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

Submission date	Recruitment status No longer recruiting	Prospectively registered		
09/08/2004		☐ 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

Contact name

Dr Hein van Hout

Contact details

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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 Eurogol (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