particularly attitude [48], which was excluded as a key determinant from the UTAUT model [35].

Attitudes can be defined as cognitive or affective evaluative judgments of psychological objects, for instance, in terms of one's positive or negative feelings toward performing a behavior [36,53-55]. These attitudes are often associated with outcomes of health interventions [56,57]. As positive perception of and satisfaction with using a health technology [58], attitudes have been proposed as an essential precondition for the adoption of e-mental health services [59-62]. Recent meta-analyses support the integration of attitudes and UTAUT beliefs in technology acceptance models [48] and the way that beliefs about the usefulness and ease of use strongly influence attitudes, which positively affect behavioral intentions to use mHealth apps [63].

In turn, negative attitudes could play a more relevant role for the poor uptake of e-mental health interventions than structural barriers [34]. Negative attitudes can involve skepticism and perceptions of risks of e-mental health interventions [61]. For example, data security or privacy concerns represent common reasons for not using the internet or mobile phones for mental health purposes [30,34,64-66], whereas anxiety toward using technology can negatively affect behavioral intention to use mHealth [50].

Hence, we assumed a positive influence of attitudes (as a driver) and negative influences of skepticism and related negative beliefs (as barriers) on the acceptance of using mHealth for stress coping.

Also, low awareness of mHealth apps and deficient mHealth literacy represent barriers to adoption [67,68]. Studies indicate a positive influence of experience with health-related internet or mobile phone use [32,34,46] on the acceptance of e-mental health services [32] and the real-world adoption of mHealth apps [69]. Although mHealth app users were found to be younger [70,71], more highly educated, and healthier than nonusers (eg, [71]), findings regarding demographic variables on the acceptance of e-mental health services are less consistent. More favorable views on e-mental health services were found among young adults [34,62,72], women [62,73], and adults with higher education [34,62,72,73], whereas other studies found no gender difference [34,64].

Remarkably, the motivating influence of current needs (eg, for support in stressful situations) on intentions to use e-mental health services has not been consistently clarified. On the one hand, there is evidence for an association between stress perceptions and attitudes toward using e-mental health treatments [33,74] and a higher interest in using stress management apps [75]. On the other hand, there is evidence for "digital stress" caused by online multitasking and overload (eg, [76]). A recent study showed an association between intense media use for social networking and relaxation/entertainment and emotional stress [77]. Also, stress due to permanent online availability has been demonstrated as a barrier for inpatients' acceptance of Web-based aftercare [34].

In view of the inconsistent or limited findings on the role of background variables, as well as stress and coping appraisals on the acceptance of mHealth, we proposed influences of these constructs on acceptance in terms of control variables.

Another influencing factor for the adoption of mHealth apps could be the way they are described to consumers in app stores. Huang and Bashir [78] found positive associations of information cues (reviews, ratings in app stores) with the number of downloads of mental health apps for anxiety. In contrast, Healey et al [79] identified no impact of expert and user testimonials on registrations for an unguided, Web-based depression intervention (MoodGym). Another RCT investigating public attitudes toward e-mental health treatments [59] observed a positive influence of information supplemented with scientific claims on an exemplary e-mental health service on attitudes, but not on intentions of use. In clinical contexts, there is also evidence of a positive impact of psychoeducational information on patients' acceptance of e-mental health treatments [43,44]. However, the heterogeneous evidence base demonstrates the need for further research on the relevance of information cues in app descriptions for the uptake in the relevant target.

Based on what is already known from other contexts, we expected a positive influence of scientific claims on stress coping apps on general acceptance.

Preference for and Readiness to Use Mobile Health for Stress Coping

The outcomes of psychological services are associated with individual preferences [80]. Concerning mHealth, a German panel survey showed that 53.29% of participants were not considering using apps for consultation or treatment [81]. Moreover, research points to a clear public preference for face-to-face treatment over e-mental health treatment services [32,34,62,65,82,83]. A study on the public acceptability of e-mental health treatments found the lowest likelihood for using mHealth apps, whereas the readiness to use Web-based interventions and self-help books were equivalent [83]. Another study found differences in the likelihood of using traditional services (eg, psychologist) and digital services (eg, information website) between people who either preferred or did not prefer e-mental health, but not for self-help books or medical treatment (general practitioner, prescribed medication) [82]. In addition, studies conducted in Germany showed a high interest in using health information websites and a low-to-moderate acceptance of mHealth apps and Web-based programs for dealing with stress [34,84].

In contrast to surveys, real-world self-help activities can hardly be condensed into a forced-choice format because services are often used simultaneously (eg, app and website search). Hence, it would be interesting to learn more about patterns of preferences for apps versus other available or prototypical mental health services. This would help to integrate findings on mHealth acceptance in a greater practice-oriented context and enable practitioners to tailor their recommendations of mental health services to clients' needs and preferences.

Based on these considerations in the context of health promotion, we assumed a preference for using digital self-help services (apps, websites) and psychological support over medical help for dealing with everyday stress.

Goals of This Study

The primary aim of this survey study was to assess the determinants of public acceptance of mHealth stress coping apps in an online sample of adults. We expected a positive influence of mHealth-related attitudes and beliefs and a negative influence of skepticism or perceived risks on the acceptance of stress management apps. Furthermore, in direct relation to the primary outcome, we were interested in the potential differences in acceptance and its determinants based on information cues in the description of a sample stress coping app (either with or without scientific claims).

Another purpose was to assess preferences for mHealth apps compared with other psychological services for dealing with stress to set the main findings in a greater context of the general readiness to use stress prevention services.

Methods

Study Design and Data Collection

Data for this cross-sectional 54-item survey applying a descriptive predictive research design were collected anonymously at the University of Hagen in Germany between May 25, 2017, and June 16, 2017, using Unipark (Enterprise Feedback Suite survey, version summer 2017, Questback, Germany). All items were only available in the German language. The average completion time was 10 to 15 minutes.

Participants were informed about the study's objective and procedure beforehand (eg, health psychological research project in terms of a survey the general acceptance of and preferences for digital solutions for stress reduction) and were required to give an informed consent online (click-to-agree) following the recommendations of the German Psychological Association [85].

As part of a research agenda with different subprojects, this survey was the pilot study for a follow-up project with an equivalent objective and methodology (public acceptance of certified stress management programs), which has received ethical approval by the recently founded institutional review board/local EC of the new Faculty of Psychology at the University of Hagen, Germany (reference: EA_85_2019).

To establish a consistent understanding of the type of mHealth under study (stress management app), participants were presented a brief description of a sample or hypothetical app (similar to plain lay product information for consumers on websites or in app stores) before answering acceptance-related questions. The hypothetical app in our study was described as a digital solution that helps consumers cope with stress in everyday life or at work.

The text for the description of the sample app was adapted and modified from the German website of the digital program StudiCare Stress/Fernstudierende [23] that provided information relevant for study participation in an evidence-based digital stress coping program for distance-learning students in 2017. The idea behind describing a hypothetical app was to avoid advertising a specific app and adding a potentially confounding influence of experience with the use of real apps. The information for both groups was provided in relation to this hypothetical stress coping app (using two vignettes, as shown in Textbox 1). Therefore, participants were aware of being asked to imagine which expectations they would have regarding a fictional app, which was later confirmed by feedback from participants through online contact. The approach of implementing vignettes to describe prototypical or exemplary services in this research field is established and has been applied in several other studies (eg, [43,59,82,86-88]).

To assess whether scientific claims would contribute to greater acceptance compared with basic information, participants were randomly assigned (50:50 allocation) to one of two information groups that contained the description of the hypothetical app either with or without supplemented scientific claims (Textbox 1).

Textbox 1. Randomized subsection of the survey with text from a sample stress coping app with or without supplemented information on scientific claims.

- Both information groups 1 and 2 received the same following basic information (basic vignette):

"Stress can be triggered by different situations in daily life. If stress becomes a permanent condition, it can seriously endanger one's physical and mental health. 'COPE—Computer-gestützte, Online-basierte personalisierte Entspannung [Computer-aided, online-based, personalized relaxation],' is an app that helps you to better cope with stress, especially in everyday/working life, and to support you flexibly in terms of time."

- Scientific claims were only visible for the participants randomized to group 2 (supplemented vignette):

"Efficacy studies have shown that 'COPE' has an excellent effect and reduces stress sensations even after one year of training. There are also reports of fewer depressive symptoms, emotional exhaustion, and anxiety. The app was developed by leading international scientists in the field of stress and e-mental health research."

- Finally, both information groups received this instruction:

"Imagine if you would own this app—what expectations would you have?"

Participants and Recruitment

Using convenience sampling, an online sample of German-speaking adults was recruited via social media websites (eg, Facebook) and personal contacts of the study team.

Exclusion criteria were age younger than 18 years and a decline or withdrawal of consent. A summary of aggregated findings was offered as compensation for participation. Participants could contact the study team via email in case of having questions or any feedback.

An a priori power analysis using G*Power [89], version 3.1 (linear multiple regression, F tests, fixed model, R^2 increase) resulted in a required sample size of at least N=135 to determine a minimum moderate effect size of f^2=0.15 [90] (alpha=.05, power=.85; noncentrality parameter=20.25, critical $F_{11,123}$=1.87). The effect size was justified based on similar research on e-mental health acceptance [34,46].

Measures

Primary Outcome: Determinants of Acceptance of Stress Management Apps

Measures of the adapted and extended predictive mHealth acceptance study model (Figure 1) are presented in Table 1. Multimedia Appendix 1 (Table S1) contains a full overview of the content and reference studies of UTAUT-related items; we slightly adapted to the context of mHealth for stress coping based on face validity.

Figure 1. Conceptual study model using an adapted and extended UTAUT model for the assessment of acceptance of mHealth apps for stress coping. mHealth: mobile health; UTAUT: Unified Theory of Acceptance and Use of Technology.
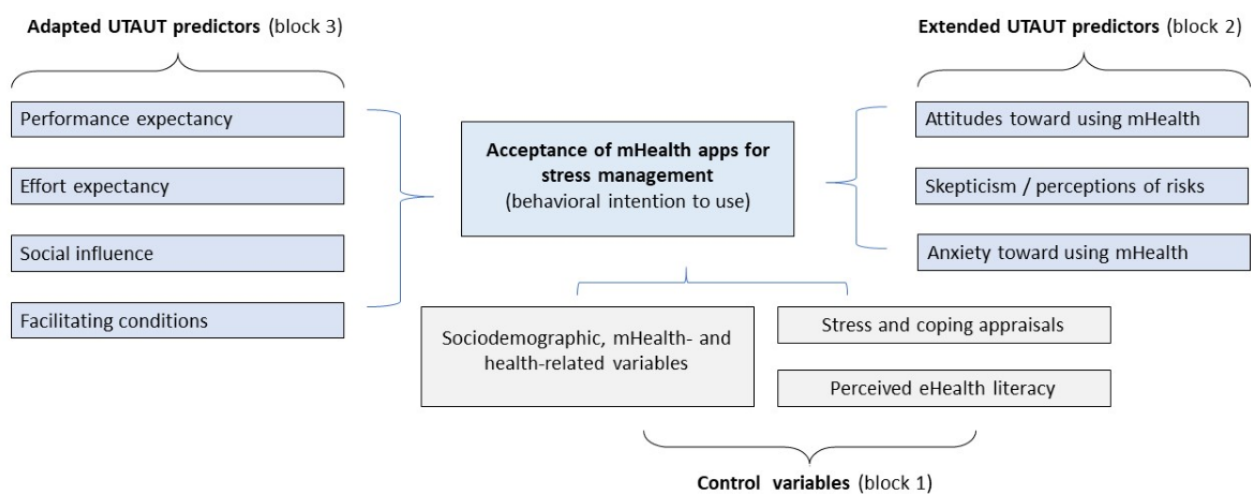
Table 1. Summary of constructs, measures, and scales for the assessment of determinants of acceptance of mobile health for stress coping.

Construct	Measure	Items, n	Cronbach alpha
Dependent variable			
Acceptance of mHealth[a] for stress management	UTAUT[b]: behavioral use intention[c,d,e]	3	.88
Core UTAUT determinants			
Performance expectancy	UTAUT	4	.91
Effort expectancy	UTAUT	4	.84
Social influence	UTAUT	3	.82
Facilitating conditions	UTAUT	2	.86
Extended UTAUT determinants			
Attitudes toward use of technology (positive affect toward using apps)	UTAUT[f]	4	.90
Anxiety toward use of mHealth	UTAUT	4	.83
Skepticism and perceived risks (negative attitudes)	APOI[c,e,g]	3	.67
Control variables			
eHealth literacy	G-eHEALS[e,h]	8	.91
Permanent smartphone availability	Self-constructed (single item)[e,i]	N/A[j]	N/A
Stress due to overload (past 3 months)[i,k]	SCI: stress scales[l,m]	7	.76
Stress symptoms (severity, past 6 months)[i,l]	SCI: stress scales[k]	13	.86
Positive thinking[k,n]	SCI: coping scales[k,n]	4	.71
Active coping[k,n]	SCI: coping scales	3	.87
Social support[k,n]	SCI: coping scales	4	.88
Cigarettes and alcohol consumption[k,n]	SCI: coping scales	4	.74
Demographic/descriptive variables	Age (metric), gender, experience with using a smartphone (yes/no; filter question: frequency), educational level, suffering from a chronic illness or enduring/recurrent complaints for more than 3 weeks (yes/no; filter question: category of illness), experience with use of any kind of mHealth app (yes/no; filter questions: frequency and duration of use), awareness of and experience with internet-based psychotherapy (each with 1 item; yes/no)[o]	N/A	N/A

[a]mHealth: mobile health.

[b]UTAUT: Unified Theory of Acceptance and Use of Technology.

[c]Adapted to mHealth for stress management/coping (Multimedia Appendix 1, Table S1).

[d]German Unified Theory of Acceptance and Use of Technology (GUTAUT) measure for Web-based aftercare by Hennemann et al [34], which the test authors developed based on prior work [43-45,91].

[e]Assessed on a 5-point Likert scale ranging from 1 (fully disagree) to 5 (fully agree).

[f]Adapted from the original UTAUT questionnaire by Venkatesh et al [35], dropped scale in the final UTAUT model.

[g]Assessed with three suitable items of the 4-item subscale "skepticism and perception of risks" of the Attitudes toward Psychological Online Interventions questionnaire (APOI) [61].

[h]Measured using the 8-item German eHealth literacy scale (G-eHEALS) [92].

[i]Based on prior research [34], we constructed a single-item scale ("Do you feel stressed when you are always available via your mobile phone or smartphone?").

[j]N/A: Not Applicable.

[k]We used two scales (20 items) out of five stress scales (originally 34 items) and further 15 items from four out five coping-scales (originally 20 items) of the German 54-item/10-scale Stress and Coping Inventory (SCI) by Satow [93]. The SCI measures everyday stress perceptions in different areas of life and general coping strategies. It is possible to select scales of interest instead of using the full instrument.

[l]The 7-item-scale SCI (Stress and Coping Inventory)-stress subscale [93] "stress due to overload" related to seven events (eg, item 1: debts or financial issues) concerning the past 3 months was assessed on a 7-point Likert scale ranging from 1 (not overloaded) to 7 (very overloaded).

[m]The 13-items SCI-stress subscale [93] "stress symptoms" covered physical and psychological stress sensations (eg, item 1: "I sleep badly") concerning the past 6 months was assessed on a five-point Likert scale ranging from 1 (fully disagree) to 5 (fully agree).

[n]Of the coping-scale of the SCI [93], we included four of five subscales, which we assessed on a four-point Likert scale ranging from 1 (fully disagree) to 4 (fully agree). "Active coping" was assessed with three items (originally four items). The scale "support in religion" was dismissed due to questionable relevance.

[o]We evaluated the awareness of and experience with internet-based psychotherapy, each with one item (yes/no). These questions were contributed by the first author to the German Socio-Economic Panel Innovation Sample in the fall 2016 wave [94].

Secondary Outcome: Preference for and Readiness to Use Mobile Health for Stress Coping

Based on a help-seeking questionnaire [95] and research on "e-preference" [82,87], the readiness or likelihood to use mHealth apps (strength of preferring mHealth apps over other services) was assessed with a self-constructed 10 item-scale on a five-point response scale ranging from 1 (very unlikely) to 5 (very likely). The question was: "If you would feel distressed, how likely would you use the following services?" The service types were as follows: app versus information website, online self-help training, online counseling, self-help literature, psychologist, psychiatrist, general practitioner (GP), prescribed medication, and on-site group training (face-to-face). Cronbach alpha was good (Cronbach alpha=.80).

Statistical Analysis

Only completed surveys were entered in the data analysis using SPSS version 24 (IBM Analytics). Based on prior research [34], the mean score of acceptance was categorized as low (1-2.34), moderate (2.35-3.67), or high (3.68-5). The Stress and Coping Inventory (SCI) [93] is not designed as a diagnostic instrument; therefore, no cut-off scores or indexes for stress outcomes are provided.

Following significant zero-order correlation testing, predictors of acceptance were selected to enter a hierarchical stepwise regression analysis. Based on theoretical considerations (eg, [35,36,53-55]) and empirical research (eg, [34,46,61]), we chose three blocks for the stepwise order for entering of predictors. Block 1 contained sociodemographic, mHealth-related variables, and stress-related variables (control variables); block 2 contained attitudes and beliefs related to mHealth (UTAUT extension regarding the affective component; R^2 increase beyond control variables); and block 3 contained the core UTAUT determinants (elaborated beliefs of classic UTAUT; R^2 increase after accounting for the influence of attitudes).

Differences in mean scores for acceptance and its determinants between the two information groups (see Textbox 1) were assessed using t tests or Welch F tests in case of variance inhomogeneity, respectively.

To assess the preference for mHealth apps for stress coping, differences between mean scores of the likelihood of future use of mHealth apps compared with nine other mental health service types were analyzed using paired t tests. Effect sizes were classified based on Cohen's criteria [90,96]. The significance level for the hypotheses was alpha<.05.

Results

Sample Characteristics

Descriptive data on the 141 participants are presented in Table 2. Multimedia Appendix 2 (Table S2) contains an overview of self-reported chronic complaints, which were most often upper or lower back pain with 14.2% (20/141).

Table 2. Sample characteristics (N=141).

Variables	Participants
Gender, n (%)	
Female	86 (61.0)
Male	55 (39.0)
Other	0 (0)
Age (years)	
Mean (SD)	34.84 (11.09)
Median (range)	31.00 (19-76)
Education level, n (%)	
No certificate of education (pupil or left school without certificate)	4 (2.8)
Certificate of secondary education[a]	6 (4.3)
General certificate of secondary education[b]	21 (14.9)
Advanced technical college entrance qualification[c]	6 (4.3)
General qualification for university entrance[d]	17 (12.1)
University degree (bachelor level)	42 (29.8)
University degree (master level)	41 (29.1)
Postdoctoral degree (doctorate or habilitation)	4 (2.8)
Stress- and technology-related variables	
Having chronic complaints, n (%)	41 (29.1)
Smartphone use (familiarity with use), n (%)	136 (96.5)
mHealth[e] app use experience (filter question), n (%)	
No	71 (51.1)
Yes	69 (48.9)
Frequency of mHealth app use, n (%)	
Daily	15 (10.6)
Several times a week	14 (9.9)
Weekly	4 (2.8)
Several times a month	11 (7.8)
Once a month or less	25 (17.7)
Duration of mHealth app use, n (%)	
More than 2 years	37 (26.2)
Less than 2 years	32 (17.4)
Awareness of Internet therapies (filter question), n (%)	
Yes	30 (21.3)
No	111 (78.7)
Prior use of internet therapies, n (%)	
Yes	5 (3.5)
No	25 (17.7)

[a]German "Hauptschulabschluss" as basic school qualification.

[b]German secondary school level I certificate ("Mittlere Reife").

[c]German "Fachhochschulreife" or "Fachabitur".

[d]German "Allgemeine Hochschulreife" ("Abitur" or A-Level).

[e]mHealth: mobile health.

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Preliminary Analyses

Acceptance of using mHealth for stress coping was moderate on average (mean 3.10, SD 1.02; range 1-5). Nearly half of participants could be categorized as reporting a moderate (46.8%, 66/141) acceptance; 29.1% (41/141) reported a low acceptance and 24.1% (34/141) reported a high acceptance.

