Research protocol

The pilot evaluation of an online platform for delivering integrated high-intensity Cognitive Behavioural Therapy for depression (INTERACT Phase 2)

THE interact STUDY

Study Identifiers

Research Programme: The INTERACT Study

Co-ordinating Centre: University of Bristol

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Short title: Pilot evaluation of integrated CBT for depression (INTERACT Phase 2)

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Background:

Cognitive Behavioural Therapy (CBT) is an effective treatment for depression. Substantial investment in the Improving Access to Psychological Therapies (IAPT) services (Department of Health, 2011) has increased provision of brief, low intensity interventions in England. However, there is still a substantial variation in the provision of high intensity treatments (Radhakrishnan et al., 2013).

Computerised CBT interventions (cCBT) were designed to make CBT more accessible and widely available at lower cost. However, adherence to cCBT is often poor and, in the absence of therapist support, effects are modest and short-term (Richards & Richardson, 2012). Moreover, cCBT is often inflexible and does not allow identification of conditional beliefs or detailed formulations (Helgadottir et al., 2009), yet the latter are crucial elements of CBT.

Delivering CBT online by therapists using instant messaging is clinically and cost-effective (Kessler et al., 2009; Hollinghurst et al., 2010). However, most existing platforms are limited to instant messaging sessions only, without the support of "homework" activities between sessions. Moreover, they also depend on the access to online sessions via a desktop computer, which can be a barrier to those who do not have access to a computer or have to share one with family members. Making the platform also available on mobile devices could address these barriers, especially given that the use of smartphones and tablets to access the internet has greatly increased over the last 10 years: currently, 76% of UK adults own a smartphone and 58% own a tablet (Ofcom, 2017). Therefore, interventions that incorporate online resources accessed via mobile devices may reach more effectively into people's lives, allowing more immediate recording of thoughts and experiences. Mobile devices may also enable discreet and convenient completion of worksheets (such as thought diaries) thereby addressing concerns about the risk of "getting caught" completing homework tasks in public (Barnes et al., 2013). Use of such devices may therefore increase engagement with CBT "homework" which is an important mediator of outcome (Westra et al., 2007; Mausbach et al., 2010).

The INTERACT study is a 6-year programme of research funded by the National Institute for Health Research (NIHR PGfAR) that aims to integrate online CBT materials and high intensity therapy from an accredited therapist to deliver effective CBT to those who need it. This could save costs and increase availability, including for those for whom access is difficult (e.g. working full-time/living in remote areas/with caring responsibilities and hard-to-reach groups).

The project brings together a large multi-disciplinary team, including mental health academics and practitioners, human-computer interaction researchers, software engineers and end users. It consists of three stages: 1. the development of an online platform for delivering integrated high-intensity CBT for depression, 2. the pilot evaluation of the platform, and 3. a randomised controlled trial (RCT) to fully evaluate the clinical and cost effectiveness of our integrated approach to CBT for depression. The protocol for the present study relates to the second stage of the INTERACT programme, i.e. the pilot evaluation.

Aims:

This study aims to explore primary care patients' and therapists' views and experiences of the platform developed during the first stage of the INTERACT programme, in order to ensure that the online platform and CBT materials are acceptable to patients and therapists; and to identify

areas for improvement and ways in which they can be addressed prior to the planned RCT. We have built in sufficient design and programming capacity to respond to this learning.

Overview of planned work:

We will be running several design and evaluation activities to enable us to test the platform and revise its design based on multiple types of user feedback. The study will consist of three strands of work running in parallel:

1. A longitudinal evaluation study with **12-16 primary care patients with depression**, who will receive a full course of treatment delivered by a therapist through the platform
2. Participatory design work with **2-3 therapists** delivering the therapy, and their clinical supervisor(s). These individuals will also act as co-designers and provide ongoing feedback
3. Usability testing sessions with **9-12 people who received CBT in the past**, who will test specific changes to the platform arising from patient and therapist feedback

Each strand of work is described in detail below.

1. Longitudinal pilot evaluation of the platform with primary care patients

Participant recruitment:

We aim to recruit 12-16 primary care patients from 2-4 GP practices in the Bristol area. These practices will be purposefully selected to include a mixture of affluent and more deprived areas.

It is important that the individuals recruited to take part in this platform evaluation are recruited in the same way as those who will be approached to take part in the large-scale randomised controlled trial (RCT) that will follow on from this work. Therefore, the inclusion/exclusion criteria for the present study will mirror the inclusion/exclusion criteria for the main RCT.

Inclusion and exclusion criteria:

We will include those who: are aged 18 years or older; score ≥14 on Beck Depression Inventory (BDI-II; Beck et al., 1996); and meet ICD-10 criteria for depression (CIS-R; Lewis et al., 1992; Lewis, 1994).

