A pilot study evaluating engagement with a platform supporting online interventions for common mental health problems

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Title

A pilot study evaluating engagement with a platform supporting online interventions for common mental health problems

Summary

This pilot study investigates a new platform for supporting online interventions for common mental health problems called SilverCloud. It was developed from insights into interactive system design to address the problem of high attrition rates and poor engagement with online interventions. Through a range of methods, the study considers the role of four design strategies in engaging users in cognitive behavioural therapy. A service-based study, it concentrates on a clinical population with mild or moderate depression. Clinical outcome measures will be taken pre and post intervention use; demographic data of who did and did not choose the intervention collected, patterns of usage will be extracted from the log data and analysed; and qualitative interviews will be done to understand the relationship between patterns of usage and levels of engagement. The findings will be used to inform further developments of this and other online interventions and contribute to the development of methods for assessing online interventions.

Aims, Objectives and Research Questions

Online interventions present the possibility to substantially increase provision of, and access to, care for common mental health problems at the mild or moderate level. Studies have shown good efficacy for online interventions for depression and anxiety,[1-4] but high attrition rates in non-trial settings make it difficult to reach the perceived potential.[5,6] The online intervention evaluated in this pilot study attempts to address these issues through explicitly designing for engagement. This pilot study aims to evaluate and contribute to these design strategies.

The objectives of the pilot study are:

- To evaluate engagement with the online intervention in a realistic primary mental health care setting
- Assess engagement from multiple perspectives, including clinical efficacy and interaction design
- Contribute to further development of the online intervention
- Support preparation for a full-scale clinical trial

Research questions include:

- Does the online intervention decrease symptoms of depression?
- Who chooses to use the online intervention?
- What are the patterns of use of the online intervention?
- How successful are the four design principles, *personal, interactive, supportive and social,* in supporting engagement?

Intervention description

SilverCloud platform

SilverCloud is a platform on which to quickly build online interventions for common mental health problems. It utilises four design strategies that have been drawn from research in human-computer interaction: personal, interactive, supportive and social.

- Personal: Users are encouraged to draw together all strands of the programme and build their own plan or "toolbox" for staying well and managing current and future mood difficulties.
- Interactive: Users can engage with the range of media, such as interactive quizzes, video presentation, online exercises and activities, homework, and mobile diary-keeping. These are meant to encourage reflection and personalization of the information.
- Supportive: Though mainly self-directed, each user in the programme will be assigned a therapist who will support them and provide feedback at specified intervals throughout the intervention on the activities that the user has chosen to share.
- Social: Users can gain a sense of other people using the system be seeing how many people liked an activity, or by sharing answers to an activity that are visible to all after moderation.

SilverCloud is unusual among online interventions for its utilisation of current interactive design approaches.

Mindbalance programme

Mind Balance is a six-module programme built on the SilverCloud platform, incorporating psycho-educational and therapeutic elements of managing difficulties with low mood and depression. The programme draws primarily on the principles of cognitive behavioural therapy (CBT) and incorporates elements of mindfulness.

The first two modules encourage the user to "tune in" to their mood, behaviour and thought patterns and build their own feelings, thoughts and behaviour cycles. The remaining modules focus on supporting the user to challenge behavioural (including physiological feelings) and cognitive (including thoughts, memories, images and attention) aspects of any unhelpful cycles they have identified for themselves. Where users have not generated their own cycles, examples will be provided for users to work with. A module examining core beliefs will be part of the programme but will only be made available to users who have completed the basic content.

Mind Balance has been developed as part of the Technology Enhanced Therapy project funded via the National Digital Research Centre in Ireland and has been developed in partnership between the Mater Community Adolescent Mental Health Service, Parents Plus and Department of Computer Science at Trinity College Dublin.

Service-based use

The SilverCloud online intervention will be used as part of IAPT: Improving Access to Psychological Therapies.[7] IAPT is a recent, centrally-developed, nationally- implemented, service model to implement National Institute for Clinical Excellent (NICE) guidelines for common mental health problems in primary care. It provides high throughput talking therapies at two levels of intensity to the adult population. The higher level provides therapy with a clinical psychologist and the lower level, guided self-help with a trained IAPT worker.

The SilverCloud online intervention will be provided at the lower level of intensity as an alternative to manual-based guided self-help. Participants will receive up to eight reviews on a weekly or fortnightly

basis as agreed with their IAPT worker with the intervention running not more than three months. Participants will have continued use of SilverCloud without support from the IAPT worker for a further four months.

Background

Poor mental health affects about 16% of the population at any one time.[8] Depression is the single most common source of disability in developed countries and is on the increase in many others.[9] In 2005, Richard Lanyard presented a paper to the UK government entitled: 'Mental Health: Britain's Biggest Social Problem,' arguing that poor mental health was one of the biggest causes of misery in the UK and a significant drain on resources, about 2% of GDP.[10] He proposed substantial investment in mental health, including greater access to psychological therapies for common mental health problems such as depression and anxiety.

Lanyard's arguments, including economic ones,[11] have led to the establishment of the Improving Access to Psychological Therapies (IAPT) service model (described above). Following a successful pilot from 2006 – 2009,[12] the program has expanded rapidly. As of March 31 2011, IAPT services are available in 142 of the 151 Primary Care Trusts in England, serving 50% of the population.[7] Recent UK policy documents encourage further expansion providing services to children and older people as well.[13,14] The IAPT service is growing and innovating rapidly, finding the best ways to serve the large need that exists.

Cost-effectiveness is important success measure for IAPT and substantial efforts are made to measure it. Initial evaluations suggest that the cost-effectiveness of IAPT is still borderline[12] and further studies are being undertaken to consider alternative mechanisms to reduce cost, such as phone interventions.[15] The rapid developments in IAPT have yet to include computerised or online CBT interventions despite consistent mention in NICE guidelines and policy documents.[11,13] Online interventions have the potential to expand both provision of, and access to, cognitive behavioural therapies in a cost effective way.

Existing online interventions for depression and anxiety have shown good effectiveness,[1-4] but attrition rates in non-trial settings are high.[5,6] Some researchers are addressing this problem through support of online interventions through the telephone. This decreases attrition, but has cost implications. Other researchers have focused on the "need to respond with a science (and an art) of participation and encouragement."[16] The SilverCloud platform intends to do both. It uses human support, but in a less time-consuming way than telephone or email, and focuses on achieving engagement through interactive features known to work in other domains.[17-19] This pilot study aims to evaluate whether this approach to engagement is successful.

Methods

Design

This pilot is designed as a service-based study to ensure that its results will be applicable in settings in which it is likely to be used. It utilises a mixed-methods approach to understand engagement. Outcome data will be collected to assess whether users have engaged with CBT through SilverCloud; aggregate demographic data explored to understand who chooses an online intervention; log data of the SilverCloud usage will be mined to illuminate both temporal and interactive feature patterns of use; and contextual interviews will link the findings from the log data analysis to users' sense of engagement. The study is organised into two phases: intervention use and contextual interviews.

Setting

This pilot study will take place in the IAPT services in all geographical regions of Cambridge Peterborough Foundation Trust, including Cambridge, Huntingdon, Peterborough and Mid-Essex. This choice will provide a population that is appropriate to the SilverCloud intervention, diversity in socio-economic status and ethnic mix across regions, and enough throughput for recruitment.

This study is done under the auspices of the NIHR-funding Collaborations for Leadership in Applied Health Research and Care (CLAHRC) which has enabled a working relationship between health professionals in the Cambridgeshire Peterborough Foundation Trust and the University of Cambridge.

Data collection for intervention use phase

Participant identification/recruitment/sampling

Participants will be identified during the IAPT service's initial assessment of a person upon entering the service. If they satisfy the following inclusion and exclusion criteria, they will be given a choice between the SilverCloud online intervention and the currently used paper manual for guided self-help.

