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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

Primary study design
Interventional

Study design
Randomised controlled trial

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