Based on significant zero-order correlations with acceptance, 11 of 25 variables were selected for the hierarchical stepwise regression analysis (Textbox 2). The highest correlations with acceptance were found for attitudes toward using mHealth (r=.77) and performance expectancy (r=.64), as shown in Multimedia Appendix 2 (Table S3).

Textbox 2. Predictors of mobile health (mHealth) acceptance investigated in the stepwise regression analysis.

The order for the stepwise entering of 11 variables in three blocks was as follows:

Block 1 (control variables):

1. mHealth app use (dummy-coded)

2. Having a chronic illness or enduring complaints (dummy-coded)

3. Stress symptoms

4. Stress due to overload

Block 2 (mHealth-related attitudes/affect):

5. mHealth-related attitudes

6. Skepticism/perceived risks

7. Anxiety toward use

Block 3 (classic UTAUT (Unified Theory of Acceptance and Use Technology) determinants):

8. Performance expectancy

9. Effort expectancy

10. Social influence

11. Facilitating conditions

Main Results

Primary Outcome: Determinants of the Acceptance of Stress Management Apps

The significant hierarchical stepwise regression model (Table 3) included 4 of 11 eligible variables from two of three blocks in four steps ($F_{4,136}$=56.28, P<.001). There was no sign of severe multicolinearity (Durbin-Watson statistic=1.91). The explained variance was 62% in the final step 4 (R^2=.62, $F_{1,136}$=6.26, P=.01, f^2=1.63), whereas attitude entered in block 2 (step 3, Table 3) alone added 46% (large effect of f^2=0.85) after accounting for the influence of the control variables of block 1 (steps 1 and 2, Table 2). Effect sizes for R^2 increase were small to moderate for stress symptoms (f^2=0.12) and skepticism/perceived risk (f^2=0.16).

As shown in Table 4, three of four predictors of acceptance remained significant in final step 4: attitude toward using mHealth was the strongest predictor (step 3, beta=0.69, P<.001) followed by skepticism/perceived risks (step 4, beta=−0.14, P=.01) and stress symptoms (step 2, beta=0.12, P=.03). Prior use of mHealth apps became insignificant (beta=0.04, P=.54) after accounting for the influence of skepticism/perceived risks. None of the UTAUT predictors (entered as block 3) added a predictive contribution to acceptance after accounting for the influence of attitudes (entered in block 2). Group differences in acceptance ratings based on mHealth use experience are presented in Textbox S1 of Multimedia Appendix 2.

Figure 2 shows a summary of the main findings of the primary outcome.

Table 3. Model summary of the hierarchical stepwise regression analysis on predictors of the acceptance of stress management apps (N=141).

Model 1[a]	R	R^2	Adjusted R^2	SE	Change in R^2	Change in F (df1,df2)	P value
Step 1[b]	.32[a]	.10	.10	.98	.10	16.18 (1,139)	<.001
Step 2[c]	.38[b]	.14	.13	.96	.04	6.23 (1,138)	.01
Step 3[d]	.78[c]	.61	.60	.65	.46	161.04 (1,137)	<.001
Step 4[e]	.79[d]	.62	.61	.64	.02	6.26 (1,136)	.01

[a]Dependent variable: acceptance of mobile health (mHealth; behavioral use intention). Model 1 refers to the main model according to the statistical plan in distinction to post hoc analyses. (Models 2 and 3 as presented in Multimedia Appendix 2).

[b]Predictors: (constant), mHealth app use (entered in block 1).

[c]Predictors: (constant), mHealth app use, stress symptoms (block 1).

[d]Predictors: (constant), mHealth app use, stress symptoms (block 1), attitude toward using mHealth (block 2).

[e]Predictors: (constant), mHealth app use, stress symptoms (block 1), attitude toward using mHealth, skepticism/perceived risks (block 2). The UTAUT determinants (entered as block 3) added no further significant predictive contribution and were thus excluded.

Table 4. Coefficients of the hierarchical stepwise regression analysis (N=141).

Model 1 and step[a]	Unstandardized coefficient B (SE)	Standardized beta (β)	P value	95% CI
Step 1				
(Constant)	2.78 (0.12)	__[b]	<.001	2.55, 3.01
Use of mHealth[c] apps (yes)	0.66 (0.17)	0.32	<.001	0.34, 0.99
Step 2				
(Constant)	2.13 (0.28)	—	<.001	1.57, 2.69
Use of mHealth apps (yes)	0.59 (0.16)	0.29	<.001	0.26, 0.91
Stress symptoms	0.35 (0.14)	0.20	.01	0.07, 0.62
Step 3				
(Constant)	−0.10 (0.26)	—	.72	−0.61, 0.42
Use of mHealth apps (yes)	0.10 (0.12)	0.05	.42	−0.14, 0.33
Stress symptoms	0.18 (0.10)	0.10	.06	−0.01, 0.37
Attitude toward mHealth	0.84 (0.07)	0.73	<.001	0.71, 0.97
Step 4				
(Constant)	0.52 (0.36)	—	.14	−0.18, 1.22
Use of mHealth apps (yes)	0.07 (0.12)	0.04	.54	−0.16, 0.30
Stress symptoms	0.21 (0.09)	0.12	.03	0.03, 0.40
Attitude toward mHealth	0.78 (0.07)	0.69	<.001	0.65, 0.92
Skepticism/perceived risks	−0.17 (0.07)	-0.14	.01	−0.31, −0.04

[a]Dependent variable: acceptance of mHealth (behavioral use intention). Model 1 refers to the main model according to the statistical plan in distinction to post hoc analyses. (Models 2 and 3 as presented in Multimedia Appendix 1).

[b]Not applicable.

[c]mHealth: mobile health.

Figure 2. Main findings of the stepwise regression model on the determinants of the acceptance of stress management apps. mHealth: mobile health; UTAUT: Unified Theory of Acceptance and Use of Technology.
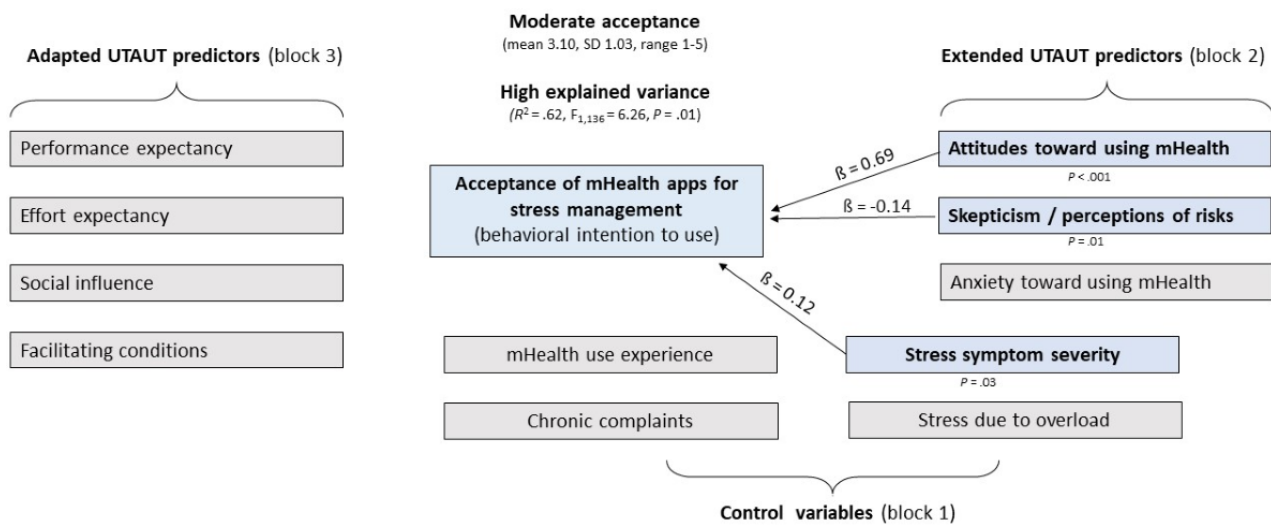
Additionally, a post hoc hierarchical analysis with all 11 variables (see Textbox 2) was performed, with the inclusion method instead of the stepwise method for entering the variables. When all 11 predictors (Multimedia Appendix 2, Tables S4 and S5, model 2) were included, the total R^2 or explained variance was at 64% and thus marginally higher (2%) than for the study model with four variables or steps (62%, see Table 3). In this overall significant post hoc model ($F_{11,129}=20.75$, $P<.001$), the increase of explained variance of 1% ($R^2=.01$) added by the four UTAUT variables in block 3 was not significant ($P=.59$).

Another post hoc hierarchical stepwise regression analysis showed the added predictive value of both positive and negative attitude constructs beyond the UTAUT variables. In contrast to the insignificant contribution UTAUT variables and their exclusion from model 1 as block 3 (Table 3), attitudes and skepticism/perceived risks significantly added explained variance (R^2 increase=.13) when entered as block 3 (Multimedia Appendix 2, Table S6, model 3) beyond three significant UTAUT variables (performance expectancy, facilitating conditions, and social influence). This post hoc model was significant ($F_{7,133}=32.48$, $P<.001$). It included seven variables or steps and explained 1% more total variance ($R^2=.63$) than the study model with four variables or steps ($R^2=.62$, Table 3). The increase of explained variance of the UTAUT variables after accounting for the control variables was 35% (performance expectancy with 28% as step 3, facilitating conditions with 4% and social influence with 3%) and therefore lower than for

attitudes alone (46% R^2 increase) in the study model (see model 1 in Table 3). With the inclusion of attitudes in step 6, all UTAUT variables became insignificant ($P>.05$) and remained so in the final step 7 after entering skepticism/perceived risks (Multimedia Appendix 2, Table S7, models 1-3). Table S8 of Multimedia Appendix 2 shows a summary of all three regression models.

Research Question: Influence of Scientific Claims on Mobile Health Acceptance Ratings

The *t* test showed no significant differences in acceptance between participants who read the app description both with (group 1: 70/141, 49.6%; mean 3.37, SD 0.95) and without (group 2: 71/141, 50.4%; mean 3.32, SD 0.86) supplemented scientific claims ($t_{139}=0.31$, $P=.80$; Cohen $d=0.06$). Furthermore, there were no significant differences between the two information groups regarding the four UTAUT determinants, attitudes, skepticism/perceived risks, and anxiety (all $P>.05$).

Secondary Outcome: Preference for and Readiness to Use Mobile Health for Stress Coping

As shown in Table 5, mHealth apps were preferred over medication, a psychiatrist, online counseling, online self-help training, and face-to-face group courses. No differences in the likelihood of future use were identified between mHealth apps versus self-help literature, psychologists, and GPs. Only health information websites were preferred over mHealth apps ($P<.001$).

Table 5. Preference for mobile health (mHealth): the likelihood of future use of mHealth apps for stress-related purposes in comparison with other mental health service types (N=141). Dependent variable: likelihood of future use in case of emotional distress (range: 1=very unlikely to 5=very likely).

Service type	Mean (SD)	Mean difference versus mHealth apps (SD)	SE of mean difference	95% CI	t (df)	P value
mHealth apps	2.67 (1.26)	—a	—	—	—	—
Health information website	3.07 (1.29)	−0.40 (1.12)	0.09	−0.58, −0.21	−4.21 (140)	<.001
Online self-help training (ie, computer- and internet-based)	2.45 (1.26)	0.22 (1.18)	0.10	0.02, 0.42	2.21 (140)	.03
Online counseling	2.20 (1.17)	0.48 (1.11)	0.09	0.29, 0.66	5.10 (140)	<.001
Self-help literature	2.73 (1.40)	−0.06 (1.60)	0.13	−0.31, 0.19	−0.45 (140)	.65
Psychologist (therapist or counselor)	2.67 (1.31)	0.01 (1.75)	0.15	−0.28, 0.30	0.05 (140)	.96
Psychiatrist	2.13 (1.07)	0.54 (1.60)	0.13	0.27, 0.81	4.01 (140)	<.001
General practitioner	2.67 (1.27)	0.00 (1.66)	0.14	−0.28, 0.28	0.00 (140)	>.99
Medication-assisted treatment	1.90 (1.10)	0.77 (1.43)	0.12	0.54, 1.01	6.41 (140)	<.001
On-site group course (face-to-face)	2.16 (1.18)	0.51 (1.33)	0.11	0.29, 0.73	4.54 (140)	<.001

aNot applicable.

Discussion

Principal Results

This study explored the determinants of public acceptance of stress management apps before their integration into statutory health services and the general preferences for mHealth apps compared to other mental health services.

This study indicates a moderate public acceptance of stress management apps in an online sample of German-speaking adults. Considering the relatively early stage of the adoption of e-mental health services in German health care [97], acceptance of mHealth apps probably varies largely based on individual experiences and target populations. The sampling method in this study and the focus on health promotion instead of treatment or aftercare need to be considered as potential reasons for higher acceptance of e-mental health services compared with research in more heterogeneous patient populations [34,44,45] and similar earlier online surveys with nonclinical samples [33,82,83].

Determinants of the Acceptance of Stress Management Apps

As a main finding, we identified positive affect or attitude toward using mHealth, skepticism or perceived risk of mHealth (negative cognitive attitudes), and the severity of stress symptoms as significant determinants of the acceptance of mHealth for stress coping. The high magnitude of explained variance of 62% according to Cohen criteria [90,96] is equivalent to other studies on the acceptance of e-mental health services focusing on classic UTAUT determinants, which did not consider attitudes (eg, [34]).

Our main results substantiate research evidence on the key role of attitudes in shaping eHealth and mHealth service acceptance in particular [58,63,98]. Post hoc analysis showed that attitudes and skepticism still added explained variance beyond the control variables and UTAUT determinants, whereas the more elaborated beliefs of UTAUT determinants failed to add a

predictive contribution beyond attitudes. This finding can be interpreted in the context of other research on attitude formation and behavioral intentions, which indicated that different levels of elaboration likelihood among end users should be taken into account in early stages of mHealth adoption [99]. For instance, Chen et al [99] showed a moderating effect of privacy concerns on the influence of both perceived usefulness (central route) and trust (peripheral route) on the continuance intention of mHealth apps in a developing market. In our study, the uncertain motivation (low stress levels) and insufficient abilities or knowledge to evaluate mHealth-related questions (nearly half of our sample did not have any mHealth experience) could have yielded a lower elaboration likelihood (peripheral route) reflected by rather undecided views (moderate ratings, tendency toward the middle) and skepticism. In other words, positive attitudes in the sense of an early affective form of opinion formation (regardless of specific knowledge or experience) may be a more relevant initial precondition of acceptance than elaborated cognitive beliefs on usefulness or usability.

Attitudes toward using mobile phones for mental health purposes can differ regarding specific design features or functions [64]; therefore, upcoming surveys could investigate relationships between attitudes, beliefs, and acceptance with respect to distinct components and functionalities of available stress management apps. Among other components, perceived value by users, visual design, usability, the potential to improve user engagement, tailoring and personalization, gratification, and information and content have been suggested as key drivers of the real-world uptake and user retention in eHealth and mHealth interventions (eg, [100-103]). These cannot be evaluated with the predictive acceptance model we applied. Nonetheless, our results on the major role of attitudes in mHealth acceptance provide implications on aspects to consider in practice. For instance, future efforts aiming at improving the adoption of e-mental health services could put emphasis on the pleasant or joyful aspects of using apps. For example, the yet not fully utilized potential of gamification for supporting the acquisition of

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behavior change techniques could be promoted as a clear benefit of mobile versus Web-based stress management programs [104].

Effective interventions to increase user retention in mental health services usually involve a comprehensive approach targeting attitudes, knowledge, needs, and barriers [105]. As a relevant barrier, our findings confirmed the negative influence of skepticism and perceptions for stress management apps, which complements findings from clinical settings (eg, [61]) and a recent meta-analysis [63], showing that both attitudes and perceived risks are determinants of the behavioral intention to use mHealth apps. Trustworthiness, data security, and privacy are main issues raised by consumers [102] and health professionals [106]. It is important to address concerns and misconceptions with acceptance-facilitating interventions, as effectively demonstrated by RCTs in different German health care settings (eg, [43,45]). Fostering positive attitudes toward mHealth would also be important in the context of the workplace, which is a common source of stress and stress-related disorders [107]. In accordance with social influences on the acceptance of health services, research indicates a higher interest in using apps for workplace health promotion among leaders with positive attitudes [9]. Therefore, health professionals and other multipliers and stakeholders should be involved in the dissemination of mental health apps.

Furthermore, personal relevance and mental health needs may affect the acceptance of mHealth apps; therefore, public health initiatives on mHealth could highlight the benefits of preventive innovations that tend to diffuse very slowly (delay of reward after adoption), as proposed by Rogers [108]. Although our results correspond to findings on the relationship between stress and interest in using mHealth for stress management [75], it is important to mention that self-reported stress severity in our sample was low to moderate. Considering that the main target group for primary prevention and health promotion in Germany is healthy adults [109], such apps may have the highest potential to reach populations that are already rather privileged in terms of having the necessary resources and knowledge to efficiently use mental health services, as was the case in our sample. The challenge is to increase the uptake of self-help tools in populations that are traditionally hard to reach and among those with mental health needs who are unlikely to use psychological services [32,62].

Considering the positive influence of personal experience (with mobile phones [110] and/or mHealth [69,100]) on the acceptability or uptake of mHealth apps, our findings support the suggestion to increase the availability of expert-guided possibilities for consumers or patients to try quality-approved apps. This would require making mental health professionals familiar with such services since prior research has shown personal use experience as a driver for use in their practice [111].

Influence of Information Cues in an Exemplary App Description

Beyond the identification of determinants of acceptance, to our knowledge, our study was one of the first to explore the influence of scientific claims on consumer acceptance of a hypothetical app. Keeping the elaboration likelihood model in mind, the fact that we found no difference to the group receiving basic information only is somewhat consistent with the major role of attitudes in our study, the very low awareness of e-mental health treatments, and the moderate level of mHealth experience. However, it is also possible that vague scientific claims were not persuasive for a selective, overall well-educated sample of mobile phone users, considering that the reputation or credibility of the source of information cues were shown as a relevant factor in the formation of attitudes and use intentions of e-mental health and mHealth services (eg, [59,99]). Overall, the main issues may be that the text we used for both vignettes was created based on modified information from a website on a digital stress coping program for university students (academic audience) and the variances between both vignettes (content and length) were too small to find a significant difference.

Accordingly, quality of content and validity of information have been identified as important domains for the real-world uptake of mHealth apps [102]. However, the evidence base for the quality and efficacy of most mental health apps is limited [112], even among those mental health apps that claim to be effective [113]. Importantly, a study by Schueller et al [69] showed that perceived usefulness of mental health apps rated by consumers is not necessarily equivalent to what the research evidence suggests. The influence of perceived credibility by users could be another option for surveys on the acceptance of e-mental health studies [88,114].

Preference for and Readiness to Use Mobile Health for Stress Coping

Another aim was to assess the preference of mHealth for stress coping. We identified preferences for mHealth apps over face-to-face group training, Web-based self-help programs, medication, and consulting psychiatrists. This points to an additional potential of digital or app-based courses versus traditional face-to-face group courses in primary prevention in reaching further populations that are not severely stressed and are familiar with using mobile phones. Wahbeh et al [115] showed a preference for a Web-based over group format for mindfulness interventions. That study and our findings show that online recruitment should be considered as a potential reason for a higher preference of e-mental health services compared to more diverse samples in health care. However, the lower interest in using Web-based than app-delivered self-help programs contrasts with findings from an Australian study by Batterham and Calear [62]. A possible explanation is that our study was conducted in an environment where eHealth or mHealth availability in German routine care—and thus adoption—is still in an earlier stage than in other European countries such as Sweden (eg, [116-118]). In contrast, mHealth apps can be downloaded by everyone and used outside of health care. Hence, we assume that our online sample of German-speaking participants was overall less familiar because German-speaking countries (ie, Germany, Austria and some regions in Switzerland) less often have openly accessible Web-based psychological programs available than publicly available mHealth apps. In comparison, countries such as Australia (eg, [119]) have such Web-based programs already established and available for the public. This issue is reflected by the very low awareness of e-mental health therapies (21%)

in our sample and in other online surveys [33,59,74] and a German panel survey (SOEP-IS innovative modules, internet-based psychotherapy, [94] written communication with Apolinário-Hagen J, unpublished raw data, 2016). Another reason might be that, for health promotion purposes, app-delivered programs may be seen as more convenient to use in daily life [83].

