

# Cognitive-behavioural therapy for treatment-resistant depression: early intervention study

<b>Submission date</b> 28/09/2007	<b>Recruitment status</b> Stopped	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 28/09/2007	<b>Overall study status</b> Stopped	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 29/04/2016	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

**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**  
N0573188386

# Study information

## Scientific Title

Cognitive-behavioural therapy for treatment-resistant depression: early intervention study

## Study objectives

Is cognitive-behavioural therapy (CBT) more effective than treatment-as-usual (TAU) for depression that has been resistant to anti-depressants and other primary care interventions?

## 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)

Hospital

## Study type(s)

Treatment

## Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

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

Depression

## Interventions

Patients are randomised to:

1. CBT
2. Treatment-as-usual

Face to face interviews and video recording will also take place.

## Intervention Type

Other

## Phase

Not Specified

**Primary outcome measure**

1. CORE
2. Hamilton Depression Scale (HAM-D)
3. Beck Depression Inventory (BDI)
4. Beck Hopelessness Scale (BHS)

**Secondary outcome measures**

1. Quality of Life and Social Functioning: to be determined through discussion with Psychological Therapies Research Network
2. Mediating Variables: Dysfunctional Attitudes Scale (DAS), Automatic Thoughts Questionnaire (ATQ), Sentence Completion Test for Depression (SCD), Roles and Goals Questionnaire (RAG).

**Overall study start date**

01/05/2006

**Completion date**

01/05/2009

**Reason abandoned (if study stopped)**

Lack of staff/facilities/resources

## **Eligibility**

**Key inclusion criteria**

24 depressed NHS patients, aged 18 - 65 years, will be recruited from routine referrals to the Newcastle CBT Centre (NCBTC) and secondary care mental health services within the 3Ns Trust.

Inclusion criteria:

1. Adults aged 18 - 65 years
2. Major depressive episode as the primary diagnosis, first or second major episode, lasting at least 12 months duration
3. Moderate or severe depression symptoms
4. Treatment-resistance to at least one course of anti-depressant previously administered at an adequate dose for adequate period, treatment resistance to other primary care interventions

**Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

18 Years

**Upper age limit**

65 Years

**Sex**

Both

**Target number of participants**

**Key exclusion criteria**

1. Previous individual or group CBT following a recognised protocol within secondary care services
2. Three or more major episodes of depression
3. People with bi-polar disorder, psychosis, learning disability, borderline personality disorder, alcohol or addiction problems

**Date of first enrolment**

01/05/2006

**Date of final enrolment**

01/05/2009

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

England

United Kingdom

**Study participating centre**

**University of Newcastle**

Newcastle upon Tyne

United Kingdom

NE1 7RU

**Sponsor information****Organisation**

Record Provided by the NHSTCT Register - 2007 Update - Department of Health

**Sponsor details**

The Department of Health

Richmond House

79 Whitehall

London

United Kingdom

SW1A 2NL

+44 (0)20 7307 2622

dhmail@doh.gsi.org.uk

**Sponsor type**

Government

**Website**

<http://www.dh.gov.uk/Home/fs/en>

**Funder(s)****Funder type**

Government

**Funder Name**

Northumberland, Tyne and Wear 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****IPD sharing plan summary**

Not provided at time of registration