

# 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

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<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

**Contact name**  
Prof G.I.J.M. Kempen

**Contact details**  
Universiteit Maastricht  
Faculty of Health Sciences  
Department of Health Care Studies  
Section Medical Sociology  
P.O. Box 616  
Maastricht  
Netherlands  
6200 MD  
+31 (0)43 3882204  
g.kempen@zw.unimaas.nl

## 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

Maastricht

Netherlands

6200 MD

**Sponsor information****Organisation**

Maastricht University, The Netherlands

**Sponsor details**

Faculty of Health Sciences and Care and Public Health Research Institute

P.O. Box 616

Maastricht

Netherlands

6200 MD

+31 (0)43 3881738

voorlichting@facburfdgw.unimaas.nl

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