Contrary to prior research considering clinically relevant mental health issues (eg, [83,86]), we found no difference in the readiness to use mHealth apps in comparison with services provided by psychologists and self-help literature for stress-related purposes. Potentially, participants in our study viewed stress as a usual, rather mild issue that can be better addressed through different ways of self-help (with or without psychological support) than with clinical interventions or through medical support.

Consequently, the highest likelihood of use was found for health information websites for stress-related purposes, as already shown in other German studies [34,84]. A possible reason is that health information websites are self-help options with the lowest barrier to access because they can be retrieved publicly

with several devices (eg, desktop computer, tablet, mobile phone), are usually free of cost and do not require downloading another app and/or any registration. In this sense, "Dr. Google" enables tailored advice for mental health purposes on demand, which may explain their high acceptance [86]. Likewise, a qualitative study [120] showed that employees characterized an optimal e-mental health intervention as a website with interactive elements that involve temporarily unlimited access to state-of-the-art information and advice.

There are several initiatives providing guidance on e-mental health and mHealth quality criteria and certification (eg, [27,103]), but such information should be connected with certified services and brought to the awareness of more consumers and health professionals. Information websites in the sense of a low-threshold public health service could provide evidence-based information on stress prevention, stress screening tools, and access to mHealth apps. Psychoeducational information could be used to improve e-mental health literacy, which would help improve help-seeking intentions and behavior [121] or could be integrated into a stepped care prevention approach [122]. Textbox 3 shows the main findings and implications of our study.

Textbox 3. Summary of key findings and novel insights.

What this study shows that was already known:

- Attitudes are a key determinant of behavioral intention to use mobile health (mHealth)

- The low rates of awareness and use of electronic mental (e-mental) health treatments in our sample are in line with findings from other online surveys and panel surveys from Germany

- Skepticism and perception of risks (eg, privacy) are important barriers for e-mental health and mHealth acceptance

- Perceived stress needs further consideration in mHealth acceptance models

- Preference is for information websites over (less accessible) mental health services for stress prevention, including mHealth apps and face-to-face group interventions

Which novel implications and insights this study adds to the research evidence:

- Moderate and slightly higher acceptance of mental health apps and e-mental health services compared with other online surveys with community samples and studies with patient populations (implication: scope on health promotion and stress prevention rather than on treatment with disorder-specific focus or clinical wording for e-mental health programs)

- Unified Theory of Acceptance and Use Technology (UTAUT) studies on acceptance of mental health apps should consider attitudes and more elaborated beliefs (implication: adaptations of predictive acceptance models across stages of diffusion of mHealth adoption)

- Preference for mHealth over Web-based programs and state-of-the-art group stress management programs (implication: outline specific benefits of mHealth for stress management to use in daily life, but also educate about the potentials of Web-based and face-to-face courses)

- Comparable preferences for mHealth and traditional psychological services (implication: provide a set of choices tailored to individual needs and preferences)

Limitations

The exploratory nature of our study has several limitations to be considered when interpreting the findings.

First, the online recruitment and sample size limit the generalizability of our results; therefore, we cannot draw conclusions for the general German population. Also, the focus of this study on the public acceptance of stress coping apps and health promotion, and the necessary slight adaptations of some scales to the mHealth context, impede the comparability with most studies in this field that targeted e-mental health treatments [33,82,83] or specific mental disorders, such as depression

[43,123,124]. In addition, due to the absence of norm values, we classified acceptance as moderate based on prior work [34]; therefore, it is debatable whether the acceptance was really moderate (external validity).

Second, the subjective stress level in this sample was relatively low, with a mean sum score of 26.63 (SD 7.71) compared with the norm sample in the SCI test manual (mean 34.07, SD 7.96, possible range 13-65). Also, the selective sample of 96% mobile phone users of mostly young and higher educated adults (more than 60% with academic degree) may further explain the moderate acceptance of mHealth. A next step could be to compare the acceptance of e-mental health services in samples

with different stress levels. To overcome the self-selection bias, recruitment in primary care with referrals from GPs could be an option.

Third, the lack of a passive control condition makes it impossible to state whether the information about an exemplary app may have biased the acceptance ratings toward more positive ratings (eg, [59]). Future studies should control for the impact of information about real, well-known apps on acceptance using a pre-post design and a manipulation or intervention check before implementation. We have also applied a similar, but more elaborated, approach with text-based information on two existing evidence-based programs for stress coping (StudiCare for students and GET-ON for employees) in winter 2018 and found that the majority did not know these programs [88]. Therefore, it is debatable whether it would have made a difference to name an existing program in our sample. Potentially, as previously outlined, it would be another option to test our hypotheses with freely available commercial apps with the highest download rates, although this would impede the assessment of the general acceptance of mHealth apps.

Fourth, formulating expectations on a fictional app was likely to be difficult compared with rating an app that is known to the participants or has been used already, as the feedback from our participants suggested. Furthermore, of 230 participants who started the survey, 89 dropped out (half of them after the first UTAUT questions). In addition, the differences between both vignettes were a few abstract sentences including vague information on the effectiveness of a hypothetical app. Since the text of both vignettes was adapted from a website that recruited distance-learning students for a RCT on the effectiveness of an evidence-based digital stress intervention, the content may have been rather academic or too abstract for the broader population targeted in our study. Therefore, this experimental approach may have been too artificial (eg, questionable content validity) and be the main reason for finding no group differences.

Fifth, the readiness to use mHealth was assessed without standardized information on service types, similar to "real-world" help-seeking situations. In addition, we did not ask for what the participants understood under each service. Finally, similar to most UTAUT studies [49,125], we used a cross-sectional study design with acceptance as the dependent variable. This cannot address the well-known problem of the intention-behavior gap (eg, [126]), in which attitude strength related to personal relevance and experience has been suggested as a factor to bridge this gap in technology use [127]. Hence, our findings should be seen as preliminary and interpreted with caution.

Conclusions

Attitudes may play a pivotal role in shaping public acceptance toward stress management apps in an early stage of the adoption of e-mental health services. Concerns regarding the use of apps for stress management purposes could be addressed through health information websites and public health campaigns that can help increase knowledge about the benefits of stress prevention and information on mental health services.

Conflicts of Interest

None declared.

Multimedia Appendix 1
Methods supplementary data.
[PDF File (Adobe PDF File), 736 KB - mental_v6i11e15373_app1.pdf]

Multimedia Appendix 2
Results supplementary data.
[PDF File (Adobe PDF File), 1084 KB - mental_v6i11e15373_app2.pdf]

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Abbreviations

GP: general practitioner
mHealth: mobile health
RCT: randomized controlled trial
SCI: Stress and Coping Inventory
UTAUT: Unified Theory of Acceptance and Use Technology

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Original Paper

Comparing a Tailored Self-Help Mobile App With a Standard Self-Monitoring App for the Treatment of Eating Disorder Symptoms: Randomized Controlled Trial

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Abstract

Background: Eating disorders severely impact psychological, physical, and social functioning, and yet, the majority of individuals with eating disorders do not receive treatment. Mobile health apps have the potential to decrease access barriers to care and reach individuals who have been underserved by traditional treatment modalities.

Objective: The objective of this study was to evaluate the effectiveness of a tailored, fully automated self-help version of *Recovery Record*, an app developed for eating disorders management. We examined differences in eating disorder symptom change in app users that were randomized to receive either a standard, cognitive behavioral therapy–based version of the app or a tailored version that included algorithmically determined clinical content aligned with baseline and evolving user eating disorder symptom profiles.

Methods: Participants were people with eating disorder symptoms who did not have access to traditional treatment options and were recruited via the open-access *Recovery Record* app to participate in this randomized controlled trial. We examined both continuous and categorical clinical improvement outcomes (measured with the self-report Eating Disorder Examination Questionnaire [EDE-Q]) in both intervention groups.

Results: Between December 2016 and August 2018, 3294 *Recovery Record* app users were recruited into the study, out of which 959 were considered engaged, completed follow-up assessments, and were included in the analyses. Both study groups achieved significant overall outcome improvement, with 61.6% (180/292) of the tailored group and 55.4% (158/285) of the standard group achieving a clinically meaningful change in the EDE-Q, on average. There were no statistically significant differences between randomized groups for continuous outcomes, but a pattern of improvement being greater in the tailored group was evident. The rate of remission on the EDE-Q at 8 weeks was significantly greater in the group receiving the tailored version (d=0.22; P≤.001).

Conclusions: This is the first report to compare the relative efficacy of two versions of a mobile app for eating disorders. The data suggest that underserved individuals with eating disorder symptoms may benefit clinically from a self-help app and that personalizing app content to specific clinical presentations may be more effective in promoting symptomatic remission on the EDE-Q than content that offers a generic approach.

Trial Registration: ClinicalTrials.gov NCT02503098; https://clinicaltrials.gov/ct2/show/NCT02503098.

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Introduction

Background

The need for scalable delivery of eating disorder (ED) care services that are clinically effective and broadly accessible is now a major public health priority. EDs are common mental disorders that are both psychologically debilitating and physically threatening. Approximately 13% of young women and 1.93% to 6% of adults will meet the criteria for an ED in their lifetime, and 3% to 3.5% of men also struggle with an ED [1-4]. Despite the severity and burden of EDs, they often remain undetected, and the majority of individuals with EDs do not seek or receive mental health care [5,6]. Recent systematic reviews found that as few as 23% of people with a diagnosable ED seek conventional treatment [5], and about only 1 in 10 individuals with this illness receive treatment [7].

There are significant barriers to access to ED treatments, including high cost of care, inadequate insurance coverage [8,9], paucity of trained clinicians [10,11], and experiences of shame or fear of stigmatization [12]. One study found that it took individuals, on average, 3.6 years to acknowledge that they were suffering from an ED and a further 4.2 to 6.3 years to seek treatment [13]. Unfortunately, these delays are costly, as over time, EDs become more severe and less responsive to treatment [12,14]. There is evidence that the duration of ED is adversely associated with the treatment outcome [15,16]. However, even if all people with EDs were to seek conventional treatment, the current models of treatment delivery would be insufficient to meet the enormous need. A major shift in intervention practice is warranted with a focus on reaching more individuals in a more cost-effective manner, while at the same time achieving clinically meaningful improvement. Mobile health (mHealth) apps will almost certainly play a role because of their reach and breadth of functionality.

At least 271 million people in the United States or 94% of the population own a mobile phone, and smartphone use has reached 77% population penetration, with uptake spanning all socioeconomic groups [17]. mHealth apps have the potential to decrease the aforementioned treatment access gap for EDs and reach individuals who have traditionally been underserved by existing treatment modalities. By offering anonymous, accessible, affordable, and engaging interventions, barriers to receiving care can be reduced. The convenience of an intervention that can be accessed in moments of need at any location may enhance acceptability, and the scalable nature of technology holds promise for delivering support in a cost-effective manner [18].

Objectives

One example of an mHealth app for EDs is Recovery Record (RR). RR has established population-level reach and user acceptability [19]. Although RR was initially developed as an adjunctive tool to support clinical treatment, a large portion of app users access the tool without the accompanying forms of traditional face-to-face treatment. A 2014 case report surveyed over 100,000 RR app users and found that 46% were not receiving clinical treatment, and 33% of users reported that they had not told anyone about their ED [19]. The study further found

that 80% of users had experienced symptoms for 5 to 10 years, and 58.3% had Eating Disorder Examination Questionnaire (EDE-Q) global scores of 2 or more SDs above community norms [20]. Hence, the RR app was found to be successful at reaching and engaging many people with severe and enduring ED symptoms who were otherwise not receiving care.

Incorporated into RR app's core functionality are cognitive behavioral therapy (CBT)–based eating and symptom monitoring, CBT-style coping skills, goal setting, and motivational messaging. Self-help CBT can be an effective intervention for some EDs, and preliminary data suggest that RR might be effective as a stand-alone self-help intervention. Data from 1178 RR app users who were not receiving clinical treatment revealed that after using RR for 1 month, 28% of participants no longer scored in the clinical range on the EDE-Q and 39% were clinically improved [21]. These response rates approximate those observed in studies of therapist-assisted internet-based treatments for EDs [22,23]. Another study found that RR users naturally clustered into 5 clinical groups that could be mapped onto the existing Diagnostic and Statistical Manual of Mental Disorders ED categories [24]. Of further interest, a signal detection analysis revealed that RR intervention response was not homogenous across the sample and that outcome varied by clinical presentation. For example, those with binge eating and purging symptoms were found to be more likely to respond to the RR app than those with mostly restrictive behaviors [21].

Overall, these data indicate that there are distinct RR user groups who already utilize the app and may derive greater clinical benefit from a personalized intervention that targets their specific clinical needs [25]. As a next step, a new tailored version of the RR app was developed, including an 8-week program of personalized content specifically addressing baseline and evolving clinical characteristics. A pilot study demonstrated the feasibility of deploying the tailored version of the app to a sample of 189 app users and validated acceptability of the new intervention developed by the study team [26].

The purpose of this study was to examine whether a personalized app for EDs would be superior to the universal app in reducing negative outcomes when used in self-help capacity. Specifically, we were interested in studying the differences in symptom change in users of RR that were randomized to either the standard RR app (RR-S) or the tailored version of RR (RR-T), which included algorithmically determined content aligned with user baseline ED symptom profiles. Our primary hypothesis was that those who received RR-T would demonstrate greater clinical improvements compared with those who received RR-S.

Methods

Participants

RR app is free and publicly available via the Google Play (Android) and iTunes (iPhone) app stores. Potential participants were recruited from within the app registration system. All users were asked to provide consent. Users were eligible for inclusion if they (1) had downloaded the app on their iPhone, (2) were located in the United States, and (3) recorded at least three self-monitoring entries before being contacted about the study.

The focus of this study was on underserved populations who might not have access to best practice treatment options. As such, individuals were considered ineligible to join the study if they were using RR linked with a treatment provider or indicated that they were receiving treatment at least weekly from a specialist ED provider. The study received Institutional Review Board approval, and participants did not receive any payment for completing assessments.

Study Design

Randomization

Participants randomized to RR-T were probabilistically assigned to 1 of the 5 clusters based on their baseline demographic characteristics and EDE-Q scores. Each participant was randomly assigned to a cluster with a probability inversely proportional to his or her distance to each cluster mean. This distance was defined as the Euclidean distance between a participant's coordinates (ie, all baseline measures) and the cluster mean. This method meant that participants were more likely to be assigned to the symptom cluster they were most similar to.

Tailored Intervention

Details on the app and the development of the tailored intervention have been described in earlier reports [24,26]. Informed by baseline cluster assignment and existing knowledge about CBT-based strategies for addressing ED symptoms and cognitive distortions, novel and tailored content was developed for each baseline symptom cluster group. Descriptions and examples of each key feature are provided in Table 1. The tailored intervention took the form of an 8-week program that delivered tailored content to complement the standard app. Specifically, the tailored app is configured with cognitive behavioral self-monitoring questions that are differentiated according to user baseline symptom cluster assignment. Users in the tailored group were also invited to complete a progress review on a weekly basis. Components of the progress review included the following: a summary of recovery-oriented milestones achieved (see Figure 1); a self-guided review of goal progress and perceived helpfulness of coping skills (see Figure 1); the selection of new goals and coping strategies from a curated, tailored list for the week ahead; and, finally, the identification of possible obstacles to achieving chosen goals (see Figure 1).

The weekly goal selection was designed to encourage task practice of specific activities each day and then to facilitate rating of activities on the degree of mastery and/or pleasure in the weekly progress review. Goal options follow the CBT for EDs framework and aim to disrupt mechanisms that may be maintaining symptoms reflected in baseline profiles and ongoing meal logs. Skill-based components of the tailored version of the app provide the opportunity to learn and implement strategies for managing distorted cognitions that fuel both the emotional and behavioral responses to engage in unhealthy eating or weight loss practices. Given the limited presentation capacity of a smartphone, content is skill- and goal-based rather than psychoeducational and aims to maximize user engagement and generalizability rather than present large amounts of data.

Table 1. Key Recovery Record tailored app features.

Feature	Description	Example
Customized self-monitoring questions	Self-monitoring questions are customized based on baseline symptoms. Participants can also optionally enable additional questions if relevant to their needs.	If a participant endorsed binge eating in their baseline questionnaire, then the questions "Did you binge eat?" and "Do you have an urge to binge eat?" are included in meal logs.
Weekly milestones	Each week the app displays 4 to 7 user achievements based on participants' daily self-monitoring entries. Participants can also optionally enter additional achievements not captured by the app.	If a participant indicated in a meal log that they were experiencing an urge and, in the same entry, endorsed the use of a coping strategy, the following weekly milestone would be displayed: "You discovered <number> new coping strategies for responding to a difficult feeling or urge."
Goal progress review	On a weekly basis, the app displays the SMART[a]-style goals that the participant had selected in the prior week and prompts them to evaluate goal progress.	If a user had previously selected a goal to preplan their meals, they would be asked how they are progressing toward the goal, with the following response options: "I haven't thought about it yet," "I have thought about it," "I have a plan and will put it into action today," "I did this several days this week," and "I did this every day."
Coping skill review	Following the goal progress review, the app displays coping skills selected in the prior week and prompts the participants to evaluate their utility and helpfulness.	If a user had selected "Mindful Eating" in the prior week, they would be asked how many times they tried the technique, with 0, 1, 2 to 3, and ≥4 response options, and to evaluate how much the skill helped on a Likert scale.
Weekly goal selection	An 8-week program of SMART-style goals was developed for each baseline symptom cluster group. Each week, 4 to 6 goals are presented to the participants who are invited to select at least two goals to work on each day of the upcoming week. Users are prompted on a daily basis during the week, at a time they select, to review their progress.	If a user has baseline dietary restriction symptoms, they may be presented with the optional goal to keep track of their triggers: "I will notice and record dietary restriction triggers in Recovery Record. To identify triggers, I will ask, 'what set me off?' Triggers amplify eating disordered thinking and make me more vulnerable to relapse. Examples: Feeling unwell, drinking alcohol, certain emotions, body comments, negative self-talk, weight gain, confrontation, financial stress, lack of sleep."
Weekly coping skill selection	An 8-week program of coping skills was developed for each baseline symptom cluster group to complement the program of goals. Each week, 4 to 6 coping skills are presented to the participants who are invited to select at least two skills to try out in the upcoming week. Users are prompted to utilize their selected skills in real time when they self-monitor relevant symptoms.	If a participant has baseline binge eating symptoms and intrusive thoughts, they may be presented with the "Questioning the Evidence" skill to: "Catch the actual thoughts you are thinking when you're in a situation that upsets you. Examine them to see if they're valid. Ask: Where's the evidence for this? What do you get if you 'buy' into that thought? Where does it leave you and does it bring you closer to your best self? Consider these example thoughts: 'If I keep X food in the house, I can prove I am strong enough to recover,' 'My eating problem has already ruined X,' 'What do I have to gain from recovering now?'."
Obstacle identification	A list of potential barriers or obstacles that participants may experience when trying to achieve their goals is presented. Participants select obstacles that are relevant to them and identify actions they can take to overcome them.	If a participant selected a goal of eating something at every meal and snack, a suggested barrier to action might be "Having to give up the short-term reward of meal skipping."

[a]SMART: 8-week program of coping skills for each symptom cluster group.

