

# Cognitive Behavioural Therapy as an adjunct to pharmacotherapy for treatment resistant depression in primary care: a randomised controlled trial

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<b>Registration date</b> 15/08/2007	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 19/01/2016	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Many patients with depression who are prescribed antidepressants by their GP do not get better after 6 weeks of treatment. Currently there is little evidence about what alternative treatment options doctors should discuss with patients at this time. Cognitive behavioural therapy (CBT) is a type of talking therapy that has been shown to help patients with mild to moderate depression but there is little evidence about its effectiveness in patients who have not initially responded to antidepressants. In this study, we will examine whether patients who have not got better on antidepressants and go on to receive CBT as well as their medication are more likely to get better than patients who just continue to take their antidepressants over 12 months. We will also look at how much this treatment costs and patients' views and experiences of it.

### Who can participate?

Patients aged 18-75 with depression who have been taking antidepressants for at least 6 weeks.

### What does the study involve?

Patients will be invited to participate by their GP (in person or by letter) and those who are interested will be invited to meet with a researcher to discuss their participation in the study. All patients will be asked to sign a consent form to confirm that they fully understand what the study will involve. If you are eligible and willing to take part in the research, you will then be randomly allocated to one of two treatment groups, either: (1) CBT in addition to usual care, which includes antidepressants; or (2) usual care, including antidepressants. If you are included in Group 1, you will be invited to attend CBT sessions. Each session will last 50 minutes. Sessions will initially take place once a week but later on you and your therapist may decide that these sessions will occur less frequently. You would receive 12-18 sessions of CBT over about 6 months. If you are included in Group 2, you will continue to be under the normal care of your GP for the management of your depression. There will be no restrictions on the treatments that you can receive. Participants will be asked to complete a questionnaire at this time and again after 3, 6, 9 and 12 months. By comparing the two groups, we will be able to determine whether CBT is

an effective treatment for this patient group. Participants will also be asked for their permission for the research team to have access to your medical records held at your GPs surgery and to any hospital records. You would also be asked to give your consent for any CBT treatment sessions to be recorded using a digital voice recorder.

What are the possible benefits and risks of participating?

We hope that the treatment will help those who take part. However, this cannot be guaranteed. The results of the study will help doctors in the future to decide on the best treatment for someone who is depressed. Some of the questions that you will be asked during the assessment are personal and sometimes people can find it upsetting to discuss these issues. However, you don't have to answer anything you don't want to. The researcher will be able to offer support during the appointment if you are upset, but would also contact the doctors or care workers who normally provide care for you, if further support is necessary.

Where is the study run from?

University of Bristol (UK).

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

The study started in May 2008 and will run until March 2015.

Who is funding the study?

NIHR Health Technology Assessment Programme - HTA (UK).

Who is the main contact?

Dr Nicola Wiles

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## Contact information

**Type(s)**

Scientific

**Contact name**

Dr Nicola Wiles

**Contact details**

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## Additional identifiers

**Protocol serial number**

## Study information

### Scientific Title

Cognitive Behavioural Therapy as an adjunct to pharmacotherapy for treatment resistant depression in primary care: a randomised controlled trial

### Acronym

CoBalT

### Study objectives

To determine the clinical and cost-effectiveness of Cognitive Behavioural Therapy (CBT) in addition to pharmacotherapy in reducing depressive symptoms and improving quality of life over the following 12 months (compared to pharmacotherapy plus usual care) in patients with Treatment Resistant Depression (TRD)

In addition, a qualitative study will be conducted to:

1. Explore patient's views and experiences of CBT
2. Identify patient's reasons for completing or not completing therapy
3. To describe 'usual care' for this patient group

More details can be found at: <http://www.nets.nihr.ac.uk/projects/hta/0640402>

Protocol can be found at: [http://www.nets.nihr.ac.uk/\\_\\_data/assets/pdf\\_file/0019/51418/PRO-06-404-02.pdf](http://www.nets.nihr.ac.uk/__data/assets/pdf_file/0019/51418/PRO-06-404-02.pdf)

Added 19/02/2013:

In addition, to determine whether the intervention is effective in reducing depressive symptoms and improving quality of life over the long-term (approximately 4 years post-randomisation), compared with usual care alone, and whether this strategy is cost-effective

Added 04/09/2014:

A nested qualitative study will also be conducted with those who completed the long-term follow-up study questionnaire in order to explore how patients from both arms of the trial continued to manage their depression over the long-term (since the 12-month follow-up). Amongst those who received CBT during the trial, the study will also explore the extent to which they have continued to use the techniques learnt and to incorporate CBT strategies into their lives.

