

Patient Information Leaflet

CoBaIT

Cognitive Behavioural Therapy for depression (CoBaIT) (ISRCTN38231611)

We would like to invite you to take part in a research study. Before you decide you need to understand why the research is being done and what it would involve for you. Please take time to read the following information carefully. Feel free to discuss the study with family and friends if you wish. Please ask us if there is anything that is not clear or if you would like more information.

What is the purpose of the study?

Each year, many people visit their General Practitioner (GP) with depression and are given antidepressants by their doctor. Unfortunately, some people continue to feel depressed even though they have taken antidepressants for 6 weeks or more. This problem is far more common than often realised. Doctors are not certain about the best way to treat these patients. There is some evidence to suggest that a type of “talking therapy” called cognitive behavioural therapy (or CBT) may be helpful. In order to find out whether CBT when given in addition to antidepressants can reduce symptoms over the following year, we need to compare two approaches to treating depression by carrying out what is called a randomised controlled trial.

What is cognitive behavioural therapy?

CBT is a type of talking therapy. CBT is based on the idea that the way people think affects how they feel. 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. As part of this process, you may be asked to think about some of the issues discussed between sessions. We hope that CBT will help you develop ways of managing your depression better.

Why have I been asked to take part?

You have been prescribed antidepressants by your GP and have been taking these tablets for more than 6 weeks. Your GP has written to you to ask whether you would be willing to take part in the study organised by us, the **CoBaIT** research team based at the universities of Bristol, Exeter, and Glasgow.

What will happen now?

If you agree to take part in the study, we will send you a short questionnaire, by post, during the next week to ask you about your medication and symptoms.

Based on the answers that you give to this questionnaire, we may then contact you to ask you to consider taking part in the study. Not everyone who completes the questionnaire will be contacted to take part in the study. If we contact you again, we would invite you to an appointment with a member of our research team who would discuss the study with you in more detail. At this time, you would also be given a more detailed information leaflet about the study to read. If you agreed to take part in the study you would be asked to give written consent.

Do I have to take part?

You do not have to take part in this study. If you agree to us sending you a questionnaire, this will not commit you to taking part in the study. We hope that as many people as possible will take part but, when the questionnaire is sent to you, it is up to you to decide whether or not to take part. If you decide not to participate, please return the questionnaire blank in the envelope provided. If you decide to take part you are still free to withdraw at any time, without giving a reason. A decision to withdraw at any time, or a decision not to take part, will not affect the standard of care you receive.

Are there any disadvantages of taking part in this study?

Some of the questions in the questionnaire ask about symptoms of depression such as feeling low and self harm. Whilst most people do not mind answering these questions, some people may feel upset. However, it is important that we ask these questions and find out if the treatments can improve these symptoms.

There are no other disadvantages associated with taking part in the study.

Will my taking part in the study be kept confidential?

The information you give is entirely confidential and will not be disclosed to anyone outside the **CoBaIT** research team without your permission. However, if you suggest that you may harm yourself (or others), we may have to inform your GP because of possible concerns about your safety (or the safety of others). Wherever possible the **CoBaIT** team would consult you before contacting your GP.

If you complete the questionnaire and are not eligible for the study or do not want to take part, with your permission, we can provide your GP with some information that he/she may find useful. This will consist of a summary telling your GP about the symptoms that you have experienced and use of antidepressant medication. It will not give your answers to specific questions. All the information collected will be stored securely according to the Data Protection Act 1998.

Who is organising and funding the research?

The study is organised by the Department of Community Based Medicine at the University of Bristol, in collaboration with the Peninsula Medical School, the University of Exeter and the University of Glasgow. It is funded by a grant from the Health Technology Assessment Programme, which is part of the Department of Health. The study is also supported by the Mental Health Research Network (MHRN) for England, the Scottish MHRN, and the Primary Care Research Networks in both England (PCRN) and Scotland (SPCRN).

Who has reviewed the study?

This study has been reviewed and approved by the West Midlands Research Ethics Committee.

Who do I contact for further information?

For further information about the study, please contact the Trial Co-ordinator at the University of Bristol 0117 954 6660 or your local **CoBaIT** team (see below).

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Thank you for considering taking part in this research