fall after stroke, determinants and intervention

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Movement disorders (incl parkinsonism)
Study type	Interventional

Summary

ID

NL-OMON41135

Source
ToetsingOnline

Brief title
fall after stroke

Condition

- Movement disorders (incl parkinsonism)

Synonym
hemiplegia, stroke

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit
Source(s) of monetary or material Support: NWO

Intervention

Keyword: determinants, fall, gait parameters, stroke

Outcome measures

Primary outcome

The primary measures are:

- Fall events.

- variability measures.

- spatio temporal measures.

- stability measures.

Secondary outcome

subject characteristics.

Time up and Go test.

questionnairs.

Study description

Background summary

The fall incidence of stroke patients is high. Most falls occur during gait activity, and consequences can be severe. Although effective fall prevention programs exist for healthy elderly people, these programs are not effective in people with a stroke. Therefore the etiology appears to be different in this population.

In this study we would like to investigate which gait parameters, measured in a laboratory setting and at home, are associated with fall risk. This knowledge helps us identifying stroke patients at risk of falling. Furthermore it helps to develop a novel fall prevention program specifically designed for this population. Furthermore we will exam if it is possible to improve the with

fall associated gait parameters in these stroke patients.

Study objective

This research project exists out of two research questions:

Firstly we will determine which gait parameters are associated with fall risk. Secondly develop a novel fall prevention program based on the associated fall risk gait parameters. To determine the possible effectiveness of the intervention we will exam whether it is possible to improve the with fall associated gait parameters in this population.

The aims of this research project are:

1) Which gait parameters are associated with fall events in stroke patients?

2) Can we improve the with fall risk associated gait parameters by using the developed fall prevention program?

Study design

To answer the first research question we will track down or patients fall in the past six months. Based on this information we will divide patients into two equally sizes groups, 'fallers' and 'non fallers'. Subsequently, fall events will be registered prospectively during the next six months with a fall diary and monthly phone calls.

To determine the association with gait parameters prior to the prospective monitoring period we will perform a gait assessment in an laboratory. Furthermore subjects will wear an accelerometer during 1 week at home to determine gait parameters derived in an at home setting as well.

The second research question will be answered by a 'proof of concept'. Stroke patients at risk of falling will an intervention. We will exam if the group improves at the associated fall risk gait parameters.

The gait assessments and intervention will be executed with the Gait Real Time Analysis Interactive Lab (GRAIL).The GRAIL is a treadmill with virtual environment, it gives us the opportunity to measure not only steady state gait parameters but as well measure the responses of a patient after the patient received an external perturbation during gait.

Intervention

The fall prevention intervention will be performed together with the GRAIL*. Patients will train on the GRAIL one hour twice a week, during a zeven week

period. each training session will last no longer than 1 hour. The training will mainly focus on the fall associated gait parameters. For instance if the results from research question 1 indicate that medio-lateral perturbations during gait are strongly associated with fall events, in this case the training will frequently be focussed on medio-lateral perturbations.

* The GRAIL is a treadmill with virtual reality environment. The GRAIL is capable of accurately detecting gait parameters, gait performance can be tested combined with a dual task furthermore the GRAIL is capable of perturbating gait at a fixed moment in the gait cycle.

Study burden and risks

The risk when participating in the study is limited. The experiments will be performed at the GRAIL. Subjects will wear a fall armour, which make falling during the experiments impossible.

The subjects will be tested at preferred gait speed and so will not be pushed towards maximum performances. There is sufficient recovery time between the trails. There is sufficient time to build in extra breaks if the patient wishes so.

The amount of testing time is limited.
The first research question will take 1 visit from a proximally 2 hours.
Subsequently the patient will wear an accelerometer during one week.

The second research question will require more visits and time. The intervention lasts for 7 weeks, each week contains 2 training sessions and each session will not take longer than 1 hour. Furthermore a pre and post test will be executed similarly to the test in research question 1 and as well patients will wear an accelerometer prior and after the intervention.

If the training is effective, patients will benefit from this intervention in terms of a more stable gait patterns and possibly fewer falls.

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

- * Diagnosed with a stroke at least 3 months geleden.
- * Age older than 18 jaar.
- * Independent living.
- * Agreement of (house) doctor to take part in research.

Exclusion criteria

- * Insufficient cognitive skills (Mini Mental State Examination < 19) to understand instructions.
- * Not faster than 2km/hour lopen.
- * Functional Ambulation Categories >2.
- other co morbidities that could affect gait performance such as a knee replacement.

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-12-2014
Enrollment:	85
Type:	Actual

Ethics review

Approved WMO

Date:	23-07-2014
Application type:	First submission
Review commission:	METC Brabant (Tilburg)

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	NL49126.028.14