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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

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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