A randomised single blind controlled trial evaluating an evidence-based psychological therapy package for dementia

Submission date	Recruitment status No longer recruiting Overall study status	Prospectively registered	
23/01/2004		☐ Protocol	
Registration date		Statistical analysis plan	
23/01/2004	Completed Condition category	[X] Results	
Last Edited		Individual participant data	
08/12/2008	Nervous System Diseases		

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

Protocol serial number RDC01638

Study information

Scientific Title

Study objectives

The study is a randomised single blind controlled trial evaluating an evidence-based psychological therapy package for people with dementia, both in day care and in residential care. In addition, the study will develop and evaluate a training package which will enable a variety of disciplines to organise and run similar groups.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomised single blind controlled trial

Primary study design

Interventional

Study type(s)

Not Specified

Health condition(s) or problem(s) studied

Nervous system diseases: Dementia

Interventions

- 1. Psychological therapy
- 2. Standard care

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

Mini Mental State Examination (MMSE) (Folstein et al., 1975) A brief, well established valid and reliable test of cognitive function. Widely used in the evaluation of drug trials and psychological therapies. The MMSE would enable the results of this study to be compared with the results of other researchers.

Key secondary outcome(s))

Not provided at time of registration

Completion date

01/03/2002

Eligibility

Key inclusion criteria

220 patients (65 or over) with dementia attending psychiatric day hospitals or dementia day centres, or in residential homes.

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

01/10/1999

Date of final enrolment

01/03/2002

Locations

Countries of recruitment

United Kingdom

England

Study participating centre University College London Medical School London

London United Kingdom W1N 8AA

Sponsor information

Organisation

NHS R&D Regional Programme Register - Department of Health (UK)

Funder(s)

Funder type

Government

Funder Name

NHS Executive London (UK)

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	01/11/2007		Yes	No