Stability and adaptability of prosthetic gait: the development of a clinical evaluation method

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This study aims to develop an efficient clinical protocol for evaluation of functional walking ability in rehabilitation practice

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

Summary

ID

NL-OMON32950

Source
ToetsingOnline

Brief title
Functional walking ability of prosthetic gait.

Condition

- Other condition

Synonym
lower-limb amputees, prosthetics

Health condition

vasculair of traumatische eenzijdige boven- of onderbeen amputatie met prothesegebruik als gevolg

Research involving
Human

Sponsors and support

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

Intervention

Keyword: functional walking ability, gait analysis, prosthetic gait, rehabilitation

Outcome measures

Primary outcome

Primary study parameters of 'free walking' are: preferred speed, step length, step width, asymmetry in step length, step time, and phase (phase cordination index, Plotnik et al. 2007), steptime variability (standard deviation, coefficient of variation, Hausdorff, 2007), and dynamic stability measures (e.g., correlations in consecutive steptime intervals (Ainsworth et al. 2007).
Primary stdy parameters of obstacle avoidance are the number of succesfull crossings, adjustments times, and adjustment type (shortening/lengthening strategies (Hofstad et al. 2006; Weerdesteyn et al. 2005)).
Primary study parameters of the steppings stones trials are the root mean square difference between footplacement and stepping stone position.

Secondary outcome

Secundary study parameters are the standard clinimetrics and assessmenst of fall risk and confidence.

Study description

Background summary

Gait adaptability -the ability to adjust gait to changes in the environment- is

an important aspect of prosthetic gait, yet difficult to assess in clinical settings.

Study objective

This study aims to develop an efficient clinical protocol for evaluation of functional walking ability in rehabilitation practice

Study design

Participants walk on an instrumented treadmill (the C-Mill) at their preferred speed in three conditions. The first condition is 'free walking'. The C-Mill enables automatic registration of the prosthetic gait pattern over a large number of strides, allowing for analyses of dynamic stability of gait. In the second condition, participants are instructed to avoid real-virtual visual obstacles projected on the treadmill using a beamer. Obstacles will be projected in such a manner that the participant would step on them if gait is not adjusted. Response time (short and long) and side (prosthetic vs. non-prosthetic side) will be varied across trials to gain insight in reactive and anticipatory obstacle avoidance behavior. In the third condition, participants are instructed to walk visually-projected stepping stone patterns that vary in predictability. Online gait adjustments are required to follow the pattern. Stability and flexibility outcome measures will be related to standard clinimetric measures. The results will be used in developing an efficient protocol for clinical evaluation of gait stability and adaptability.

Study burden and risks

Participants are asked to walk on a treadmill for 4 x 4 minutes after a period of familiarization. Participants of the control group walk 8 x 4 minutes; 4 times on their own preferred speed and 4 times on the mean preferred speed of the prosthetic groups.
The risks associated with the proposed research are minor. The treadmill is equipped with the usual safety precautions (safety stop, handrail). In addition, participants wair a safety harnas attached to the ceiling to prevent them from falling in case of a trip. Furthermore, a spotter is available for assistance.

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

Inclusion criteria: age between 18-65 years and physically able to walk 4 minutes on a treadmill. For prosthetic groups subsequent criteria hold: unilateral transfemoral or transtibial amputation, Sigam mobility classification C-F, use of own protheses to ensure a good fitting. A mechanically movable knee is required for transfemoral amputees.

Exclusion criteria

Cardio-respiratory, neurologic, orthopedic, or vestibular impairments that could influence 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:	Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-06-2009
Enrollment:	36
Type:	Actual

Ethics review

Approved WMO

Date:	08-05-2009
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	NL27613.029.09