We will exclude individuals who have major alcohol or substance use problems (in the past year); bipolar disorder, psychosis or dementia; who cannot complete questionnaires unaided; are currently receiving CBT, other psychotherapy or secondary care for depression; have received individual, high-intensity CBT in past 4 years; are taking part in another research study; or who need an interpreter. See “Assessment of eligibility” below for more details.

The broad inclusion criteria will result in a heterogeneous population (those with a new episode of depression who prefer psychological treatment; those who have not responded to initial treatments; those with severe/chronic depression). These are all groups for whom psychological interventions are recommended by the National Institute for Health and Care Excellence (2009) and are effective.

Recruitment of general practices:

GP practices will be sent a letter *('Invite letter to GP'*) and information sheet *('GP information sheet'*), inviting them to participate in the study. The study team will contact interested practices to provide further information.

Patient recruitment procedures:

Participating GPs will be able to refer patients directly to the research team and searches of practice electronic records will also be used to identify potential participants.

For recruitment during a consultation, the GP will explain the study to the patient, give them an information leaflet *('Participant Information Leaflet for patient (Longitudinal Study)'*), and then ask for permission for their details to be passed onto the research team. If they agree, the GP will send a referral form *('GP referral form')* and the patient's completed permission to contact form *('Permission Release Details')* to the research team by fax. Researchers will then contact potential participants to assess their eligibility (see the next section for details).

The search of practice records will be conducted by practice staff, or by Clinical Studies Officers if the practice requests support. Potential participants will be mailed an invitation letter *('Invitation to participate (GP record search)')* and an information leaflet *('Participant Information Leaflet for patient (Longitudinal Study))'* about the study by their GP practice, asking whether they are willing to be contacted by the research team. Potential participants will be asked to return a reply slip to the research team in a pre-paid envelope. A reminder will be sent by the practice to those who do not respond to the initial invite *('Invitation (GP record search) reminder'*). Those who do not wish to participate will be asked to indicate on the reply slip their age, gender, and reason for non-participation, in order to assess the generalisability of findings. They will also be able to indicate whether they would be happy to take part in a brief telephone interview to discuss their reasons for non-participation. The interviews will be conducted by KT or DT, and will provide additional information on the acceptability of the proposed intervention and its presentation to potential participants. These interviews will take place within a month of receiving the reply slip and will last approx.15 minutes. They will be audio-recorded and verbal consent will be taken (*'Topic guide for decliners')*.

Assessment of eligibility:

Those who agree to being contacted will be telephoned by a researcher to explain the study and conduct brief telephone screening ('Longitudinal study phone screening questionnaire') to assess whether they are eligible for a baseline visit. Those who meet the telephone screening criteria will be invited to attend a face-to-face baseline appointment with a researcher to further establish eligibility and to discuss the study in more detail and answer any further questions they have about taking part. The baseline appointment will take place at patient's home, GP surgery, the University of Bristol or another mutually convenient location. The researcher will ask the patient to provide written informed consent to complete the screening questionnaires *('Consent form for pilot CBT evaluation (Part A)'*), and will be given a copy to keep.

At this face-to-face appointment, potential participants will be asked to complete the Beck Depression Inventory (BDI-II; Beck et al., 1996) as a measure of their depressive symptoms and to complete the computerised version of the Clinical Interview Schedule – revised version (CIS-R; Lewis et al., 1992; Lewis, 1994) to establish whether they meet ICD-10 criteria for a depressive episode. Additional information will be gathered on socio-demographic details (age, gender, ethnicity, marital status) and markers of socio-economic status (employment

status, housing situation, financial stress) as well as information on their current depressive episode, history of depression and use of/adherence to antidepressant medication.

To enable comparison with IAPT data, eligible participants will also be asked to complete additional measures of depression (PHQ-9; Kroenke et al., 2001) and anxiety (GAD-7; Spitzer et al., 2006). The baseline assessment will usually last 60-90 minutes. Those who are eligible will be asked to provide further written consent to participate in the longitudinal study, including the CBT therapy and research interviews ('Consent form for pilot CBT Evaluation (Part B)'), and will be given a copy to keep.

For those individuals who are eligible and take part in the CBT therapy and interviews, we will offer a £10 gift voucher for participation in each interview. We can also reimburse reasonable travel expenses to attend the face-to-face research interview.

Contact with the GP:

We will inform the patient's GP of the outcome of the screening process, and inform them when the patient has completed (or withdrawn from) the therapy and/or study. Should any concerns about safety (of the participant or others) be identified as part of the recruitment process, therapy, or qualitative interviews, the team will follow the study's safety protocol. This may involve contacting the patient's GP to pass on risk information, and this will be explained in the Patient Information Leaflet and mentioned in the Consent Form.