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Figure 1. Select recovery record adaptive application features.
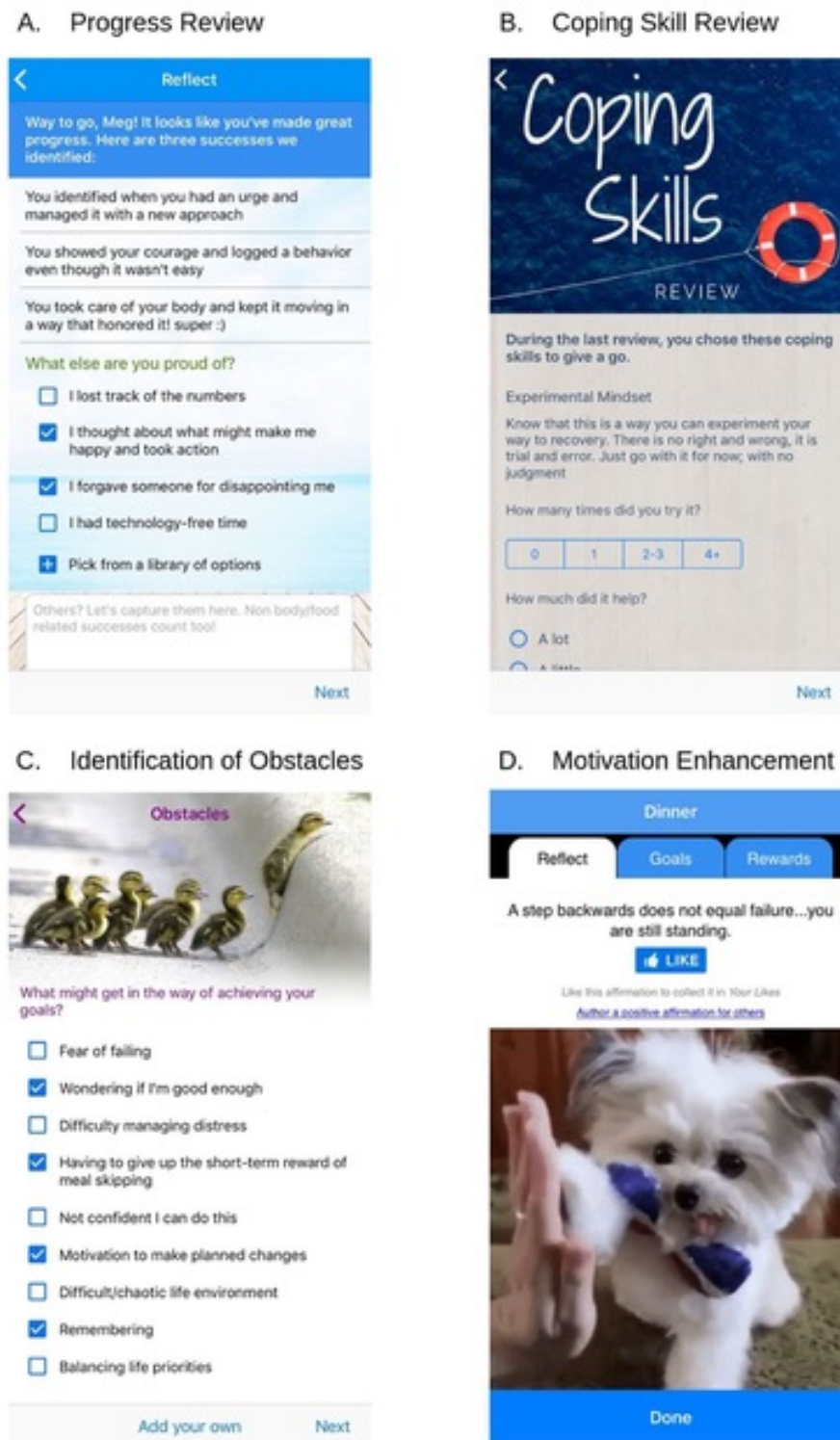
Standard App Intervention

Users randomly assigned to the standard app were also prompted to complete meal and symptom self-monitoring in an evidence-based CBT format that has been described previously [19]; however, they did not have access to the weekly progress review, including tailored milestone feedback, coping skill and goal content, or obstacle identification. Both versions of the app also included psychoeducation regarding skills to increase

distress tolerance and overcome urges to engage in disordered behaviors and included textual and image affirmation content targeting motivational enhancement (see Figure 1).

Clinical Outcomes

The EDE-Q is a self-report measure of ED psychopathology and behaviors that has been shown to have good reliability [20,27]. We examined both continuous and categorical outcomes related to clinical improvement in ED psychopathology in the

randomized groups at baseline, 4 weeks, and 8 weeks. At the relevant time intervals, participants were prompted with a banner on the home screen within the app to complete the in-app EDE-Q assessment. An automated email was also delivered to participants to notify them when an assessment was available within the app.

Primary Outcome

The primary dichotomous outcome of a response, that is, clinically meaningful change, was defined as an improvement (ie, decrease) in the EDE-Q global score by a 0.5 SD. A secondary outcome of remission on the EDE-Q was defined as being within the range of 1 SD around the mean, based on the global EDE-Q (community norm of 1.55) [20].

Secondary Analysis

Frequencies of objective binges, vomiting, and excessive exercise over the previous 28 days were derived from EDE-Q questions 14, 16, and 18, respectively. The categorical outcomes for abstinence were defined as whether the participant endorsed 0 instances of binge eating (or purging or excessive exercise) at follow-up. We also examined continuous outcomes defined as the differences in the EDE-Q item 14 between baseline, week 4, and week 8. We repeated this outcome analysis using items 16 and 18 on the EDE-Q.

Statistical Analysis

Primary Analysis

To address the primary hypothesis that RR-T improves EDE-Q total score, a complete case analysis was used. All participants randomized to the 2 treatment conditions and who had outcome data (week 4 or 8) were included in the analysis. To determine whether a clinical improvement in the RR-T arm occurred at 4 and 8 weeks, two-sample z tests for proportions were used. Effect sizes (ie, success rate differences) were reported. All tests were 2-sided and performed at the 0.05 level of significance.

We note that complete case analysis will only be unbiased under the missing completely at random (MCAR) assumption, that is, it is valid only when the missingness probability does not depend on the outcome [28].

Covariate adjustment was performed to address a secondary hypothesis of whether there was conditional independence between the treatment assignment and clinical improvement, given other variables, that is, we tested a secondary hypothesis of whether there was a treatment effect *within* strata defined by the variables mentioned above. This covariate adjustment analysis addresses a different null hypothesis than the primary hypothesis of testing the unconditional treatment effect. Covariate adjustment was performed using generalized linear mixed models and linear mixed models as appropriate, with the treatment assignment indicator, treatment by time interaction, and other variables including baseline severity and duration of app usage. Gender and treatment frequency were not used because of sparsity in groups.

Secondary Analysis

A sensitivity analysis was conducted using clinical end points defined by a change in EDE-Q global score by 0.75 SD and by

0.25 SD. We conducted an analysis using the outcome of remission as defined above. Outcomes of remission were binary and remission rates, that is, proportions were computed for each arm at each time point. Differences between the remissions rates observed in RR-T and RR-S arms at weeks 4 and 8 were evaluated by z tests for proportions, with a significance level of 0.05. We also constructed graphical summaries of the proportion of remitters over time per arm.

A per-protocol analysis was performed, excluding subjects who failed to submit logs over a duration of less than 35 days (out of 69 possible days). The threshold for the inactive period, that is, 35 days, was determined via exploratory data analysis including histograms. To determine whether a clinical improvement in the RR-T arm occurred at 4 and 8 weeks as the clinical end points, z tests for proportions were used. All tests were 2-sided and performed at the 0.05 level of significance.

Subgroup analyses were performed for ED behaviors such as objective binge eating, vomiting, and excessive exercise as indicated by items 14, 16, and 18 on the EDE-Q, respectively. We performed a subgroup analysis among participants who endorsed nonzero instances of binge eating, purging, and excessive exercise, as indicated by items 14, 16, and 18, respectively, on the EDE-Q at baseline. Participants who did not endorse such behaviors at baseline were excluded from this analysis. To compare proportions of abstainers across randomized groups, an intention-to-treat (ITT) analysis was used. To determine whether group differences in eating behaviors (with respect to binge eating, purging, and over exercise) occurred at 4 and 8 weeks, z tests for proportions were used. Proportions of individuals who experienced a worsening of the raw global EDE-Q score were assessed at weeks 4 and 8. It should be noted that in the absence of a known cut point for clinically meaningful negative change in the EDE-Q global score, any negative directional change in this score was included in this portion of the analysis.

Results

Sample Characteristics

A total of 3440 RR users met eligibility criteria between the months of December 2016 and August 2018 and were invited to complete an in-app EDE-Q self-assessment as per current procedure (see Figure 2 for a Consolidated Standards of Reporting Trials diagram). Of these, 146 declined to participate in the study, leaving 3294 who were randomized: 1665 participants were randomized to the standard, fully automated self-help intervention (RR-S) and 1629 participants were randomized to the personalized, tailored self-help intervention (RR-T). Chance imbalances in the randomized group numbers are attributable to our use of a simple randomization procedure. A total of 123 participants reported 1 of the following exclusion criteria after the start of the trial: dizziness, hospitalization, fainting, or suicidal ideation—requiring them to be withdrawn from the study. There were 15 participants (13 RR-S and 2 RR-T) who were excluded at 4 weeks because their EDE-Q was completed outside of a 7-day window from the expected completion at day 30. There were 39 participants (6 RR-S and 33 RR-T) who were excluded at 8 weeks because their EDE-Q

was completed outside of a 7-day window from the expected completion at day 60.

Table 2 presents a summary of demographic and usage characteristics of the sample at week 4. All demographic characteristics were balanced between groups. Moreover, 93% (426/458) participants in the standard group were female and 95% (455/501) participants in the tailored group were female,

with 4.6% (21/458) [2.6% (13/501) tailored] reporting male gender and 2.4% (11/458) [2.2% (11/501) tailored] reporting *other*. The mean age of the participants was 34 (SD 12.3) years in the standard group and 34.9 (SD 12.5) years in the tailored group. Quartiles of the global EDE-Q score were all severe (Quartile 1: [0.35, 3.12]; Quartile 2: [3.12,3.84]; Quartile 3: [3.84,4.58]; Quartile 4: [4.58,5.95]).

Figure 2. Consolidated Standards of Reporting Trials diagram. There were 15 excluded (13 RR-S and 2 RR-T) at 4 weeks because their EDE-Q was completed outside of a 7-day window from the expected completion at day 30. There were 39 excluded (6 RR-S and 33 RR-T) at 8 weeks because their EDE-Q was completed outside of a 7-day window from the expected completion at day 60. EDE-Q: Eating Disorder Examination Questionnaire; RR-S: standard Recovery Record app; and RR-T: tailored version of Recovery Record app.
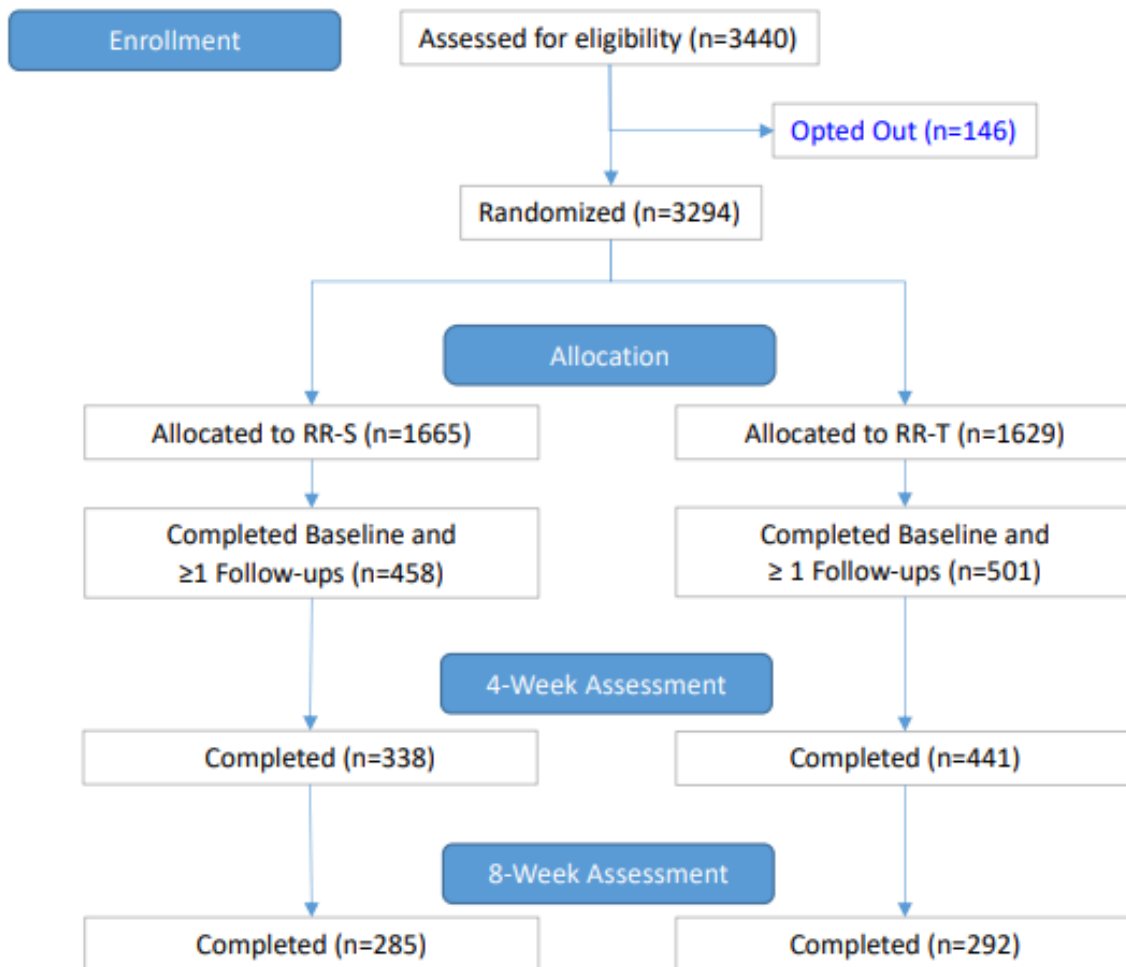
Table 2. Demographic characteristics of participants.

Demographical descriptors	Standard Recovery Record app (RR-S; n=458)	Tailored version of Recovery Record app (RR-T; n=501)
Age (years), mean (SD)	34.0 (12.3)	34.9 (12.5)
Gender, n (%)		
Female	426 (93.0)	477 (95.2)
Male	21 (4.6)	13 (2.6)
Other	11 (2.4)	11 (2.2)
Race or ethnicity, n (%)		
White	385 (84.1)	407 (81.2)
Hispanic or Latino	14 (3.1)	22 (4.4)
Asian	13 (2.8)	20 (4.0)
Black or African American	13 (2.8)	13 (2.6)
American Indian or Alaska Native	1 (0.2)	1 (0.2)
Multiple race or ethnicity	29 (6.3)	22 (4.4)
Unknown	3 (0.7)	16 (3.2)
Eating problem—how long? (years), n (%)		
0	19 (4.1)	20 (4.0)
1-5	130 (28.4)	113 (22.6)
6-10	80 (17.5)	102 (20.4)
11-15	57 (12.4)	58 (11.6)
15-25	70 (15.3)	90 (18.0)
≥25	102 (22.3)	118 (23.6)
Body mass index[a], mean (SD)	29.0 (8.9)[b]	28.7 (8.6)[c]
Treatment history, n (%)		
I have never received treatment for an eating disorder	239 (52.2)	249 (49.7)
I have received treatment for an eating disorder in the past	145 (31.7)	169 (33.7)
I am currently receiving treatment for an eating disorder	74 (16.2)	83 (16.6)
Treatment frequency (for those currently receiving treatment for an eating disorder), n (%); (N=74 RR-S, N=83 RR-T)		
2-3 times per month	46 (62.2)	57 (68.7)
Monthly or less	19 (25.7)	19 (22.9)
Occasionally or as needed	9 (12.2)	7 (8.4)
Treatment types (participants could choose more than one; N=74), n (%); (N=74 RR-S, N=83 RR-T)		
Licensed mental health professional	64 (86.5)	66 (79.5)
Dietitian or nutritionist	36 (48.6)	46 (55.4)
Life coach or mentor	2 (2.7)	5 (6.0)
Support group or advocacy organization	9 (12.2)	13 (15.7)
Other	5 (6.8)	5 (6.0)

[a]Excluded 2 standard and 3 tailored Recovery Record app participants with body mass index >65.

[b]n=427.

[c]n=469.

Analyses

Unadjusted Analysis

The responder proportions in the tailored and standard groups were moderately large. At week 4, approximately half (51.5%; 227/441) of the tailored group achieved a clinically meaningful change in EDE-Q, compared with 46.2% (156/338) of the standard group. At week 8, the proportion of treatment responders was slightly greater, with 61.6% (180/292) of the tailored group achieving a clinically meaningful change, compared with 55.4% (158/285) of the standard (see Figure 3). Responder proportions were not statistically different across treatment and control groups at week 4 or 8 (*P*=.16 or *P*=.15; effect sizes=0.05 and 0.06, respectively). Both groups experienced slight improvements in the global EDE-Q score from baseline to week 4 (−0.8 and −0.7 for treatment and control groups, respectively) and from baseline to week 8 (−0.99 and −1.0 for treatment and control groups, respectively).

Figure 3. Proportions of responders at weeks 4 and 8. EDE: Eating Disorder Examination; RR-S: standard Recovery Record app; RR-T: tailored version of Recovery Record app.
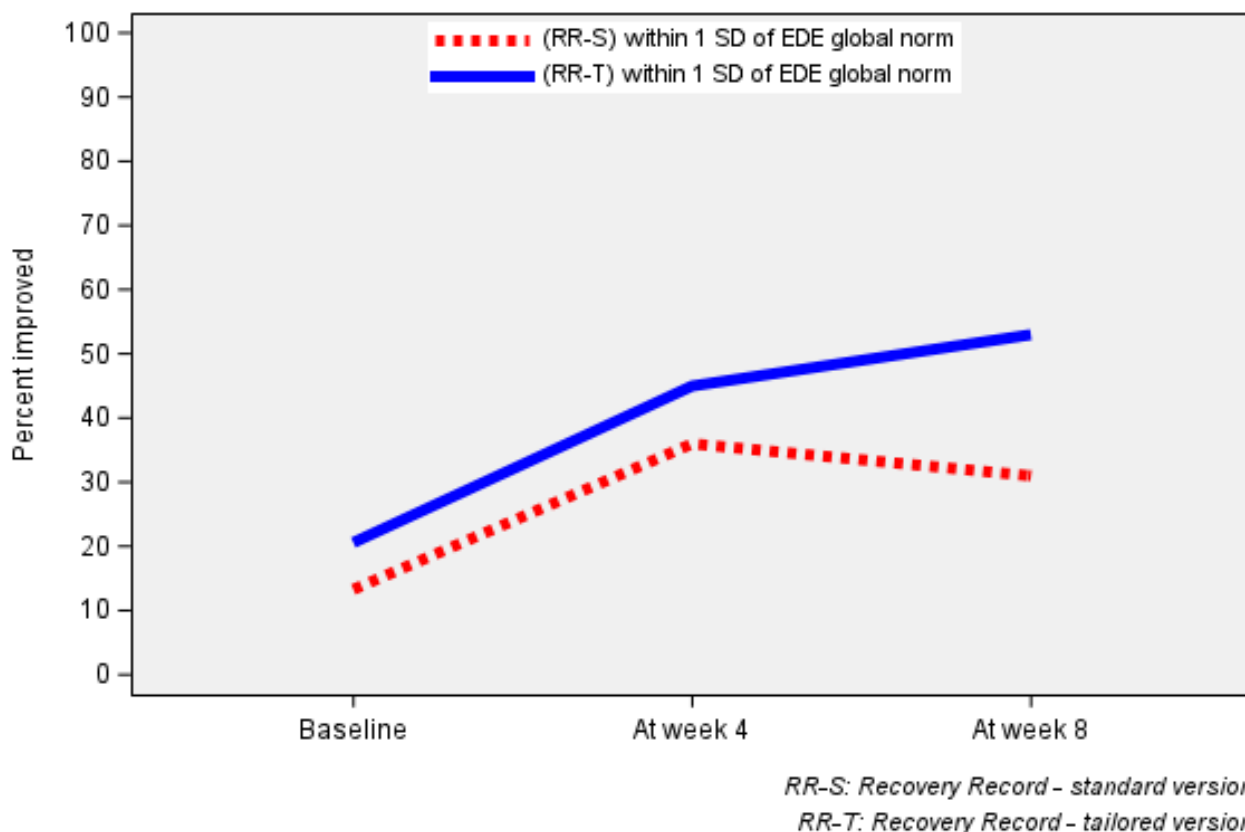
Sensitivity Analysis

We repeated the unadjusted analysis replacing the outcome of clinically meaningful change based on a 0.25 SD change and 0.75 SD change, respectively. Figure 3 presents the sensitivity analysis. There were no statistically significant differences between randomized groups found in this analysis.

Covariate Adjustment

The covariate-adjusted treatment effect is consistent with the ITT analysis (conditional odds ratio [OR] 1.2; *P*=.59). Results from generalized linear mixed-effects model estimates showed that subjects with a higher baseline severity (>3 global EDE-Q) were more likely to achieve a clinically meaningful change (conditional OR 3.5; *P*<.001). Although treatment and comparison groups did not differ over time, the effect of time was significant (conditional OR 1.12; *P*=.01): users were 12% more likely to achieve improvement for each additional week of being in the study, holding group assignment constant.

