A novel instrument to support fall prevention in extramural care

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1) To test and improve fall detection algorithms and predict the risk of falling during normal daily life. 2) To develop a feasible and effective training, that is suitable for diverse groups of elderly.

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

Summary

ID

NL-OMON39612

Source
ToetsingOnline

Brief title
FARAO

Condition

- Other condition

Synonym
fall-risk and stability

Health condition

bewegingsapparaat: vallen en valrisico

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit
Source(s) of monetary or material Support: NWO (ZonMw) TOP subsidie,AGIS innovatiefonds

Intervention

Keyword: ageing, fall risk, inertial sensors, physical exercise

Outcome measures

Primary outcome

For the first objective: the number of actual falls (based on fall calenders)

and detected falls (based on motion monitor).

For the second objective: a feasible training.

Secondary outcome

For the first objective: the compliance with the motion monitor and fall risk

prediction based on stability measures obtained from motion monitor data.

For the second objective: the effectiveness of the training in terms of daily

activities, physical performance and confidence.

Study description

Background summary

Elderly people fall frequently and are not always capable to get up independently. New technologies that allow automatic fall detection could be very useful, e.g. to warn caregivers in time. In addition, fall prevention interventions are often prescribed when a person has already experienced one or multiple falls, whereas earlier interventions based on a high fall risk might be more effective. To detect falls and high risk behavior, observation of daily activities is necessary. In this study, falls and daily activities will be investigated in combination with an intervention focused on increasing physical activity.

Study objective

1) To test and improve fall detection algorithms and predict the risk of falling during normal daily life.
2) To develop a feasible and effective training, that is suitable for diverse groups of elderly.

Study design

An observational study (using a motion monitor) focused on the detection of falls and assessment of fall risk; and a feasibility study (10 weeks of training, combined with medication action review and vitamin D supplementation) aimed at the development of an effective fall prevention training.

Intervention

Ten weeks of physical training (2 group sessions, optionally 1 individual session and home exercise each week), vitamin D supplementation and a medication review.

Study burden and risks

Wearing the motion monitor for 15 weeks requires several minutes daily to attach the monitor and does not involve any risks. Filling in the fall calender will take maximum 15 minutes per week.
The intervention program requires 10 weeks of about 3 hours of exercise effort and 3 times of about 1 hour to run the physical performance tests and fill in questionaires. The risks of this intervention programm are small, injuries due to training are possible but unlikely since the training is adapted to each individual fitness level.

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

- Males and females in the age of 65-99 years;
- Able to walk continuesly for 20 meters (with walking aid if necessary), without complaints of shortness of breath, diziness, or chest pain;
- Able to remember an exercise.

Exclusion criteria

- Severe cognitive decline (Mini Mental State Examination score < 18/30);
- Contra indications for participation in physical exercise program (indicated by general practicioner)

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):	12-04-2011
Enrollment:	160
Type:	Actual

Medical products/devices used

Generic name:	Dynaport MoveMonitor
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	11-04-2011
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	22-04-2013
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	07-02-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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	NL35603.029.11