Inclusion criteria:

- Diagnosis of depression with no co-morbidity of anxiety
- Appropriate for guided self-help in a primary care setting as determined by current IAPT procedures
- Owns a computer and has access to broadband internet
- Chooses to participate
- Gives consent to take part in the research

Exclusion criteria:

- Are not comfortable reading in English
- Do not have adequate reading ability to use a guided self-help intervention
- Have had a CBT intervention within the past year

A person can join the trial up to 14 days after their assessment by contacting their IAPT worker. If they make no contact, a letter will be sent asking them if they want to stay in the service. If a participant chooses the paper manuals, they can switch to SilverCloud up to 28 days after their initial appointment.

We will recruit 30 people with the aim of 25 people completing both the pre and post outcome measures. They will be recruited in order of offer and acceptance of the SilverCloud intervention. There will be no group differentiation at the pilot stage as the sample is small and one of the research questions focuses on who chooses an online intervention.

Withdrawal of subjects

Participants using SilverCloud will have been assessed as being appropriate for guided self-help treatment. If the participant's mental health deteriorates and this is no longer the case, as seen through the participant's session scores and the material reviewed by the IAPT worker, the participant and their data will be withdrawn from the study. The IAPT worker will follow the same procedures currently in place for manualised guided self-help and "step up" the participant to a higher level of care, usually face-to-face treatment.

The participant may decide that they do not like an online intervention and would prefer to switch to the paper-based alternative. This can be discussed in the exchange between the participant and IAPT worker as is currently done if either feels that the treatment approach is not correct. If the IAPT

worker feels that the participant has given this a fair chance, another treatment approach will be agreed upon. The participant will be withdrawn from the study but their data until withdrawal will remain in the study. They will be given the opportunity to answer a question regarding their choice to leave the study.

The number of people withdrawn from the study will be reported and if appropriate compared against step-up data available from IAPT.

Data Collection Tools

Outcome measures

Three outcome measures will be used:

- Beck Depression Inventory (BDI)[20]
- Patient Health Questionnaire (PHQ-9)[21]
- Work and Social Adjustment Scale (WSAS)[22]

Beck Depression Inventory: The 21-item self report instrument is intended to assess the existence of the severity of symptoms of depression according to the DM-IV. The Inventory is a four-point scale ranging 0-3. The BDI scores are analyzed using the BDI score break down; 0-13 minimal depression, 14-19 mild depression, 20-28 moderate depression and 29-63 severe depression. It has been successfully used in the evaluation of online interventions,[3] including in a previous pilot of SilverCloud in a different setting.

Patient Health Questionnaire: The 9-item self report instrument is used to consider symptoms and functional impairment from depression, make a tentative diagnosis, and derive a severity score to help select and monitor treatment. It is a measure stipulated by the Department of Health for all IAPT services.

Work and Social Adjustment Scale: The 5-item scale measures general social impairment and is used in this pilot study to consider wellbeing in addition to level of depression. It is also a stipulated measure by the Department of Health.

Log data

Log data will be collected about application use. This will include:

- Sign-in and sign-out time
- Order, identification of, and time spent viewing pages in the intervention
- Interactive features used and timings of use

No data inputted by the user will be visible to the researcher.

Data collection

The BDI measures will be collected pre and post intervention electronically. The pre-intervention measure will be collected at the first log-in. The post-intervention measure will be sent after eight reviews have been completed. The PHQ-9 and WSAS will be integrated into SilverCloud and collected before each review by the IAPT worker as stipulated by the Department of Health. An automated email will prompt the participant to fill them in two days before their scheduled review. The first measure will be collected at assessment and the last measure will be the one before the last IAPT worker review. Additionally, the PHQ-9 and WSAS will be requested via a link in an email three months after the date of the last IAPT worker review.

Data collection for contextual interview phase

Participant identification/recruitment/sampling
All pilot study participants (excluding those who have withdrawn) will be invited to interview by email following completion of the intervention. They will have been made aware of this part of the study in the original information sheet. It is expected that 1/2 to 1/3 of people will accept the invitation to interview. Participants may leave the interview at any time.

