Identify subjects at risk for falling using an acceleration based gait analysis system

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

Summary

ID

NL-OMON31509

Source
ToetsingOnline

Brief title
fall risk assessment using accelerometer

Condition

- Muscle disorders
- Age related factors
- Bone and joint therapeutic procedures

Synonym
effects of ageing on fall risk

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Maastricht

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: accelerometry, fall risk, gait test, stumble detection

Outcome measures

Primary outcome

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

Important parameters are for

- cognitive test: the average reaction time and the amount of errors are calculated for each time interval
- Strength test: maximal force is measured during extension and flexion
- gait analysis: walk speed, frequency, step length, variability, vertical displacement, asymmetry and regularity
- balance: sway area, frequency, velocity and root mean square
- stumble experiment: to develop an inertial based algorithm to detect stubmles, to registrate the compensation mechanism and which can be applied for younger subjects and elderly.

Secondary outcome

Subject data is collected like height, weight and date of birth, 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. Falling because of tripping or slipping while walking is also a commonly reported cause of falls, responsible for 17 to 60% of falls in healthy older adults. 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 and partly caused by trips, this study will investigate fall risk by detecting fall related movement characteristics and by detecting stumbles inclusive the compensation mechanism to recover from the trip. Based on the promising results using accelerometry for accurate and objective gait analysis, fall risk will be measured in younger and older (>60y) subjects using a triaxial accelerometer.

Study design

To investigate fall risk objectively, fall related movement characteristics (based on gait and balance) and the ability to compensate for near falls are analyzed in younger and older (>60y) subjects under standardized laboratory conditions.

Four tests will be performed to link specific movement parameters, balance performance and the ability to recover from a trip with fall risk:

a. Fall risk will be assessed using the Tinetti Scale, the gold standard for fall risk assessment . This scale consist of a gait and balance score. Based on this scale, subjects are classified as being at risk/ not at risk for falling.

b. 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.

c. 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.

d. Finally a stumble experiment is done to assess the ability to compensate for a trip. Subjects are asked to walk at their preferred speed on a treadmill, while wearing the accelerometer attached at the sacrum. After 2 minutes of normal walking, stumbles are simulated unexpectedly using an extending tripping leash attached to both legs. The subjects are able to move freely due to unwinding and winding of the cord on a spill on a fixed frame behind the treadmill. This spill has a blocking device capable of blocking the leash very shortly. During the mid or initial swing of one of the legs, the examiner blocks the leash causing the subject to trip. Falling, however, is not possible due to a safety harness attached to the ceiling. When this harness starts bearing weight an emergency switch is engaged stopping the treadmill immediately. After a perturbation, subjects get several seconds to recover until a new perturbation is applied. This measurement is repeated while walking at a slow (40% Fr preferred speed) and fast (20% Fr preferred speed) speed. The whole experiment will be recorded on video to validate the acceleration based stumble detection.

To investigate the underlying mechanism of age related mobility changes, two other tests are incorporated:
* The cognition of hte subjects will be tested using a reaction time test. Subjects sit behind the computer with their middle and forefinger on two keys of the typewriter. Four squares will appear at the computer screen. Or all sqares are red and one of them will change in green (=uncued condition) or two red squares appear at the left (right) side while one square at the rigth (left) side will turn green. Subjects have to push the corresponding key on the typewriter as fast but also as accurate as possible. With this test the ability to change an automatich repons (in stead of responding left when stimulus appears left) can be investigated using reaction times. First the subjects get an instruction, than they get the possibility to try and esxercise 10 times, while afterwards the real test will start. 120 attempts are performed in which the cued and uncued stimuli appear with different time intervals (100ms, 250ms, 500ms, 750ms and 12000 ms).

* Muscle strenght of the right lower leg is tested using the Cybex. Subjects have to produce maximal force during an extension and flexion test.

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 and the ability to recover from a trip. Moerover Pearson correlations and regression analysis will be done to investigate the relation of cognition and muscle strength with fall risk (gait, stumble recovery and

balance). Pearson correlation will also be used to validate the objective gait and balance test with the Berg Balance Scale. Differences in muscle strengt, cognition gait, balance and compensation ability between younger and older subjects will be investigated using ANOVA ($p < 0.005$).

Study burden and risks

The total study takes maximal one hour and is performed once.
Because balancing and walking are activities of daily life, no additional burden or risk is associated with participation.

Only the stumble experiment can be fatique for the participants, but provide no risk because the subjects are protected by a safety harness.

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

- able to walk without walking aids
- signed informed consent
- willing to participate
- healthy volunteers <= no musculo skeletal or neurological disease
- the younger volunteers are aged between 18 and 40 years, while the elderly are 60 years or older

Exclusion criteria

- history of dizziness, vestibular dysfunction, neurological disorders, low-back pain, lower extremity infirmity/pathology
- suffering from any osteoarthritic or musculo skeletal disease at the time of testing
- unable to walk

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):	01-03-2008
Enrollment:	100
Type:	Actual

Ethics review

Approved WMO

Date:	15-08-2007

Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	20-02-2008
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	NL17267.068.07