

Energetic costs for balance control during walking in stroke patients.

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

Summary

ID

NL-OMON34158

Source

ToetsingOnline

Brief title

Energetic costs and balance control

Condition

- Central nervous system vascular disorders

Synonym

cerebrovasculr accident, stroke

Research involving

Human

Sponsors and support

Primary sponsor: Heliomare

Source(s) of monetary or material Support: eigen middelen Heliomare

Intervention

Keyword: Balance control, Energy expenditure, Gait, Stroke

Outcome measures

Primary outcome

Main outcome: Energy costs (J/kg/m)

Secondary outcome

In all conditions parameters of gait will be calculated as: walking speed

(m/s), cadence (stride/s), stride length (m), step width (m) and symmetry

(paretic stance phase (s) * non-paratic stance phase (s)).

In the Ps and Pns condition the performance on the pattern walking task will be quantified as the error in foot placement, which will be measured as the amount of variation of the position of Center of Pressure with respect to the projected foot prints

Study description

Background summary

Post-stroke fatigue is a major problem in stroke patients. A factor that might contribute to this fatigue is higher levels of energy expenditure in stroke patients during walking. The exact cause of this fatigue remains unknown. Since impaired balance control is often present in stroke patients who regain walking ability, it is of interest to investigate the influence of balance impairments on energy expenditure in stroke patients during walking.

The relation between energy expenditure and balance control is already been investigated in static conditions in healthy persons as well as stroke patients. Energy expenditure increases significantly when balance is perturbed in healthy subjects as well as stroke patients. The energy expenditure tends to increase more in stroke patients compared to healthy subjects when balance control is perturbed. Since we expect balance to be challenged more during a dynamic task compared to a static task, this trend might become significant in

a dynamical situation.

Study objective

No studies concerning the relation between energy expenditure and balance control in stroke patients during dynamic conditions are published so far.

Therefore, the aims of this study are;

- (1) To investigate the effect of balance manipulations on energy expenditure during walking in stroke patients compared to healthy controls
- (2) To determine whether differences in energy expenditure correlate with different measures of balance control.

Study design

During the experiment, participants are asked to walk on a treadmill. During different walking trials, walking stability will be manipulated while energy expenditure will be assessed.

Energy expenditure measurements will be performed in four different conditions, which will be randomly distributed;

- (1) walking without support (Wns)
- (2) walking with support (Ws)
- (3) walking without support while walking stability is perturbed (Pns)
- (4) walking with support while walking stability is perturbed (Ps).

In the Wns condition, participants walk on the treadmill without any manual or mechanical support. The Ws condition consists of walking on the treadmill while walking stability is facilitated by instructing the participants to hold the handrail of the treadmill (without excessive weight bearing on this handrail).

In the Pns and Ps condition walking stability will be perturbed. Perturbations will be applied by projecting the participants* own walking pattern, measured during Wns, in the form of virtual footprints on the surface of the treadmill.

Participants are asked to walk within the projection of these foot prints.

Each trial will have duration of four minutes. For stroke patients it can be difficult to walk independently for four minutes. For this reason handrail support is allowed in the first two minutes of each trial when steady state has to be reached and no data are collected yet. Data will be collected in the last two minutes of each trial. Between each trial, participants will be able to rest until they feel comfortable enough to start the next trial. Participants will be asked to wear comfortable shoes.

Study burden and risks

Subjects walk four times four minutes on a treadmill at self selected speed. In two conditions balance will be perturbed. In case of a loss of balance subjects are required to grab the handrail of the treadmill. In addition, subjects wear a safety harness, fixed to the ceiling, which will catch them in case of a fall. This will also engage the emergency break. One of the investigators will

be close to the subject to assist if necessary.

With these precautions the risk of falling and injury is minimized.

Participation in this research does therefore not include serious risks. Both physical and mental burden for participants of this study is low.

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

- Age: 35-75 years old
- Able to walk independently indoors for 4 minutes (minimal FAC 3)
- Maximum score on Berg Balance Scale of 50 (for patientgroup)

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

Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	01-03-2011
Enrollment:	28
Type:	Actual

Ethics review

Approved WMO	
Date:	14-09-2010
Application type:	First submission
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	NL32034.029.10