

# A feasibility study to determine the potential for developing a pilot RCT to evaluate the effectiveness of a 10 week psychotherapy group for people with dementia in reducing levels of depression compared to a relaxation group

<b>Submission date</b> 29/09/2006	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 29/09/2006	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 28/09/2011	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

**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**

N0038161728

## **Study information**

**Scientific Title**

**Study objectives**

Can a 10 week programme of group psychotherapy reduce levels of depression for people with dementia compared to 10 weeks of group relaxation?

**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)**

Not specified

**Study type(s)**

Not Specified

**Participant information sheet**

**Health condition(s) or problem(s) studied**

Mental and Behavioural Disorders: Dementia

**Interventions**

Pilot RCT. Random allocation to [A] 10 week group psychotherapy; [B] 10 week group relaxation.

**Intervention Type**

Other

**Phase**

Not Specified

**Primary outcome measure**

Cornell Scale

**Secondary outcome measures**

RAID, the BASDEC depression scale, the Beck Anxiety Inventory, BASQUID scale and the ZARIT carer burden scale. Pilot will test feasibility of blinding, determine effect size, determine attrition rate.

**Overall study start date**

23/03/2005

**Completion date**

31/03/2006

**Eligibility****Key inclusion criteria**

28 participants in each of the two arms. Participants with a diagnosis of Alzheimer's disease or other dementia and MMSE score of at least 18, recruited from patients who have attended either the memory monitoring service in Bradford and Warminster or who have been assessed by a Consultant Psychiatrist.

Modified 18 July 2008: the trial recruited 9 (and not 28) participants to each arm.

**Participant type(s)**

Patient

**Age group**

Not Specified

**Sex**

Not Specified

**Target number of participants**

28 anticipated. Modified 18 July 2008: 9 to each arm, total 18

**Key exclusion criteria**

1. Significant premorbid history of functional mental health problems
2. Spouse not giving assent
3. Not living with a carer and/or if the social support is not sufficiently well-developed.

**Date of first enrolment**

23/03/2005

**Date of final enrolment**

31/03/2006

**Locations**

**Countries of recruitment**

England

United Kingdom

**Study participating centre**

**Charter House**

Trowbridge

United Kingdom

BA14 8LS

## **Sponsor information**

**Organisation**

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

**Sponsor details**

The Department of Health, Richmond House, 79 Whitehall

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**Sponsor type**

Government

**Website**

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

## **Funder(s)**

**Funder type**

Government

**Funder Name**

Avon and Wiltshire Mental Health Partnership NHS Trust (UK), NHS R&D Support Funding

## **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

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	01/05/2009		Yes	No