

Integrated CBT for depression trial (INTERACT RCT)

Submission date 30/09/2020	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 11/11/2020	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 06/11/2024	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Cognitive Behavioural Therapy (CBT) is an effective type of talking treatment that can help people who have depression. However, many people are unable to get one-to-one CBT. One of the reasons for this is a lack of CBT therapists; another is cost. There are computerised self-help packages based on CBT. However, these are of only small benefit, and patients often do not engage with them. The aim of the INTERACT study is to bring together online CBT materials and input from a qualified CBT therapist. CBT materials are worksheets, information about depression, and short films. This is a way of making CBT more widely available in the NHS.

The INTERACT team have developed a new way of providing therapy. The therapist and patient meet face-to-face (either in person or via videocall) for the first session, but after that they meet for therapy online in real-time at pre-arranged appointments (using instant messaging and/or by telephone). Patients will also have online CBT materials to work with between sessions. Online therapy appointments and CBT materials can be accessed using a computer, smartphone or tablet, so people can access therapy from home, and can do between-session exercises (such as recording their thoughts and feelings) at convenient times.

This study is trying to find out whether this new form of therapy, 'integrated CBT', helps people with depression. The study will find out whether the treatment is effective, cost-effective, and acceptable to patients. In order to do this, we are carrying out what is called a randomised controlled trial. We would also like to find out patients' views and experiences of this way of delivering CBT, and of participating in the trial, by carrying out interviews with a small number of participants.

Who can participate?

Adults who are currently depressed, not already receiving a talking therapy, and who have not received one-to-one 'high-intensity' CBT in the last four years. We can't include people who: are currently receiving treatment from a psychiatrist; have other serious mental health problems such as schizophrenia, bipolar disorder, or dementia; or who are dependent on drugs or alcohol. In order to take part, you would also need to be willing to receive a course of CBT delivered by a

qualified therapist both face-to-face (in person or via videocall), and online (using instant messaging and by telephone). To receive the therapy in this way, you would need access to a computer, tablet or smartphone.

What does the study involve?

There's a brief (10 min) telephone call with a researcher to check if the study might be suitable for you. We would then invite you to an appointment (90-120 mins) with a researcher to discuss the study, go through a consent form, and ask you to complete some questionnaires. The researcher will look at your answers and tell you whether you meet the study criteria. If your answers suggest you are suitable for the study, you will be asked some further questions, and to complete some simple computerised tasks. One of two treatments will then be randomly chosen for you by computer: either integrated CBT, or usual GP care. If you are allocated integrated CBT, you would be offered 9-12 sessions of CBT - the first session is face-to-face (in person or via videocall) and subsequent sessions are delivered by instant messaging over a secure, online therapy platform. You would be asked to complete some follow-up questionnaires and computer tasks at 3, 6, 9 and 12 months, and may also be invited to take part in an interview to discuss your views of the treatment you were allocated.

What are the possible benefits and risks of participating?

Participants will have an opportunity to help us evaluate this new way of delivering CBT, and we hope they will find this interesting and rewarding. Whether you are allocated integrated CBT or usual care, we hope that this treatment will help you develop ways of managing your depression better, however this cannot be guaranteed.

Where is the study run from?

The study is organised by the University of Bristol, in collaboration with the University of York and University College London (UK)

When is the study starting and how long is it expected to run for?

January 2019 to August 2024

Who is funding the study?

National Institute for Health Research (NIHR) (UK)

Who is the main contact?

Debbie Tallon, bris-interact@bristol.ac.uk

Study website

<https://interact.blogs.bristol.ac.uk/>

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers**EudraCT/CTIS number**

Nil known

IRAS number

257620

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

CPMS 41172, IRAS 257620

Study information

Scientific Title

Multi-centre randomised controlled trial of integrated therapist and online CBT for depression in primary care (INTERACT)

Acronym

INTERACT RCT

Study objectives

An integrated approach to delivering CBT will reduce depressive symptoms in depressed patients from primary care

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 20/03/2019, South West - Frenchay Research Ethics Committee (Level 3, Block B, Whitefriars, Lewins Mead, Bristol, BS1 2NT, UK; +44 (0)207 104 8041; nrescommittee.southwest-frenchay@nhs.net), ref: 19/SW/0038

Study design

Interventional randomised controlled trial with nested qualitative study

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

GP practice

Study type(s)

Treatment

Participant information sheet

<https://interact.blogs.bristol.ac.uk/patients/>

Health condition(s) or problem(s) studied

Depression

Interventions

Eligible participants will be randomised to one of two treatment arms; either a course of individual integrated CBT (9 sessions of therapist-led CBT, with (up to) a further 3 sessions if deemed clinically appropriate), or usual care, which may include referral to local psychological services or antidepressant medication, as appropriate.

The INTERACT therapy protocol utilises the standard Beckian intervention for depression (Beck et al, 1979; Beck 1995). Participants who are randomised to receive the therapy will receive login details to the platform before the first session to enable them to familiarise themselves with the platform. 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 first session of therapy will take place face-to-face (in person or via videocall) and may take up to 90 minutes. This will enable completion of history taking, introduction of the CBT model and other relevant psychoeducation. In addition, therapists will help the patient become familiar with the INTERACT platform. When the first session is face-to-face in person, this will usually take place in the patient's GP surgery or other local NHS premises. However, it could also be offered at the local University premises if the patient prefers this and a suitable space is available.

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 the telephone. 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 utilise CBT worksheets/other materials embedded within the INTERACT platform.

