# Evaluation of CBT in older persons with anxiety: a pilot study

Submission date	Recruitment status	<ul><li>Prospectively registered</li></ul>
29/09/2006	No longer recruiting	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
29/09/2006	Completed	Results
Last Edited	Condition category	☐ Individual participant data
12/08/2016	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

#### Contact name

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### Additional identifiers

**EudraCT/CTIS** number

**IRAS** number

ClinicalTrials.gov number

Secondary identifying numbers

N0081165259

### Study information

#### Scientific Title

Evaluation of CBT in older persons with anxiety: a pilot study

### **Study objectives**

The aim of this study is to

- 1. Test the research methodology of a CRT designed to evaluate the short term and medium term benefits of manualised cognitive behaviour therapy (MCBT) over treatment as usual (TAU), in older adults experiencing anxiety with or without mild depression in inpatient and day care settings
- 2. Obtain an estimate of any treatment effects in order to carry out a power calculation for a larger study

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

Not provided at time of registration

### Study design

Randomised controlled pilot study

### Primary study design

Interventional

### Secondary study design

Randomised controlled trial

### Study setting(s)

Not specified

### 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

Mental and Behavioural Disorders: Anxiety disorders

#### **Interventions**

Participants in the study will be recruited from an inpatient setting and a day hospital setting; information regarding the purpose and nature of the study will be given. Informed consent to enter the study will be obtained and participants will be randomly allocated to either the intervention group or the treatment as usual group in each setting. Randomisation will be achieved by using a sealed envelope technique, for each setting (inpatient/day hospital) an equal number of envelopes marked intervention group or control group, an envelope will be picked for each individual entering the trial.

The intervention group will receive a fifteen-week course of group CBT using a treatment manual. Measures will be applied pre and post treatment and at one month and six month intervals. As this is a pilot study it is anticipated that 6-10 participants will be recruited for each group (treatment as usual and CBT) in both settings (inpatient care and day hospital). Six being the lowest number required to run the group, ten allows for some drop out during treatment.

### **Intervention Type**

Other

#### Phase

**Not Specified** 

### Primary outcome measure

The following measures will be used: Penn State Worry Questionnaire (Meyer et al 1990) Beck Anxiety Inventory (BAI) Beck et al (1988) Beck Depression Inventory 1 (BDI) Beck et al (1986)

Outcome measures will be completed pre and post treatment, and at one month and six month intervals after completion of treatment. All groups (intervention and control in both settings) will complete measures at the same times. The member of research staff responsible for collection and completion of the measures will be blind to the participants status within the trial.

### Secondary outcome measures

Not provided at time of registration

### Overall study start date

01/03/2005

### Completion date

31/05/2007

### **Eligibility**

### Key inclusion criteria

- 1. Diagnosis of generalised anxiety disorder, panic with or without moderate depression
- 2. Have the capacity to give informed consent
- 3. Have a sufficient level of literacy in order to use the materials provided during the course
- 4. Have a maximum score of no more than 29 (a score of 30 plus indicates severe depression) on the Beck Depression Inventory 1 (Beck et al 1986)
- 5. Any current physical health problems are stable and expected to be stable for the duration of the trial

### Participant type(s)

Patient

### Age group

Senior

Sex

### Target number of participants

20

### Key exclusion criteria

- 1. Clinical diagnosis of an organic brain syndrome including dementia as assessed by their consultant
- 2. Severe sensory impairment that could prevent use of the material provided during the course
- 3. Non-English speaking
- 4. Should participants experience a significant change in their physical health during the trial they may continue with the trial if they wish, but their data will be excluded from the analysis.

### Date of first enrolment

01/03/2005

### Date of final enrolment

31/05/2007

### Locations

### Countries of recruitment

England

**United Kingdom** 

## Study participating centre c/o Barnsdale Ward

Leicester United Kingdom LE5 4PW

### Sponsor information

### Organisation

Department of Health

### Sponsor details

Richmond House 79 Whitehall London United Kingdom SW1A 2NL +44 20 7307 2622 dhmail@doh.gsi.org.uk

### Sponsor type

Government

### Website

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

### ROR

https://ror.org/03sbpja79

### Funder(s)

### Funder type

Hospital/treatment centre

### Funder Name

Leicestershire Partnership NHS Trust

### **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