Details of CBT therapy that will be provided:

The INTERACT protocol utilises the standard Beckian intervention for depression (Beck et al, 1979; Beck 1995). In considering the detailed content of Beck's intervention for depression, we refer to the UCL competence framework for CBT (UCL, n.d.-a) and the problem specific competences (UCL, n.d.-b).

Participants will receive up to nine one-hour sessions led by a therapist. Therapy will be provided on an individual basis by an accredited CBT therapist who will receive supervision in accordance with professional (BABCP) standards and local NHS practice. Therapists will be employed or seconded to the study one month prior to the start of delivery of therapy in order for them to receive training in the use of the platform and study procedures, and to enable them to familiarise themselves with the range of resources available.

The first therapy session will take place face-to-face and patients will be advised that this therapy session may take longer (up to 90 minutes). This longer duration will enable completion of history taking, introduction of the CBT model and other relevant psychoeducation. In addition, therapists will be expected to help the patient become familiar with the INTERACT platform. This first session will take place in the patient's GP surgery or other local NHS premises.

Participants will receive login details to the platform before the first session to enable them to familiarise themselves with the platform prior to this first session. They will also be asked to provide some brief details about the problems that bring them to therapy, previous treatment, depressive symptoms (using the PHQ-9) and to plan for their first session within the platform. The therapist will be able to answer any queries regarding the platform during the first session.

Participants will be able to view the various psychoeducational resources within the platform when they log in but other worksheets/resources will be released as appropriate (tailored to the individual) by the therapist during treatment.

Subsequent sessions will take place online using the INTERACT platform. This platform enables the patient and therapist to communicate online in real-time and to use a collaborative workspace to view, edit and discuss CBT resources within the platform. Online communication will take place using instant messaging and may also involve voice communication. As per standard face-to-face CBT, therapists and patients will agree tasks ("homework") for the patient to try out between therapy sessions. These tasks will utilize CBT worksheets/other materials embedded within the INTERACT platform. Patients will also be able to access transcripts/audio-recordings of their online sessions.

In order to help facilitate engagement with the intervention and platform, the platform will allow patients to send their therapist a message between sessions, e.g. if they need advice or clarification regarding an agreed between session task, or are struggling to use the platform. Patients will be advised that therapists will aim to respond within 3 working days to such messages.

The expectation is that the first four one-hour therapy sessions will take place weekly. Later therapy sessions may be spaced at fortnightly or monthly intervals. In such instances, therapists may schedule a shorter 'check-in' (max. 20 minutes) between regular therapy sessions. The purpose of 'check-ins' is to facilitate engagement and to briefly review tasks; agree additional tasks to be undertaken before the next session; and/or check if patients experience any problems using the platform. Therapists may schedule up to 3 such 'check-ins' but time for these should be part of the total maximum contact time of 9 hours set out in the protocol.

At the end of therapy, patients will be offered the opportunity to download materials from the platform for future use. The patient's GP will be informed that they have completed therapy; if they withdraw from therapy; or are discharged for non-attendance.

Fidelity to the CBT model:

All the CBT sessions will be recorded using transcripts of instant messaging sessions or audio-recordings of voice communications. Recordings may be reviewed by the therapist and their clinical supervisor as part of the clinical supervision process. All recordings will be anonymised (indexed by study number only) and will be stored securely on a password-protected computer at the University.

Patients will provide optional informed consent to their therapy transcripts and/or recordings being accessed for research purposes. Where consent has been provided, recordings will be randomly sampled for fidelity testing. CBT experts within the research team will evaluate fidelity to the CBT model using a recognised CBT rating scale (Blackburn et al. 2000).

Platform evaluation procedures:

As part of this design process, it is important that early feedback from patients receiving therapy can be incorporated into the platform and then the improved design evaluated with patients who commence at a later time. Therefore, we will be recruiting 12-16 participants over a period of three months.

To gather initial views on the platform, its content, and the experience with this integrated approach to delivering CBT, participants will be interviewed by a researcher over the telephone after their second or third therapy session (*'Platform evaluation – Initial patient*

interview guide'); the interviews will take 15-45 minutes. Patients will be interviewed again once they have completed the therapy. This second interview will be held face-to-face with the researcher and will explore patients' views and experiences of receiving integrated CBT, their views of the platform, and their reflections on how the platform has changed based on their feedback (*'Platform evaluation – Final patient interview guide'*); the interview will last 60-90 minutes. During the final interview participants will be asked to complete the standardised System Usability Scale (SUS; Brooke, 1996; Bangor et al., 2009), which asks about subjective experience of using the system, including its perceived effectiveness and efficiency, and users' satisfaction. SUS will be used to guide the discussion and elicit further feedback. Those who withdraw from therapy or are discharged for non-attendance will also be interviewed to understand their reasons for this decision and/or explore how the platform could better facilitate engagement (*'Platform evaluation – Discontinuation patient interview guide'*). All interviews will be audio-recorded and fully transcribed. Consent to record interviews will be obtained as part of the initial baseline consent process, and at the start of the interview the researcher will verbally check that the participant is still willing to be recorded.

