ISRCTN14850613 https://doi.org/10.1186/ISRCTN14850613

Pilot evaluation of integrated CBT for depression

Submission date
05/02/2018

Recruitment status
No longer recruiting

Registration date
19/02/2018

Overall study status
Completed

Last Edited
19/06/2020

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
CBT is an effective treatment for depression. Investment in the Improving Access to Psychological Therapies (IAPT) services has increased provision of brief, low intensity interventions in England. However, variation in the provision of high intensity CBT treatments remains. CBT-based computerised interventions (cCBT) were designed to make CBT available at low cost and have often been delivered as low intensity interventions with minimal or no practitioner support. However, engagement with cCBT is poor and, in the absence of support, effects are modest and short-term. Using technology and integrating online materials into therapy could increase efficiency, reduce costs, and widen access to therapy, whilst maintaining the long-term effectiveness of CBT delivered by high intensity therapists. We are developing a new intervention that will blend high intensity therapy with innovative use of technology to maintain effectiveness of face-to-face CBT. The aim of this study is to explore the views of service users, therapists and their clinical supervisors regarding the new online platform to ensure that the platform and CBT materials are acceptable, and to identify areas for improvement prior to a large study.

Who can participate?
The longitudinal study involves patients from GP practices in the Bristol region. Participants are 18 years or older and have a diagnosis of depression. The usability testing study involves patients recruited from psychology services in the Bristol area. Participants are 18 years or older and have received individual 'high-intensity' CBT for depression

What does the study involve?
Those invited to take part in the study will receive an information sheet detailing what the study will involve. In the longitudinal study, participants are asked some brief screening questions over the phone. If they meet the screening criteria, they are invited to a face-to-face appointment. This usually takes 60-90 minutes. Participants complete a consent form and some further questionnaires to see if the study will be suitable for them. Those who meet the criteria are then be offered up to nine, one-hour sessions of integrated CBT therapy, delivered by a therapist. The first session is face-to face, and subsequent sessions are delivered online (e.g. using instant messaging and/or voice communication). Participants are also asked to attend two interviews with a researcher so that they can share their views of the integrated therapy. In the usability

testing study, potential participants are asked some questions over the telephone to check if the study is suitable for them. If it is, the participant is invited to attend a usability-testing session. Sessions are conducted individually and take 45-60 minutes. At the session, participants complete a consent form and a brief questionnaire. Participants are asked to look at the online CBT platform, and to test parts of the system (e.g. to complete a CBT worksheet online, read some of the online CBT resources, or test the online chat facility). At the end of the session, participants complete a questionnaire about their views on the platform, and how easy they found it to use.

What are the possible benefits and risks of participating?
In the longitudinal study, participants will have an opportunity to help inform the design of a new way of delivering CBT, and may find this interesting and rewarding. CBT is an effective treatment for depression. CBT can help participants develop ways of managing depression better, however this cannot be guaranteed. As this is a pilot study of a newly developed system of therapy, participants may experience minor technical issues with the online platform.
As with any talking therapy for depression, participants may find sessions emotionally challenging or upsetting. Our experienced therapists will be able to provide support within the sessions. The researchers will approach the screening appointment and interviews in a sensitive and supportive way. Although we do not anticipate that the sessions will be distressing, we will be able to contact a study clinician to offer support if necessary. In the usability testing study, participants will have an opportunity to help inform the design of a new way of delivering CBT, and may find this interesting and rewarding, however this cannot be guaranteed. As this is a pilot study of a newly developed system of therapy, participants may experience minor technical issues with the online platform. Our participants have an important role in helping us to identify any potential issues. The focus of the sessions will be on potential designs of the new therapy programme, rather than on participants' personal experience of depression. The researchers will approach any discussions in a sensitive and supportive way.

Where is the study run from?
University of Bristol (UK)

When is the study starting and how long is it expected to run for?
February 2017 to December 2018

Who is funding the study?
National Institute for Health Research (UK)

Who is the main contact?
Ms Debbie Tallon (Scientific)
d.tallon@bristol.ac.uk)

Contact information

Type(s)
Scientific

Contact name
Ms Debbie Tallon

ORCID ID
http://orcid.org/0000-0001-9195-5010

Contact details
Centre for Academic Mental Health
Population Health Sciences
Bristol Medical School
University of Bristol
Oakfield House
Oakfield Grove
Bristol
United Kingdom
BS8 2BN

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
36408

Study information

Scientific Title
The pilot evaluation of an online platform for delivering integrated high-intensity Cognitive Behavioural Therapy for depression

Acronym
INTERACT Phase 2

Study objectives
The aim of this study is to explore the views of service users, therapists and their clinical supervisors regarding the online platform we have developed, to ensure that the platform and CBT materials are acceptable, and to identify areas for improvement prior to a planned multi-centre randomised controlled trial.
We will conduct several design and evaluation activities in parallel to test the platform and revise its design based on user feedback:
1. A longitudinal evaluation with 12-16 primary care patients with depression. Patients will receive a full course of CBT delivered by a therapist through the platform.
2. Participatory design work with 2-3 therapists who are delivering the therapy within the study, and their clinical supervisor(s). They will also act as co-designers providing ongoing feedback.
3. Usability testing sessions with 9-12 people who received CBT in the past. These service-users will be recruited through local psychological services and will test changes to the platform arising from feedback.

