The cost of being stable: Does the effort for balance control affect the energy cost of walking in amputees and stroke patients?

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The objective of this study is to investigate whether impaired balance control is (partly) responsible for the increased energy cost of walking in stroke patients and amputees by evaluating the effect of external stabilization and destabilization on…

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Bone disorders (excl congenital and fractures)
Study type	Interventional

Summary

ID

NL-OMON38508

Source
ToetsingOnline

Brief title
The effect of balance control on energy cost of walking

Condition

- Bone disorders (excl congenital and fractures)
- Central nervous system vascular disorders

Synonym
CVA patients; stroke patients; Lower limb amputees; subjects with a lower limb amputation

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit
Source(s) of monetary or material Support: Ministerie van OC&W,OIM Stichting

Intervention

Keyword: Amputee patients, Balance control, Energy cost, Stroke patients

Outcome measures

Primary outcome

Primary outcome parameter is energy cost of walking (in J*kg-1m-1), calculated from breath by breath gas analysis

Secondary outcome

The following balance control related outcome parameters will be calculated: steplength, stepwidth, trunk acceleration and the variability of these measures, as well as gait stability and regularity. Gait stability will be quantified with the Lyapunov exponent and gait regularity will be quantified with the sample entropy. Additionally muscle activity will be measured in stroke patients using surface electromyography.

Study description

Background summary

Regaining walking ability is an important rehabilitation goal. Gait economy (i.e. the energy cost of walking) and gait stability are important aspects of walking ability. Both of these aspects are generally impaired in patients with movement disorders, such as stroke patients or amputees. However, it is unknown whether the highly increased energy cost of walking in these patients is (partly) the result of impaired balance control. Finding the cause of the extra energy cost during walking is important to develop adequate interventions to regain and maintain walking ability during and after the rehabilitation

process.

Study objective

The objective of this study is to investigate whether impaired balance control is (partly) responsible for the increased energy cost of walking in stroke patients and amputees by evaluating the effect of external stabilization and destabilization on the energy cost of walking.

Study design

Cross-sectional study

Intervention

For amputees: An external stabilization device consisting of spring like chords will be used to facilitate balance control during walking on a treadmill. A destabilizing task task, in which subjects have to walk on an imposed (projected) step pattern, will be used to impede balance control.

For stroke patients: Balance control will be facilitated by providing handrail support while walking. In one condition subjects are allowed mechanical support of the handrail, while in a second condition only light touch is allowed (providing somatosensory information). This will be compared to an unsupported condition.

Study burden and risks

During the experiment, subjects will complete one questionnaire about their balance confidence. Furthermore all subjects will complete five practice walking trials and four experimental walking trials on a treadmill with a duration of five minutes each. Due to the measurement of metabolism all subjects will be asked to refrain from heavy exercise the day of the experiment and abstain from food at least one hour prior to the experiment.
The mental and physical burden and risk*s of the experiment for the participants are low. The experiment will take approximately 1.5-2 hours to complete and the intensity of the walking trials is low. During the walking trials participants will wear a safety harness to prevent falling. Furthermore the treadmill is equipped with a double emergency stop (one manual stop, and an electronic eye at the back of the belt).

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

All subjects: above age 18 years and able to walk on a treadmill during five uninterrupted minutes from which the last three minutes without handrail support. Additionally they have to be able to walk an imposed step pattern.
Stroke patients a score of 4 or higher on the Functional Ambulatory Category (FAC)
Amputees a SIGAM mobility scale D-F (being able to walk more than 50 meters independently on an even surface with or without an assistive device), and a proper fitting prosthesis for at least six months.

Exclusion criteria

All subjects: cognitive and communicative disorders that could interfere with the protocol, cardiovascular or pulmonary co-morbidities contra-indicating moderate exercise, visual impairments that could interfere with the protocol, and medication and/or co-morbidities that could interfere with balance control or energy expenditure.
Amputees: stump problems (pain, swelling, pressure sores) and significantly fluctuating

stump volume within the last six months.

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	21-03-2013
Enrollment:	60
Type:	Actual

Ethics review

Approved WMO Date:	28-05-2013
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	09-08-2013
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	29-01-2014
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	NL43003.029.12