

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

<b>Submission date</b> 30/09/2004	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 30/09/2004	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
<b>Last Edited</b> 10/11/2022	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Prof Glyn Lewis

**Contact details**  
Academic Unit of Psychiatry  
Bristol University  
Cotham House  
Cotham Hill  
Bristol  
United Kingdom  
BS6 6JL  
+44 (0)117 954 6796  
Glyn.lewis@bristol.ac.uk

## 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?
<a href="#">Results article</a>		21/08/2007		Yes	No