Remission Analysis

Figure 4 presents the remission analysis. At week 4, the proportions of users reporting symptoms within community norms in both groups increased; however, the difference between groups also widened: 44.8% (198/441) of participants receiving the tailored app were remitters, and 35.5% (120/338) of participants receiving the standard app were remitters (*P* value for *z* test of proportions=.008; effect size=0.09). At week 8, the proportion of participants receiving the tailored app meeting the community norms criteria increased to 53.3% (137/257), whereas that of participants receiving the standard app slightly decreased to 31.1% (70/225; *P* value for *z* test of proportions ≤.001; effect size=0.22).

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Figure 4. Proportions of individuals whose EDE-Q scores were within community norms at weeks 4 and 8. EDE-Q: Eating Disorder Examination Questionnaire; RR-S: standard Recovery Record app; RR-T: tailored version of Recovery Record app.
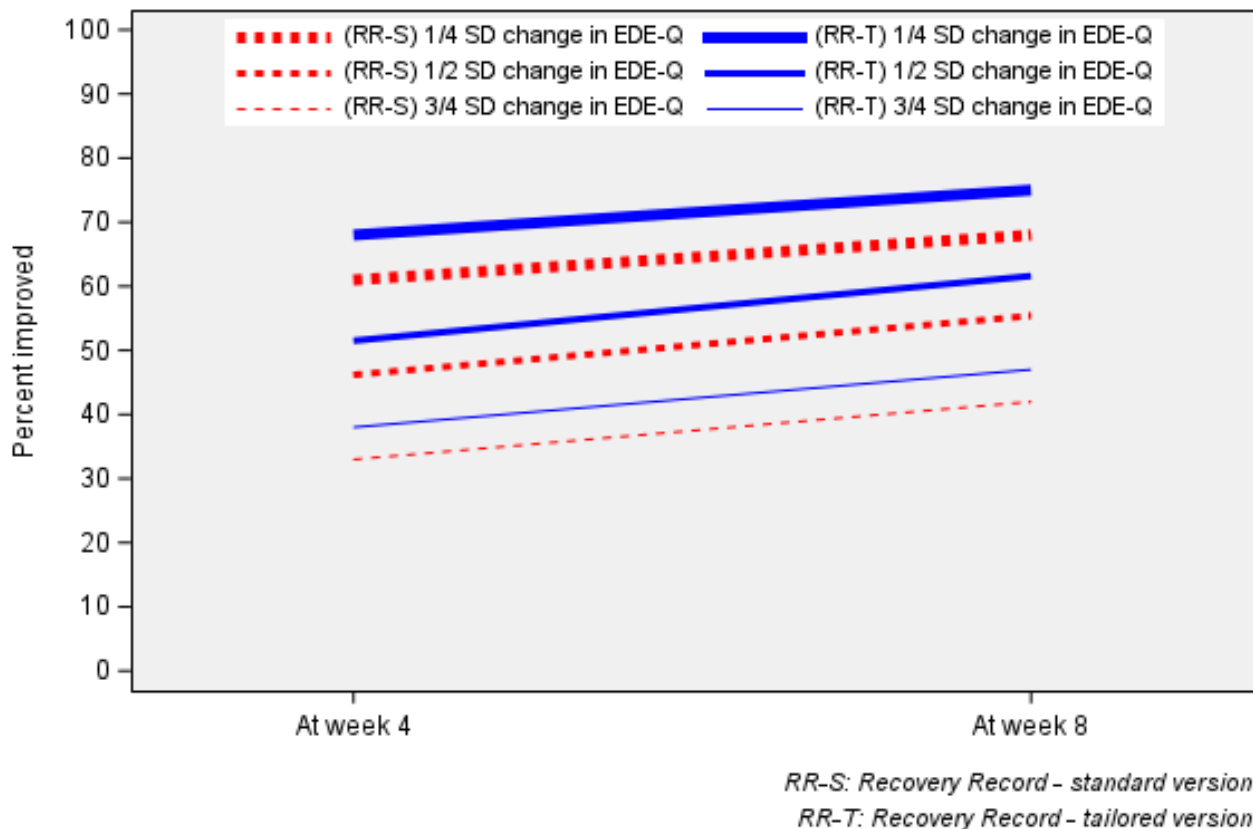
Per-Protocol Analysis

Among the tailored group, 57% (166/290) achieved a clinically meaningful change in EDE-Q at week 4, compared with 48% (47/98) in the standard group (P=.16; effect size=0.09). At week 8, the proportion of responders was slightly greater, with 63% (138/219) of the tailored group achieving a clinically meaningful change, compared with 53% (62/118) of the standard (P=.08; effect size=0.10).

Subgroup Analyses

Table 3 presents the proportions of abstainers. At baseline, the number of participants who endorsed any binge episodes did not vary significantly by group: 1390 participants in the tailored versus 1407 in the standard arm endorsed some binge eating

(tailored=409 and standard=422 endorsed purging; tailored=705 and standard=753 endorsed excessive exercise). At week 4, the proportion of abstainers for binge eating was 14% (51/359) and 13% (38/287) of the tailored and standard groups, respectively. For purging, abstainers comprised 28% (27/96) and 35% (28/81) of the tailored and standard groups, respectively. For excessive exercise, higher proportions were observed— 40.6% (73/180) and 29.5% (44/149) in the tailored and standard groups. At week 8, the proportion of abstainers slightly increased with respect to binging [20% (49/241) vs 18% (40/227)] and purging [42% (21/52) vs 40% (26/64)], but the proportion of abstainers for excessive exercise decreased [45% (47/104) vs 40% (47/116)]. There were no significant differences between groups on any of these variables.

Table 3. Eating behaviors of subgroups of participants who endorsed eating behaviors at baseline.

Eating behaviors	Standard Recovery Record app		Tailored version of Recovery Record app		P value
	Total number of participants	Values[a]	Total number of participants	Values	
Week 4					
Objective binge[b]					
Abstinent[c], n (%)	359	51 (14.2)	287	38 (13)	.81
Change in score[d], mean (SD)	359	–4.3 (9.4)	287	–4.2 (10.8)	.87
Purge[e]					
Abstinent, n (%)	96	27 (28.1)	81	28 (34.6)	.41
Change in score, mean (SD)	96	–2.0 (10.3)	81	–2.8 (6.4)	.55
Objective binge and purge					
Abstinent, n (%)	373	47 (13)	295	37 (13)	.99
Change in score, mean (SD)	373	–4.4 (12.1)	295	–4.8 (11.4)	.67
Excessive exercise[f]					
Abstinent, n (%)	180	73 (40.6)	149	44 (29.5)	.05
Change in score, mean (SD)	180	–5.1 (2.9)	149	–3.4 (2.4)	.12
Week 8					
Objective binge					
Abstinent, n (%)	241	49 (20.3)	227	40 (17.6)	.37
Change in score, mean (SD)	241	–5.5 (11.0)	227	–7.0 (9.8)	.11
Purge					
Abstinent, n (%)	52	21 (42.0)	64	26 (40.6)	.99
Change in score, mean (SD)	52	–4.6 (7.9)	64	–3.7 (8.1)	.54
Objective binge and purge					
Abstinent, n (%)	249	48 (19.3)	238	42 (17.6)	.71
Change in score, mean (SD)	249	–6.0 (11.7)	238	–7.6 (11.5)	.14
Excessive exercise					
Abstinent, n (%)	104	47 (45.2)	116	47 (40.5)	.57
Change in score, mean (SD)	104	–5.0 (7.9)	116	–4.4 (7.7)	.57

[a]Values: Values refer to "n (%)"; or "mean (SD)" as appropriate.

[b]Objective Binge: participant report of eating what other people would regard as an unusually large amount of food and experiencing a sense of loss of control while eating.

[c]Abstinent: participants who abstained from behavior.

[d]Change in Score: the difference in the binge (or purge) items from the EDE-Q questionnaire.

[e]Purge: participant report of making oneself sick (vomit) as a means of controlling shape and weight.

[f]Excessive exercise: participant report of exercising in a "driven" or "compulsive" way as a means of controlling weight, shape or amount of fat or to burn off calories

Worsening of Pathology in Terms of Raw Eating Disorder Examination Questionnaire Global Score

At week 4, we observed that 16% (59/374) of the tailored group experienced a directional worsening of raw EDE-Q global score, compared with 23% (67/296) of the standard group (*P*=.03, before multiple comparison correction). After correcting for multiple comparisons, the difference at week 4 was not significant. At week 8, 15% (39/250) of the tailored group experienced a directional worsening of raw EDE-Q global score, compared with 19% (47/238) of the standard group (*P*=.28). In the absence of a known cut point for clinically meaningful negative change in the EDE-Q global score, any negative directional change in this score was included in this portion of the analysis.

Discussion

Individuals with EDs are in urgent need of more affordable, accessible, empirically supported, and engaging interventions. This study is important because it is the first randomized controlled trial to evaluate the efficacy of a personalized app for the self-management of EDs. The study makes an important contribution to the field in its focus on an under-researched and underserved population—people with ED symptoms who may not otherwise have access to traditional treatment options.

Principal Findings

Although there were no statistical differences (including in the sensitivity analyses) between randomized groups for continuous outcomes, the pattern of improvement was greater in the personalized, tailored version of the app. However, participants in both the tailored and standard app groups achieved a high overall level of response, with more than 50% of participants in each group achieving clinically meaningful change on the EDE-Q at week 8. These response rates indicate that both versions of the app may be beneficial. It should be noted that as yet, there is no standard definition of clinically meaningful change in EDE-Q global scores [29]. As such, a moderate effect size was utilized in this primary analysis.

When examining remission status on the EDE-Q as a categorical outcome, we detected a statistically significant difference between the groups associated with a small effect size. In this study, remission was defined as a score within 1 SD of the community norm, which suggests that symptoms are no longer in the clinical range. These results are encouraging as many app users do not have access to therapists or other treatments, and the tailored version moves more of them out of the clinical range than the standard app.

Contrary to previous research findings [21], we did not find substantial evidence that individuals with mostly restrictive behaviors are less likely to respond to the RR app. Given the transdiagnostic approach to EDs, adults with restrictive symptoms may benefit from a CBT-focused app [30]. This is an important contribution to the literature, given that there are very few studies of self-help for anorexia nervosa. Clinical improvement instead appeared to be related to symptom severity. Participants with higher baseline severity were more likely to achieve clinically meaningful change. It is noteworthy, however, that according to baseline EDE-Q scores, the sample as whole was extremely ill. Therefore, although clinical change was greatest in the most severe group, it might be less dramatic in the groups, overall [30]. It is also possible that there are attributes of participants with high symptom severity not captured in this study that moderated outcome. We also examined changes in objective binge eating, purging, and exercise in the 2 randomized groups (see Table 3). There were improvements in these behaviors across the sample, with no differences between the 2 groups. Finally, we examined whether some participants worsened using the app. We found that approximately 15% to 20% of the participants experienced a directional worsening of their EDE-Q global score during the study app, with no differences between the groups. In the absence of validated negative change cut point for the EDE-Q

scores, it is difficult to determine what portion of these individuals experienced clinically meaningful deterioration.

Strengths and Limitations

Several novel aspects of the study should be emphasized: design of the intervention components; use of a tailored randomization scheme for the *tailored arm*, that is, probabilistically assigning people to clusters; naturalistic recruitment within the app's existing user pool; and all screening, recruitment, randomization, and assessments being completed within the app. Nevertheless, there are significant limitations of the study. As the intervention is disseminated through an app, our study inherits a host of challenges that come with the large-scale usage of mobile devices in intervention research. Among the challenges addressed during the study were the implementation of the intervention and recruitment of nonpatient participants, strategies to assess compliance and engagement, and problems related to study retention in the absence of the accountability that in-person recruitment affords.

Although we attempted to obtain complete records to the extent possible through the delivery of reminder emails and a lottery for a gift card, it should be noted that of those who were initially randomized, 23.6% (779/3294) provided outcome data at week 4 and even fewer at week 8 (577/3294, 17.5%). Given the high proportion of missing data, an imputation approach would have forced the reliance on an imputation model for 67% of the data and thus presented an infeasible option. To handle the missing data issue, we used a complete case analysis (see the study by Little and Rubin [28] for more details on this approach). A limitation of the complete case analysis is that the unbiasedness of a complete case analysis is predicated on the validity of the MCAR assumption. Although not without limitations, we deemed that it was the most reasonable analytic strategy, given the percentage of data observed. This limitation should be noted in our instance, and the inferences are based on a subset of participants who adhered to the assessment completion. This result, in fact, provided a point to consider for future work, in that a brief period of app usage assessment before randomization should be incorporated in other or future randomized studies to address this data problem.

With regard to study retention, there is a known high variability of dropout rates in studies using self-help treatments for EDs, ranging from 0% to 62% [31]. High dropout rates are common in patients with EDs, even in face-to-face therapy [32]. Within-app recruitment may have additionally contributed to attrition and/or lack of adherence during the study, although attrition rates did not differ based on treatment allocation. These challenges may also have been related to the population of interest, that is, individuals lacking in adjunctive support structures outside of the app. Therefore, the attrition rate observed in this study should not be surprising, considering the in-app recruitment and realities of smartphone app compliance [33]. In fact, the observed rate could offer a perspective to the literature as it provides evidence for appropriate and realistic considerations for power that should be taken into account at the early stages of study design. We should note that we accounted for the probability of a high attrition rate when designing the study, such that our resultant power calculations

were based on the number needed in each group to detect a difference of at least 80% power.

Another important limitation is that follow-up data on maintenance of treatment effects is limited because of the short 8-week follow-up period. The effect of time was significant in the study, with users 12% more likely to achieve improvement for each additional week of being in the study. This raises the question of optimal intervention duration. Future studies should aim to assess duration of treatment effects and whether this relates to user characteristics such as symptoms, severity, demographics, motivation or compliance, and/or app content during the intervention period. Diversity across ethnic groups represented in the sample was a limitation of the study. An additional avenue for future research may be to explore the relative effect of ethnicity on outcome.

Conclusions

The results of this study suggest that a significant proportion of ED app users benefit from using a self-help version of the RR app; however, overall clinical improvements may be greater and symptomatic remission may be significantly greater, with a more specific matching of content to specific clinical groupings as in the tailored version of the app used in this study. More research should be conducted on how app-based self-help can be integrated into a stepped care model of ED interventions, thereby closing the treatment gap. The results suggest that apps that use tailored contents are feasible to use; likely effective for many in improving clinical symptoms; scalable; and, thus, may reduce disease burden in those with EDs at low cost.

Conflicts of Interest

The authors declare the following potential conflicts of interest with respect to the research, authorship, and/or publication of this paper: JT is a cofounder of and shareholder in RR Inc. Although JT was involved in the design of the interventions (the app and the tailored version of the app), the study design, the acquisition of funding, collection of data, and writing the paper, she was not involved in data analysis. Owing to the possibility of perceived conflicts of interest as an owner of RR, all data analysis procedures were conducted independently by the researchers at Stanford University. There are no other conflicts of interest to declare.

Multimedia Appendix 1
CONSORT-EHEALTH checklist (V 1.6.1).
[PDF File (Adobe PDF File), 2420 KB - mental_v6i11e14972_app1.pdf]

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Abbreviations

CBT: cognitive behavioral therapy
ED: eating disorder
EDE-Q: Eating Disorder Examination Questionnaire
ITT: intention-to-treat
MCAR: missing completely at random
mHealth: mobile health
OR: odds ratio
RR: Recovery Record
RR-S: standard RR app
RR-T: tailored version of RR app

Original Paper

A Web-Based Self-Help Psychosocial Intervention for Adolescents Distressed by Appearance-Affecting Conditions and Injuries (Young Persons' Face IT): Feasibility Study for a Parallel Randomized Controlled Trial

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Abstract

Background: Disfigurement (visible difference) from wide-ranging congenital or acquired conditions, injuries, or treatments can negatively impact adolescents' psychological well-being, education and health behaviours. Alongside medical interventions, appearance-specific cognitive behavioural and social skills training to manage stigma and appearance anxiety may improve psychosocial outcomes. YP Face IT (YPF), is a Web-based seven session self-help program plus booster quiz, utilising cognitive behavioural and social skills training for young people (YP) struggling with a visible difference. Co-designed by adolescents and psychologists, it includes interactive multimedia and automated reminders to complete sessions/homework. Adolescents access YPF via a health professional who determines its suitability and remotely monitors clients' usage.

Objective: To establish the feasibility of evaluating YPF for 12-17 year olds self-reporting appearance-related distress and/or bullying associated with a visible difference.

Methods: Randomized controlled trial with nested qualitative and economic study evaluating YPF compared with usual care (UC). Feasibility outcomes included: viability of recruiting via general practitioner (GP) practices (face to face and via patient databases) and charity advertisements; intervention acceptability and adherence; feasibility of study and data collection methods; and health professionals' ability to monitor users' online data for safeguarding issues. Primary psychosocial self-reported outcomes collected online at baseline, 13, 26, and 52 weeks were as follows: appearance satisfaction (Appearance Subscale from Mendleson et al's (2001) Body Esteem Scale); social anxiety (La Greca's (1999) Social Anxiety Scale for Adolescents). Secondary outcomes were; self-esteem; romantic concerns; perceived stigmatization; social skills and healthcare usage. Participants were randomised using remote Web-based allocation.

Results: Thirteen charities advertised the study yielding 11 recruits, 13 primary care practices sent 687 invitations to patients on their databases with a known visible difference yielding 17 recruits (2.5% response rate), 4 recruits came from GP consultations. Recruitment was challenging, therefore four additional practices mass-mailed 3,306 generic invitations to all 12-17 year old patients yielding a further 15 participants (0.5% response rate). Forty-seven YP with a range of socioeconomic backgrounds and

conditions were randomised (26% male, 91% white, mean age 14 years (SD 1.7)); 23 to YPF, 24 to UC. At 52 weeks, 16 (70%) in the intervention and 20 (83%) in UC groups completed assessments. There were no intervention-related adverse events; most found YPF acceptable with three withdrawing because they judged it was for higher-level concerns; 12 (52%) completed seven sessions. The study design was acceptable and feasible, with multiple recruitment strategies. Preliminary findings indicate no changes from baseline in outcome measures among the UC group and positive changes in appearance satisfaction and fear of negative evaluation among the YPF group when factoring in baseline scores and intervention adherence.

Conclusions: YPF is novel, safe and potentially helpful. Its full psychosocial benefits should be evaluated in a large-scale RCT, which would be feasible with wide-ranging recruitment strategies.

Trial Registration: ISRCTN registry ISRCTN40650639; http://www.isrctn.com/ISRCTN40650639

Introduction

Background

Approximately 1 in 44 individuals has a condition or injury that noticeably affects the appearance of their face, skin, or body shape [1]. Referred to as visible differences, these distinct changes result from congenital (eg, cleft lip and birthmark), neurological (eg, facial palsy), genetic (eg, neurofibromatosis), or acquired conditions (eg, acne). Advances in life-saving treatments are also increasing survivorship associated with an altered appearance resulting from traumatic injury (eg, burn) and disease (eg, meningitis). Appearing *different* in a society that venerates looks can have profound effects during adolescence, a vulnerable period when social comparison with peers/celebrities is high, romantic interest is burgeoning, and appearance impacts self-esteem [2]. Research shows commonalities in the experiences of young people (YP) with a variety of appearance-altering conditions [3]; 30% to 50% struggle with social stigma (eg, teasing, bullying, peer rejection, and unwanted attention from strangers [4]) and/or experience appearance-related distress [5]. If not addressed, these experiences can lead to low self-esteem, social anxiety and avoidance [6,7], poor social and emotional development [8], reduced school performance [9], difficulties with romantic relationships [10], unemployment [11], depression [12], and self-harm and suicidality [13], a health, social, and economic burden to society.

Although surgical and medical advances to ameliorate appearance-altering conditions are advancing, they are not a cure-all [3], and contrary to expectations, the severity, cause, and location of a visible difference do not reliably predict distress [14]. Adjustment is largely determined by intervening sociocognitive factors, including perceived satisfaction with social support and acceptance, Fear of Negative Evaluation (FNE) by others, and social confidence [15]. These factors are potentially amenable to change via psychosocial interventions that offer an adjunct or alternative to medical/surgical solutions and provide skills to tackle stigmatization and appearance-related distress.