Throughout the study, through a feedback form available on each page of the platform, participants will be able to report any issues with the platform or share their comments on its functionality and available materials. Anonymous feedback will be sent directly to the design team, and will not be available to therapists or other participants. In addition, before each session, patients will be asked to set an agenda for their next therapy session, and as part of this the form will include questions about how patients are getting on using the platform and whether they need any technical help. Answers to the technical questions will be shared anonymously with the design team. As this is an evaluation study, participants will be made aware that the user interface (e.g. button labels or placement of items) may change during their treatment based on feedback. We will ensure that these changes do not interfere with their therapy (see the section 3 on *Usability testing sessions,* for details).

To gain a better understanding of the blended approach to CBT and the role of technology, whenever users log in to the platform, their behaviour will be automatically logged, including login dates, worksheet views, interactions with resources, interactions with the therapist through the platform (e.g. filling worksheets recommended by the therapist, sharing responses), duration of online therapy sessions etc. We will also log the user flow through the system, i.e. the order in which patients and therapists visit specific pages or access resources, to better understand the effectiveness of prompts (e.g. do people click on links in the reminder emails?) and patients' behaviour (e.g. do they explore the psychoeducational materials on their own or do they only read materials shared by the therapist?). The logged data will be limited to types, frequency, duration and order of interactions and will be available to the research team on an on-going basis and used for research purposes to inform the development of the platform. The recording, and use of, such data will be made clear to participants.

As a default, therapy session transcripts, worksheets and PHQ-9 scores collected during therapy will be available only to the patient, their therapist and the clinical supervisor/clinical PI. The research team will not have access to any content posted by participants during therapy sessions unless participants provide written consent to make this available to the researchers.

The consent form *('Consent form for pilot CBT evaluation (Part B)'*) will ask participants whether they are willing to (optionally) share their session transcripts, recordings, completed

worksheets and PHQ-9 scores with the research team for research purposes. Where patients have consented to share this information, data will be reviewed by the research team to understand how people are using the system, to inform the design improvements prior to the RCT, and also (as outlined earlier) review fidelity of the CBT intervention being delivered.

Data analysis:

Data collection and analysis will proceed in parallel, so that analytical insights from earlier data can shape later data collection. The data gathered will be analysed thematically, as this will enable comparisons to be made within and across the interviews. This approach will entail members of the research team reading and re-reading transcripts to gain an overall understanding of the patients' views and experiences, and to identify emerging themes and develop a coding frame. Transcripts will be independently coded by different researchers, who will then meet to discuss their coding and interpretation of the data. This will help to control for researcher bias and may lead to the coding frame being revised, with new codes being added and existing codes being removed or defined more clearly. Once the coding frame has been agreed, transcripts will be uploaded to the software package NVivo, so that data can be electronically coded and retrieved. The SUS scores gathered during the interviews will be analysed and interpreted following the instructions from Bangor et al. (2009).

Usage statistics (e.g. number of views per page or per resource, frequency of access, etc.) will be aggregated to identify the most commonly used as well as 'underused' features and materials. Activity and session logs will be first analysed separately for each participant to understand how they used the platform, and later will be aggregated to identify wider usage patterns. Usage statistics and session logs, together with feedback provided by the participants via the platform's feedback mechanism and agenda setting tool, will allow us to identify any areas that require further improvements and clarifications, e.g. unclear labels, confusing workflow, materials that are difficult to understand. Reported issues will be addressed on a case-by-case basis: small tweaks, as well as critical issues that could make the system unusable or annoying, or could potentially interfere with therapy, will be fixed and changes deployed straight away. Any bigger changes (e.g. changing the steps required to fill in and share a worksheet) will be tested during separate usability testing sessions before being deployed (see Section 3).

2. Participatory design with therapists

Therapist involvement:

2-3 therapists will deliver the therapy. Therapists will be accredited CBT practitioners from local psychological services (e.g. IAPT) who will work with the research team to deliver therapy for this evaluation study. Clinical supervision will be arranged in accordance with professional standards (BABCP, n.d.). The therapists' role during the evaluation study will be twofold: they will deliver the therapy and at the same time they will be acting as co-designers, providing ongoing feedback on the platform and helping to improve it.

