The Senior Step Study: How elderly help themselves maximally forward

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON37276

Source
ToetsingOnline

Brief title
Senior Step Study

Condition

- Other condition

Synonym
Fall risk

Health condition

de deelnemers aan de Senior Stap Studie kunnen elke aandoening hebben, hier worden ze niet op geselecteerd.

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Sint Radboud
Source(s) of monetary or material Support: ZonMw

Intervention

Keyword: Fall risk, Gait speed, Older subjects, Selfmanagement

Outcome measures

Primary outcome

Gait speed, falls, well-being and self management.

Secondary outcome

Mobility, fall-related injuries, mobility range and fear of falling.

Cost-effectiveness of the self management tool. Feasibility, contentment and

motivation of elderly to use the self management tool.

Study description

Background summary

Falling is an important problem among community-dwelling elderly. The number of falls and concomitant health costs will rise within an aging population. Fall related injuries and fear of falling decrease mobility and have a negative impact on social functioning, mood, well-being and autonomy. Research from a medical perspective has concentrated on casefinding and fall prevention. Currently, insufficient possibilities are available for elderly and caregivers to assess and improve their own mobility and fall risk. The Senior Step Study aims to provide a tool for elderly to improve their self management abilities in monitoring and improving fall risk and thus mobility.

Study objective

With a randomized controlled crossover trial the effect of using this tool on mobility, fall risk and well-being, and its effect on self management of fall risk will be assessed. Costeffectiveness of this strategy to improve self management of fall risk will be compared with regular care after an accidental fall. Qualitative research will study the feasibility, contentment and

motivation of elderly to use such a self management tool.

Study design

A randomized controlled crossover trial of six months will be executed among 150 frail elderly (70+ years) within three settings: at home, a home for the elderly and a community center. With this design the elderly serve as their own control. the elderly in the intervention group will use the tool weekly for three months to measure their gait speed. Also, they will receive an instruction book which they can use to train their balance and mobility on the basis of the results from the tool. The control group will receive only the instruction book, which they can use at their own discretion. After three months, both group wil switch between the intervention group and the control group.
During the study all participants will be followed with the falls telephone to register and monitor the number of falls.
After the study a small group of participants will be asked to participate in a qualitative interview using semistructured interviews, to uncover the feasibility, contentment and motivation of elderly to use such a self management tool to monitor their own mobility and fall risk.

Intervention

Weekly use of the self management tool to measure and monitor mobility and fall risk.

Study burden and risks

Subjects will participate for six months. During those months they will receive weekly calls from the falls telephone. Also, they can train their balance and mobility using the instruction book, at their own discretion in the control group and on basis of the self management tool in the intervention group. By use of a diary they can register if and what exercise they performed that day. When the participant is in the intervention group, they will use the self management tool once a week.
During the study the participants will receive seven small assessments which will be performed by the researcher and the researcher's assistent (T0 - T6). All assessments take place at home, the home for the elderly or in the community center.
T0 is at baseline of the study and will consist of the following tests: Minimum Data Set (of the Dutch National Program for the Care for Elderly), SMAS-30 (questionnaire for self management), MOS-20 (well-being), LAPAQ (mobility range), (m)-FES (fair of falling), Timed Up and Go test and the Short Physical Performance Battery (both a measure for balance and mobility). This assessment will take approximately 1.5 hours and will be repeated after three months when both groups will switch (T3), and at the end of the study (T6).

During the other assessments (T1, T2, T4, and T5) only the Timed Up and Go test and the Short Physical Performance Battery will be measured to register changes in balance and mobility.
At the end of the study qualitative research will take place through semistructured interviews in a small group of participants coming from all participating centers. With these interview the feasibility, contentment and motivation of elderly to use a self management tool for monitoring balance and mobility will be assessed.
There will be no invasive tests performed in the participants which indicate that there will be no risks associated with participation.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

1. Subjects of 70 years and over
2. Subjects who experienced at least 1 fall in the previous year
3. Subjects who can walk independently or with a walking aid
4. Informed consent on the basis of Dutch legislation (WMO)

Exclusion criteria

1. Subjects not able to peak Dutch
2. Subjects not able to understand and remember simple Dutch instructions
3. Subjects not capable of using the falls telephone, only when there is no informal caregiver who can answer the falls telephone

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-01-2012
Enrollment:	150
Type:	Actual

Ethics review

Approved WMO

Date:	18-12-2012

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	NL41111.091.12