

Improving the needs of people with dementia in care homes

Submission date 14/10/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 14/10/2005	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 05/02/2016	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Dementia is a term given to a group of conditions that involve the gradual decline of a person's mental faculties. People with dementia have difficulties with mental processes such as memory, language, reasoning and identifying people and objects, which become progressively worst over time. This can make it very difficult to deal with daily life and so many sufferers are often placed in nursing homes so that they can receive round-the-clock care. There are many facilities in nursing homes aiming to help residents with a range of difficulties, however the particular needs of patients with dementia are still not really known and these unmet needs could lead to a poorer quality of life. The aim of this study is to try to identify the unmet needs of nursing home residents with dementia.

Who can participate?

Nursing home residents over 60 years old who are showing signs of dementia.

What does the study involve?

Participating nursing homes are randomly allocated to one of two groups. Residents attending nursing homes in the first group provide feedback about their specific needs, which are discussed in weekly hour-long sessions with a research nurse or clinical psychologist, over a period of 20 weeks. This information is then used to try and develop a way of ensuring that the needs of these residents are met. Residents attending nursing homes in the second group continue as normal for the 20 weeks of the study. At the end of the study, residents complete a number of questionnaires so that their needs and quality of life can be assessed.

What are the possible benefits and risks of participating?

Not provided at time of registration

Where is the study run from?

University College London (UK)

When is the study starting and how long is it expected to run for?

May 2000 to July 2014

Who is funding the study?
Wellcome Trust (grant reference: 061627) (UK)

Who is the main contact?
Professor Martin Orrell

Contact information

Type(s)
Scientific

Contact name
Prof Martin Orrell

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
061627

Study information

Scientific Title

A single blind randomised controlled study to identify and address the needs of older people with dementia in residential care

Study objectives

1. To compare the met and unmet needs of dementia sufferers in residential care from a range of areas
2. To investigate the relationship between costs of care, quality of life and met and unmet needs
3. To determine and cost appropriate interventions to meet unmet needs and provide systematic feedback on the needs and suggested interventions to the care staff for a 50% sample
4. To follow up all dementia sufferers six months later and examine whether systematic

feedback of needs resulted in interventions being carried out, the actual cost of the individual interventions and the costs of other outcomes (e.g. hospital admission)

As of 10/03/2009 this record was updated to include an amended end date; the initial end date at the time of registration was 31/05/2005. All other changes can be found under the relevant field with the above update date.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Added 10/03/2009: London MREC gave approval on the 1st November 2000 (ref: MREC/00/2/77)

Study design

Single-blind cluster randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Dementia

Interventions

Single-blind cluster randomised controlled trial involving 238 people with dementia living in residential care. 50% of the residential care homes (12 of 24) received feedback on needs of residents and one hour per week over 20 weeks liaison by a research nurse or clinical psychologist.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

1. Camberwell Assessment of Need for the Elderly
2. Quality of Life in Dementia (QoL-AD)

Secondary outcome measures

Added 10/03/2009:
Quality of life at four months.

Overall study start date

01/05/2000

Completion date

31/07/2004

Eligibility

Key inclusion criteria

Inclusion of residents into the study was completed using the following procedure:

1. All residents over 60 years old, either sex, who showed signs of dementia
2. Had resided permanently in the home for the past month
3. Had intentions of staying
4. Were identified by the home manager and the researcher using the National Institute of Social Workers (NISW) Noticeable Problems checklist (Levin, Sinclair, & Gorbach, 1989)

The list of residents with probable and possible dementia was then further screened by the researcher to ensure they had a diagnosis of dementia (Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition [DSM-IV]; APA, 1994) using care home notes and clinical assessments. Those with a DSM-IV diagnosis of dementia were entered into the randomisation procedure.

Participant type(s)

Patient

Age group

Senior

Sex

Both

Target number of participants

238

Key exclusion criteria

Does not meet with inclusion criteria

Date of first enrolment

01/05/2000

Date of final enrolment

31/07/2004

Locations

Countries of recruitment

England

United Kingdom

Study participating centre
University College London
London
United Kingdom
W1W 7EY

Sponsor information

Organisation
University College London

Sponsor details
Mental Health Services
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Sponsor type
University/education

ROR
<https://ror.org/02jx3x895>

Funder(s)

Funder type
Charity

Funder Name
Wellcome Trust

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype

International organizations

Location

United Kingdom

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	01/01/2006		Yes	No