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

West Midlands Research Ethics Committee, 26/02/2008, ref: 07/H1208/60

### Primary study design

Interventional

### Study design

Multi-centre randomised controlled trial

**Study type(s)**

Treatment

**Health condition(s) or problem(s) studied**

Depression

**Interventions**

Patients will be randomised to one of two groups. All patients will be taking antidepressants at the point of randomisation. Both groups will continue their antidepressants as directed by their GP.

In Group 1 (intervention group), subjects will be randomised to receive CBT in addition to usual care (including pharmacotherapy). Each patient will receive a course of 12-18 sessions of CBT.

In Group 2 (control group), subjects would continue to receive their usual care from their GP (including antidepressants).

**Intervention Type**

Mixed

**Primary outcome(s)**

BDI score at 6-months post-randomisation, specifically a binary variable representing response, defined as a reduction in depressive symptoms of at least 50% compared to baseline.

**Key secondary outcome(s)**

Current secondary outcome measures as of 19/02/2013:

Remission of symptoms, quality of life and use of antidepressants at 6 months post-randomisation, together with outcomes measured at 12 months post-randomisation and long-term outcomes measured approximately 4 years post-randomisation.

Previous secondary outcome measures until 19/02/2013:

Remission of symptoms, quality of life and use of antidepressants at 6 months post-randomisation, together with outcomes measured at 12 months post-randomisation.

**Completion date**

31/03/2015

**Eligibility****Key inclusion criteria**

1. Aged 18-75 years
2. Patients currently taking antidepressant medication and who have done so for at least 6 weeks at an adequate dose
3. Patients who score 14 or more on the Beck Depression Inventory (BDI)
4. Have adhered to their medication
5. Meet the World Health Organization International Statistical Classification of Diseases and Related Health Problems 10th Revision (ICD-10) criteria for depression

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 Years

**Upper age limit**

75 Years

**Sex**

All

**Key exclusion criteria**

1. Bipolar disorder
2. Psychosis or alcohol/substance abuse/dependence
3. Not able to complete the study questionnaires
4. Currently receiving CBT or other psychotherapy or secondary care for depression
5. Have received CBT in the past 3 years
6. Patients who would not be able to benefit from talking therapy without an interpreter
7. Women who are pregnant at time of recruitment will be excluded from the trial but women who become pregnant during the trial may continue, providing they have approval and permission to do so from their GP

**Date of first enrolment**

04/11/2008

**Date of final enrolment**

30/09/2010

**Locations****Countries of recruitment**

United Kingdom

England

**Study participating centre**

Centre for Academic Mental Health

Bristol

United Kingdom

BS8 2BN

**Sponsor information**

## Organisation

University of Bristol (UK)

## ROR

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

## Funder(s)

### Funder type

Government

### Funder Name

Health Technology Assessment Programme

### Alternative Name(s)

NIHR Health Technology Assessment Programme, Health Technology Assessment (HTA), HTA

### Funding Body Type

Government organisation

### Funding Body Subtype

National government

### Location

United Kingdom

## Results and Publications

### Individual participant data (IPD) sharing plan

#### IPD sharing plan summary

#### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	02/02/2013		Yes	No
<a href="#">Results article</a>	economic evaluation results	01/01/2014		Yes	No
<a href="#">Results article</a>	results	01/05/2014		Yes	No
<a href="#">Results article</a>	adherence to and divergence from trial criteria results	01/06/2014		Yes	No

<a href="#">Results article</a>	follow-up results	01/02 /2016		Yes	No
<a href="#">Protocol article</a>	protocol	01/03 /2012		Yes	No
<a href="#">Other publications</a>	patients' reasons for declining contact	01/05 /2012		Yes	No
<a href="#">Other publications</a>	comparison of four different approaches to measuring health utility	09/05 /2013		Yes	No
<a href="#">Other publications</a>	depressed clients' experiences	01/11 /2013		Yes	No
<a href="#">Other publications</a>	patients' experiences	01/12 /2013		Yes	No
<a href="#">Participant information sheet</a>	Participant information sheet	11/11 /2025	11/11 /2025	No	Yes
<a href="#">Study website</a>	Study website	11/11 /2025	11/11 /2025	No	Yes