Participant Information Sheet

Trial of integrated Cognitive Behavioural Therapy (CBT) for depression

We invite you to take part in a research study

- Before you decide whether to take part, it is important for you to understand why this research is being done and what it will involve.
- Please take the time to read the following information carefully. Discuss it with friends and relatives if you wish.
- You are free to decide whether or not to take part in this research. Take time to decide. If you choose not to take part, this will not affect the care you get from your GP.
- Ask us if there is anything that is not clear or if you would like more information.

Important things you need to know

- We are evaluating a new way of delivering Cognitive Behavioural Therapy (CBT) for depression. Integrated CBT combines input from a CBT therapist with online CBT resources.
- This new way of delivering CBT could make CBT more accessible and more widely available to people with depression in primary care.
- **We would like your help in evaluating this new way of delivering CBT.**
- By taking part in the study and completing some questionnaires, you will help us to find out how effective and acceptable this new treatment is.
- Taking part in this research is voluntary and you can withdraw at any time without giving a reason.

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How to contact us

If you have any questions about this study, please talk to the researcher:

Laura Thomas
Centre for Academic Mental Health, Bristol Medical School, University of Bristol, Oakfield House, Oakfield Grove, Bristol BS8 2BN
Telephone: 0117 3313345
Email: bris-interact@bristol.ac.uk

Why we are doing this study

Cognitive Behavioural Therapy (or 'CBT' for short) 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 via videocall for the first session, but after that they meet for therapy online in real-time at pre-arranged appointments (using instant messaging). 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.

What do we hope to find out?

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.

2 How the study works

How do we find out whether integrated CBT helps?

We are hoping to include 434 people in this study. People who are experiencing symptoms of depression will be invited to take part.

People who join the study will receive one of two treatments: half will be offered a course of integrated CBT (which will include 9-12 sessions of therapy), and half will continue with usual GP care (which may include referral to other local psychological services). Anyone enrolled in the study can continue to take any antidepressant medication prescribed by their GP as well.

We then ask people about their health at 3, 6, 9 and 12 months after they enrol in the trial.

How is it decided who gets integrated CBT?

A computer will choose which treatment you will receive – this is called 'randomisation'. It is a bit like rolling a dice to decide and it means you have an equal chance of being allocated to either integrated CBT or usual care.

3 Why have I been invited take part?

We have asked local GP surgeries to help us find suitable participants by inviting some of their patients to take part. You will have received an invitation letter and this information leaflet from your GP, either during a consultation, or through the post if you have recently discussed low mood with the GP. Your GP practice will not pass on

your details to INTERACT researchers without your consent.

If you are interested in taking part, please ask your GP to refer you to the study. They will then pass your contact details to the study team. Or, if you received an invitation in the post, please complete the reply form and return this to the research team in the prepaid envelope provided. The researcher will then contact you to explain the study in more detail.

If you decide that you are **not** interested or are unable to take part, it would be helpful if you tell us on the reply slip your reasons for declining and whether you would be willing to take part in a brief telephone interview with a researcher about your reasons for declining. A small number of those willing to be interviewed will be contacted by phone. The interview would take up to 20 minutes and would be audio-recorded with your consent. The recording would be typed up (transcribed). We will remove any information such as names from the transcript so that you cannot be recognised from it. The information will help us to understand people's views of the study and any concerns they may have about taking part.

4 What does taking part involve?

Enrolling you in the study

The researcher will check if the study might be suitable for you by asking you some brief questions over the telephone (about your experience of depression; CBT; current health; and availability to take part). At this point you will be able to ask any questions you might have. This call will take about 10 minutes.

Who will be eligible to take part?

We are looking for 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 via videocall, and online (using instant messaging). To receive the therapy in this way, you would need access to a computer, tablet or smartphone.

If the study is right for you, and you are interested in going forward, you will be invited to an appointment with a researcher. This would either take place remotely (via videocall or telephone) or face-to-face (at your home/GP surgery/local University) depending on local availability. Remote appointments will involve completing questionnaires online using your own smartphone, tablet or computer, and speaking to the researcher by videocall or telephone.

