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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

Registration date
29/09/2006

Last Edited
28/09/2011

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] 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
London
United Kingdom
SW1A 2NL
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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
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?
Results article	results	01/05/2009		Yes	No