Even though therapists will be working as co-designers as part of their role, they will also be asked if they are willing to take part in research activities. They will be given an information sheet (*'Participant Information Sheet for Therapists*') and asked to complete a consent form indicating their willingness to take part in participatory research activities and for their information (e.g. anonymised transcripts and demographic data) to be used as part of this

research (*'Therapist Consent Form'*). If they consent, they will be asked to complete a short questionnaire (*'Therapist & supervisor demographics questionnaire'*).

Training on delivering CBT using the platform, as well as an introduction to co-design, will be provided to therapists and their clinical supervisor(s) at the start of the study. Training sessions will be audio-recorded and other researchers may be present to observe and take notes. Audio-recordings, transcripts and observer notes will be used for the purposes of documenting and improving the training sessions, and informing the qualitative interviews later in the study. Technical support will be provided by the design team throughout the study.

Participatory design procedures:

As part of the training programme, therapists and supervisors will be introduced to the user-centred design process and trained in principles of participatory design. This will allow us to engage the therapists and supervisors fully in the design process as co-designers, whose role will be to gather information and feed back to the design team throughout the study.

Therapists' feedback will be gathered in several different ways. They will be asked to regularly report on their experience (what they like, what causes problems, what could be improved) using the built-in feedback mechanisms and will participate in fortnightly debriefing sessions with the HCI researcher (lasting 15-30 minutes) to elaborate on the feedback they submitted and to discuss potential improvements. In addition, every 4-6 weeks the design team will conduct 60-90 minute design discussion sessions with the therapists to talk in more detail about the platform, their interactions with the patients, integrated therapy as a whole, resources that are available, and any improvements to training materials based on their interactions with the platform. We will also use the design sessions to discuss paper prototypes representing proposed improvements to the platform that arise from the ongoing feedback. These sessions will inform the ongoing improvements to the platform and therapists will be able to suggest changes and comment on the design. During each session, therapists will also receive the standardised System Usability Scale (SUS; Brooke 1996, Bangor et al. 2009), which will be used to guide the discussion. The monthly sessions will be conducted individually or in groups, depending on therapists' availability.

After the therapists have completed CBT with all their allocated patients, they will be interviewed individually in order to gain a deeper understanding of their experience in delivering integrated therapy. The interviews will be face-to-face, take 60-90 minutes, and will be conducted by a researcher not involved in the co-design process to ensure unbiased approach (see *'Final interviews with therapists – interview guide'*). Interviews will be held at the therapist's workplace or the University of Bristol.

About 3-4 weeks after the last therapist interview, therapists will be invited to a final focus group to discuss the main points raised in the final interviews and identify any final changes to the platform that may still be needed; the focus group will take up to 90 minutes, will be facilitated by the HCI researcher, and is likely to be held at the University of Bristol.

We will also interview the clinical supervisor(s) to understand better how the platform is used in the supervision process and how this could be improved during the RCT ('I*nterview guide for clinical supervisor'*). Supervisors who used the platform to support supervision will also be invited to the final focus group and asked to complete the SUS (adapted) questionnaire. We will also ask supervisors to answer a brief demographics questionnaire (*'Therapist & supervisor demographics questionnaire'*). All will be provided with an invitation letter (see

'Invite letter – supervisor') and information sheet *('Participant information sheet for clinical supervisors'*), and asked to complete an informed consent form *('Clinical Supervisor Consent Form'*).

All debriefing sessions, design discussion sessions, focus groups, and interviews with therapists and supervisors will be recorded with consent. Recordings of the debriefing sessions will be summarised to extract key issues and identify areas for improvements. Design sessions and the focus group will be partially transcribed to ensure key parts of the discussion are captured. Final interviews will be transcribed in full. All transcripts will be analysed in detail to identify broader themes highlighting the factors that influence the experience of conducting integrated therapist and online CBT.

Throughout the study, all therapists' actions within the system will be automatically logged: login dates, visited pages, comments added, worksheet review dates, etc. In addition, we will also track detailed interactions with the materials: what worksheets therapists recommend to and/or share with patients the most often, whether they modify them, what modifications they make before sharing, etc. Therapists will be informed at the beginning of the study that this information will be collected automatically by the platform and that it will be used to help us improve the materials for the platform to be used in the RCT.

The platform will also record any editing of online CBT worksheets (i.e. information added by therapists and patients) and therapy voice communication / instant messaging transcripts, but access to this information will be restricted to the patient, therapist, and their clinical supervisor(s) for the purposes of delivering the therapy, unless patients provide additional (optional) written consent for this information to be shared with the wider research team. Where consent is provided, this information will be used to understand how the online CBT worksheets are used, to inform improvements to the platform's design, and to undertake CBT fidelity testing.

