

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	<input type="checkbox"/> Prospectively registered
Registration date 12/09/2005	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 21/12/2011	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> 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

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

Study type(s)

Quality of life

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(s)

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)

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Senior

Sex

All

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)

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

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