Research [16] points to a dearth of evidence-based, cost-effective, and appearance-specific interventions for YP.

Within UK primary health care, these YP rarely meet criteria for referral to Child and Adolescent Mental Health Services or waiting lists are long, and those receiving secondary health care for their condition often have no/limited access to psychological support [17]. Stakeholders (eg, clinicians and parents) also report barriers preventing YP from seeking or accepting psychological, particularly face-to-face, support around such a sensitive issue. These include traveling to specialist appointments, fear of further stigmatization, and social anxiety/avoidance [18]. Acknowledging that number of YP experiencing poor mental health is increasing as psychological services are rationed, the United Kingdom's National Health Service (NHS) has called for innovative and cost-effective interventions that promote self-management and resilience [19]. An appearance-specific Web-based psychosocial intervention could broaden access to support for those with appearance-related distress and improve quality through evidence-based standardized care.

In adults with a visible difference, a randomized controlled trial (RCT) of a multisession Web-based intervention (Face IT) has proved beneficial. Centered on Kent's Integrated Model of Psychosocial Distress and Intervention for Individuals with Visible Differences [20], Face IT integrated cognitive behavioral therapy (CBT) and social skills training (SST), reduced anxiety-related concerns, and was comparable with face-to-face CBT [21]. Following the Medical Research Council framework for the development of complex interventions [22], the authors worked with YP to co-design an age-appropriate and guided self-help Web-based intervention (Young Person's Face IT or YP Face IT) based on Face IT [18]. YP Face IT (YPF) is for 12- to 17-year-olds with any appearance-affecting condition who are experiencing social stigma and/or appearance-related distress.

This paper reports the results of a study, which explored the feasibility of evaluating YPF compared with usual care (UC) using an RCT design and provided data to estimate the parameters required to design a definitive trial. There is no standardized treatment for this patient group, and the type and frequency of UC were therefore recorded. The feasibility of recruiting participants via primary care and charitable organizations was also examined. General practitioners (GPs) are accessible to most YP and parents, and charities for those

with a wide range of appearance-altering conditions are approached by parents or YP for advice [18]. Both could provide immediate access to evidence-based appearance-related support, including while the YP is waiting for, or to preclude, referral to secondary care services.

Objectives

The objectives of this study were as follows: (1) to estimate the numbers of eligible participants recruited via primary care practices and charities, including reasons for nonparticipation; (2) to assess participants' views on study design; (3) to determine the acceptability of the YPF intervention and adherence as well as safeguarding processes; (4) to determine the completion of outcome and resource use measures (for future economic evaluation); (5) to determine the variation of UC provided; (6) to assess the responses to patient-reported outcome measures, to inform the selection of a primary outcome measure and test for harm and potential effectiveness of YPF (the trial was not powered to test statistically significant impact); and to estimate the sample size for a definitive trial.

Methods

Trial Design

This parallel-group, randomized controlled feasibility trial compared YPF plus UC with UC only (control) and included a nested economic and qualitative study and online pre- and postassessments at 13, 26, and 52 weeks after randomization. Data analysts (PW, EM, and TP) were blind to group allocation, whereas participants were not. The trial was preregistered, and full protocol published [23]. Ethics approval was given by the UK National Research Ethics Service Committee South West (Ref 14/SW/0058).

Recruitment

Recruitment was via GP practices and charitable organizations supporting those with a range of appearance-altering conditions (eg, the UK's Cleft Lip and Palate Association; www.clapa.com). Charities promoted the study via their websites or newsletters. Advertisements were designed alongside service users' involvement, outlined the study, and included the research team's contact details.

GP practices were briefed on the study protocol in a 30-min session. Practices used a medical diagnosis coding system to identify eligible patients with an appearance-affecting condition and excluded those deemed unsuitable (eg, condition resolved). Identified YPs were posted a personal invitation and information sheet. For those aged younger than 16 years, letters were addressed to parents/carers who were asked to discuss participation with their child. A reminder, sent 4 weeks later to nonrespondents, included a response form to indicate why they declined and a study-addressed envelope. Staff were also

encouraged to introduce the study to potential participants during consultations and provide a leaflet.

In a user-involvement meeting, GPs noted that database records were inaccurate, and they had difficulties identifying eligible patients. Therefore, in a change to the published protocol, subsequent GP practices that joined the study used mass mail out to all their patients aged 12 to 17 years using an online mail management solution (www.cfhdocmail.com); rather than GPs deciding who to invite, all 12- to 17-year old patients could decide on their eligibility. Letters were addressed to parents/carers of those aged younger than under 16 years, as above.

Interested YP/parents contacted the research team who answered questions and confirmed eligibility with the YP (including parent/carer if YP aged <16 years) via the telephone. Informed consent was obtained by participants completing and posting a consent form or verbally consenting via a recorded telephone call.

Participants

When developing YPF, we sought advice from YP, parents, and health professionals regarding the age range of the intervention's target audience and other eligibility criteria [18]. Eligible YP were 12- to 17-year-old UK residents with any appearance-affecting condition who self-identified as experiencing appearance-related distress, teasing or bullying, and were fluent in English (YPF has a reading age of 12 years, and audio clips are available on YPF for those who struggle reading text), with internet literacy and access to an internet-enabled device. YP were ineligible if they had a registered learning disability, a diagnosis of clinical depression, psychosis, eating disorder, and posttraumatic stress disorder (PTSD) or were within 12 months of a traumatic injury. PTSD is a risk for those disfigured through trauma [24]. Those aged younger than 16 years required a parent/carer to join the study, and those aged 16 and 17 years were encouraged to inform and involve their parent/carer, but this was not mandatory. Practice staff provided views on recruitment procedures and supervising their patients using YPF.

Intervention

YPF was developed by the Centre for Appearance Research, is owned by the University of the West of England, and is hosted by Dataphiles plc (www.dataphiles.co.uk). Details of creators and affiliations were provided on the homepage. The participatory action approach used to develop YPF was reported elsewhere [18]. Version 3 (www.ypfaceit.co.uk) was used in this trial during which the content was frozen, and program glitches addressed. The YPF homepage (Figure 1) is freely accessible to all (only the sessions require a personal login) and provides easy-to-understand videos describing the intervention for YP and comprehensive details of the therapeutic content for health professionals.

Figure 1. Young Persons' Face IT homepage.

YPF aims to help YP overcome social anxiety, manage social stigma, and reduce negative thoughts about their appearance that can lead to unhelpful behaviors. It has 7 weekly sessions (each taking approximately 30-40 min to complete) including homework (eg, to practice strategies for managing teasing), and a booster session (quiz) completed 6 weeks later. Sessions are summarized in Table 1 with more detail in the YPF development and protocol papers [18,23]. YPF has a restricted administration area where user accounts are set up by a supervising health professional, and usage is recorded (eg, date and duration of access, pages viewed, and text/numeric responses to embedded reflective and homework activities/quizzes). YP can use a journal that stores personal data and quiz/survey responses and a closed forum to share and receive advice from fellow participants, moderated Monday to Friday by researchers.

Participants were allocated a participant identification number, and data were protected via a secure portal using 128-bit Secure Sockets Layer encryption. Users are provided with an e-mail address to report glitches. To check for safeguarding issues (eg, disclosure of abuse, suicidality, and intervention-related adverse events), researchers with safeguarding training (eg, www.nsahealth.org.uk) reviewed users' activity weekly. The feasibility of nominated staff at 6 GP practices performing this task for their patients was assessed; they received 10-min training and a prompt sheet detailing how to access the administration area and were advised to follow their safeguarding protocols and note actions on the website. Researchers also recorded and referred concerns to the team's clinical psychologist who decided what, if any, additional support was required.

Table 1. Content of Young Persons' Face IT.

Session title	Session description
Common problems	Common difficulties and feelings experienced by young people with visible differences, shared experiences from similar others, and a review of helpful and unhelpful coping strategies.
Improve your social skills	Using positive body language and talking skills to promote self-confidence and manage negative reactions from others.
Don't be SCARED, REACH OUT	Recognizing the impact of one's behavior on others and using the *REACHOUT* toolbox to manage social stigma and challenging situations (Reassurance, Effort and Enthusiasm, Assertiveness, Courage, Humor, Over there, Understanding, and Try again). Interactive videos allow users to practice new techniques.
Think, Feel, Do	Introducing the link between thoughts, feelings, and actions; the common misconceptions young people with visible differences have about the thoughts and actions of others; tips on how to challenge negative thoughts using *catch it; check it; change it*. Users practice this process using interactive social scenarios.
SMART goals	Realistic and achievable goal-setting to overcome social anxiety and to combat self-imposed limitations. Goal-setting examples and testimonials from positive role models. Option to explore issues around romantic relationships.
Beating anxiety	Symptoms of anxiety; anxiety management techniques; using *testing the water* and the *fear ladder* techniques to overcome social anxiety and achieve goals, creating their own fear ladder and setting goals.
Looking at your progress	Revision session on whole program.
Booster quiz	Interactive quiz on key learning points. Facility to identify and revisit areas that the user is struggling with or wishes to revise.

Control

All participants received UC, with those in the intervention arm receiving YPF in addition to UC. As there is no standardized treatment for this patient group, details of the type and frequency of UC received were collected via health economic data collection tools, primary care note reviews, and patient interviews.

Procedure

Following baseline assessments, participants were randomized to the intervention or control group in block sizes of 4, to ensure similar numbers in each group, using an automated Web-based service provided by Bristol Randomised Trials Collaboration (independent clinical trials unit). The intervention group received an email with instructions on how to log-on using a unique username and password. Additional guidelines for YP and parents on how to make the most of YPF and support their child and a log to record health resource usage were emailed and posted. Participants were advised to complete all 7 weekly sessions consecutively but could choose to complete a session over 2 days. They were prompted to select a time for their next session via an embedded diary and sent automated reminders (to a parent/carer if preferred) via text and/or email 24 and 2 hours before their session was due. Automated text/emails reminded participants to complete homework if not completed 5 days after a session and invited participants to complete the *booster* quiz 6 weeks after session 7. At the end of sessions, participants could complete an embedded 2-min survey about their views of the session.

Control participants received an email or telephone call informing them of the allocation and emphasizing the importance of continued participation. During the trial, 4 newsletters were sent to all YP and parents to encourage engagement.

At 13, 26, and 52 weeks, YP and parents were emailed a link to a Web-based questionnaire hosted by www.qualtrics.com designed to take 30 min to complete. Noncompleters were prompted via email to complete questionnaires up to 3 times. After 13 (5 parents and 11 YP) or 52 weeks (3 parents, 5 YP, and 8 practice staff), participants were invited to share their experiences via a 30-min semistructured telephone interview.

Outcomes

To inform future recruitment into a trial and YPF's acceptability and safety, the study focused on comparison of recruitment rates via targeted letters, mass mail out, charities, and consultations; reasons YP with an appearance-altering condition declined participation; questionnaire completion rates and missing data; YPF acceptability (indicated by logged user statistics, session feedback, and percentage of YP/practice staff reporting login issues); YP and parent/carer views on YPF/UC; and the number and nature of safeguarding concerns and any action required. To determine the acceptability of the trial protocol, participants were asked about recruitment processes, random allocation, communicating with researchers, and safeguarding procedures. Proposed psychosocial outcome measures for the future definitive RCT were assessed at baseline and at 13, 26, and 52 weeks via online self-report questionnaires. Candidates for a primary outcome measure in the definitive trial were as follows:

1. 10-item Appearance Subscale from the Body Esteem Scale (BES-A) using a Likert scale (0=never to 4=always). Higher scores indicate greater appearance satisfaction. Scale reliability and validity have been previously demonstrated in adolescents [25]. In this study, the BES-A also showed strong internal consistency (alpha=.88).
2. 22-item Social Anxiety Scale (SAS) for adolescents using a Likert scale (1=not at all to 5=all the time). We used total SAS score and subscales scores for FNE, Social Avoidance and Distress in new situations (SAD-N) and in general situations, for example, with peers (SAD-G). Higher scores indicate greater anxiety. Scale reliability and validity have been previously demonstrated in adolescents [26]. In this study, the total SAS (alpha=.93), the FNE (alpha=.91), and the SAD-N (alpha=.86) also showed strong internal

consistency. However, the internal consistency of SAD-G was comparatively less acceptable (alpha=.60).

Secondary outcome measures explored for their acceptability and sensitivity to change were as follows:

1. 5-item Romantic Appeal (RA) and 5-item Global Self-Esteem (SE) subscales from the Self-Perception Profile. YP choose which of 2 statements are "really true for me" =1 or "sort of true for me" =2 and decide whether the selected statement is "really true for me" =3 or "sort of true for me" =4. Higher scores indicate greater satisfaction with RA or higher SE. Scale reliability and validity have been previously demonstrated in adolescents [27]. In this study, the RA showed reasonable internal consistency (alpha=.68) and the SE good internal consistency (alpha=.77).

2. 21-item Perceived Stigmatization Questionnaire (PSQ) using a Likert scale with reversed scored items (never=5 or 1 to always=5 or 1). We calculated total PSQ score and subscales scores for absence of friendly behavior (AFB), confused and staring behavior (CSB), and hostile behavior (HB) by others. Higher scores indicate greater perceived stigmatization. Scale reliability and validity have been previously demonstrated in adolescents [28]. In this study, the total PSQ (alpha=.92), the CSB (alpha=.90), and the HB (alpha=.93) also showed strong internal consistency. However, the internal consistency of AFB was comparatively less acceptable (alpha=.68).

3. Communication, Cooperation, Assertion, Responsibility, Empathy, Engagement, and Self-control subscales (46 items) from the Social Skills Improvement System (SSIS) with a Likert scale (0=never to 3=almost always). Higher scores indicate greater perceived competence. Scale reliability and validity have been previously demonstrated in adolescents [29]. In this study, internal consistency scores for these subscales were good and ranged from alpha=.70 to alpha=.84.

4. Health-related quality of life was measured by the 5-level EuroQol-5D (EQ-5D-5L) questionnaire, a standardized instrument to measure generic health status for clinical and economic appraisal. The EQ-5D-5L has been validated in a diverse patient population in multiple countries [30]. Responses to this questionnaire are given utility values to produce a utility score for the health state quality-adjusted life years (QALY), which can be adjusted by weighting time spent in that health state by its utility score.

YP were asked if they had engaged in deliberate self-injury (DSI) over the past 3 months (no, once or twice, and 3 times or more). YPF was not designed to target DSI, but our previous evidence, suggesting DSI may be associated with appearance-related anxiety, demanded an assessment of its prevalence to determine if YPF should address this issue in the future. To establish the feasibility of collecting parent data as proxy indicators of their child's well-being and the impact of the intervention, parents/carers completed parent versions of the SAS and SSIS at the same assessment points. YP were given a £10 Amazon voucher on completion of measures at 13, 26, and 52 weeks.

Identifying and Measuring Resource Use

Resource use data were collected at 13, 26, and 52 weeks. Parents/carers completed an online study-specific Resource Use Questionnaire (RUQ) to collect data regarding all-cause and appearance-related health care and other resource use. The RUQ included questions on community-based contacts, including contacts with the GP, mental health nurse, psychologist, 111 service (UK telephone service for accessing nonemergency health care), school nurse, orthodontist, and mental health services; secondary care contacts with emergency, outpatient, and inpatient visits; contacts with social worker; charities; and personal costs accessing private services, make-up, and wig specialists and equipment. YP were also asked about days off school, which would potentially expand the future economic evaluation to take a societal perspective on costs. Those aged 16 and 17 years completed the RUQ if a parent/carer was not recruited. For comparison, study-specific case report forms were mailed to participants' GP practices to report on health care resource use.

Sample Size Considerations

No formal power calculations are undertaken in feasibility studies; instead, a suitable number of participants are recruited to gain knowledge about factors such as attrition and recruitment in relation to feasibility outcomes [31]. We aimed to recruit 60 YP to allow acceptability and completion rates to be estimated with error margins of ±13%, and with 1:1 randomization, 30 YP allocated to YPF would have in excess of 80% power for detecting a 50% or lower completion rate against an anticipated rate of 75%.

Analysis

Acceptability of Intervention and Study Design

Descriptive statistics report YP sample characteristics; website use; and rates of recruitment, retention, and data completion. To inform acceptability of the chosen outcome measures, percentage missing values were determined at each assessment point, and qualitative feedback was collated from parents and YP via interviews. Interviews were digitally recorded and transcribed verbatim. Practice staff, parent, and YP data were analyzed separately using inductive thematic analysis [32]. Coding and theme development were driven by data content rather than existing concepts and involved: reading and becoming familiar with the full dataset; preliminary data coding to identify initial themes, which were clustered with a descriptive summary provided for each; and discussion of findings to reach consensus. Practice staff findings are published elsewhere [33], and only data relevant to the study objectives are reported here.

Health Economic Data Analysis

We applied the Devlin et al's [34] UK preference weights for the 5L version to derive utility scores for YP, with the caveat these preference weights were developed for adults. We derived a 1-year QALY using the area under the curve method [35] and report QALY gain from baseline per trial arm. We derived rates of RUQ completion at 13, 26, and 52 weeks, compared resource use reported by participants and GP practices, and costed

resources using of UK health and social care estimates of unit costs [36,37]. Analyses were performed in STATA v14.

Primary Outcome and Intervention Impact

The trial was not powered to test statistically significant impact; however, to inform the selection of a primary outcome measure and test for harm and potential effectiveness of YPF, the impact on repeated outcome measures was analyzed descriptively with some inferential methods used to describe the sample and estimate parameters. Statistical comparisons of outcomes were made between the 2 arms at 13-, 26-, and 52-week follow-up. Independent samples t test assessed if they differed at any given stage. Prior reasoning would suggest no or minimal systematic change in the control group and a high degree of correlation between baseline and follow-up data. If there is a systematic effect in the intervention group, there is the possibility that those at the worrying end of a scale may show greater change compared with those with relatively less worrying scores. Consequently, the rate of change in outcomes with baseline may differ between the 2 arms. Using analysis of covariance (ANCOVA), the groups were therefore compared on the primary outcome candidate measures allowing for initial commensurate baseline value (ie, main effect was *randomized group*, *baseline* was the covariate, and the interaction effect was group by covariate). For the intervention group, multiple regression considered outcome with respect to engagement (number of YPF sessions completed) after factoring in baseline position. At each stage, all available data were analyzed, and P values and partial eta-squared, a measure of effect size, are used to describe the data rather than confirm effects. Analyses were run using SPSS V23 (IBM).

Results

Recruitment Rate and Participants

A total of 13 charities advertised the study once, resulting in 11 participants. A total of 13 practices in South West UK (practice sizes ranged from 3618-15,750 patients; mean 11,523, SD 3597), with a range of index of multiple deprivation (IMD) scores (1-10, where 1=10% most deprived), posted personalized invitations to 687 YP with an appearance-affecting condition. Identifying potential participants took 2 to 3 hours per practice. Overall, 17 YP consented to participate, giving a recruitment rate of 2.5%. Over 3 months, 4 additional GP practices (practice size=8314-10,726 patients; mean 9450, SD 8830) mass-mailed 3306 letters to all 12- to 17-year old patients, this took approximately 45 min per practice, and 15 YP consented to participate, giving a recruitment rate of 0.5% (Figure 2). Including this extension, recruitment was done from March to October 2015, and the last participant completed follow-up in September 2016.

YP and parents reported that letters from GPs provided credibility, with some expressing a preference for generic letters because YP were not singled out based on their difference and could decide if they had appearance-related distress. Practice staff preferred mass mail out over targeted letters because it was time efficient, and they found it difficult to judge patient suitability for targeted letters. In-consultation recruitment was low (n=4). Some staff found raising the option of appearance-related psychosocial support during consultations was difficult, especially when they perceived YP were expecting medical treatment only.

Overall, 47 Y*P* (26% male, 91% white; mean age 14.2 years, SD 1.7) from a range of socioeconomic backgrounds (IMD sample scores ranged from 1 to 10 with a mean of 6.78, SD 2.71) and with various conditions were randomized to YPF (n=23) or UC (n=24). In addition, 40 parents/carers were recruited. Demographic information is given in Table 2 and descriptive statistics for YP at all time points is given in Multimedia Appendix 1. Of 47 YP, at baseline, 25 (53%) reported being bullied. In comparison with population norms [25,26], 25 (53%) YP reported lower than average body esteem (mean 2.3, SD 0.8), 25 (53%) YP reported higher than average social anxiety (mean 44.5, SD 13.5), and 8 (17%, majority female) disclosed DSI.