Data Collection Tools
A contextual interview approach that links people's actions in an application with their experience of it will be used to assess engagement.[23] The interviews will be structured in three stages. The first is to establish the participant's view of engagement and to relate it to SilverCloud through word-storming and card-sorting activities. The second will consider motivations for patterns of use, such as temporal use and choices to start and stop. The last section will consider design feature use and preference through forced-choice paper-prototyping[24] of features that represent the four design strategies (personal, interactive, supporting, and social). These will be chosen based on participant's log data. If the interviewee is not forthcoming, the interview questions will use the technique of asking for recommendations for a friend.

Data Collection
Interviews will last 1.5 hours and be held at the most convenient IAPT premises for the participant. They will be audio recorded.

Data Analysis

Outcome data
The outcome data will be analysed for the following questions comparing group means using repeated measures t-tests. The results are intended to address the question of whether SilverCloud decreases depressive symptoms. The results will be considered indicative rather than conclusive given the small sample size.

- Do participants using SilverCloud show a significant decrease in PHQ-9 measures over the period of the intervention?
- Do participants show a decrease in the BDI over the period of the intervention?
- Do participants using SilverCloud show a significant decrease in the WSAS scale over the period of the intervention?
- Are there changes in the PHQ-9 and WSAS at 3-month follow up post-intervention?

Choice of intervention
Descriptive statistics will be used to address the question of who chooses to use SilverCloud. These will focus on demographics, in particular, gender and ethnic minority status as those are known to have low utilisation rates of IAPT,[12] age, as it could affect technology use, and severity of condition, as it can diminish the motivation to use self-help. These will be explored against current case-mix for each IAPT service and the reasons given for people not choosing SilverCloud. The findings will be interpreted carefully given the small sample size and utilised to inform the design of the larger trial.

Log data
Explorative analysis will be done on the log data. It is anticipated to cover the following themes:

- choice of navigation strategy
- pattern of usage over time (e.g. once a week for three months)
- frequency and duration of use

- time spent on different activity types
- usage of interactive design elements
- pathway of activities
- initial and final activity

Contextual interviews
Interviews will be analysed with synthesis methods from contextual design.[23] These include drawing out notions of engagement and their relationship to different design features; understanding the motivations of use; and gleaning specific understandings of the way that design features are used and could be improved.

Bias
Those who chose to use SilverCloud will be a self-selected group. However, we feel that in an initial trial this is necessary as we start to understand what type of group this intervention is appropriate for. This matches IAPT's philosophy of taking into account the choices of its service users between a range of therapy options that best fit their needs and lifestyle.

It is possible that there could be researcher bias in the post+3 months data, but it is necessary to do the interviews as soon as possible once the participant stops using the intervention to ensure the best possible data is gained. This will be considered in the analysis and should not affect the main efficacy study which is looking only at pre and post data.

Timeline
Recruitment and use of SilverCloud is expected to take place over a five month period. Invitation to interview will follow immediately on a participant's completion of the intervention period of SilverCloud. Interpretations and findings of the quantitative and qualitative data will happen in the following three months in preparation for designing a full-scale trial. The final report should be available no more than one year after the start of the trial.

Ethics

Risks, Burdens, Benefits

Risk to participants

- Decreasing mental health

Participants using SilverCloud will have been assessed as being appropriate for guided self-help treatment. If the participant's mental health deteriorates and this is no longer the case, as seen through the participant's session scores and the material reviewed by the IAPT worker, the participant and their data will be withdrawn from the study. The IAPT worker will follow the same procedures currently in place for manualised guided self-help and "step up" the participant to a higher level of care, usually face-to-face treatment.

- Emergency situations

SilverCloud is a platform for managed self-help and is not an appropriate resource for emergency mental health situations. This is clearly stated in the introduction to SilverCloud. Emergency numbers are highly visible on the participant's personal page in SilverCloud.

- Disclosure

The participant has the ability to share material and activities from the intervention. If the IAPT worker determines that there is a risk to the patient or someone in their environment, they have the professional duty to intervene and contact the patient. The program clearly indicates what is shared through the shared paged that both the participant and IAPT worker can see to avoid unintentional disclosure.

