

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

Registration date

23/01/2004

Overall study status

Completed

☐ Statistical analysis plan

☒ Results

Last Edited

08/12/2008

Condition category

Nervous System Diseases

☐ 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

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

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