

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

Submission date 28/09/2007	Recruitment status Stopped	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 28/09/2007	Overall study status Stopped	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 29/04/2016	Condition category 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