Relative aerobic load and energy cost of balance control in elderly people walking with a unilateral lower limb prosthesis

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Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON32471

Source
ToetsingOnline

Brief title
Relatieve aerobic load and balance control in amputee walking

Condition

- Other condition
- Vascular injuries

Synonym
lower limb amputations

Health condition

beenamputaties

Research involving
Human

Sponsors and support

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

Intervention

Keyword: amputation, balance control, gait, oxygen consumption

Outcome measures

Primary outcome

The main study parameters investigated are; peak aerobic capacity, metabolic energy consumption during standardised (perturbed) walking, walking stability (quantified by stride time and kinematic variability, local dynamic stability, orbital stability, extrapolated centre of mass and co-activation indexes measured by EMG).

Secondary outcome

Secondary outcome measurements arte functional walking ability and balance measures.

Study description

Background summary

Learning to walk with a prosthesis is a challenge. Part of the motor and sensory system has been removed and walking becomes a task which requires continuous attention. Although a recent review shows that there is limited knowledge available concerning the relationship between walking ability and physical capacity, it is generally known that physical capacity plays a crucial role in regaining walking ability. Due to long periods of inactivity preceding and following amputation and co-morbidity accompanying the amputation, physical capacity is reduced. Concurrently, the physical load of walking with an prosthesis amputation is increased. If the physical load exceeds a reasonable fraction of the available physical capacity, walking ability will be

restricted. In order to train people to attain an adequate level of walking ability, evidence-based knowledge of both physical load and physical capacity and their interaction is required. Regaining walking ability can be accomplished by either increasing physical capacity or reducing the physical load of walking. In order to reduce the physical load during walking, an explanation for the increased physical load needs to be established. An explanation often proposed in literature is a reduced stability of amputee gait, requiring more balance control to maintain a stable walking pattern as to prevent falls. Since stability of gait has been difficult to assess, its relation to energy cost has not yet been investigated.

Study objective

The objective of this study is twofold. The first objective is to investigate the relative aerobic load during walking of people with a lower limb prosthesis. The second objective is to investigate the influence of balance control as a possible physical factor responsible for the increased aerobic load of walking with a lower limb prosthesis.

Study design

quasi experimental study

Study burden and risks

The patients will visit the rehabilitation centre twice. During the first visit the participant is first screened by a physiatrist to check for abnormalities. The participant is asked to walk twice at their comfortable speed on a treadmill. At one of these trials balance is perturbed by directing attention away from the walking task. In addition to the comfortable walking speed the patient is asked to walk on a treadmill for four minutes at four fixed speeds, proportional to his/her comfortable walking speed. Participants will wear a safety harness, attached to the ceiling. During the second visit, the participant is asked to perform a 10 meter walk test, a timed up-and-go test, a one-legged balance test and a two minute walk test. After a sufficient rest period, a maximal graded exercise test is conducted using a one-legged cycle ergometer. Oxygen, blood pressure, heart rate and ECG are recorded throughout the experiment so cardiovascular responses are continuously monitored.

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

For control participants
--> Participants are within between 50 and 75 years of age
--> Participants are able to walk for at least 4 minutes for 6 subsequent trials, between trials 20 minutes of rest is given to prevent fatigue.;For participants with amputation
--> The participants have acquired a walking ability of degree C-F on the SIGAM mobility grade [24, 25], indicating, that they participants are able to walk a minimum of 50 meters.
--> The participants are able to walk for at least 4 minutes for 6 subsequent trials, between trials 20 minutes of rest if given to prevent fatigue.
--> During the last minute of the trial the participant should be able to walk without support.
--> Time since amputation is more than 1 year.
--> Participants are comfortable with and accustomed to walk with their prosthesis.

Exclusion criteria

--> Abnormalities found in the resting ECG or blood pressure.
--> Problems noted by the physiatrist which could interfere with the results or the participants well being during the measurements.

--> Participant scoring less than 24 points out of the 30 that can be gained< 24/30 on the Modified Mini Mental State Examination questionnaire.
-->Neurological or musculoskeletal disorders which have an effect on the execution of gait other than disorders related to the amputation.
--> problems with the stump which could interfere with walking ability.

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:	Other

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-10-2008
Enrollment:	75
Type:	Anticipated

Ethics review

Approved WMO

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	NL24196.029.08