Ethics approval required
Old ethics approval format

Ethics approval(s)

South West - Central Bristol Research Ethics Committee, 15/11/2017, ref: 17/SW/0243

Study design
Non-randomised; Both; Design type: Treatment, Psychological & Behavioural, Qualitative

Primary study design
Observational

Secondary study design
Longitudinal study

Study setting(s)
GP practice

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Specialty: Primary care, Primary sub-specialty: Mental Health; UKCRC code/ Disease: Mental Health/ Mood [affective] disorders

Interventions
The study involves three strands of work running in parallel:
1. A longitudinal evaluation study with 12-16 primary care patients with depression, who will receive up to nine one-hour sessions of integrated Cognitive Behavioural Therapy delivered by a therapist through an online platform. Participants will be interviewed twice about their experience of 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 of the platform and will provide ongoing feedback.
3. Usability testing sessions with 9-12 people who have received CBT therapy in the past, who will test specific changes to the platform arising from patient and therapist feedback.

Those invited to take part in the study will receive an information sheet detailing what the study will involve. In the longitudinal study, participants are asked some brief screening questions over the phone. If they meet the screening criteria, they are invited to a face-to-face appointment. This usually takes 60-90 minutes. Participants complete a consent form and some further questionnaires to see if the study will be suitable for them. Those who meet the criteria are then be offered up to nine, one-hour sessions of integrated CBT therapy, delivered by a therapist. The first session is face-to face, and subsequent sessions are delivered online (e.g. using instant messaging and/or voice communication). Participants are also asked to attend two interviews with a researcher so that they can share their views of the integrated therapy. In the usability testing study, potential participants are asked some questions over the telephone to check if the study is suitable for them. If it is, the participant is invited to attend a usability-testing session. Sessions are conducted individually and take 45-60 minutes. At the session, participantsl complete a consent form and a brief questionnaire. Participants are asked to look at the online CBT platform, and to test parts of the system (e.g. to complete a CBT worksheet online, read

some of the online CBT resources, or test the online chat facility). At the end of the session, participants complete a questionnaire about their views on the platform, and how easy they found it to use.

Intervention Type
Other

Primary outcome measure
The purpose of this study is to gather initial qualitative feedback on the integrated CBT platform. Clinical outcomes are not evaluated as part of this study. Qualitative feedback on the integrated CBT platform will be assessed as detailed below.
1. Patients in the longitudinal study will be interviewed by a researcher after their second or third therapy session, and again once they have completed therapy. Those who withdraw from therapy or are discharged for non-attendance will also be interviewed. The purpose of the qualitative interviews is to gather initial views on the platform, its content, and the experience with this integrated approach to delivering CBT. The System Usability Scale (SUS) will also be used to guide discussion of the platform.
2. Therapists and clinical supervisors will provide ongoing feedback regarding their experience of the platform. Data collection methods will include design discussion sessions, individual interviews and focus groups, and use of the System Usability Scale (SUS).
3. The usability testing sessions will be task-oriented and analysed qualitatively and results summarised by the task they relate to. Types of issues will be counted to identify the most common and most serious ones. The SUS scores will be analysed and interpreted.

Secondary outcome measures
There are no secondary outcome measures.

Overall study start date
01/02/2017

Completion date
22/02/2019

Eligibility

Key inclusion criteria
Longitudinal study:
1. Aged 18 years or older
2. Score ≥14 on Beck Depression Inventory (BDI-II; Beck et al., 1996)
3. Meet ICD-10 criteria for depression (CIS-R; Lewis et al., 1992; Lewis, 1994)

Therapists and Clinical Supervisors
Working as therapists and clinical supervisors to deliver or supervise the INTERACT integrated therapy for this (Phase 2) study.

Usability testing sessions
1. Aged 18 years or older
2. Have a history of depression
3. Have previously received high-intensity CBT for depression (online and/or face-to-face)

Participant type(s)

Mixed

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 43; UK Sample Size: 43

Total final enrolment
30

Key exclusion criteria
Longitudinal study with primary care patients:
1. Major alcohol or substance use problems (in the past year)
2. Have bipolar disorder, psychosis or dementia
3. Cannot complete questionnaires unaided
4. Are currently receiving CBT or other psychotherapy or secondary care for depression
5. Have received individual, high-intensity CBT in past 4 years
6. Taking part in another research study
7. Need an interpreter

Usability testing sessions with service-users:
1. Unable to complete questionnaires
2. Have not received CBT for depression
3. Are currently receiving treatment from a psychiatrist for depression
4. Have a history of bipolar disorder, schizophrenia or personality disorder
5. Have a history of substance misuse/alcohol addiction (in the past year)
6. Are currently not well enough to attend a session
7. Have taken part in Phase 1 of the INTERACT study

Therapists and clinical supervisors
No exclusion criteria

Date of first enrolment
01/03/2018

Date of final enrolment
17/12/2018

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of Bristol
Oakfield House
Oakfield Grove
Bristol
United Kingdom
BS8 2BN

Sponsor information

Organisation
University of Bristol

Sponsor details
Senate House
Tyndall Avenue
Bristol
England
United Kingdom
BS8 1TH

Sponsor type
University/education

ROR
https://ror.org/0524sp257

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type

Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal.

Intention to publish date
01/03/2020

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version V1.1	08/02/2018	29/03/2018	No	No
Results article	pragmatic study results	21/04/2020	18/06/2020	Yes	No
HRA research summary			28/06/2023	No	No