- Data storage

Health data is sensitive and must be appropriately secured. SilverCloud utilises industry standard technologies to protect its data. This includes encrypting sensitive and identifiable information in the database using SHA1 encryption a cryptographic hash function designed by the National Security Agency and published by the NIST as a U.S. Federal Information Processing Standard. The information is also combined with a dynamic salt, which ensures that data is one time encrypted cannot be decrypted back even if the database was accessed. Within the team strict password policies and organisation polices ensure data is kept safe at all times. Only essential staff have database and administration system access and all staff members are bound by legal contracts and non-disclosure agreements.

Risk to Researcher

The only contact that the researcher will have with participants is at interviews. The participant group is not unpredictable and the interviewees are self-selecting, so it is unlikely that any problems will arise. The interviews are taking place in IAPT premises so that help is available if needed.

Burdens

- Difficulties of use

There is a risk that some participants may find internet programs unfamiliar and not get started with treatment because they find logging-in confusing. This risk has been minimized by a careful, usable log-in approach; a support video to get started; and the availability of an appointment to support getting started.

- Dislike of online intervention

The participant may decide that they do not like an online intervention and would prefer to switch to the paper-based alternative. This can be discussed in the exchange between the participant and IAPT

worker as is currently done if either feels that the treatment approach is not correct. If the IAPT worker feels that the participant has given SilverCloud a fair chance, another treatment approach will be agreed upon. The participant will be withdrawn from the study but given the opportunity to answer a question about why they chose to switch.

- Interviews

Interviews will take place to understand what aspects of SilverCloud encourage engagement. Due to the stigma attached to mental health problems, some people may find talking about their use of the intervention uncomfortable. The interview activities have been selected to avoid direct discussion of the treatment unless the participants chooses. If the interviewee is uncomfortable at any time, all questions will be related to making recommendations for a friend. The interviews will take place in the IAPT offices to enable access to help if any issue arises.

Benefits

Study participants should benefit from the opportunity to use an online intervention which is both engaging and convenient and as yet, unavailable to the general public. It also provides them the opportunity to contribute to its development if they so wish, something many people are often pleased to do.

All participants will receive an email of the study's findings.

Consent

Participants will be explained the study during their first (assessment) appointment and given the opportunity to ask questions. They will then be sent an informational email with links to the information sheet, explanatory video, and consent form. They will be expected to contact their IAPT worker with their choice of treatment, during which they can ask further questions about the study. Upon indicating to the IAPT worker that they would like to join the study, they will receive log-in details. The electronic consent form will be presented before their first log in.

If participants opt for guided self-help with paper manuals, they will be given and information sheet, and allowed to join the study up to 28 days after their assessment.

Consent will be asked again for those who attend an interview as a reminder of what they have previously consented. The participant will have an opportunity to ask questions by email or make a phone call appointment with the researcher.

Language

SilverCloud is currently an English language intervention. It is necessary that the participants are comfortable reading in English to take part in the intervention as per the exclusion criteria. We therefore do not foresee language issues relating to misunderstanding of the consent form.

Capacity

Capacity to consent will be judged by the IAPT workers with the assumption that if someone is appropriate for treatment at the lower level of intensity in a primary care setting than they have the capacity to consent.

Data Management

Data Handling

Storage of intervention data: Online interventions have data associated with them as part of the intervention, such as activities, measure scores, and communication between participant and therapist. The data specific to the intervention is held in a database in a secure server room in Trinity

College Dublin. Industry standard technologies are utilised to protect the data in the SilverCloud database. This includes encrypting sensitive and identifiable information in the database using SHA1 encryption, a cryptographic hash function designed by the National Security Agency and published by the NIST as a U.S. Federal Information Processing Standard. The information is also combined with a dynamic salt, which ensures that data is one-time encrypted and cannot be decrypted back even if the database was accessed.

The database administration team has strict password policies and organisation polices ensure data is kept safe at all times. Only essential staff have database and administration system access and all staff members are bound by legal contracts and non-disclosure agreements.

Study database: A second database, referred to as the study database, will be used to track participants in the study. For participants, it will contain the email address provided, their IAPT identification number (PCMIS number), and their progression in the trial. For those who chose not to participate, it will hold their PCMIS number and any reason given for not participating. This database will be put in an encrypted container using Truecrypt and stored in the cloud. It will support the coordination of the trial and will only be accessible by the researcher, the IAPT workers, the team leaders, and the system administrator for SilverCloud. It will also enable the researcher to link demographic data from the IAPT system with usage data from the SilverCloud database, and enable aggregate data extraction from the IAPT system.

Transmission: SilverCloud data transmission is protected by 256bit SSL certificate encryption – the same type of security used by tier 1 banking websites such as Barclays and Nat West. The site also uses custom built intrusion detection system which is used to both detect and block security threats.

Interview data: Interview recordings will be kept in an encrypted container on a password protected machine.

Data archiving:
Data in aggregate and anonymised form will be kept on an encrypted hard-drive in a lock cupboard in the Engineering Design Centre, University of Cambridge for five years. Access to the data for follow-up research will be given by the researcher, Dr Cecily Morrison.

Anonymity
The intervention data, study progress data, and demographic/personal data are held in three different databases. Data can be link by the researcher with separate identifiers.

IAPT workers will have access to the activities that the participant has shared for review. It is clearly visible to the participant what is shared with the IAPT worker. The participant can unshared, or delete entirely, their activities at any time. Their log-data and scores on the measures will remain in the system.

The researcher will have access to usage data (e.g. number of logins, pages visited), measures, email address of participants who volunteer for interview and aggregate demographic data. The researcher holds a research passport.

Paying participants

Participants will be offered £20 plus travel expenses to take part in a contextual interview. This incentive is seen as important to avoid getting a bias sample that includes only those with strong emotions (positive or negative) about SilverCloud. We do not believe that it will alter what people tell us as the interview technique is firmly grounded in behaviour and choices and not preferences.

Quality assurance

Delivering therapy through SilverCloud is new to the IAPT workers involved. For this reason, a small number will of IAPT workers will be responsible for the participants. They will be trained by a senior clinician experience in the use of SilverCloud. Initial training will last for 3 hours and individual support will be given during an IAPT worker's first online review.

IAPT team leaders undertake regular supervision of their workers to discuss any issues that arise during assessment or while giving therapy. The two team leaders on the steering group will pay particular attention to the IAPT workers utilising SilverCloud.

Limitations of the pilot study

Small sample size

This study has a small sample size which hinders anything other than descriptive statistics. We do not see this as a problem in this instance as the main focus of this study is the analysis of log data and the contextual interviews. Moreover, as online interventions are fairly new, it provides an important opportunity to consider some of the practicalities of deploying SilverCloud in a service setting and to verify the study design decision, (e.g. mechanisms of recruitment) to enable planning for a larger trial. It is known for example that it can be difficult to recruit for an online interventions because of often incorrect, preconceptions, of how the online intervention works.[25]

Non-stratified recruitment

Many studies stratify recruitment to get an even balance of different parties, such as men or women. As we are keen to see who chooses an online intervention, we have not done this.

Engagement and Dissemination

Engagement

User engagement

SilverCloud was developed using a "user-centred" design approach. This approach uses activities with service users, carers, and the organizations that represent them to determine the best way the design would support them. In this case, service users were drawn from Parents Plus (*www.parentsplus.ie)* and BodyWhys (*www.bodywhys.ie)*.

The design of this pilot study includes further opportunity for service users in IAPT to influence the development of SilverCloud through the interview questions and activities. We expect to make changes based on the views that are expressed before starting the full trial.

