Preventing further falls and functional decline among elderly persons presented to the Accident and Emergency (A&E) department with a fall: randomised controlled trial

Submission date	Recruitment status No longer recruiting	Prospectively registered		
27/08/2004		[X] Protocol		
Registration date 11/10/2004	Overall study status Completed Condition category	Statistical analysis plan		
		[X] Results		
Last Edited		Individual participant data		
02/09/2021	Injury, Occupational Diseases, Poisoning			

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

945-02-053

Study information

Scientific Title

Preventing further falls and functional decline among elderly persons presented to the Accident and Emergency (A&E) department with a fall: randomised controlled trial

Acronym

Interval

Study objectives

The main objective of our current study is to evaluate the effects of a multidisciplinary intervention programme on recurrent falls and functional decline among elderly persons who have visit a general practitioners' cooperative (GP cooperative) and/or an accident and emergency department (A&E department) because of a fall. This objective has resulted in the following research questions:

- 1. Is a multidisciplinary intervention programme more effective than usual care in preventing new falls and functional decline among community-dwelling elderly people who visit a GP cooperative and/or A&E department at a hospital because of a fall?
- 2. Is the multidisciplinary intervention programme cost-effective compared to usual care when assessed from a societal perspective?

Ethics approval required

Old ethics approval format

Ethics approval(s)

The study design and protocols were approved by the Medical Ethics Committee of the University Hospital and University of Maastricht.

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Prevention

Participant information sheet

Health condition(s) or problem(s) studied

Falls

Interventions

- 1. Patients in the intervention group underwent a detailed medical and occupational-therapy assessment with referral to relevant services if indicated
- 2. Those assigned to the control group received usual care only

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

- 1. Number of falls (recorded continuously by means of a fall calendar during the twelve-month follow-up period):
- 1.1. The percentage of elderly people sustaining a fall during the one-year follow-up period
- 1.2. Recurrent falls during follow-up (i.e., the percentage of elderly people sustaining two or more falls)
- 1.3. Injurious falls during follow-up (the percentage of elderly people receiving medical care after a fall)
- 2. Daily functioning, measured using the Frenchai Activity Index (FAI) at baseline and after four and twelve months

Secondary outcome measures

Secondary outcome measures:

- 1. Recuperation from the fall
- 2. Health complaints
- 3. Perceived health measured by means of the first two items of the RAND 36-Item Health Survey
- 4. Activities of Daily Living (ADL) and Instrumental Activities of Daily Living (IADL) disability measured by means of the Groningen Activity Restriction Scale (GARS)
- 5. Mental health measured by means of the Hospital Anxiety and Depression Scale (HADS)
- 6. Quality of life measured by means of the European Quality of Life instrument (EuroQol)

The secondary outcome measures are assessed by means of self-administered questionnaires at four and twelve months.

Overall study start date

01/12/2002

Completion date

01/02/2004

Eligibility

Key inclusion criteria

- 1. Aged 65 years or older
- 2. Community-dwelling
- 3. Having visited the A&E department or GP cooperative at the University Hospital Maastricht with consequences resulting from a fall
- 4. Living in Maastricht or its surroundings

Participant type(s)

Patient

Age group

Senior

Sex

Not Specified

Target number of participants

328

Key exclusion criteria

- 1. Not able to speak or understand Dutch
- 2. Not able to complete questionnaires or interviews by telephone
- 3. Cognitive impairment (a score of less than 4 on the Abbreviated Mental Test 4 (AMT 4)
- 4. Long-term admission to a hospital or other institution (more than four weeks from the date of inclusion)
- 5. Permanently bedridden
- 6. Fully dependent on a wheelchair

Date of first enrolment

01/12/2002

Date of final enrolment

01/02/2004

Locations

Countries of recruitment

Netherlands

Study participating centre University Maastricht Maastricht

Netherlands 6200 MD

Sponsor information

Organisation

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

Sponsor details

Laan van Nieuw Oost Indië 334 P.O. Box 93245 The Hague Netherlands 2509 AE +31 (0)70 349 5111 info@zonmw.nl

Sponsor type

Research organisation

ROR

https://ror.org/01yaj9a77

Funder(s)

Funder type

Research organisation

Funder Name

The Netherlands Organisation for Health Research and Development (ZonMw) (The Netherlands) (ref: 945-02-053)

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?
Protocol article	Protocol	14/01/2005		Yes	No
Other publications	process evaluation	24/09/2008	26/02/2021	Yes	No
Results article	results	01/03/2008	26/02/2021	Yes	No