

Participant Information Sheet

REEACT-2: Computerised Cognitive Behaviour Therapy 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 the 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. Take time to decide whether or not you wish to take part.
- You are free to decide whether or not to take part in this research. 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.
- Thank you for reading this information sheet. If you decide to take part please sign the consent form and post it back to us in the prepaid envelope provided.

Important things you need to know

- We want to find out more about how computerised cognitive behaviour therapy (CBT) may help people suffering from depression.
- We are particularly interested in exploring whether providing telephone support to patients using computerised CBT has an added benefit to their health.
- Everyone involved in the research study will receive access to a computerised CBT programme.
- By asking you to complete some questionnaires before you start the programme and again at 4 months and 12 months after you enter into the study we hope to understand more about what helps.
- You can stop taking part in the study 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:

<<Local researcher Name>>

<<Address>>

<<Tel>>

Why we are doing this study

What are we studying?

Depression causes misery to many people and is a major health problem in the UK. The majority of people with depression receive care from their GP and never really see a specialist. However, lots of people experiencing depression would also like to receive a “talking treatment” (counselling or psychotherapy).

What therapy are we looking at?

Cognitive Behaviour Therapy (or ‘CBT’ for short) is an effective type of talking treatment that can help people who have depression. At present CBT is not always immediately available in the NHS. Recently, therapists have developed a form of CBT that can be delivered by computer, which might make it easier to access this form of treatment. We call this “computerised CBT”. Computerised CBT is recommended by the National Institute for Clinical Excellence (NICE) for people experiencing depression, but we need more information about how best to support people who are using it.

What do we hope to find out?

At the moment there is some evidence that suggests people who are using computerised CBT may benefit from receiving additional support from a telephone support worker. The telephone support worker is able to help with any technical difficulties relating to the programme and may also help keep people motivated to continue using it.

This study investigates if providing people with weekly telephone support whilst they use computerised CBT leads to an improvement in their symptoms of depression.

2 How the study works

How do we find out whether telephone support helps?

We do this by setting up everyone who takes part in the study with access to a computerised CBT programme. We then randomly allocate people into one of two groups: one group receives weekly telephone support calls and the other group does not.

How is it decided who gets telephone support?

A computer will choose whether you will receive the telephone support calls – this is called ‘randomisation’. This is a bit like rolling a dice to decide whether you receive telephone support or not. It means you have an equal chance of receiving the telephone support or not.

The rest of this leaflet explains how you might be involved in our research study.

3 Why am I being asked to take part?

Your GP is involved in the study and has identified you as suffering from depression. We hope to get 200 people with depression into the study to help us improve treatment.

4 What will happen to me if I take part?

Enrolling you in the study

If you are interested in taking part you will need to complete the enclosed consent form and return this to your local researcher in the prepaid envelope provided. You will then be contacted by the researcher who will check if you are eligible to take part in the study by asking you some brief questions.

At this point you will also have the opportunity to raise with the researcher any questions you might have about the study. You do not have to enter the study unless you feel completely happy with what you are being asked to do.

Collecting information

If you are eligible to take part and you are happy to proceed with the study the researcher will then ask a series of questions relating to your health. The researcher can either ask you these questions over the telephone or we can arrange to meet you in person. These baseline questions will take about half an hour to complete.

Setting you up with computerised CBT

Everyone who takes part in the study will receive access to a computerised CBT programme called

Moodgym. This is available online and you can use it in your own home if you have internet access. If you do not have internet access at home you will be able to talk through with the researcher where else you may be able to use the programme.

The programme is split into 6 sessions with each session taking about one hour to complete. You will be asked to work your way through the programme completing a session about once a week.

After the initial baseline interview the researcher will provide you with a web address, username and password which will allow you access the Moodgym programme. You will then be able to start the computerised CBT straight away. The researcher will also be able to tell you whether you will be in the group that receives telephone support calls or not.

Telephone support

If you are in the telephone support group you will be contacted by one of the telephone support workers who work on the study. The telephone support worker will explain how they may be able to help you with the computerised CBT and will arrange a suitable time to call you on a weekly basis for up to 8 weeks.

It is important that you are aware that the telephone support workers are not trained counsellors. They will provide technical and motivational support to help you benefit from the computer package. They will not be able to offer advice relating to your emotional health.

If you are in the group without telephone support you will not receive regular telephone calls. You

will however be provided with a free-phone helpline number to ring in case of any problems with the computer programme.

