

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

Submission date 29/09/2006	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 29/09/2006	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 28/09/2011	Condition category 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

Protocol serial number
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

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Not Specified

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(s)

Cornell Scale

Key secondary outcome(s)

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.

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

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Not Specified

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**

United Kingdom

England

Study participating centre**Charter House**

Trowbridge

United Kingdom

BA14 8LS

Sponsor information

Organisation

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

Funder(s)

Funder type

Government

Funder Name

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

Results and Publications

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?
Results article	results	01/05/2009		Yes	No