

# 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

<b>Submission date</b> 29/09/2006	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 29/09/2006	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 15/03/2017	<b>Condition category</b> Nervous System Diseases	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**

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

### **Study design**

Randomised controlled trial

### **Primary study design**

Interventional

### **Secondary study design**

Randomised controlled trial

### **Study setting(s)**

Hospital

### **Study type(s)**

Treatment

### **Participant information sheet**

### **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 measure**

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

**Secondary outcome measures**

Not provided at time of registration

**Overall study start date**

01/11/2005

**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

**Age group**

Senior

**Sex**

Not Specified

**Target number of participants**

Not provided at time of registration

**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**

England

United Kingdom

**Study participating centre**

**Old Age Psychiatry**

Brentwood

United Kingdom

CM15 5HQ

## **Sponsor information**

**Organisation**

Record Provided by the NHSTCT Register - 2006 Update - Department of Health (UK)

**Sponsor details**

The Department of Health, Richmond House, 79 Whitehall

London

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dhmail@doh.gsi.org.uk

**Sponsor type**

Government

**Website**

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

## **Funder(s)**

**Funder type**

Government

**Funder Name**

North East London Mental Health NHS Trust (UK)

## **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