

Reduction of fear of falling and associated increase in functional ability, activity level and quality of life in community-living older adults who are at risk for falling: a randomised controlled trial

Submission date 07/10/2004	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 09/11/2004	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 01/09/2009	Condition category Other	<input type="checkbox"/> 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

014-91-052

Study information

Scientific Title

Study objectives

Fear of falling and associated activity restriction is common in older persons living in the community. Adverse consequences of fear of falling and associated activity restriction, like functional decline and falls, may have a major impact on physical, mental and social functioning of these persons. This paper presents the design of a trial evaluating a cognitive behavioural group intervention to reduce fear of falling and associated activity restriction in older persons living in the community.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomised controlled parallel group 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

Fear of falling in older adults in the community

Interventions

The intervention group receives a cognitive behavioural group intervention developed to reduce fear of falling and to promote physical, social, and functional activity. This intervention is derived from 'A Matter of Balance', which is developed and evaluated by Tennstedt and colleagues in

Boston, US. The protocol is translated and adapted to the Dutch context. The intervention program consists of eight weekly group sessions of two hours and a booster session six months after the last session. The intervention aims to increase self-efficacy beliefs with regard to falling as well as the sense of control over falling.

The control group receives usual care, meaning they receive no intervention as a result of this trial.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

Fear of falling and daily activity. Fear of falling is assessed by a single question "Are you afraid of falling?" (1= never to 5= always). Falls related self-efficacy is assessed by an adapted version of the Falls Efficacy Scale (FES). Daily activity is assessed by the Frenchay Activity Index (FAI). To assess activity restriction due to fear of falling a single question was incorporated in the questionnaire: "Do you avoid certain activities due to fear of falling?" (1= never to 5= always).

Secondary outcome measures

Psychological, physical and social functioning. The Hospital Anxiety and Depression Scale (HADS) assessed psychological functioning. Physical functioning is assessed by the ADL subscale of the Groningen Activity Restriction Scale (GARS). Social functioning is assessed by a social support measure (SSL) and by a loneliness question.

Overall study start date

01/03/2002

Completion date

31/03/2007

Eligibility

Key inclusion criteria

Age 70 or older, living independently in the community, reporting fear of falling and associated activity restriction.

Participant type(s)

Patient

Age group

Senior

Sex

Both

Target number of participants

540

Key exclusion criteria

Confined to bed, restricted by permanent use of wheelchair, on waiting list for nursing home admission.

Date of first enrolment

01/03/2002

Date of final enrolment

31/03/2007

Locations**Countries of recruitment**

Netherlands

Study participating centre

Universiteit Maastricht

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Sponsor information**Organisation**

Maastricht University, The Netherlands

Sponsor details

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Sponsor type

Not defined

ROR

<https://ror.org/02jz4aj89>

Funder(s)

Funder type

Research organisation

Funder Name

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

Alternative Name(s)

Netherlands Organisation for Health Research and Development

Funding Body Type

Private sector organisation

Funding Body Subtype

Other non-profit organizations

Location

Netherlands

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	21/03/2005		Yes	No
Results article	results	01/08/2006		Yes	No