Improving gait stability; the effect of step length and step frequency manipulations on the margins of stability in stroke patients.;Amendement on: Evaluating the risk of falling during gait: Which strategies do stroke-patients and transtibial amputees use to maintain dynamic stability and gait adaptability?

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The objectives of this study are to investigate: - which strategies patients use to maintain gait stability and gait adaptability; - whether the strategies used by patients to maintain gait stability and gait adaptability, differ from strategies...

Ethical review	Approved WMO
Status	Pending
Health condition type	Central nervous system vascular disorders
Study type	Observational non invasive

Summary

ID

NL-OMON39137

Source
ToetsingOnline

Brief title
Evaluating the risk of falling during gait

Condition

- Central nervous system vascular disorders

Synonym
CVA, Stroke

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit
Source(s) of monetary or material Support: Ministerie van OC&W,Motek medical b.v.

Intervention

Keyword: Gait adaptability, Gait stability, Step characteristics, Strategies

Outcome measures

Primary outcome

- Walking speed

- Step length

- Step frequency

- Step width

AMENDEMENT - additional outcome measure:

- Sideward and backward margins of stability

Secondary outcome

N.A.

Study description

Background summary

With their high incidence and associated costs, falls in patients form a

considerable problem in modern society. Despite the importance of this problem, until now there is no univocal protocol to evaluate the risk of falling during a rehabilitation process. To prevent falling, patients have to be stable during steady state walking and capable to adapt their gait pattern when required by the environment (e.g. to avoid an obstacle or to walk over uneven terrain). By manipulating these concepts of walking structurally, and measuring the effect of these manipulation on performance measures related to dynamic stability and gait adaptability, the risk of falling can be quantified. But, probably more important is to get an overview of the strategies patients use to withstand these manipulations, because these strategies will give us information about the effort of the patients to maintain a certain level of gait stability and adaptability, which can be used for further treatment. Examples of strategies are adaptations in walking speed and different step parameters like step length, step frequency, and step width.

AMENDEMENT:
The results of this previous experiment showed us that stroke patients seem to have more difficulties, compared to able-bodied people, with adapting step frequency and step length, while preventing a decrease in walking speed, which limits their ability to control and preserve their backward margins of stability. However, based on the results of our previous study it is not yet possible to conclude whether the observed adaptations in the gait pattern reflect the inability to adjust the gait pattern adequately or reflect a voluntary, but maybe incorrect, response of the patient. Information about this aspect of walking in stroke patients would help us to better understand which aspects of the walking pattern should be trained in the rehabilitation of walking of stroke patients.

Study objective

The objectives of this study are to investigate:
- which strategies patients use to maintain gait stability and gait adaptability;
- whether the strategies used by patients to maintain gait stability and gait adaptability, differ from strategies used by healthy people;
- and whether gait adaptability and dynamic stability differ between patient and healthy controls.

AMENDEMENT - Additional experiment

The objectives of the additional experiment are to investigate:
- whether stroke patients are able walk at different combinations of step frequency and step length at the same walking speed.
- whether these subjects are able to increase walking speed by increasing step length and step frequency independently.
- how the different combinations of step length, step frequency at the same walking speed will influence the size of the sideward and backward margins of

stability.
- how the increase in walking speed by an increase in step length or by an increase in step frequency will influence the size of the sideward and backward margins of stability.

Study design

During this experiment subjects will complete 3 trials of 4 minutes walking on a treadmill, placed in a virtual environment (CAREN). The conditions are (1) unperturbed walking, (2) walking with a balance perturbation and (3) walking while executing an additional task. The balance perturbation will exist of medio-lateral translations of the walking surface following a multi-sine function. During the additional task, targets will be projected within the virtual environment. Subjects will be asked to hit the targets with their knees, as accurate as possible. During all experimental trials the treadmill will be set in the self-paced mode, which means that subjects can determine their own comfortable walking speed by moving forward or backward on the treadmill. Before the experiment will start, subjects will perform a couple of warming-up trials to practice with the experimental conditions. During the experiment markers will be attached at the feet, legs, and pelvis of the subjects. A Vicon infra-red camera system will be used to register the movements of these markers.

AMENDMENT - additional experiment:
During this experiment subjects will complete 6 trials of 2 minutes walking on the treadmill. By giving visual feedback subjects will be asked to walk at different combinations of step length and step frequency. The experimental conditions are:

1. A trial at comfortable walking speed, step frequency and step length.
2. A trial at comfortable walking speed, at 90% of comfortable step frequency and at 111% of comfortable step length.
3. A trial at comfortable walking speed, at 111% of comfortable step frequency and at 90% of comfortable step length.
4. A trial at 111% of comfortable walking speed, at 100% of comfortable step frequency and at 111% of comfortable step length.
5. A trial at 111% comfortable walking speed, at 111% of comfortable step frequency and at 100% of comfortable step length.
6. A trial at 123% comfortable walking speed, at 111% of comfortable step frequency and at 111% of comfortable step length.

Study burden and risks

Subjects will walk 3 times during 4 minutes on a (self-paced) treadmill, at comfortable walking speed. During one of these trials balance will be perturbed by translating the walking surface. During another trial subjects will execute

an additional task during walking. To prevent falling, subject will wear a safety harness, and one of the investigator will stand close to the subject to assist if necesarry. The system has an emergency stop, which can stop the complete system. With these precautions the risk of falling and injury is minimized. Participation in this research does therefore not include serious risks.

AMENDEMENT - Additional experiment:
Subjects will walk 6 times during 2minutes on a treadmill. During 3 of these trials will walk at comfortable walking speed, during the other 3 trials subjects will walk slightly above comfortable walking speed. During these trials subjects will be asked to walk at different combinations of step frequency and step length, with the help of visual feedback. For this additional experiment the same security will be utilized as described above.

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 independently in daily life without help of any walking assistive device (Stroke patients: minimal FAC 4; Amputees: minimal SIGAM D)

Exclusion criteria

- cognitive or communicative disorders that can affect the protocol (Mini Mental State Examination >= 24),
- visual impairments that can affect the protocol
- attention impairments that can affect the protocol
- severe cardiovascular diseases that contra indicate moderately intense exercise
- other co-morbidities that could affect balance control or energy expenditure during walking
- medication that could interfere with balance control or energy expenditure during walking.

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-04-2012
Enrollment:	10
Type:	Anticipated

Ethics review

Approved WMO

Date:	22-12-2011
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	27-02-2013
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	NL35402.029.11