RANDOMIZED CONTROLLED TRIAL TO REDUCE FALLS AND FEAR OF FALLING IN FRAIL ELDERLY

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-To test the efficacy and determine the costs of a multifaceted intervention program to reduce falls incidence rate and fear of falling, and thereby improve mental wellbeing in community dwelling frail elders, with high level of comorbidity and...

Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON30537

Source
ToetsingOnline

Brief title
Carthago-Phoenixstudy

Condition

- Other condition
- Anxiety disorders and symptoms
- Age related factors

Synonym
falling, fear of falling

Health condition

vallen

Research involving

Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Sint Radboud
Source(s) of monetary or material Support: Ministerie van OC&W,Stichting Nuts-Ohra en ZonMw (in afwachting van toekenning AGIKO stipendium)

Intervention

Keyword: fall prevention, fear, frail elderly, intervention

Outcome measures

Primary outcome

In patients the falls incidence rate, fear of falling (FES) and quality of life

(MOS-20) are the primary outcome measures. Total observation time of falls will

be 6 months after start of the intervention.

Secondary outcome

In patients the secondary outcome measures are fall risk, quality of life,

balance confidence, depression and general anxiety, functional performance in

activities of daily life, physical activity, mobility, gait parameters, body

sway and biomarkers of endothelial function and frailty. For the caregiver the

secondary outcome measures are sense of competence, caregiver*s burden and

mood.

Intraindividual variability of cognition, balance and gait in both patients and

caregivers.

Cost-effectiveness of the intervention.

Study description

Background summary

Approximately 750.000 Dutch elderly people fall at least once a year, which often results in physical injuries and fear of falling, with high costs and far-reaching consequences on functionality, physical activity, quality of life and mental wellbeing. Falling is not only a burden for patients, it also is a burden for their caregivers, with frustration, distress and mood disorders as a possible result for both. Dementia or milder cognitive impairment, fear of falling, difficulties in performing dual tasks while walking, and disorders in gait and balance determine the complexity of the problem of recurrent falling in the growing group of frail elderly people, because they all result in an increased risk of falling. However, the pathophysiological background of falls, gait problems and dementia is largely unknown. The general pathophysiological hallmark of aging is lability in homeostatic mechanisms of organs (the inability to generate stable organ output). This lability results in an impaired ability to adapt to stress and in increased biological variation in outcome measures within individuals. In this study we aim at developing an intervention to reduce recurrent falling in frail elderly fallers and their fear of falling because so far no secondary prevention study proved efficacy in this high-risk patients.

Study objective

-To test the efficacy and determine the costs of a multifaceted intervention program to reduce falls incidence rate and fear of falling, and thereby improve mental wellbeing in community dwelling frail elders, with high level of comorbidity and cognitive impairment, who fell at least once in the past 6 months and consulted an outpatient geriatric clinic.
-To train and support the informal caregivers, which we consider as absolute precondition for an effective intervention in this group, and to improve their feeling of competency in taking care of these patients.
-To test, as secondary outcomes, whether this intervention reduces fall related injuries, improves physical activity, functional performance measures, and biomarkers for vascular health/endothelial function and frailty.
- To test wether a high short term intraindividual biological variability in gait and cognition
variables predicts a higher chance of falling, worse gait performance and cognitive decline in
older people after long term follow up.

Study design

randomized controlled, single-blind trial

Intervention

A multifaceted fall prevention program for frail elders to reduce fear of falling and fall incidence rate, consisting of physical and cognitive components. Moreover, it includes a trainings program for caregivers to learn to provide supervision and advice the patients.

Study burden and risks

The outcome of this study may have important reflections on protocols to prevent falling and reduce fear of falling among elders and on health care decision makers to stimulate starting new fall clinics and implement these protocols. Through this study the wellbeing and functionality of frail elders and their caregivers could be improved. As falling has an enormous economic burden, a new effective fall prevention intervention could reduce health care costs substantially. The tests consisting of questionnaires, and gait and balance measurement are non-invasive and safe. Taking blood samples is an invasive procedure, although no serious adverse effects will be expected. There are no foreseeable risks associated with the participation in this study. However, a burden will be placed on participating individuals because the training sessions and measurements are time-consuming.

Contacts

Public
Universitair Medisch Centrum Sint Radboud

Postbus 9101
6500 HB Nijmegen
NL
Scientific
Universitair Medisch Centrum Sint Radboud

Postbus 9101
6500 HB Nijmegen
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Patients:
-age: 70 years or older
-experience of a fall at least once in the past 6 months
-living in their own home or in a home for the aged
-availability of a primary caregiver who cares for the subject at least once a week
-ability to walk 15 meters independently (usage of a walking aid is permitted)
-life expectancy of more than 6 months as judged by their geriatrician;Caregiver:
- caring for the patient at least once a week
- sufficient cognitive capacity to advise and supervise the patient during the training and fall registration;Additional inclusion criterion for variability measurements: Caregiver need to be 70 years or older.

Exclusion criteria

-dyads of patients and caregivers in whom outcome assessment is highly unlikely to succeed, for -example because they proved not to be able to register falls in the three months before randomization;Additional criteria for patients:
-suffering from Parkinson*s disease (Hoehn and Yahr rating scale score equal to or higher than 3)
-severe cognitive impairment (MMSE cut off score equal to or less than 13 out of 30)

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)

Primary purpose: Prevention

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-05-2007
Enrollment:	320
Type:	Anticipated

Ethics review

Approved WMO

Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL16149.091.07