Development of an acceleration based fall risk detector

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON33775

Source
ToetsingOnline

Brief title
development fall risk detector

Condition

- Other condition
- Joint disorders
- Age related factors

Synonym
fall risk

Health condition

vallen

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Maastricht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: accelerometer, fall risk, field measurements, target group

Outcome measures

Primary outcome

The primary study outcome is the possibility to determine fall risk objective.

Important parameters are for

- gait analysis: walk speed, frequency, step length, variability, vertical displacement, asymmetry and regularity

- balance: sway area, frequency, velocity and root mean square

- Get Up and Go test: time and speed

- one day measurement: to investigate the mobility and extra fall related movement parameters. This is the first step to monitor subjects in the field.

- investigate relation between fall risk, activity pattern (from acceleration data day measurement) and fear of falling

Secondary outcome

Subject data is collected like height, weight and date of birth, fear of falling, but also information about health state is collected

Study description

Background summary

Falls in the elderly are a major public health issue because of their associated injuries, morbidity and mortality rates, social cost and financial cost. Most falls in older adults are caused by impaired locomotion and balance, reduced vision and other age related body adaptations like reduced muscle strength. With the increased life expectancy of the elderly and their more active lifestyle there is now an emphasis on identifying subjects at risk for falling.
Currently fall risk assessment is performed using questionnaires and scales which lack diagnostic accuracy because of their subjectivity. Other methods are expensive, complicated and laboratory based. Previous studies used accelerometers for several targets, like gait analysis in which movement characteristics were derived from the acceleration signals using specific algorithms. These studies showed promising results.

Study objective

Because the increasing fall problem, mainly due to an impaired gait and balance ability, this study will investigate fall risk by detecting fall related movement characteristics. Based on the promising results using accelerometry for accurate and objective gait analysis, fall risk will be measured using a triaxial accelerometer.

At the moment our group is performing a study titled 'identify subjects at risk for falling using accelerometry*. In this study, fall related movement characteristics (gait, balance, stumble reaction) are identified in healthy younger and onder subjects under standardised laboratory circumstances. In this way, specific characteristics can be selected which are responsible for fall risk.

The aim of this study is investigating if the acceleration based fall risk detector can be applied in daily life with target groups.

Study design

A first step to field measurement with target group is the measurement of elderly with a certain fall risk in a simple field condition like a nursing home.

First fall risk is assessed in elderly using the Tinetti scale (score <24) which is the gold standard for fall risk assessment . This scale consist of a gait and balance score. Only subjects who have a fall risk are included for further measurements.

a. A gait test will be performed to analyze movement parameters. Subjects have to walk 6 times a 20 meter distance at preferred speed while a small (56mmx61mmx15mm), light weight (5g) and ambulant accelerometer is attached on

the sacrum with an elastic belt. The accelerometer measures accelerations of the body in three directions (antero-posterior, media-lateral and cranial-caudal) with a sample frequency of 100Hz.

b. The balance ability will be tested by performing 4 balance tasks while the same accelerometer measures the movements of the body. Subjects have to stand with feet closed on a normal or foam surface while having the eyes open and closed.

c. The Get Up and Go test is performed: subjects start in sitting position, have to rise, walk 3m, turn around, walk back and sit again. The time needed to perform this test is measured.

d. 40 subjects (remaining in Scharweyerveld and Zorgboog) are monitored for one day to investigate the mobility and more fall related movement parameters. The accelerometer is attached to the sacrum in the morning. First the other 2 measurements are performed, and then subjects wear the device during the whole day. The accelerometer is small, light and ambulant which is not interferring with daily acitivities. Subjects have to keep a diary to note all activities performed during that day. THis will be used to explain the acceleration signal. Finally a questionnaire assessing fear of falling (FES-I) is performed.

All acceleration data will be analyzed using specific algorithms programmed in Matlab(c). Statistical analysis will be performed in SPSS using pearson correlation to investigate correlations between gait parameters, balance characteristics, the ability perform the Get Up and Go test and fear of falling. Pearson correlation will also be used to validate the objective gait and balance test with the Tinetti scale. Differences in function tests between elderly at risk (measured in this study) and healthy subjects (measured in a previous study under lab conditious) will be investigated using ANOVA ($p < 0.005$).

Study burden and risks

The questionnaire and the 3 function tests (gait, balance, Get Up and Go test) takes more or less 45 minutes. For the day measurement, the accelerometer is attached to the sacrum in the morning and is removed when the subject goes to bed.

The measurements are performed once, all on one day. Moreover they are performed at the care center where the subject is living. So the subjects don't need to travel.

Because balancing, walking, sitting and rising from a chair are activities of daily life, no additional burden or risk is associated with participation. Moreover because subjects have to behave like normally during the one day measurement and because the accelerometer is small, light and ambulant subjects

are not limited in performing daily activities and no additional risk is associated by performing this test.

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- Having a fall risk (Tinetti score <24)
- Men and women * 65 years at risk for falling
- able to walk without walking aids
- voluntary and willing to participate
- fully competent

Exclusion criteria

- unable to walk
- denying

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-10-2008
Enrollment:	100
Type:	Actual

Ethics review

Approved WMO

Date:	23-09-2008
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Approved WMO

Date:	28-05-2009
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Not approved

Date:	26-08-2009

Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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	NL22858.068.08