

Fitness And Functioning After Stroke. The Relative Aerobic Load of Daily Life for People after Stroke

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This study will provide reference values for the (relative) aerobic load of daily activities for people after stroke. Furthermore, it will assess the impact of relative aerobic load on daily life activity levels for people after stroke.

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

Summary

ID

NL-OMON46699

Source

ToetsingOnline

Brief title

FAFAS

Condition

- Other condition
- Central nervous system vascular disorders

Synonym

cerebrovascular accident (CVA), Stroke

Health condition

cerebrovasculair accident

Research involving

Human

Sponsors and support

Primary sponsor: Heliomare

Source(s) of monetary or material Support: Ministerie van OC&W, Heliomare

Intervention

Keyword: Activities of Daily Living (ADL), Aerobic capacity, Aerobic load, Stroke

Outcome measures

Primary outcome

This study will assess the absolute and relative aerobic load of various daily activities for people that have experienced a stroke. For this purpose, oxygen consumption will be measured during these activities and during a maximal cardiopulmonary exercise test. Furthermore, activity levels in daily life will be assessed through activity monitoring and the relationship between activity level, fatigue and relative aerobic load will be determined.

Secondary outcome

The aerobic load of daily tasks will additionally be expressed in heart rate and rating of perceived exertion. Furthermore the influence of cognitive and functional characteristics on aerobic load and on activity level will be assessed.

Study description

Background summary

People after stroke often have a lower aerobic capacity than their able-bodied peers. On top of that, the aerobic load of daily activities appears to be higher in this patient group. Often, these issues are investigated separately, but the actual impact on daily functioning can only be perceived when they are considered jointly. Currently, reference values on aerobic load of daily

activities for people after stroke are not available. Furthermore, the relationship between aerobic load and aerobic capacity; the relative aerobic load, has not been quantified. It can be expected that people with a high (predicted) relative aerobic load of daily activities will either experience more fatigue in daily life or be less active. This fatigue or inactivity can have a large impact on daily life and participation in the community.

Study objective

This study will provide reference values for the (relative) aerobic load of daily activities for people after stroke. Furthermore, it will assess the impact of relative aerobic load on daily life activity levels for people after stroke.

Study design

This study consists of a cross-sectional study assessing the (relative) aerobic load of different types of daily activities. A second observational study will assess the relationship between predicted relative load of daily activities and activity levels and experienced fatigue in daily life.

Study burden and risks

Participants in the first experiment will perform various activities of daily life on a maximum of two days, each visit lasting a maximum of 2.5 hours. During these activities oxygen uptake will be measured by means of breath by breath respirometry using a mobile device. Able-bodied control subjects will perform a cardiopulmonary exercise test (CPET) prior to the daily activity measurements. Stroke subjects will perform a CPET as part of clinical practice prior to participation. On the first of these visits, they will fill in questionnaires on their functional status and participation. Participants in the second experiment will be instructed to wear an activity monitor during five consecutive days. The instruction visit lasts approximately 1 hour.

Contacts

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Heliomare

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

- Is over 18 years old.
- Meets the American College of Sports Medicine (ACSM) inclusion criteria for maximal exercise testing (Thompson et al. 2013; Pescatello et al. 2014); Only applicable for people after stroke:
- Suffered a first or recurrent stroke, as diagnosed by a neurologist
- Receives rehabilitation treatment care in Heliomare
- Time since stroke between 7 days and 6 months at time of inclusion (subacute stroke; Bernhardt et al. 2017)
- Scheduled for a CPET as part of clinical practice
- Functional Ambulation Category (FAC) 2 or higher, indicating that the patient is able to perform balancing and coordinating tasks with or without some assistance
- For ambulatory activities; Berg Balance Score > 45 to limit fall risk during the activity (Berg et al. 1989)
- Able to understand instructions

Exclusion criteria

- Exclusion criteria for CPET as determined by the ACSM (Pescatello et al. 2014)
- Absolute contra-indications for exercise as determined by the ACSM (Pescatello et al. 2014)
- Cognitive or communicative disorders leading to inability to understand instructions or exercises
- Non-stroke related sensory, motoric or orthopaedic disorders influencing movements of daily living

- Non-stroke related disorders that influence aerobic load or aerobic capacity

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):	16-04-2018
Enrollment:	260
Type:	Actual

Ethics review

Approved WMO	
Date:	21-03-2018
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	NL64431.029.18