InveStigating and Stimulating long Term walking Activity IN stroke

Published: 06-12-2011
Last updated: 29-04-2024

To explore the underlying mechanisms explaining walking ability and walking activity.

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

Summary

ID

NL-OMON39971

Source
ToetsingOnline

Brief title
SUSTAIN

Condition

- Central nervous system vascular disorders

Synonym
CVA, Stroke

Research involving
Human

Sponsors and support

Primary sponsor: Hogeschool Utrecht
Source(s) of monetary or material Support: Stichting Innovatie Alliantie (http://www.innovatie-alliantie.nl/)

Intervention

Keyword: Energy cost of locomotion, Physical Activity, Stroke, Walking

Outcome measures

Primary outcome

Dependent variables are walking ability and walking activity.

Secondary outcome

Independent variables are VO2peak, functional strength, energy cost of

locomotion, dynamic balance, fatigue, perceived exertion, falls efficacy and

depression.

Study description

Background summary

Sedentary stroke survivors show detrimental walking ability and walking ability over time, causing increased health risk in this population and decreased quality of life. It is not clear which underlying mechanisms explain this decrease in walking ability. To develop tailor made interventions to address this problem it is necessary to further investigate this. It is hypothesised that VOpeak, energy cost of locomotion, fatigue, experienced exertion, depression and falls efficacy have a role in walking ability and walking activity.

Study objective

To explore the underlying mechanisms explaining walking ability and walking activity.

Study design

To explore the underlying mechanisms explaining walking ability and walking activity.

Study burden and risks

The participants are requested to participate in 5 measurements during a 2 year period. All participants start with an assessment during which subject characteristics age, body mass index (BMI), gender, hemiplegic side, blood pressure (BP), resting heart rate (HR) and resting VO2 are determined These

assessments are followed by the assessment of walking capacity, using the 6 Minute Walk Test (6MWT) during which HR and gas exchange are monitored and which is video-recorded. During the first measurement, the participants wear an activitymonitor. Immediately afterwards perceived exertion during the 6MWT is assessed. Gait asymmetry, using a gait observation is assessed at a later point in time with help of the video recording. Following this assessment after a period of rest the VO2peak is assessed with the treadmill protocol as described by Macko (1997). All testing and safety procedures are according to the recommendations of the ACSM. The tests are conducted by the same physical therapist experienced in exercise testing and gait evaluation. A second assessor is present in case of adverse events. All assessors are AED-trained. A physician is always stand-by in the immediate surroundings to act in case of emergency. The testing location at the Faculty of Healthcare of the HU is within 2 minutes of the University Medical Centre Utrecht, where full medical care can be obtained. Testing is terminated if it is the patient's request, if gait instability or cardiovascular decompensation is observed, according to guidelines of the American College of Sports Medicine. All risks accompanying exercise testing are reduced to an absolute minimum by honouring the safety procedures recommended by the ACSM.
Besides the exercise tests, the participants fill out 4 questionnaires to determine fatigue, depression, falls efficacy and walking activity. Also, functional strength of the lower extremities as well as balance are assessed. Before the first measurement the participants come for a familiarisation visit. During this visit a preparticipation health screening using the AHA/ACSM Health/Fitness Preparticipation Screening Questionairre (Balady, 1998) and risk stratification is performed according to guidelines of the American College of Sports Medicine (ACSM, 2009). Also, the participants conducted a 6MWT while wearing the gas analyser and the activitymonitor and performed a short test on the treadmill.
The study will provide with new insights in walking capacity and walking activity in stroke, thus providing possibilities to develop more efficient interventions to prevent loss of function and health risk. The individual patients will receive a testreport which they may share with their care-givers to integrate in ongoing treatment if applicable.

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

Stroke according to the definition of the WHO at least three months ago
Older than 18 years
Independent walker; Functional Ambulation Categories 3,4,5.

Exclusion criteria

Severe cognitive disorder (Mini Mental State Examination <24 points)
Severe communicative disorder (Utrecht Communication State < 4 points)

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled

Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-04-2012
Enrollment:	100
Type:	Actual

Ethics review

Approved WMO Date:	06-12-2011
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	05-09-2012
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	01-05-2013
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	17-12-2013
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	23-06-2014
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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	NL36930.041.11