

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

Registration date

23/01/2004

Overall study status

Completed

Last Edited

08/12/2008

Condition category

Nervous System Diseases

☐ Prospectively registered

☐ Protocol

☐ Statistical analysis plan

☒ Results

☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr Martin Orrell

Contact details

University College London Medical School
Wolfson Building
Riding House Street
London
United Kingdom
W1N 8AA

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

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

Nervous system diseases: Dementia

Interventions

1. Psychological therapy
2. Standard care

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

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.

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/10/1999

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

Age group

Senior

Sex

Not Specified

Target number of participants

220

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

England

United Kingdom

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)

Sponsor details

The Department of Health
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL
+44 (0)20 7307 2622
dhmail@doh.gsi.org.uk

Sponsor type

Government

Website

<http://www.doh.gov.uk>

Funder(s)

Funder type

Government

Funder Name

NHS Executive London (UK)

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	01/11/2007		Yes	No