Appointments usually take 60-90 minutes. The researcher would explain the study and answer any questions you may have. They will ask you to complete a consent form to show your willingness to take part. You will then be asked to complete some questionnaires about your background, health and previous treatment. 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, and you are willing to take part, you will be asked some further questions about your health. One of two treatments will then be randomly chosen for you by computer: either integrated CBT, or usual GP care. Taking part in the study will not stop your GP offering or changing your medication or offering other therapy if this is considered the best thing to do.

5 What treatment will I be offered as part of this study?

This will depend on whether you are allocated to receive 'usual care' or 'integrated CBT' as part of the study.

If you meet the study criteria and are one of the people allocated to receive 'usual care', you will continue to receive care from your GP.

If you are allocated integrated CBT, the researcher will arrange for you to start a course of integrated CBT with one of our study therapists.

CBT is based on the idea that the way people think affects how they feel and changes what they do. During CBT sessions, the patient and therapist discuss difficulties the patient is experiencing and how their thoughts and feelings affect the problem. The patient and therapist then work together to find ways of helping the person cope with their depression. CBT is an educational approach where patients learn skills that they can try out for themselves, skills that they can continue to use after the therapy is finished.

The INTERACT therapists are all experienced CBT practitioners. Each participant who is allocated integrated CBT will be offered 9-12 sessions of individual CBT sessions with their therapist.
For the first session, you will meet your therapist by videocall for 60-90 minutes. The therapist will ask about your current difficulties and tell you more about CBT and how it can help. The therapist will also explain the integrated therapy system and how the online sessions will work.

After the first session, therapy sessions will usually take 50 mins and will be scheduled to take place online (using instant messaging), at a convenient time. Your therapist may ask you to practise some CBT exercises in-between your sessions. This might include reading some online resources or keeping some online records of your thoughts and feelings. Your therapist will review this practice with you at your next online session.

The first four sessions are likely to be weekly. Later sessions may be spaced at fortnightly or monthly intervals.

While you are taking part in the study you will continue to be looked after by your GP, as normal. No treatment will be withheld from you during the study.

6 What else will I be asked to do?

Follow-up

The study will last one year. You will be asked to answer some short questionnaires over the telephone or by videocall 3 and 9 months after joining the study. These questionnaires will take about 10-15 minutes and will be scheduled at a time convenient to you.

You will also be asked to complete some questionnaires 6 months and 12 months after joining the study. These appointments will normally take about 30 minutes and will be scheduled at a time convenient to you. These appointments would either take place remotely (via videocall or telephone) or face-to-face (at your home/GP surgery/local University) depending on local availability.

It is important that we follow-up as many people as possible – both those who are allocated to continue with usual care from their GP and those allocated to integrated CBT. Only by following up people in **both** groups are we able to find out whether this new way of delivering therapy helps people with depression. Even if you do not receive integrated CBT as part of the study, we still want to follow you up for 12 months and find out how you are. This will help us to better

answer our research question and will make the results of the study much more useful.

If scheduling a follow-up appointment is difficult for you, the researcher can arrange to collect your answers by post or online.

Participants will be offered a £10 shopping voucher at the 6- and 12-month follow-ups.
As part of the consent process, we will ask for your permission for us to have access to your medical records. This is to help us understand if the therapy has had an effect on how often you see your GP or have other contacts with the health service. If you agree, any information we record will have your name and address removed so that you cannot be recognised from it.

If you receive integrated CBT, information about your use of the online platform will recorded (for example, how many sessions you attended, which materials you accessed online, how often you logged in). We will ask whether you are also willing to provide consent for the content of INTERACT therapy sessions (transcripts, recordings, completed worksheets, practice at home tasks and questionnaire scores collected as part of integrated therapy) to be used by the research team for research purposes.

Interview study

If you are eligible for the study, we may also ask if you would consider being interviewed by a researcher about your views of integrated CBT and/or of taking part in the study.

If you agree to be interviewed, this would take place at a time and place that is convenient for you. The interview will take less than 60 minutes and will be audio-recorded with your consent so that we have an accurate record of the conversation. The interview will be typed up (transcribed) by an external, approved transcribing service and the recording will then be destroyed. Only members of the research team and transcribing service will have access to the recorded interview. We will remove any identifiable information such as names from the transcript so that you cannot be recognised from it. The transcript will then be stored for use in future research studies and may be shared with other researchers.