Figure 2. Consolidated Standards of Reporting Trials flow diagram. GP: general practitioner; YP: young people; YPF: Young Persons' Face IT.
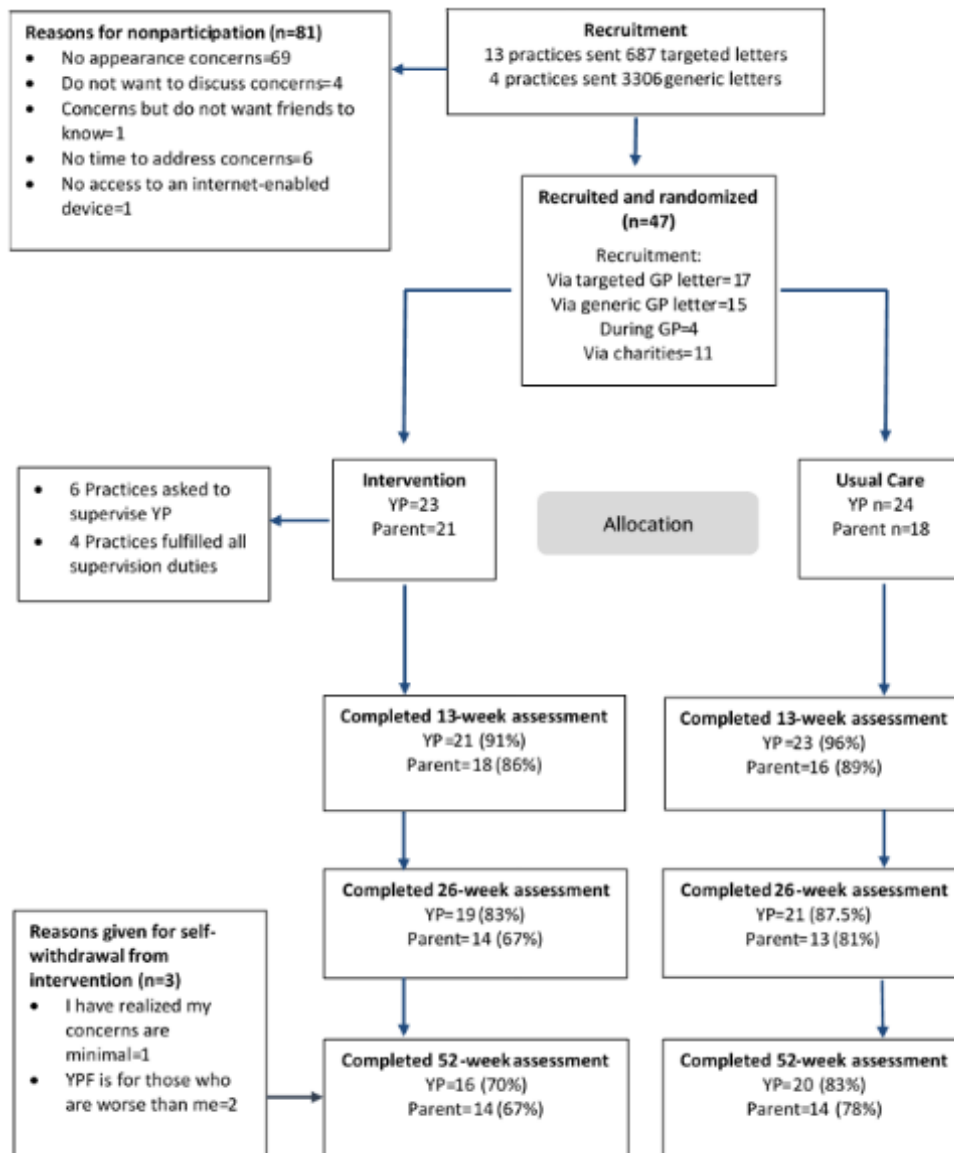
Table 2. Key characteristics of young people at baseline.

Characteristics	Control (n=24)	Young Persons' Face IT (n=23)
Age, mean (SD)	14 (1.95)	14 (1.42)
Female, n (%)	15 (63)	20 (87)
Ethnicity, n (%)		
White British	20 (83)	23 (100)
White other	—[a]	—
Chinese	1 (4)	—
Black African	—	—
Black Caribbean	—	—
Black British	—	—
Indian	—	—
Asian British	—	—
Dual heritage	2 (8)	—
Other	1 (4)	—
Condition, n (%)		
Skin (eg, psoriasis and eczema)	11 (46)	11 (48)
Craniofacial (eg, cleft and facial palsy)	5 (21	5 (22)
Scarring (eg, burns and surgery)	3 (13)	4 (17)
Birthmark (eg, port wine stain)	1 (4)	—
Body form (eg, visible pacemaker, leg longer, missing finger, and fused toes)	4 (16)	3 (13)
Deliberate self-injury[b], n (%)		
Once or twice	1 (4)	4 (17)
Thrice or more	1 (4)	2 (9)
Total incidence (% female)	2 (100)	6 (60)

[a]Not applicable.

[b]Deliberate self-injury in the past 3 months.

Reasons for Participation and Nonparticipation

Parents and YP cited lack of alternative support as a reason for participating:

> *I was hoping something like this would come our way one day.* [parent, child with craniofacial condition]

> *You can't get help about these concerns.* [female, 17 years, scars]

> *The students that bullied me got offered counselling and I didn't get anything!* [female, 16 years, craniofacial condition]

Of the 687 YP approached via targeted letters, 81 (11%) provided reasons for declining. Of these, 69 (85%) had no appearance concerns, 4 (5%) had concerns they did not wish to discuss, 6 (7%) had no available time, 1 (1%) did not want their friends to know, and 1 (1%) had no internet-enabled device.

Acceptability of Study Design

Interviewees typically endorsed an RCT design:

> *I got UC, I didn't really mind, as long as I was using my time to help.* [female, 16 years, craniofacial condition]

However, parents who cited lack of alternative support as a reason for participation reported their children were disappointed when allocated UC:

> *She really wanted to be the one that tried YP Face IT, so that was very disappointing.* [parent, child with skin condition]

Study newsletters and the facility to complete measures online were credited for maintaining study engagement:

> *The newsletters were really nice ... It keeps people engaged on my side of the study.* [female, 17 years, Eczema, UC group]

> *Questions were easy, I did them on my phone which was useful.* [male, 12 years, skin condition]

Retention of Participants

In the intervention group, 3 patients self-withdrew. Of 3 patients, 1 decided the following after viewing YPF:

Helped me realise there are bigger problems and I could be a lot worse off, I'm happy the way I am. [female, 16 years, skin condition]

Two felt it was more suitable for those with greater concerns:

It's more for people that are very insecure and need help. [female, 15 years, birthmark]

Acceptability of Intervention and Safeguarding Processes

Table 3 details YPF usage and session feedback. The number of those attempting each session decreased as participants progressed through the intervention. Notably, of 23 patients, 12 (52%) attempted 7 sessions, and 9 (39%) completed the booster quiz. The time spent on each session by those who attempted it varied, from 1 (signed in to and left session) to 100 min, with a mean time ranging from 26.17 min (for session 7, which provides revision) to 47.60 min (session 2, which has the most content). Some completed a single session in 2 sittings. Percentage of session content viewed (an indication of adherence), by those attempting sessions, also varied and ranged from 10% to 100%. Sessions with the lowest completion rates were 1 (mean 87.13%) and 2 (mean 88.85%), but most of those who persisted with the program viewed all of the 7 sessions' material (indicated by a median of 100%).

The only login errors and glitches reported (n=8) were with the booster quiz; these were addressed but accounted for 5 participants not completing the quiz. Of those attempting sessions, the majority agreed sessions were interesting, easy to understand and helpful. This was expanded on during interview:

It was really good, I found it very interesting listening to different ways of dealing with situations and the emotional side and sometimes you feel like you are the only one, but with YPF you know it's not just you. [female, 14 years, scarring]

Greatest variation in opinion was found in response to sessions 3 and 4 (managing challenging social interactions and challenging negative thoughts) where some indicated benefit from CBT more than SST and vice versa:

I had social skills... but YPF made me think, notice things which were positive, made me aware of things, like the subconscious, it's a reminder that you're not the centre of the world. People will look and go "ooh," but then carry on. It made me not wait till it's

[skin condition] better and get on with life now. [male, 15 years]

The bit on anxiety was really helpful. [male, 12 years, craniofacial condition]

Some YP reported benefits from both:

The SCARED acronym was helpful and Testing the Water was good for starting small changes, like talking to people. [female, 14 years, craniofacial condition]

YP reported that YPF validated their concerns and increased their confidence in seeking psychological support via primary care:

It's made me aware that you can get help, I'd be more open to see a GP, and more comfortable talking about it now. [male, 13 years, skin condition]

There were also suggestions that YPF affected decisions around appearance-altering surgery:

He's been asking us to look into an aesthetic operation. We had the appointment after he had started YPF but he's changed his mind and decided he doesn't want it now, so YPF has been very useful. [parent, child with scars]

Practice staff found supervision responsibilities brief (2-5 min per participant, per session) and straightforward, but only 59% of supervision tasks were completed, and forgetting and lack of time were barriers to completion. YP did not disclose safeguarding issues via YPF data collection tools, nor did they use the discussion forum. There was no evidence (from following up those who withdrew and analyses of outcome measures) of any intervention-related adverse events, but incidences of DSI at baseline were reviewed by the team's clinical psychologist who adhered to NHS guidelines for its management. This resulted in 6 YP with DSI being advised to seek GP support, and in 2 cases, their GP was also informed via a letter.

The number of completed resource use categories over 1 year is small. Participants who completed questionnaires did not use some community-based services, such as GP nurse telephone calls and visits. Potential cost drivers of the intervention include GP visits, community mental health services, and secondary care visits. When asked about appearance-related resource use only, differences between arms were smaller, and fewer participants reported use. Resource use completion rates were higher using GP practices medical records review proformas. Practice staff completed these resources for 27 to 30 of the 47 patients in the trial, whereas only 19 patients self-reported these contacts.

Table 3. Young Persons' Face IT intervention content and usage by participants (n=23) in the intervention group and online session feedback.

Session	Young people in intervention group attempting session, n (%)	Average minutes spent per session per person		Percentage of session content viewed per person		Median (minimum to maximum) response (1=strongly agree, 2=agree, 3=do not know, 4=disagree, and 5=strongly disagree)		
		Mean (SD)	Median (minimum to maximum)	Mean (SD)	Median (minimum to maximum)	Whether session was interesting	Easy to understand	Helped me
1	23 (100)	33.04 (26.80)	27 (1-100)	87.13 (24)	100 (28-100)	2 (1-2)	2 (2-2)	2 (1-2)
2	20 (87)	47.60 (26.10)	46 (6-90)	88.85 (24.82)	100 (10-100)	2 (1-3)	2 (1-2)	2 (1-2)
3	17 (74)	29.18 (21.76)	25 (2-76)	94.53 (14.78)	100 (42-100)	2 (1-3)	2 (1-2)	2 (1-3)
4	14 (61)	38.64 (23.69)	34.50 (14-83)	100 (0)	100 (100-100)	2 (1-3)	2 (1-3)	2 (1-3)
5	13 (57)	42.92 (25.25)	33 (13-91)	96.15 (7.68)	100 (80-100)	1 (1-1)	2 (2-2)	2 (1-2)
6	12 (52)	40.25 (23.95)	34 (6-89)	95.42 (8.91)	100 (75-100)	1 (1-2)	2 (2-2)	2 (1-3)
7	12 (52)	26.17 (18.64)	22.50 (5-67)	100 (0)	100 (100-100)	2 (1-2)	2 (1-2)	2 (1-2)
Quiz	9 (39)	31.33 (13.63)	30 (12-63)	100 (0)	100 (100-100)	__[a]	—	—

[a]Not applicable.

Completion of Outcome and Resource Use Measures for Future Economic Evaluation

The percentage of participants providing data via online questionnaires at each assessment point was high for YP in both arms ranging from 96% to 70% with (76%) overall completion at 52 weeks, but there was a 13% comparative reduction in completion at 52 weeks among the intervention group (see Figure 1). Data completion was 100% for psychosocial measures. For the EQ-5D-5L, 70% (16/23) of patients in the YPF and 75% (18/24) in the UC group provided enough data to derive QALY. Completion of the online RUQ was more than 50% at 52 weeks for all categories, except community mental health services and days off school (Table 4). The control group provided more complete data than in the YPF group. Table 5 reports resource use for all medical reasons.

Table 4. Completeness of the 5-level EuroQol-5D and resource use data.

Number of completers of 5-level EuroQol-5D and resource use data	Young Persons' Face IT (n=23), n (%)			Usual care (n=24), n (%)		
	Week 13	Week 26	Week 52	Week 13	Week 26	Week 52
5-level EuroQol-5D	21 (91)	19 (83)	16 (70)	23 (96)	21 (88)	20 (83)
Quality-adjusted life years complete cases	__[a]	—	16 (70)	—	—	18 (75)
General practitioner services	13 (57)	13 (57)	15 (65)	19 (79)	14 (58)	18 (75)
Mental health services	7 (30)	2 (9)	9 (39)	8 (33)	7 (29)	13 (54)
Social services	13 (57)	13 (57)	15 (65)	19 (79)	14 (58)	18 (75)
Other National Health Services Community services	13 (57)	13 (57)	15 (65)	19 (79)	14 (58)	18 (75)
Outpatient appointments	17 (74)	16 (70)	12 (52)	21 (88)	16 (67)	13 (54)
Accident and emergency	19 (83)	16 (70)	14 (61)	21 (88)	17 (71)	16 (67)
Inpatient nights	19 (83)	16 (70)	16 (70)	21 (88)	17 (71)	17 (71)
Hospital tests	19 (83)	16 (70)	16 (70)	21 (88)	16 (67)	18 (75)
Private services/expenses	19 (83)	15 (65)	15 (65)	19 (79)	16 (67)	17 (71)
Days off school	7 (30)	9 (39)	8 (35)	10 (42)	10 (42)	6 (25)
Resource complete cases	5 (22)	2 (9)	5 (22)	5 (21)	5 (21)	9 (38)

[a]Not applicable.

Table 5. Number of participants who completed the resource use questions at each time points, the number who used the resource, the mean units of resource used, and their mean costs.

Resource	Young Persons' Face IT				Usual care			
	N[a]	N[b]>0	Resource use, mean (SD)	Cost (£), mean, (SD) (£)	N[a]	N[b]>0	Resource use, mean (SD)	Cost (£), mean (SD)
GP[c] visits	6	3	3.0 (3.3)	132 (147)	13	9	2.0 (2.3)	88 (103)
GP calls	6	1	0.2 (0.4)	5 (11)	13	2	0.7 (2.2)	19 (60)
GP home visits	6	0	0.0	0.0	13	0	0.0	0.0
GP nurse visits	6	2	1.3 (2.2)	19 (31)	13	4	0.7 (1.2)	10 (17)
GP nurse calls	6	0	0.0	0.0	13	0	0.0	0.0
GP nurse home visits	6	0	0.0	0.0	13	0	0.0	0.0
Mental health nurse	6	0	0.0	0.0	13	1	0.2 (0.6)	7 (24)
Psychologist	6	0	0.0	0.0	13	3	0.6 (1.3)	86 (184)
111 calls	6	0	0.0	0.0	13	0	0.0	0.0
School nurse	6	2	0.5 (0.8)	6 (11)	13	2	0.2 (0.6)	3 (8)
Orthodontist	6	3	1.7 (1.9)	167 (186)	13	5	0.6 (1.1)	62 (112)
Mental health services	0	0	0.0	0.0	6	1	0.7 (1.2)	75 (185)
Outpatient appointments	11	5	N/A[d]	199 (312)	14	5	N/A	210 (486)
Accident and emergency visits	13	3	0.3 (0.6)	41 (83)	16	4	0.3 (0.6)	41 (79)
Inpatient nights	13	0	0.0 (0.0)	0 (0)	16	1	0.1 (0.3)	22 (89)
Social worker contacts	6	0	0.0	0.0	13	0	0.0	0.0
Charity contacts	6	0	0.0	0.0	13	1	0.2 (0.6)	0 (0)
Private counseling	13	2	1.8 (6.4)	58 (191)	15	1	0.2 (0.8)	N/R[e]
Private services	13	2	0.3 (0.9)	5 (19)	15	0	0.0	0.0
Make-up and wig specialist	13	0	0.0	0.0	16	0	0.0	0.0
Make-up, wigs, and other equipment	12	1	0.0	1 (3)	13	1	0.1 (0.3)	4 (13)

[a]Number of people who completed the resource use question at 13, 26, and 52 weeks allowing for a 1-year cost to be derived.

[b]Of those who completed, number of participants who reported having used the resource.

[c]GP: general practitioner.

[d]Not applicable. A mix of different appointments at different costs reported.

[e]Not reported, missing data.

Variation of Usual Care

Participants were asked to record any psychosocial support they received for appearance concerns. One reported receiving support from a private counselor and one from an NHS counselor, both were in the UC arm.

Selecting Primary Outcome Measure and Estimate of Impact on Outcome Measures

Independent samples *t* tests at 13, 26, and 52 weeks did not show statistically significant differences between the 2 arms on any measure. Positive changes to the primary outcome candidate measures in the intervention arm (BES-A and the FNE subscale of the SAS) were found when factoring in baseline scores and engagement with the program (see Tables 6 and 7).

After adjusting for BES-A baseline scores, there were statistically significant main effects for randomized group at 13 weeks (P=.001), 26 weeks (P=.001), and 52 weeks (P=.02) and interaction effects at 13 weeks (P<.001), 26 weeks (P=.002), and 52 weeks (P=.006). Engagement with the intervention was a significant predictor of BES-A scores at 13 weeks (P=.02) and 26 weeks (P<.001), but this was not maintained at 52 weeks (P=.29). After adjusting for FNE baseline scores, there were statistically significant main effects for randomized group at 13 weeks (P=.05) and 26 weeks (P=.02) and interaction effects at 13 weeks (P=.03) and 26 weeks (P=.007), but no statistically significant main (P=.29) or interaction (P=.22) effects at 52 weeks. Engagement with the intervention was a significant predictor of FNE scores at 13 weeks (P=.01) and 26 weeks (P=.01), but again this was not maintained at 52 weeks (P=.25).

Although the study was not powered to confirm effects, results suggest that YPF may improve BES-A and FNE for those at the worrying end of these scales, and that increased engagement with YPF may be a contributory factor.

The BES-A would be an appropriate primary outcome measure for a future RCT. The BES-A is frequently used in adolescent body image research because it is reliable, has normative data, and has good face validity among adolescents (eg, a study by Diedrichs et al [38]); it provides a general measure of satisfaction with appearance and is not condition specific, making it appropriate for those with any appearance-affecting condition. In this study, YP fed back that it was quick and easy to complete, and results indicated it is sensitive to change among those completing the intervention.

The Consolidated Standards of Reporting Trials-electronic health checklist is provided in Multimedia Appendix 2.

Table 6. Change in appearance and social anxiety outcomes at each time point and between each arm when factoring in baseline values.

Assessment point, measure	Valid (n)	Main effect for randomized group		Measure at baseline		Interaction	
		P value	η_p^{2a}	P value	η_p^2	P value	η_p^2
13 weeks							
BES-A[b]	44	.001	0.253	<.001	0.585	<.001	0.287
SAD-N[c]	44	.08	0.071	<.001	0.534	.09	0.068
FNE[d]	44	.04	0.095	<.001	0.593	.03	0.108
SAD-G[e]	44	.91	0	<.001	0.453	.91	0
26 weeks							
BES-A	40	.001	0.257	<.001	0.388	.002	0.242
SAD-N	40	.005	0.203	<.001	0.422	.001	0.255
FNE	40	.02	0.135	<.001	0.29	.007	0.187
SAD-G	40	.23	0.039	.002	0.229	.05	0.099
52 weeks							
BES-A	36	.02	0.153	<.001	0.445	.006	0.212
SAD-N	36	.14	0.065	<.001	0.526	.08	0.088
FNE	36	.29	0.034	.002	0.273	.22	0.046
SAD-G	36	.57	0.01	<.001	0.356	.27	0.037

[a]Thresholds for partial eta-squared η_p^2: <0.0025 indicates a trivial inconsequential effect, 0.0025 to 0.01 indicates a small effect, 0.01 to 0.06 indicates a moderate effect, 0.06 to 0.14 indicates a medium-sized effect, 0.14 to 0.30 indicates a large effect, 0.30 to 0.50 a very large effect, and >0.50 indicates a huge effect.

