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Cognitive behavioural therapy (CBT) for treatment resistant depression (TRD).

Submission date	Recruitment status	[ ] Prospectively registered
30/09/2004	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
30/09/2004	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
10/11/2022	Mental and Behavioural Disorders	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N0038133700

Study information

Scientific Title
Cognitive behavioural therapy (CBT) for treatment resistant depression (TRD).

Study objectives
How effective is CBT in the treatment of resistant (refractory) depression?
About 30% of depressed patients do not respond to a course of antidepressants at the recommended dosage after 6 weeks and are sometimes described as having treatment refractory or treatment resistant depression (TRD). At present, clinical guidelines do not provide specific advice about how to manage this situation. No RCTs have investigated a psychological treatment for this patient group (Stimpson et al, 2002). However, there are indications that psychological treatments may be effective. For example, cognitive behavioural therapy (CBT) is known to be effective in those with residual depressive symptoms (Paykel et al, 1999).

CBT is the most widely available structured psychotherapy for depression in specialist mental health services in the NHS. Most research into CBT has examined the effectiveness of CBT for previously untreated depressive episodes. However, CBT is usually used for those who have not responded to pharmacotherapy in primary care i.e. those who are treatment resistant.

This study is a pilot study for a pragmatic randomised controlled trial of the clinical effectiveness of cognitive behavioural therapy as an adjunct to pharmacotherapy in treatment resistant depression. The objectives of the pilot study are to investigate the feasibility of the proposed trial. In particular, the pilot aims to (i) estimate the rate of recruitment and (ii) investigate the quality of the CBT.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Not Specified

Participant information sheet

Health condition(s) or problem(s) studied

Mental and Behavioural Disorders: Depression

Interventions
1. Usual care
2. Usual care and CBT

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Beck Depression Inventory (BDI) score at 4 months post-randomisation.

Secondary outcome measures
Quality of Life

Overall study start date
01/01/2004

Completion date
31/07/2005

Eligibility

Key inclusion criteria
Primary care based patients who have not responded to antidepressant medication given at an adequate dose for 6 weeks or longer.

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
40

Total final enrolment
316

Key exclusion criteria
Added July 2008:
1. Patients with bipolar disorder, psychosis, personality disorder or major alcohol or substance abuse problems
2. Patients who had been continually depressed for more than 5 years

3. Patients those unable to complete the study questionnaires
4. Patients who had previously or were currently receiving CBT therapy
5. Patients currently receiving other psychotherapy or secondary care for their depression

Date of first enrolment
01/01/2004

Date of final enrolment
31/07/2005

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Academic Unit of Psychiatry
Bristol
United Kingdom
BS6 6JL

Sponsor information

Organisation
Department of Health

Sponsor details
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL

Sponsor type
Government

Website
http://www.dh.gov.uk/Home/fs/en

Funder(s)

Funder type
Government

Funder Name
Avon and Wiltshire Mental Health Partnership NHS Trust (UK)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan
Not provided at time of registration

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		21/08/2007		Yes	No