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The cost-effectiveness of systematic home visits by nurses of frail elderly primary care patients and caregivers of demented patients

Submission date	Recruitment status	[_] Prospectively registered
09/08/2004	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
25/01/2005	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
15/08/2024	Nervous System Diseases	

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.emgo.nl/research_prog/care/researchprojects_58.asp

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
The cost-effectiveness of systematic home visits by nurses of frail elderly primary care patients and caregivers of demented patients

Acronym
PIKO - Preventieve Interventie bij Kwetsbare Ouderen (Preventive Intervention for Frail Older persons)

Study objectives
1. To evaluate the cost-effectiveness of systematic home visits by nurses to frail elderly primary care patients.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The Ethical Committee of the VU medical center approved the study.

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Quality of life

Participant information sheet

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

Interventions
Trained community nurses visit patients at home, assess the care needs with the Resident Assessment Instrument - Home Care (RAI-HC), a multidimensional geriatric assessment. Computerisation enables direct identification of problem areas. The nurses make and execute standardised care-plans, targeted at individual needs that comply with patient priorities. The

nurses visit the patients at least five times during a year in order to execute and monitor the care-plan. Special attention is paid to caregivers of demented persons by family meetings.

Controls receive usual care.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Health related quality of life as measured with the Short Form 36 (SF-36), and Quality Adjusted Life Years by health utilities based on Euroqol (EQ-5D), measured at baseline, 6 and 18 months.

Secondary outcome measures
1. (Days until) institutionalization: hospital stay, placement in nursing home or home for the elderly are surveyed and crosschecked at institutes, measured at baseline, 6 and 18 months
2. Hospital admissions, measured at 18 months
3. (Days until) mortality as checked with the Primary Care Physicians (PCPs), measured at 18 months
4. Direct costs as measured by patient questionnaires with three-monthly recall periods. These self-report data are supplemented by data from the centralized regional pharmacy database (medication use), regional hospital check, and nursing home checks. In case patients are not able to fill out the forms themselves a close relative will be approached, measured at baseline, 6 and 18 months

Overall study start date
01/07/2002

Completion date
30/04/2007

Eligibility

Key inclusion criteria
1. Frail elderly as defined by:
1.1. Aged 75+ years persons living at home who score in the worst quartile of at least two of six COOP-charts are considered frail
1.2. Persons at high risk on the 7-minute screen and below the threshold of the Mini-Mental State Examination (MMSE) (less than 24)
2. Caregivers of demented persons (under 1.2.)

Participant type(s)
Patient

Age group
Senior

Sex

Both

Target number of participants
1100

Key exclusion criteria
Does not comply with the above inclusion criteria

Date of first enrolment
01/07/2002

Date of final enrolment
30/04/2007

Locations

Countries of recruitment
Netherlands

Study participating centre
VU University Medical Centre
Amsterdam
Netherlands
1081 BT

Sponsor information

Organisation
Vrije University Medical Centre (VUMC) (Netherlands)

Sponsor details
EMGO Institute
Van der Boechorststraat 7
Amsterdam
Netherlands
1081 BT

Sponsor type
Hospital/treatment centre

Website
http://www.vumc.nl/

ROR
https://ror.org/00q6h8f30

Funder(s)

Funder type
Research organisation

Funder Name
Vrije University Medical Centre (VUMC) (Netherlands) (ref: 2002/121)

Funder Name
The Netherlands Organisation for Health Research and Development (ZonMw) (Netherlands) (ref: 2200-114)

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	design and pilot results	08/09/2005		Yes	No
Results article	results	01/07/2010		Yes	No
Other publications	Correction to results article	14/08/2024	15/08/2024	Yes	No