

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

Submission date 09/08/2004	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 25/01/2005	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 15/08/2024	Condition category Nervous System Diseases	<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

Contact name
Dr Hein van Hout

Contact details
VU University Medical Centre
EMGO-Institute
Van der Boechorststraat 7
Amsterdam
Netherlands
1081 BT
+31 (0)20 4448199
Hpj.vanhout@vumc.nl

Additional identifiers

Protocol serial number
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

Study type(s)

Quality of life

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(s)

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.

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Senior

Sex

All

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)

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

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
Study website	Study website	11/11/2025	11/11/2025	No	Yes