[b]BES-A: Body Esteem Appearance subscale.

[c]SAD-N: Social Avoidance and Distress in New situations.

[d]FNE: Fear of Negative Evaluation.

[e]SAD-G: Social Avoidance and Distress among peers.

Table 7. The impact of engagement with the Young Persons' Face IT intervention on appearance and social anxiety outcomes at each time point when factoring in baseline value.

Assessment point, measure	Valid (n)	R^{2a}	Baseline measure		Engagement	
			Beta	P value	Beta	P value
13 weeks						
BES-A[b]	21	0.396	.427	.03	.461	.02
SAD-N[c]	21	0.340	.627	.007	−.158	.45
FNE[d]	21	0.574	.637	.001	−.420	.01
SAD-G[e]	21	0.439	.677	.001	−.173	.35
26 weeks						
BES-A	19	0.682	.057	.69	.816	<.001
SAD-N	19	0.371	.430	.05	−.581	.01
FNE	19	0.337	.070	.73	−.571	.01
SAD-G	19	0.349	.217	.29	−.557	.01
52 weeks						
BES-A	16	0.202	.282	.27	.323	.21
SAD-N	16	0.438	.684	.008	−.331	.15
FNE	16	0.216	.344	.18	−.295	.25
SAD-G	16	0.285	.561	.04	−.292	.26

[a]$R2$: indicates the proportion of variation in outcome jointly accounted for by the baseline measure and level of engagement.

[b]BES-A: Body Esteem Appearance subscale.

[c]SAD-N: Social Avoidance and Distress New situations.

[d]FNE: Fear of Negative Evaluation.

[e]SAD-G: Social Avoidance and Distress among peers.

Recruitment for Full Randomized Controlled Trial

A future RCT design would be amenable to analysis using ANCOVA with a baseline by group interaction, and 53, 70, and 86 participants per arm would have 80%, 90%, and 95%, respectively, power for detecting anticipated effects; this power is supported by lower bounds on effect sizes from this feasibility study. This study indicates 76% full data completion at 52 weeks, recruiting 186 participants will give complete data on 140 participants (90% power).

Discussion

Principal Findings

This study explored the feasibility of using an RCT to evaluate the effectiveness and cost-effectiveness of YPF, an online psychosocial intervention to support YP with appearance-related anxiety. Results indicate YPF is a welcome, safe, and acceptable intervention with the potential to fill a gap in care provision and suggest an RCT design would be acceptable and feasible with wide-ranging recruitment strategies, using the BES-A subscale as primary outcome measure.

Lessons learned will inform a future RCT, particularly around engaging YP in appearance-related research, an extremely sensitive topic rarely discussed with adults in primary care settings [18]. Recruiting from this group is notoriously challenging [39], and pertinent barriers and facilitators to recruitment identified in this study are discussed in detail elsewhere [33]. In summary, educating staff on the importance of normalizing conversations about appearance and validating rather than minimizing concerns in primary care settings could increase YP help-seeking behavior and reduce perceived stigma around receiving psychosocial support. Despite these challenges, recruitment via charitable organizations and GP practices is feasible; but to achieve the recommended large trial sample size, in addition to advertising via a wide range of relevant charities, using social media and a mass mail out approach from large GP practices is recommended. This would also allow YP to decide whether or not their condition causes psychological distress, rather than GPs judging their suitability; which in this study often involved GPs second-guessing the objective severity of the visible difference. This recommendation aligns with evidence that an individual's subjective assessment of the impact of a visible difference is a better predictor of adjustment [14] and recommendations that health professionals should ask about, rather than assume, levels of distress [40].

The majority of YP found YPF sessions interesting and helpful, and retention and data completion strategies (eg, online questionnaires and text reminders) were largely successful. Retention (76% of all YP completed data at 52 weeks) and intervention-adherence rates (52% completed the program) were comparable with that demonstrated in similar studies using

internet-based CBT for adolescent anxiety [41]. Nonetheless, and particularly considering indications that increased engagement may improve outcomes, adherence could be improved. Feedback that YPF may not suit all (eg, some felt it was suited to those with greater concern) suggests that more stringent inclusion criteria based on level of distress could be employed in future. However, given evidence that YPF does not cause harm, the preliminary nature of these findings and our aim to provide easily accessible support for all who want it, at this stage, we recommend retaining current inclusion criteria and incorporating a subset analysis for those who score highly at baseline.

Although the potential benefits and nature of blended care (a combination of electronic health and guidance from a care provider) are being debated [42], definitive trials could also consider preventing attrition by including, for example, a telephone call from the supervising health professional to YP who do not progress as expected or support from a peer who has completed the program. Qualitative data suggest that depending on individual needs, some YP may benefit from additional motivation and support. However, the YPF forum, an opportunity to gain peer support and included on request from our YP advisory group, was not used. The value of this feature should be confirmed in a larger trial.

The safeguarding protocol for ensuring vulnerable YP were followed up by the research team was successful. Whether it is feasible or necessary for practice staff to review YP data weekly is undecided; insufficient time/forgetting resulted in some staff failing to review accounts. However, as it appears that YP do not disclose safeguarding issues via the website (all cases of DSI were reported in response to a single item within outcome measures), it may be more feasible for researchers to continue with weekly checks (to confirm this finding) while determining whether automated reminders to staff to review patient data increases adherence. These data could ultimately provide GPs with information to determine the need for a follow-up appointment after the YP has completed YPF. Finally, to replace a task fulfilled by the team's clinical psychologist in this study, in future trials, YP will be signposted to appropriate sources of support for DSI within YPF.

We found that resource use data collection via online questionnaires is potentially burdensome, and completion rates are low. Patients reported the use of resources beyond the health and social care payer perspective, with high costs of private counseling and other expenses. A future economic evaluation could include a private perspective on costs and should rely on resources being completed through GP practice proformas, complemented by participant self-report on the use of private and other mental health services. Findings from the qualitative study also highlight that the follow-up of the future RCT will need to be long enough to capture potential long-term health care savings accruing from YPF, such as cosmetic surgeries and other expensive treatments avoided.

Strengths

YPF is an innovative, easily accessible intervention with the potential to improve outcomes for YP with a visible difference and appearance-related distress who currently have limited access to evidence-based specialist support. Extensive reflection and user involvement built into the study design, identified a feasible recruitment strategy that ultimately provided sufficient data to address study objectives and inform the design of future trials. Independent randomization and use of well-established outcome measures ensured data were reliable and valid, and a primary outcome measure (BES-A) was selected.

Limitations

As there is no best alternative therapy available for YP with a visible difference, apart from limited access to a mental health practitioner, there was no active control arm. Although our initial concerns that YP randomized to receive UC may be disappointed were borne out, there was minimal evidence that this deterred participation. However, considering this disappointment and confirmation that there is little alternative support available, future trials should consider a wait-list control arm. A higher dropout in the YPF arm may have resulted from the increased burden associated with completing the intervention. Participants required an internet-enabled device, which may have restricted access to those with lower socioeconomic status; although only 1 person identified this as a reason for declining involvement, this issue requires consideration. The majority ethnicity of the sample was white, which reflects a typical bias across appearance research [43] that needs addressing in future studies. Finally, we relied on self-report measures that may result in reporting bias, and YP were not blinded to their allocation.

Conclusions

We successfully delivered a novel online intervention for YP disclosing appearance-related distress associated with an appearance-altering condition and confirmed the feasibility of evaluating it against a UC control group using an RCT design, with high levels of data completeness and reasonable intervention adherence. Despite reporting a range of negative appearance-related experiences, including bullying, self-harm, poor body esteem, and social anxiety, participants had not sought appearance-related support or known how to do so. YPF may prove to be a feasible, cheap, and acceptable source of immediate specialist support, particularly for those with low body esteem and high levels of social anxiety. YP involved in the development of YPF coproduced a video summarizing this study, available on YouTube [44].

Conflicts of Interest

None declared.

Multimedia Appendix 1

Descriptive statistics on young people's outcome measures at all time points.

[DOCX File , 18 KB - mental_v6i11e14776_app1.docx]

Multimedia Appendix 2

CONSORT-EHEALTH checklist (V 1.6.1).

[PDF File (Adobe PDF File), 146 KB - mental_v6i11e14776_app2.pdf]

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Abbreviations

ANCOVA: analysis of covariance
BES-A: Body Esteem Appearance subscale
BID: body image dissatisfaction
CBT: cognitive behavioral therapy
DSI: deliberate self-injury
EQ-5D-5L: 5-level EuroQol-5D
FNE: Fear of Negative Evaluation subscale
GP: general practitioner
HB: hostile behavior
IMD: Index of Multiple Deprivation
NHS: National Health Services
PSQ: Perceived Stigmatization Questionnaire
PTSD: posttraumatic stress disorder
QALY: quality-adjusted life years
RA: romantic appeal
RCT: randomized controlled trial
RUQ: Resource Use Questionnaire
SAD-G: Social Anxiety in General Situations subscale
SAD-N: Social Anxiety in New Situations subscale
SAS: Social Anxiety Scale
SE: Self-Esteem
SSIS: Social Skills Improvement System
SST: social skills training
UC: usual care
YP: young people
YPF: Young Persons' Face IT

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Original Paper

Prognosis Prediction Using Therapeutic Agreement of Video Conference–Delivered Cognitive Behavioral Therapy: Retrospective Secondary Analysis of a Single-Arm Pilot Trial

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Abstract

Background: The therapist-patient therapeutic alliance is known to be an important factor in cognitive behavioral therapy (CBT). However, findings by previous studies for obsessive-compulsive disorder (OCD), panic disorder (PD), and social anxiety disorder (SAD) have not been consistent regarding whether this alliance provides symptomatic improvements.

Objective: This study investigated predictors of symptom improvement in patients receiving CBT via video conferencing.

Methods: A total of 29 patients who participated in a previous clinical trial were recruited for the current study. Therapeutic alliance and clinical background in patients with OCD, PD, and SAD were measured at first session or the eighth session, which were calculated by multiple regression analyses to estimate the impact on therapeutic response percentage change.

Results: The multiple regression analyses showed that, among the independent variables, only patients' agreement in the therapeutic alliance remained viable, as other variables were a best fit for the excluded model (P=.002). The results show that patients' agreement on therapeutic goals and tasks explains the prognosis, as the normalization factor beta was 0.54 (SE 32.73; 95% CI 1.23-5.17; P=.002) and the adjusted R^2 was .266.

Conclusions: Patients' agreement on therapeutic goals and tasks predicts improvement after CBT via video conferencing.

Trial Registration: UMIN Clinical Trial Repository UMIN000026609; https://tinyurl.com/ye6dcbwt

Introduction

One of the principles of cognitive behavioral therapy (CBT) is the therapist-patient therapeutic relationship [1], which is consistently important from the initial session of therapy to its last stage [2-4]. The therapist and patient collaboratively work together over time on the patient's therapeutic goal of achieving symptomatic relief. However, the results of previous studies have not been consistent about whether the therapeutic relationship in CBT affects symptomatic outcomes [4,5].

Two systematic reviews, including a meta-analysis of depression, have shown moderate correlations between the therapeutic relationship (assessed through the Working Alliance Inventory [WAI] scale) and symptomatic outcomes [6,7]. These previous studies, conducted by correlation analysis, could not

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explain the causal relationship. Further, the causal relationship between the therapeutic relationship and its outcomes was discussed by retrospective observational studies in clinical trials, but the results were not consistent. For example, in CBT used for the treatment of panic disorder (PD), it has been suggested that a high rate on the WAI-Short Form (WAI-SF) is an important factor for a patient's symptomatic improvements [8]; however, regarding CBT for the treatment of obsessive-compulsive disorder (OCD), it has been reported that scores on the WAI-SF did not affect the patient's symptomatic improvements [9]. Furthermore, in a recent study of the WAI-SF [10], the two factors of therapeutic relationship and patient agreement were analyzed. It was found that a patient's strong agreement with CBT tasks predicted symptomatic improvements. In the past, the WAI-SF was supposed to have three factors: development of an affective bond, agreement with the task, and agreement with the goal between the therapist and patient [10]. CBT requires a restructuring of dysfunctional cognitions and behaviors that a patient has formed over many years; thus, it seems logical to infer that patients' agreement may have an impact on symptomatic improvements.

Use of the internet has spread worldwide and it has seen use by 4.536 million people (58.8%) globally as of June 2019 [11,12]. Internet-based CBT was created as a result of the incorporation of programming technology into CBT, and it has demonstrated effective results through its therapeutic processes by creating symptomatic improvements [13,14]. While the telemedicine approach is the most like traditional face-to-face treatment, previous research on video conference–delivered CBT has been limited compared to normal internet-based CBT [15-20]. A systematic review revealed that the therapeutic relationship is maintained at sufficiently high levels when using video conferencing [21]. However, to the best of our knowledge, the influence of the therapist-patient relationship developed through video conference–delivered CBT on patients' symptomatic improvement has not yet been investigated [22]. In the current study, we investigated predictors for improvement among patients after they received CBT via video conferencing.

Methods

Study Design and Participants

This study utilized secondary data analysis with data from a previous clinical, pilot, single-arm trial on video conference–delivered CBT, using Cisco WebEX as the video conferencing system [19]. A total of 29 Japanese adult participants (mean age 35.5 years old; SD 9.2), 5 of whom were male and 24 of whom were female, completed the intervention. We hypothesized that therapist-patient agreement on therapeutic goals and challenges would predict patient prognosis. Baseline data was used exploratorily and analyzed through a series of statistical analyses.

Measures

To assess the severity of symptoms as the primary outcome, we evaluated each mental health disorder of interest using a corresponding scale: OCD was assessed through the Yale-Brown Obsessive-Compulsive Scale (Y-BOCS); PD was assessed

through the Panic Disorder Severity Scale (PDSS); and social anxiety disorder (SAD) was assessed through the Liebowitz Social Anxiety Scale (LSAS) [23-25]. Furthermore, depression was assessed through the Patient Health Questionnaire-9 (PHQ-9) [26], general anxiety was assessed through the Generalized Anxiety Disorder-7 (GAD-7) scale [27], and the therapist-patient therapeutic relationship was assessed through the WAI-SF [2]. Regarding the WAI-SF sub-scales, the agreement score was composed of the total scores of items 1, 2, 6, 8, 11, and 12, and the bond score was composed of the total scores of items 3, 5, 7, and 9 [10].

In our previous clinical trial, CBT was evaluated at the first, eighth, and sixteenth session [20], but the therapeutic alliance per WAI-SF [2] was set as a predictor in the eighth session. This is because it is anticipated that a well-established treatment relationship in the first half will affect the patient's engagement with the second half of the challenge (mostly with exposure). Depressive symptoms in PHQ-9 and general anxiety in GAD-7 at baseline (first session) were also set as predictors.

Statistical Analysis

The statistical analysis was performed using SPSS Statistics, version 24.00 (IBM, Armonk, New York, United States). First, Spearman correlation analysis was performed between the treatment response percentage change and the score in each scale (WAI-SF total, PHQ-9, GAD-7), or the subscales of WAI-SF (agreement, bond). Second, to investigate the predictive effects that the patients' backgrounds at pretreatment may have had on the treatment response change post treatment, a series of multiple regression analyses were performed. The treatment response percentage change was set as a dependent variable in multiple regression analyses. Variables were entered for analysis in a multivariate model by the forward selection stepwise procedure ($F<0.05$ as inclusion and $F≥0.10$ as exclusion). Multicollinearity was measured by variance inflation factors (VIF) and tolerance. If the VIF value exceeded 4.0, or by tolerance was less than 0.2, then there was a problem with multicollinearity [28]. We excluded WAI-SF's total scores because VIF was 13.09. The treatment response percentage change was calculated by dividing the total pretreatment score with the score difference between Session 1 and Session 16. The treatment response percentage change in this study was the decline in baseline Y-BOCS, PDSS, or LSAS score. The degree of treatment response percentage change was analyzed as a continuous variable and calculated as follows:

Results

Agreement, bond, and the total score of the WAI-SF showed a significant correlation with the response percentage change as a result of correlation analysis, including Bonferroni correction (Table 1). Multiple regression analyses showed that, within the independent variables only patient agreement remained, with the other variables a better fit for the excluded model (*beta*=.54; Adjusted R^2=.266; SE 32.73; 95% CI 1.23-5.17; *P*=.002).

Table 1. Correlation relationship between response percentage change and the patient's background/symptoms.

Variable	Response percentage change (r)	P value	P value after Bonferroni correction
Patient agreement	.681	<.001	.005
Bond	.476	.009	.05
WAI-SF[a] total	.569	.001	.005
PHQ-9[b]	−.228	.23	>.99
GAD-7[c]	−.292	.12	.60

[a]WAI-SF: Working Alliance Inventory–Short Form.

[b]PHQ-9: Patient Health Questionnaire-9.

[c]GAD-7: Generalized Anxiety Disorder-7.

Using G*power 3.1 [29] for power analysis, power (1–beta error probability) was calculated to be 0.88 (effect size f^2=.36; alpha error probability=.05; sample size=29), and the number of predictors was one.

Discussion

Primary Findings

The hypothesis of this study was that agreement on therapeutic goals and challenges predicts a patient's prognosis. We performed multiple regression analyses on the variables that were significantly correlated, but only the explanatory model using the patient agreement variable from the WAI was the best fit. The results suggested that patients' agreement with the set goals and tasks during the middle stage of CBT predicted symptomatic improvement.

These results are consistent with a previous study, which provides evidence that the therapist-patient therapeutic relationship is important to symptomatic improvements in the middle to late stages of therapy [4,7]. Conversely, the results of a meta-analysis of guided, internet-based CBT (except by video conferencing) suggested that the therapeutic alliance is not important to the improvement of anxiety [5]. It is interesting that the results of the current research contrast with these results from a previous study, indicating that perhaps patients who do not agree with treatment drop out early. Thus, the therapist-patient therapeutic treatment alliance in internet-based CBT may not be relevant to the therapeutic response. The total WAI score was associated with symptomatic improvements

when the treatment was tailored specifically to the patient's condition during internet-based CBT [6]. Results from this prior research provided important knowledge on future directions CBT could take using the internet. Specifically, it is essential to adhere to the content of basic CBT skill sets [30]. Hence, we can infer that the therapist's work in implementing a personalized therapy may result in the patient's agreement with the therapeutic goals and tasks. Furthermore, this study's results did not identify a pretreatment predictor, consistent with previous studies of depression [31].

Limitations

First, this study had a small sample size, so future studies with a more significant sample size are needed. Second, factors affecting treatment responsiveness may be influenced by the quality of CBT, which can be assessed using a cognitive therapy scale, as well as a patient's background and their relationship with the therapist [32,33]. This study does not assess quality of treatment, patient background, or relationship with the therapist, therefore, further studies exploring this aspect of the treatment are needed. Finally, this study was a secondary analysis of a single-arm pilot study.

Conclusions

Our results suggest that patients' agreement with therapeutic tasks and goals predicts an improvement after intervention with video conference–delivered CBT. To the best of our knowledge, this is the first published evidence of this phenomenon. Therapists in the video conference–delivered CBT field should seek ways to apply tasks and goals that are tailored specifically to each patient's condition.

Authors' Contributions

KM contributed to the implementation and planning of the study and the writing of papers. TY contributed to the presentation of research results. SH contributed to the statistical analysis. CH contributed to the conduct of the study. YH contributed to the presentation of the research results and the development of thesis. ES contributed to the overall examination supervision and the development of the thesis.

Conflicts of Interest

None declared.

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Abbreviations

CBT: cognitive behavioral therapy
GAD-7: Generalized Anxiety Disorder-7 scale
LSAS: Liebowitz Social Anxiety Scale
OCD: obsessive-compulsive disorder
PD: panic disorder
PDSS: Panic Disorder Severity Scale
PHQ-9: Patient Health Questionnaire-9
SAD: social anxiety disorder
VIF: variance inflation factor
WAI: Working Alliance Inventory
WAI-SF: Working Alliance Inventory–Short Form
Y-BOCS: Yale-Brown Obsessive-Compulsive Scale

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