Steering group

This protocol has been agreed with a steering group made up of researchers, clinicians, and service managers. It includes the following people:

- Dr Gavin Doherty, Lecturer Trinity College Dublin & SilverCloud development team
- Dr John Sharry, Clinician Mater Hospital Dublin & SilverCloud development team
- Dr James Bligh, SilverCloud developer and manager
- Dr Tina Rothi, Cambridge IAPT team leader
- Mr Martin Liebenberg, Clinical lead for IAPT Services in Peterborough and Cambridge
- Dr Krishna Singh, Clinical director of Primary Care and Liaison Psychiatry Division for Cambridgeshire Peterborough Foundation Trust
- Dr Jamie HackerHughs, Clinical lead for IAPT services in Mid Essex

- Ms Annette Tenerowicz, Service development lead in Cambridgeshire Peterborough Foundation Trust
- Dr David Horne, Information technology consultant

Dissemination

This pilot study is designed to produce findings that are of interest to a range of people. The SilverCloud designers will gain useful knowledge about how they may improve SilverCloud at this early stage. The use of novel evaluation methods will contribute to the growing literature on evaluating online interventions. The findings will also be of interest to other IAPT services that are looking at emerging, cost-effective options for providing talking therapies in primary care. The following outputs are anticipated:

- A report to the SilverCloud designers
- A journal publication
- Presentation at the national IAPT conference

Abbreviations

- IAPT: Improving Access to Psycological Therapies
- CBT: Cognitive Behavioural Therapy
- CLAHRC: Collaborative Leadership in Applied Health Research and Care

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APPENDIX A: Participant information sheet

Technology-enhanced therapy: SilverCloud Study

Information Sheet for Participants

What is this all about?

SilverCloud is an online platform for delivering self-guided interventions for common mental problems. It has been developed by experts in interactive systems to make it an engaging experience.

We are looking for participants 18 years old or above to complete the programme over three months and provide feedback. The programme consists of six modules that you will be asked to complete in your own time and at your own pace over a three month period. Each module contains text, video and audio clips as well as activities and quizzes that you can complete as you go along. You can also interact with the programme through an internet-enabled mobile phone if you choose. You will need reliable internet access to take part in this study and the overall time you will be involved in the study should be two to three hours a week. Please do not take part if you have any known physical or health difficulty which may be affected by viewing material via a computer monitor.

What does taking part involve?

Agreeing to take part

If you agree to take part in the research, contact your therapist. You will then be sent an email with a username that you can use to log-in. When you first log-in to SilverCloud, you will be asked to give consent for taking part in the research. You will also be asked to fill-in a short questionnaire about your mood. This questionnaire will help the research team understand whether the programme has helped you feel better when it is finished. When these are both completed, you will have access to the SilverCloud programme. If you do not wish to take part this will not affect your care in any way.

Initial Telephone Conversation

You will be offered an initial telephone conversation of up to 30 minutes to orient you to the SilverCloud program. This will be arranged by your therapist. During this phone call, your therapist will make sure that you can log-in and provide a brief introduction to the different aspects of the program. At this stage, you can ask any questions you might have about the programme itself and how you use it. There are also orientation videos if you need further guidance to how to use the programme.

Completing the Programme

Once you have had the orientation session, you are asked to begin working through each of the six modules of the programme. You will do this in your own time as it suits you. Each module should take a couple of hours to complete and this can spread out over a number of days.

You will be allocated a therapist who will check-in with you regularly at a pre-determined time. This will happen via the private messaging service that is part of the programme. This check-in will also provide the opportunity for you to access some support if you feel you need it, as well as ask any questions that arise as you work through the programme. As part of the programme, you will be asked to fill-in a number of questionnaires pertaining to your mood to help your therapist understand how best to guide you. You will receive an email 2 days before your therapist reviews your progress to prompt you to fill these in.

Finishing the programme

At the end of the three-month programme you will be asked to fill in a questionnaire online about your mood to help the research team determine whether the program has helped you. At this time your therapist will have brought your treatment to a close and the programme is over. You may continue to use SilverCloud without the assistance of your therapist for a further four months if you choose.

Follow-up Interview

When you have completed the program, you will be invited to a one and a half hour interview with one of the researchers to discuss your experiences with SilverCloud. This interview will NOT discuss your therapy, but will ask you questions about how you used SilverCloud and what you liked/disliked about it. Some of the questions will be based upon how you used the program (e.g. the number of times you signed in). This will require the researcher to view your usage statistics, but she will NOT have access to anything that you wrote or shared with your therapist. The interviews will be recorded so that the researcher can consider your responses at another time.

