Measuring intervention-effects on mobility of elderly with objective ambulatory methods; A pilot study

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

Summary

ID

NL-OMON34356

Source
ToetsingOnline

Brief title
Ambulatory measurement of intervention-effects on mobility in elderly

Condition

- Other condition

Synonym
nvt

Health condition

het betreft gezonde ouderen met een enigszins verminderde balans

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: assessment, balance, elderly, mobility

Outcome measures

Primary outcome

The primary study parameter is power, measured with a new ambulatory measurement system. Power is measured in the home-situation and in a standardized situation with hybrid sensors.

Secondary outcome

Score on three questionnaires: Groningen Frailty Indicator (GFI), Falls Efficacy Scale (FES), Groningen Activiteiten RestrictieSchaal (GARS)

Score on clinical tests: Timed Up & Go (TUG), Berg*s Balance Scale (BBS), force generating capacity of hip, knee and ankle extensors and flexors, measured with a Hand Held Dynamometer.

Study description

Background summary

With the increasing number of elderly in Europe the number of falls increases. A fall-accident commonly leads to loss of independency in elderly. Mobility, lower extremity muscle function and balance are determining factors for risk of falling. To prevent elderly from falling it is necessary to detect changes in these determining factors in an early stage. If an increased fall-risk is detected participation in an exercise program can be considered.
Until now there is no clinical measurement method to detect deteriorating mobility, muscle function and balance in the home-situation. Newly developed ambulatory measurement systems are able to measure movement patterns in daily

life, from which changes in the mentioned factors can be extracted.

Study objective

The primary aim of this pilot-study is to determine the sensitivity of a new ambulatory method for measuring differences in mobility between before and after an intervention program. A secondary objective is to determine the conditions for using the new method for monitoring elderly. Another secondary objective is to determine the minimum number of subjects that need to be included to be able to measure intervention-effects with ambulatory measurement systems in future research.

Study design

This pilot study is an intervention study with two moments of measurement. Part of the participants participate in an intervention program offered by the researcher. The other part of the participants participate in an intervention program offered by a physiotherapist or MBVO. Both programs are similar with regard to content of the program, intensity and duration. The reason for this twofold method is that in this way we will be able to include the aimed number of participants. Afterward the collected data will be pooled. There is no control group, because the subject of research is the measurement method and not the intervention itself.

Intervention

Part of the participants participate in an intervention program offered by the researcher. The other participants participate in an intervention program offered by a physiotherapist or MBVO. Both programs are similar with regard to content of the program, intensity and duration. The exercise programs exists of exercises for improving balance, power and force generating capacity of the lower extremities. All subjects participate in an exercise program for eight weeks. Within every week there are two group sessions. The subjects in the program offered by the researcher will be asked to additionally perform exercises at home on the remaining work days.
When participants are joining a program offered by a physiotherapist or MBVO, only the tests will be performed on behalf of this study.
Collected data of all participants will be pooled.

Study burden and risks

During the week prior to the start of the intervention pretests will be administered. Participants will also be asked to wear a hybrid sensor underneath their clothes during the study period. There are no additional risks in wearing this sensor.
Participants in the program offered by the researcher spend approximately four

hours per week for a total of ten weeks on study participation. During the intervention period a one-hour group exercise program is offered twice a week. On work days without group session participants are expected to perform a customized exercise program at home for 30 minutes per day. Participation in the study has the risks and benefits of an exercise program for balance function and muscle function of the lower extremities. The main risks are fatigue, muscle soreness and a risk of falling comparable to the risks in daily activities.
Participants in an exercise program offered by MBVO or a physical therapist spend only eight hours on study participation, because only the tests will be performed on behalf of this study. For these elderly there are no personal benefits of participation.
The safety of the participants will be guarded during training and testing session.

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

between 70 and 80 years old
performing ADL-activities independently
able to walk without walking aid for at least 10 m.
balance function as measured with Timed Up and Go and BBS somewhat deteriorated. (12 <= TUG <= 20) en (35 <= BBS <= 48)

Exclusion criteria

Severe co-morbidity which is of influence on mobility
Co-morbidity affecting the general condition of the participant, for example heart- or lung Diseases or neurological disorders
Insufficient cognitive functioning
Not able to understand or read Dutch instructions
Participation in other intervention studies in the same period of time
Participation in exercise programs aiming at improving balance and lower extremity muscle function

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	14-06-2010
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO Date:	28-05-2010
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL32063.042.10