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

Submission date	Recruitment status	Prospectively registered
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

Protocol serial number 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

Study type(s)

Treatment

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(s)

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.

Key secondary outcome(s))

Not provided at time of registration

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

Healthy volunteers allowed

No

Age group

Senior

Sex

Not Specified

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

United Kingdom

England

Study participating centre c/o Barnsdale Ward

Leicester United Kingdom LE5 4PW

Sponsor information

Organisation

Department of Health

ROR

https://ror.org/03sbpja79

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Leicestershire Partnership NHS Trust

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type