Data analysis:

The feedback submitted by therapists using the platform's built-in feedback mechanism will be reviewed on a regular basis to help us identify areas that require improvements and clarifications (e.g. unclear labels, confusing workflow). Reported issues will be addressed on a case-by-case basis: small tweaks, as well as critical issues that could make the system unusable, annoying, or could potentially interfere with therapy, will be fixed and changes deployed straight away. Any bigger issues will be noted and discussed during debriefing sessions in more detail. Proposed improvements to the platform arising from the feedback will be discussed and evaluated during design sessions.

Affinity mapping (Beyer & Holtzblatt, 1998) will be used to analyse the data from debriefing sessions, design sessions and the final focus group. It is similar to thematic analysis (Braun & Clarke, 2006) but uses diagrams and visual thinking to identify themes, and therefore is frequently used in design research (Rogers et al., 2013). Session transcripts will be coded by researchers and codes moved onto post-it notes, which will then be grouped into clusters to identify common issues, areas for improvement, and new ideas for improving the platform and integrated approach to CBT in general. Transcripts of therapist interviews will be independently coded by different researchers, who will then meet to discuss their coding and interpretation of the data. The SUS scores gathered during the interviews will be analysed and interpreted following the instructions from Bangor et al. (2009).

3. Usability testing sessions

Participant recruitment:

We aim to recruit 9-12 people who have received high-intensity CBT for depression in the past (face-to-face and/or online) who are now well enough to participate. We will recruit individuals who have completed CBT within psychological services in Bristol and the surrounding area.

Individuals who are eligible to participate are those:

(i) aged 18 years or older,
(ii) have a history of depression, and
(ii) who have previously had high-intensity CBT for depression (online and/or face to face).

Excluded will be individuals who are unable to complete questionnaires; those who have not received CBT for depression; those who currently are receiving treatment from a psychiatrist for depression; or those who have a history of bipolar disorder, schizophrenia, personality disorder, or substance misuse/alcohol addiction (in the past year), or are currently not well enough to attend a session. In addition, we will exclude participants who took part in Phase 1 of the INTERACT project.

Clinical/Service leads at local psychological services will be asked to help identify potential participants to take part in the usability testing sessions (*'Invite letter service lead usability testing'*). Staff based within the service will conduct an electronic search of their client records to identify those individuals who meet our eligibility criteria and who have received high-intensity CBT. A Clinical Studies Officer can provide assistance with the record search and mail out if required. An invitation letter (*'Invite IAPT patient for usability study'*) and information leaflet (*'Patient Information Leaflet – usability'*) will be mailed out to potential participants by the clinical team. Those who are interested in taking part will be asked to respond directly to the research team. A reminder letter (*'Invitation reminder IAPT patient'*) will be sent (by the clinical team or CSO) to those who have not responded after 2 weeks. Those who do not respond to this reminder letter will not be contacted further.

Those who express an interest in taking part (via any of the above routes) will be contacted via phone by a member of the research team to discuss in detail what taking part would involve. Potential participants will be asked to provide brief socio-demographic details, details of their depression history and CBT treatment received in order to establish that they fulfil the eligibility criteria for the study (see *'Interact Usability Testing Participant Screening Questionnaire'*). Those who are eligible and agree to participate will be asked for their availability and will be contacted later by the researcher who will confirm session dates.

For those individuals who take part, we will offer to pay reasonable travel expenses and, as a thank you and in recognition of the participant's time, we will offer a £10 gift voucher for attending a session.

Procedures:

We will conduct three rounds of face-to-face usability sessions. The first round will take place 6-8 weeks after the start of the evaluation (to ensure the designs we are testing incorporate early feedback from participants and therapists) and the remaining two rounds will take place approximately every 4-6 weeks.

In total, we will recruit 9-12 participants; 3-4 participants will test our platform and improved designs in each round. Usability testing sessions will be conducted with each participant individually at University of Bristol and each session will last 45-60 minutes. Each participant will only be asked to attend one session.

Upon arrival, participants will be given an opportunity (in addition to the earlier telephone call with a researcher) to ask any questions about the study or taking part, and will then be asked to give written informed consent to their participation *'Consent form for usability testing'*. Once consent is obtained, participants will be asked to complete a brief questionnaire about their background, depression and treatment history *'Usability participant session questionnaire'*.

Participants will then receive a list of representative tasks to complete (e.g. completing a specific worksheet and sharing it, starting an online chat, reading specific psychoeducational materials; see *'Usability testing – example tasks'*) and will be asked to talk aloud while they complete them. The session would be audio-recorded and interactions with the system visible on screen will be captured with consent. At the end of the session, participants will be asked to fill in the SUS (adapted) questionnaire and rate the system as a whole.