What you say in the interview will not affect the care you receive from your GP or therapist in any way. You will not need to do anything to prepare for the interview.

As we will only interview around 60 of our participants, not everyone will be invited to take part in an interview. Each interviewee would be offered an additional goodwill gesture of a £10 shopping voucher.

MRI study (optional extra)

Eligible participants who are enrolled by the Bristol University research team will also be asked to consider taking part in a separate brain imaging study called *BRAIN*TERACT. The purpose of this study is to see whether integrated CBT leads to changes in the brain. If you are interested in taking part in this supplementary study, you would be provided with a further information sheet, and have chance to discuss this in detail with a researcher before deciding. They will ask you some questions to check it would be safe for you to have a brain scan.

Interested participants would be invited to attend a scan (functional Magnetic Resonance Imaging (MRI) scan) at the Cardiff University Brain Research Imaging Centre (CUBRIC) in Cardiff.

The scanning appointment would be approximately 6 months after enrolling in the INTERACT study, and it usually takes less than two hours. Participants will be offered £50 for attending the brain scan. Free return travel will also be arranged to take you from your home to (and back from) Cardiff.

Your decision to participate (or not) in the MRI study will **not** affect your participation in the rest of the trial, or any usual care you would receive

from your GP. If you decide not to be involved in the brain imaging study, you **can** still be part of the main study.

7 How is taking part in the study different from usual GP care?

While you are taking part in the study you will continue to be looked after by your GP, as normal. You can see your GP as often as you and he/she thinks necessary. No treatment will be withheld from you during the course of this study.

If you are eligible and allocated to **'usual care'** as part of this study, we will write to your GP to ask them to continue to offer the usual treatments available - this may include antidepressants and/or referral to a local psychological service, depending on your needs and preferences.

Participants who are eligible and allocated **integrated CBT** will be offered 9-12 sessions of one-to-one, therapist-led CBT, with an experienced INTERACT therapist. While GPs can routinely refer patients to psychological services for assessment, available treatments (and waiting lists) will vary depending on the local provider and patient's needs.

The researcher will also want you to complete some questionnaires at the beginning of the study and at the follow-up points detailed in Section 6.

8 Possible benefits and disadvantages of taking part

Possible benefits

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.

Possible disadvantages

As this is a trial of a newly-developed system of therapy, participants receiving integrated CBT may experience minor technical issues with the online platform. We will aim to help you with these as quickly as possible.

As with any talking therapy for depression, participants may find therapy sessions emotionally challenging or upsetting. Our experienced therapists will be able to provide support within the integrated CBT sessions. The researchers will also approach the screening appointment and interviews in a sensitive and supportive way. Although we do not anticipate that these sessions will be distressing, we will be able to contact a study clinician to offer support if necessary.

If there are concerns about your safety, or the safety of others, we may have to inform your GP. Wherever possible we would speak with you before doing this. We would only pass information to your GP without your agreement if we had immediate concerns for your welfare, or the welfare of others (for example, if you told us that you were having thoughts of harming yourself, or someone else).

9 More information about taking part

Do I have to take part?

We will describe the study and go through this information sheet with you. It is up to you to decide whether or not to take part. If you decide not to take part, you will continue to be looked after by your GP.

If you choose to take part, you are free to withdraw from the study and/or the integrated therapy at any time, without giving a reason. This would not affect the standard or type of care you receive from your GP. If you withdraw from the study, we will use the data collected prior to your withdrawal.

What information will be shared with my GP?

We will inform your GP of the outcome of the screening assessment, and whether you have been allocated 'integrated CBT' or to 'usual care'. We will also inform your GP if you have completed (or withdrawn from) integrated CBT therapy, or the study as a whole. With your permission, the letter(s) will include some summary scores from your questionnaires, which your GP may find helpful. As mentioned earlier, we would need to contact your GP if there were immediate concerns for your safety or the safety of others.

Will I receive any payment?

Participants who are eligible for the study will be given a goodwill gesture of a £10 shopping voucher for the 6 and 12-month follow-up and a further £10 for taking part in an interview.

What if there is a problem?

