

The management of anxiety in Alzheimer's disease - A pilot study of a single-blind randomised controlled trial using an intervention package with a three month follow-up

Submission date 29/09/2006	Recruitment status No longer recruiting	☐ Prospectively registered
		☐ Protocol
Registration date 29/09/2006	Overall study status Completed	☐ Statistical analysis plan
		☐ Results
Last Edited 15/03/2017	Condition category Nervous System Diseases	☐ Individual participant data
		☐ 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

N0577167824

Study information

Scientific Title

The management of anxiety in Alzheimer's disease - A pilot study of a single-blind randomised controlled trial using an intervention package with a three month follow-up

Study objectives

Does the management of anxiety in Alzheimer's disease result in a significant reduction in anxiety, improved QoL and an improvement in carer mental health?

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

Nervous System Diseases: Alzheimer's disease

Interventions

1. Systematic review of evidence.
2. Recruiting participants through day centres, lunch clubs with specialist provision for dementia.
3. Randomisation of participants.
4. Intervention package, which will involve a stepped care plan using physical, drug, social and psychological interventions.
5. Follow-up, which will be done 3 months post intervention.
6. Data-Analysis will be done on an intent to treat basis and will be achieved by using analysis of co-variance.

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

Rating of Anxiety in Dementia (RAID), QoL-AD and the General Health Questionnaire (GHQ-12)

Key secondary outcome(s)

Not provided at time of registration

Completion date

01/08/2006

Eligibility

Key inclusion criteria

Participants will be selected from 5 centres within North East London Mental Health Trust.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Senior

Sex

Not Specified

Key exclusion criteria

Not provided at time of registration

Date of first enrolment

01/11/2005

Date of final enrolment

01/08/2006

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Old Age Psychiatry

Brentwood

United Kingdom

CM15 5HQ

Sponsor information

Organisation

Funder(s)

Funder type

Government

Funder Name

North East London Mental Health NHS Trust (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration