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

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

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
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

Primary study design
Interventional

Study design
Randomised single blind controlled trial

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
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