If you have a concern about any aspect of this study you should ask to speak to the local researcher, Laura Thomas. Alternatively, you can speak to the Lead Investigators, or the Research Programme Manager. Contact details are listed in section 10.

If you remain unhappy and wish to complain formally, the normal NHS complaints process is available to you. Details can be obtained from the Programme Manager listed in section 10. In the event you suffer harm during the research you may have grounds for a legal action for damages against the University of Bristol, (or other University site if you were recruited elsewhere). Appropriate legal liability insurance is in place.

What will happen to information about me collected during the study?

Only authorised members of the research team, and those responsible for auditing the research process, will have access to your personal information. All information will be held securely and in strict confidence. The research team will use your name and contact details to contact you about the research study, and make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study. As explained earlier, members of the research team may access your medical records to collect information on your use of health services during the study, if you agreed to this. Individuals from the University of Bristol and regulatory organisations may look at your medical and research records to check the accuracy of the research study.

We will keep your questionnaire data and any interview transcripts separate from your personal details. We can only link this information together with a secure code.

If you receive integrated therapy, these sessions (voice communication, instant messaging and other use of the online platform) will be automatically recorded. This information will be used by your therapist and their supervisor as part of supervision for the therapist.

Information about your use of the platform (for example, session attendance, materials accessed, logins/number of tasks completed) will be used to describe therapy provided.

We will ask whether or not you are willing for the content of therapy sessions (transcripts, recordings, completed worksheets and questionnaire scores) to be used for research purposes.

You will be able to access transcripts of your integrated therapy sessions that take place via instant messaging within the INTERACT system. You will also be able to download blank or completed worksheets for your own records. You would be responsible for storing these transcripts and/or therapy materials securely once in your possession.

Our online therapy platform has been developed and independently tested to ensure the highest levels of data security.

We will use the information we collect to evaluate the effectiveness and acceptability of integrated therapist and online CBT. Information may also be used to support other research in the future and may be shared anonymously with other researchers.

The study is organised by the University of Bristol, in collaboration with the University of York and University College London. The research team at the University of Bristol will co-ordinate the study and will be responsible for analysing the data. All the information that is collected about you (including your contact details) will be shared between the co-ordinating research team based at the University of Bristol and the study centres. The University of Bristol is responsible for looking after your information and using it properly.

We will keep your contact details for up to 10 years after the study has finished; we will then destroy this information securely. We will keep anonymised, electronic research data indefinitely. Once we have collected information from you it is very difficult to change it. If you withdraw from the study, we will keep the information we have already obtained, but will take all steps to ensure that you cannot be identified from it. You can find out more about how we use your information by contacting the INTERACT Programme Manager, Debbie Tallon (contact details are in Section 10).

What will happen to the results of the study?

The results will be published in an academic journal so that health care professionals can see them. No named information about you will be published in any report.
If the trial shows that the integrated CBT is effective, the study team aim to make the therapy platform available to the NHS, on a not-for-profit basis. This means that the study team will not benefit financially from the results of this study.

Who is funding the study?

This has been funded by the National Institute for Health Research Programme Grants for Applied Research (reference RP-PG-0514-20012). This study has **not** received any commercial funding.

Who has reviewed the study?

This study has been reviewed by an independent group of people, called the Research Ethics Committee, to protect your safety, rights, well-being and dignity. The study has been given a favourable opinion by the South West – Frenchay Research Ethics Committee.

10 Contact for further information

Local Researcher

Laura Thomas
Centre for Academic Mental Health,
Bristol Medical School, University of Bristol,
Oakfield House, Oakfield Grove, Bristol BS8 2BN
Email: bris-interact@bristol.ac.uk
Tel: 0117 3313345

Lead Investigators

Professor Nicola Wiles
Email: Nicola.Wiles@bristol.ac.uk
Tel: 0117 3313358

Professor David Kessler
Email: David.Kessler@bristol.ac.uk
Tel: 0117 3314031

INTERACT Programme Manager

Debbie Tallon
Email: bris-interact@bristol.ac.uk
Tel: 0117 3313357

Address: Centre for Academic Mental Health,
Bristol Medical School, University of Bristol,
Oakfield House, Oakfield Grove, Bristol BS8 2BN

Thank you for taking the time to consider taking part in this study.