ISRCTN64716113 https://doi.org/10.1186/ISRCTN64716113

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
27/08/2004

Recruitment status
No longer recruiting

Registration date
11/10/2004

Overall study status
Completed

Last Edited
02/09/2021

Condition category
Injury, Occupational Diseases, Poisoning

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

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

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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