Taking part in this interview will help the research team make SilverCloud even more engaging for others who use it. If you choose to take part, you will be offered £20 + reasonable travel expenses as compensation for your time and effort.

Follow-up questionnaire

You will receive an email three months after your programme has ended to ask you to fill in a few more short questionnaires online. These will help both the research team and the service determine whether this programme has been helpful in the long-term.

What will be done with the information I give you?

All the information you share with us will be treated in strict confidence by the research team. Your allocated therapist will have your name and contact details (email or telephone number) but feedback that we pass on to the rest of the team will be made anonymous and identified only by an ID code. The online programme is accessed via a secure server and is not publicly available on the worldwide web. In addition, you can decide how much personal information you add to the programme itself as you work through the modules.

What are the benefits and risks of this study?

The programme is designed to help support people with low mood or depression. As you work through the modules you may experience some benefits in this regard. In addition, you will be providing invaluable feedback on this programme to ensure that we develop a

programme that is user-friendly and engaging. This is your chance to be involved in the development of one of the most exciting and recent developments in mental health interventions. Some people may find some of the modules difficult and there is the possibility some of the content may bring up difficult feelings for you. If you find this to be the case, your therapist person can provide support and guidance to you.

In the event that something does go wrong and you are harmed during the research and this is due to someone's negligence then you may have grounds for a legal action for compensation against Cambridgeshire and Peterborough Foundation Trust but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you (if appropriate).

What else do I need to know?

Your participation in this research is entirely voluntary. You can withdraw from this study at any time by contacting either your therapist, or any member of the team. If you choose to withdraw from the study, you can speak with your therapist about alternative treatment. All of your information will be deleted if you withdraw from the study.

After you have completed the programme, it is not possible to withdraw as we summarise all the information together and cannot identify individual responses at that stage.

The information we collect in this research study, including direct quotes, may be used in reports or articles but in a way that your anonymity will be assured. All the information used in such publications will be entirely anonymous or involve numerical summaries. We will never use personal information in any publications related to this research.

What do I do next?

If you are interested in taking part in this research, please contact your therapist in the IAPT service. If you have questions, you may speak with your therapist in the IAPT service or contact the research team

Thank you for your time in reading this.

Please contact:

- *IAPT therapist*
  (Name) IAPT worker
  Phone/email
- *Lead Researcher*
  Dr Cecily Morrison
  cpm38@cam.ac.uk

NOTE: Consent will be taken electronically as this is an online intervention

Technology-enhanced therapy: SilverCloud Study

Participant Consent Form

Researcher contact: Cecily Morrison, cpm38@cam.ac.uk

Please read this page carefully and click the appropriate button to consent. You will receive a copy of the consent form by email.

- I am 18 years and older and understand that I am giving consent to participate in the above research.
- I have read and understood the information sheet related to the above study and have had my questions answered by the research team. The nature and purpose of this research study has been adequately explained to me.
- I understand that my participation in this research study is voluntary and that I may withdraw at any time by contacting my allocated therapist or any member of the research team.
- I understand and agree that the information I provide will be used for scientific and programme-development purposes and I have no objection that my data is published in scientific or other relevant publications in a way that does not reveal my identity.
- I understand that relevant data collected during the study, may be looked at by individuals from the SilverCloud administration team, from regulatory authorities or from Cambridgeshire Peterborough Foundation Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to this data.
- I understand that I will be required to view materials via a computer monitor and if I or anyone in my family has a history of epilepsy then I am proceeding at my own risk.
- I understand that I will be asked to complete questionnaires after completing the final treatment session and will be provided the opportunity to attend an interview.
- I understand that if I choose to attend an interview, the researcher will have access to my usage statistics (e.g. number of log-ins to SilverCloud), but NOT to anything I wrote in SilverCloud nor anything that I shared with my therapist.
- I understand that if I choose to attend an interview, it will be audio recorded. The recording will be destroyed immediately following transcription.
- I consent for direct quotes from my interview to be used in research reports, and understand that these will be anonymous.
- I understand that the data will be kept and destroyed in not less than 7 years time.
- I have received a copy of this agreement by email.

BUTTON: I consent

BUTTON: Exit