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

Submission date
14/08/2007

Recruitment status
No longer recruiting

Registration date
15/08/2007

Overall study status
Completed

Last Edited
19/01/2016

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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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Study website
http://www.thecobaltstudy.ac.uk/

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
HTA 06/404/02

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

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

Study design
Multi-centre randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Treatment

Participant information sheet
Patient information can be found at: http://www.thecobaltstudy.ac.uk/docs/pt-info.pdf

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 measure
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.

Secondary outcome measures
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.

Overall study start date
01/05/2008

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

Age group
Adult

Lower age limit
18 Years

Upper age limit
75 Years

Sex
Both

Target number of participants
480

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
England

United Kingdom

Study participating centre
Centre for Academic Mental Health
Bristol
United Kingdom
BS8 2BN

Sponsor information

Organisation
University of Bristol (UK)

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Sponsor type
University/education

ROR
https://ror.org/0524sp257

Funder(s)

Funder type

Government

Funder Name
Health Technology Assessment Programme

Alternative Name(s)
NIHR Health Technology Assessment Programme, HTA

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	01/03/2012		Yes	No
Other publications	patients' reasons for declining contact	01/05/2012		Yes	No
Results article	results	02/02/2013		Yes	No
Other publications	comparison of four different approaches to measuring health utility	09/05/2013		Yes	No
Other publications	depressed clients' experiences	01/11/2013		Yes	No
Other publications	patients' experiences	01/12/2013		Yes	No
Results article	economic evaluation results	01/01/2014		Yes	No
	results	01/05			

Results article		/2014	Yes	No
Results article	adherence to and divergence from trial criteria results	01/06 /2014	Yes	No
Results article	follow-up results	01/02 /2016	Yes	No