

# 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

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

**Protocol serial number**

## 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

### Study type(s)

Quality of life

### 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(s)**

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).

**Key secondary outcome(s)**

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.

**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

**Healthy volunteers allowed**

No

**Age group**

Senior

**Sex**

All

**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**  
Maastricht  
Netherlands  
6200 MD

## Sponsor information

**Organisation**  
Maastricht University, The Netherlands

**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

**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?
<a href="#">Results article</a>	results	01/08/2006		Yes	No
<a href="#">Protocol article</a>	protocol	21/03/2005		Yes	No