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Effectiveness and cost-effectiveness of a care-programme by district nurses among elderly with dementia symptoms and their primary informal caregiver

Submission date
12/09/2005

Recruitment status
No longer recruiting

Registration date
12/09/2005

Overall study status
Completed

Last Edited
21/12/2011

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
ZonMw-number: 2200.0114; NTR66

Study information

Scientific Title

Acronym
PIKOM (in Dutch: Preventive Intervention among cognitively frail elderly and their care giver)

Study objectives
Caregivers' sense of competence will improve significantly more in participants of the intervention group compared to the participants in the usual care group.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the local medical ethics committee

Study design
Randomised, single blind, active controlled, parallel group trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Quality of life

Participant information sheet

Health condition(s) or problem(s) studied
Dementia, Dementia symptoms

Interventions
1. Usual care
2. Care programme by district nurses

Measurements are at baseline and after 6 and 12 months. Randomization takes place after baseline. The random order is established by an independent person using random number tables.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
1. Sense of mastery over the caregiver task as measured with the Sense of Competence Questionnaire (SCQ)
2. Quality of life by means of the MOS 36-item short-form health survey (SF-36)
3. Psychological well-being as determined with the Center for Epidemiologic Studies Depression Scale (CES-D)

Secondary outcome measures
1. Days until institutionalisation of the patient as checked with the GPs
2. Quality of life of the patient as measured with the Dementia Quality of Life Instrument (DQOL)
3. Days until death of the patient as checked with the GPs
4. Hospital days of the patient by means of cost diaries

Overall study start date
15/07/2002

Completion date
15/07/2006

Eligibility

Key inclusion criteria
1. Elderly are eligible for trial entry if they:
1.1. Are 65 years or over
1.2. Live outside of institutional settings
1.3. Suffer from dementia symptoms*
1.4. Have a primary informal caregiver
2. Both caregiver and patient should have a good command of the Dutch language

*Patients with dementia symptoms are persons with multiple cognitive impairments (i.e. memory impairments, aphasia, apraxia, agnosia, and impairment in executive functioning). It is assumed that these dementia symptoms lead to significant limitations in social functioning, progressive decline in general functioning.

Participant type(s)
Patient

Age group
Senior

Sex
Both

Target number of participants
100

Key exclusion criteria
1. Assistance by an outpatient geriatric team for cognitive problems
2. Terminal illness
3. Participation in other research projects and institutionalisation

Date of first enrolment
15/07/2002

Date of final enrolment
15/07/2006

Locations

Countries of recruitment
Netherlands

Study participating centre
Institute for Research in Extramural Medicine
Amsterdam
Netherlands
1081 HV

Sponsor information

Organisation
Vrije University Medical Centre (VUMC) (The Netherlands)

Sponsor details
Institute for Research in Extramural Medicine
Department of General Practice
Van der Boechorststraat 7
Amsterdam
Netherlands
1081 HV

Sponsor type
Hospital/treatment centre

Website
http://www.vumc.nl

ROR

https://ror.org/00q6h8f30

Funder(s)

Funder type
Research organisation

Funder Name
The Netherlands Organisation for Health Research and Development (ZonMw) (The Netherlands)

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	01/08/2011		Yes	No