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

| Submission date | Recruitment status | [ ] Prospectively registered |
|---|---|---|
| 28/09/2007 | Stopped | [ ] Protocol |
| **Registration date** | **Overall study status** | [ ] Statistical analysis plan |
| 28/09/2007 | Stopped | [ ] Results |
| **Last Edited** | **Condition category** | [ ] Individual participant data |
| 29/04/2016 | Mental and Behavioural Disorders | [ ] 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

**Protocol serial number**
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

## Study type(s)
Treatment

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

## Key secondary outcome(s))
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).

## 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

### Healthy volunteers allowed
No

### Age group
Adult

### Lower age limit
18 years

### Upper age limit
65 years

### Sex
All

### 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
United Kingdom

England

**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

# Funder(s)

**Funder type**
Government

**Funder Name**
Northumberland, Tyne and Wear NHS Trust (UK)

# Results and Publications

## 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? |
|---|---|---|---|---|---|
| Participant information sheet | Participant information sheet | 11/11/2025 | 11/11/2025 | No | Yes |