Tasks will be the same for all participants in each round. The sessions will focus on testing features updated in response to feedback provided by patients receiving the therapy (see Section 1), with significant changes (e.g. changing the order of actions in sharing a worksheet, adding a new section to the navigation menu) being prioritised to ensure any deployed updates do not interfere with therapy.

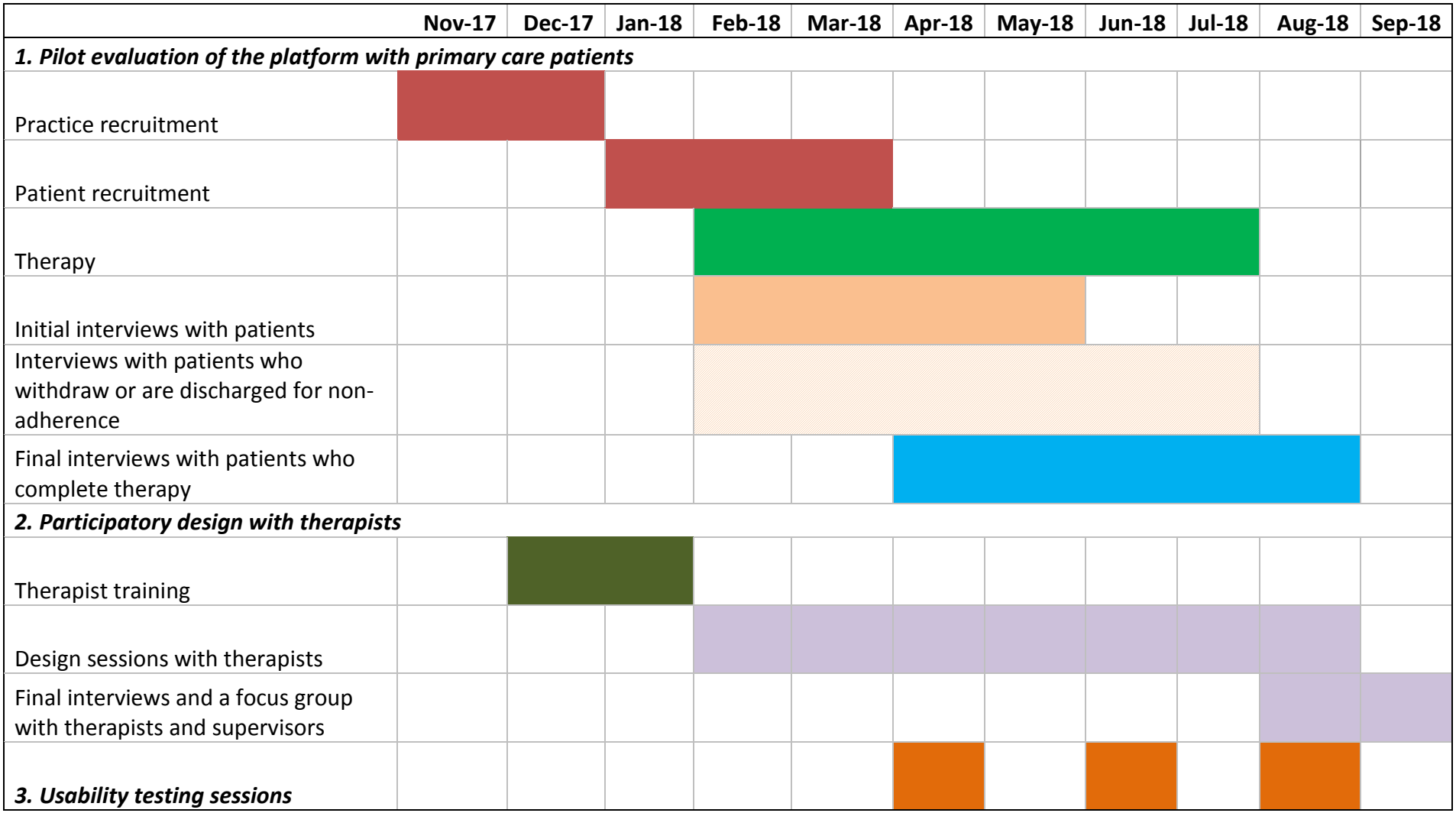
The HCI researcher will moderate the sessions and another researcher will be present to take notes. Together with participants' feedback, interaction recordings will be used for analysis of users' interactions (where people click, when they hesitate, whether they overlook specific features, etc.) and will help to identify problematic features and areas for improvement.

Data analysis:

The analysis of usability testing sessions will be task-oriented to ensure that the outcome is centred on users' needs (Rubin & Chisnell, 2008). The results will be summarised by the task they relate to, as the task represents the viewpoint of the user and a goal they are trying to achieve (Rubin & Chisnell, 2008). On the task level, types of issues will be counted to identify the most common and the most serious ones (Wixon & Wilson, 1997) that need to be addressed immediately. The SUS scores will be analysed and interpreted following the instructions from Bangor et al. (2009).