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 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 respond to their query at the next scheduled therapy session.

Patients who are allocated usual care will continue to receive usual GP care from their GP. There will be no restrictions on care provided by GPs so these patients may be offered referral to local psychological services and/or antidepressant medication as appropriate. (To be clear, the usual care group will not be given access to the INTERACT therapy platform.)

Intervention Type

Other

Primary outcome measure

Depression using the Beck Depression Inventory (BDI-II) score (measured as a continuous variable) at 6 months post-randomisation

Secondary outcome measures

1. Depressive symptoms (BDI-II) at 6 months post-randomisation, used to measure: treatment response (at least 50% reduction in depressive symptoms on the BDI-II compared with baseline); remission of symptoms (BDI-II<10); and percentage reduction in depressive symptoms
2. Depressive symptoms on PHQ-9 at 6-months post-randomisation
3. Quality of life using WSAS and EQ-5D-5 at 6-months post-randomisation
4. Anxiety symptoms (GAD-7) at 6-months post-randomisation
5. All the above outcome measures at 12 months post-randomisation
6. Economic evaluation:
 - 6.1. EQ-5D-5L (measured at 0, 6 and 12 months post-randomisation)
 - 6.2. Number of primary care consultations and prescribed medications (from GP practice medical records over 12 months)

6.3. Use of other primary and community care services; secondary care related to mental health; private treatments; use of social services; burden on informal caregivers; personal costs related to mental health; and benefits received (collected by questionnaire at 6 and 12 months post-randomisation)

Overall study start date

01/01/2019

Completion date

13/08/2024

Eligibility

Key inclusion criteria

1. Aged ≥ 18 years
2. Score ≥ 14 on Beck Depression Inventory (BDI-II)
3. Meet ICD-10 criteria for depression

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

Planned Sample Size: 458; UK Sample Size: 458 (The planned sample size for the RCT is 434; the remaining participants are 24 qualitative interviewees [up to 9 CBT therapists/supervisors and up to 15 trial 'decliners'])

Total final enrolment

478

Key exclusion criteria

1. Alcohol or substance dependency in the past year
2. Bipolar disorder
3. Schizophrenia/Psychosis
4. Dementia
5. Currently under psychiatric care (including those referred but not yet seen) for depression
6. Cannot complete questionnaires unaided or would require an interpreter
7. Are currently receiving CBT or other psychotherapy
8. Have received high-intensity CBT in past 4 years
9. Are taking part in another intervention trial
10. Not willing or able to receive CBT via computer/laptop/smartphone

Date of first enrolment

23/11/2020

Date of final enrolment

11/07/2023

Locations

Countries of recruitment

England

United Kingdom

Study participating centre**University of Bristol**

Oakfield House

Oakfield Grove

Bristol

United Kingdom

BS8 2BN

Study participating centre**University College London**

Division of Psychiatry

Maple House

149 Tottenham Court Road

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Study participating centre**Hull and York Medical School**

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Sponsor information

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Sponsor type

University/education

Website

<http://www.bristol.ac.uk/red/research-governance/>

ROR

<https://ror.org/0524sp257>

Funder(s)**Funder type**

Government

Funder Name

NIHR Central Commissioning Facility (CCF); Grant Codes: RP-PG-0514-20012

Funder Name

National Institute for Health Research (NIHR) (UK)

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

The trial will be reported in line with CONSORT guidelines. On completion of the trial, we plan to prepare peer-reviewed papers outlining the main results, and a detailed final report of the INTERACT programme will be submitted to the funder, NIHR. Following publication of the study findings, we aim to send a summary of the trial results to those trial participants who indicated they would like to receive this.

Intention to publish date

14/09/2025

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be stored in a publicly available repository.

Will individual participant data be available (including data dictionaries)?

Yes. Participant consent for sharing of anonymised data will be sought as part of the consent process.

What data, in particular, will be shared?

All of the individual participant data collected during the trial, after deidentification. The main trial data (underpinning the clinical and cost-effectiveness analyses) will be anonymised but anyone who wants to use the interview transcripts and/or data from therapy sessions (transcripts of instant messaging sessions; therapy session audio-recordings and/or platform usage data e.g. completed worksheets) will be asked to meet the costs of anonymising such data.

What other documents will be available?

Study protocol, statistical analysis plan

When will data be available (start and end dates)?

Beginning 12 months after publication of the papers reporting the clinical and cost-effectiveness of the intervention and nested qualitative study. No end date.

With whom?

'Bona fide' researchers who provide a methodologically sound proposal and evidence of ethical approval (if required), subject to the agreement of the University of Bristol Data Access Committee.

For what types of analyses?

To achieve aims in the approved proposal

By what mechanism will data be made available?

Prior to data publication, proposals should be directed to the INTERACT Lead Investigators, Professor Nicola Wiles (nicola.wiles@bristol.ac.uk) and Professor David Kessler (david.kessler@bristol.ac.uk). Subsequently, applicants should follow the process outlined below. Data will be made available as a controlled dataset managed by the University of Bristol's Research Data Repository (<https://data.bris.ac.uk/data>). To gain access, data requestors will need to apply for access at <http://www.bristol.ac.uk/staff/researchers/data/accessing-research->

data/. Data release will be contingent on a signed data access agreement. This agreement limits use of data to non-commercial research only. Requests for any other purposes must be negotiated separately.

IPD sharing plan summary

Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	20/06/2023	21/06/2023	Yes	No
HRA research summary			28/06/2023	No	No