Follow up

Four months after you have entered into the study we will contact you again to ask you a further set of questions to see how you are feeling now. We will also do this 12 months after you have entered into the study.

There are four options to choose from as to how you would like to complete the follow up questions for us:

- (1) the researcher can contact you and go through the questions with you over the telephone
- (2) we can provide you with a web address and password where you can answer the questions online
- (3) we can post you paper versions of the questions for you to complete with a prepaid envelope in which you can return them to us
- (4) we can arrange to meet you in person to go through the questions together

You can let the researcher know how you would prefer to do the follow up questions.

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

The main difference will be that you will be set up with a computerised CBT programme by your local researcher. The researcher will also want you to complete some questionnaires before you start the programme and at the follow up points

at 4 and 12 months. If you are in the telephone supported group you will also receive weekly telephone calls from the telephone support worker.

Whilst 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.

6 Possible benefits and disadvantages of taking part

What are the possible disadvantages and risks of taking part in REEACT-2?

Computerised CBT is a relatively new treatment for depression. At the moment there is still some uncertainty about how effective it is. It may be that you do not find this method of treatment helpful. At any point during the study you can stop using the programme without having to give a reason why. There are no known side effects of computerised CBT.

What are the possible benefits of taking part in REEACT-2?

We hope that you will be helped by receiving the computerised CBT programme, but this cannot be guaranteed.

By participating in this trial you may receive additional support to use the computerised CBT programme than might otherwise be available in your GP practice.

7 More information about taking part

Do I have to take part?

It is up to you to decide whether or not to take part. We will describe the study and go through this information sheet with you. You are free to withdraw at any time, without giving a reason. This would not affect the standard or type of care you receive.

Will I receive any payment for taking part?

Unfortunately we are not able to offer any expenses or payments to patients who participate in the study. However, participants will be sent a goodwill gesture of £5 with the four- and 12-month follow-up questionnaires.

What happens if new information becomes available during the course of the study?

Sometimes during a study, new information becomes available about the treatment being studied. If this happens, the research team will tell you and discuss whether you want to continue in the study. If you decide to stop taking part in the study your usual GP care will continue. If you decide to continue in the study you may be asked to sign an updated consent form. If we think you

should withdraw from the study, we will explain the reasons and arrange for your care to continue.

What happens when the study stops?

Very occasionally a study is stopped early. If this happens, the reasons will be explained to you and arrangements made for your GP care to continue as usual.

What if there is a problem?

If you have a concern about any aspect of this study you should ask to speak to the researcher who will do their best to answer your questions <<insert local tel>>. Alternatively you could speak to the chief investigator Prof. Simon Gilbody (tel: XXXX).

If you remain unhappy and wish to complain formally, the normal NHS complaints process is available to you.

If you are harmed by taking part, or if you are harmed due to someone's negligence, then you may be able to take legal action.

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

All information will be held securely and in strict confidence. We keep the information we collect about you separate from your personal details and we can only link this information together with a secure code. Only authorised members of the research team will have access to your information.

We will use the information we collect to look at how best to help people using computerised

CBT. We will keep it for 20 years and then destroy it securely. We will destroy all contact information immediately after the end of the study.

Involvement of your GP

We will tell your GP that you are taking part in the study and inform them of your results on the initial screening questions we use to check if you are eligible to take part. No other questionnaire results will be given to your GP. There is space on the consent form for you to confirm that you are aware of this. We will also inform them whether you are receiving the telephone support calls or not.

If we are worried that you are having thoughts about harming yourself, we may need to discuss these with your GP. We will of course discuss this with you.

If you send us a questionnaire through the post or complete a questionnaire online and we are worried that you are having thoughts about harming yourself, we will let your GP know of our concerns.

What will happen to the results of the study?

When the study is completed, the results will be published in a health care journal so health care professionals can see the results. If published, your identity and personal details will be kept confidential. No named information about you will be published in any report about this study. We will also provide you with a summary of our findings from the study.

Who is organising and funding the study?

This trial is organised by the University of York. The funder is the Health Technology Assessment (HTA) programme.

Who has reviewed the study?

This trial has been reviewed 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 Bradford Research Ethics committee.

8 Contact for further information

If you have any questions regarding the study or how you might be involved further contact information can be found below.

Local researcher

<<name, address, tel, email>>

Chief Investigator

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

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