Timeline:

See the following page


Nov-17
Dec-17
Jan-18
Feb-18
Mar-18
Apr-18
May-18
Jun-18
Jul-18
Aug-18
Sep-18
1. Pilot evaluation of the platform with primary care patients
Practice recruitment
Patient recruitment
Therapy
Initial interviews with patients
Interviews with patients who withdraw or are discharged for non-adherence
Final interviews with patients who complete therapy
2. Participatory design with therapists
Therapist training
Design sessions with therapists
Final interviews and a focus group with therapists and supervisors
3. Usability testing sessions

Data and record keeping:

The nature of the project will require record keeping of both paper and digital data. Table 1 provides details of how data will be stored, how the access to the data will be controlled, and who will have access to each type of data collected.

Table 1. Data storage and access

Type of data	Storage details	Access
Paper data (including signed consent forms)	Locked filing cabinets at the University of Bristol, within the offices of members of the INTERACT team.	Keys available to the key researchers only. Access to the offices is restricted to staff with authorised UoB passes.
Digital information (including interview transcripts)	Encrypted network drive at the University of Bristol. Data from interviews and usability testing sessions will be fully anonymised. Every participant will be given a research code and this code will replace identifiable information in the data. The personally identifiable information like name, etc will be kept in a separate database from the one with data.	Access to the password protected data will be given only to those named in the application. The personally identifiable information will be accessible only to key researchers and Principal Investigators.
Audio recordings	Encrypted voice recorders will be used. Data will be stored on the University of Bristol's encrypted network drive. Care will be taken not to mention names in the audio recordings and the recordings will be destroyed once transcripts are produced and checked.	Access to the data will be given only to key members of the team. Patient interviews and final therapist interviews will be transcribed by an external service approved by the University of Bristol. Password protected recordings will be sent to them via the transcriber's secured deposit service to ensure security and confidentiality. Completed transcripts will be downloaded from the secure deposit service. Audio-files and transcripts will be deleted from the transcriber's deposit service after they have been downloaded and checked by the research team.
Clinical data	The therapy details and any content generated by the patients and therapists will be stored on the secure platform. Prior to the evaluation start, the platform will be audited by independent security professionals ("penetration testing") to ensure data storage and access to the platform are secure.	Therapists and clinical supervisor will have access to clinical data. Researchers will have only have access to therapy transcripts, audio recordings and the content of completed worksheets if patients provided explicit (optional) consent for their clinical data to be shared with the research team.

Sponsorship and funding:

The study is sponsored by the University of Bristol. The Sponsor has arrangements in place to manage and monitor the research. Funding for this project is provided by National Institute for Health Research (NIHR) Programme Grants for Applied Research (reference: RP-PG-0514-20012).

Ethics and regulatory approvals:

This protocol and related documents has been approved by the South West – Central Bristol Research Ethics Committee (REC reference: 17/SW/0243) and the Health Research Authority (IRAS ID: 235168). Any subsequent protocol amendments will be submitted to the REC and HRA as applicable, on the agreement of the Sponsor.

Participant Safety

If the researcher becomes concerned for the safety of a patient participant (for example, if the participant expresses suicidal ideation or recent self-harm at any point during participation, including during the screening call) or is concerned about the safety of others, the researcher will follow the study's detailed patient safety protocol and seek advice from the Principal Investigator with clinical responsibility (Clinical PI) or nominated deputy clinician. If suicidal ideation is expressed, the researcher would speak to the patient about this, encourage the patient to speak to their own GP, and seek permission from the patient to pass the clinical information to the GP. Should the patient refuse permission, the Clinical PI would assess the risk information and call the patient if necessary. The Clinical PI would break confidentiality and pass information to the patient's GP without the patient's consent if this was deemed necessary to protect the safety of the patient and only if the patient continued to decline to give permission for their GP to be contacted: this would be explained in the patient information sheet.

We will develop a detailed, study-specific standard operating procedure for reporting and recording adverse events in line with our Sponsor's requirements. This will be in place prior to the commencement of recruitment activities.

Insurance:

The University of Bristol has arranged Public Liability insurance to cover the legal liability of the University as Research Sponsor in the eventuality of harm to a research participant arising from management of the research by the University. The University of Bristol holds Professional Negligence insurance to cover the legal liability of the University, for harm to participants arising from the design of the research, where the research protocol was designed by the University. The University of Bristol's Public Liability insurance policy provides an indemnity to employees for their potential liability for harm to participants during the conduct of the research.

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