# Active after Stroke

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Primary Objective: to investigate the validity and reproducibility of the ST for measurement of cardiopulmonary capacity in stroke survivors. Secondary Objective(s): To establish 1. the reproducibility of the exercise time during the ST, 2. safety...

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

## Summary

### ID

NL-OMON45278

**Source**
ToetsingOnline

**Brief title**
ACTS

### Condition

- Central nervous system vascular disorders
- Vascular haemorrhagic disorders

**Synonym**
Cerebrovasculair accident (CVA) stroke

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Hogeschool Utrecht
**Source(s) of monetary or material Support:** RAAK Publiek

### Intervention

**Keyword:** cardiopulmonary capacity, physical activity

## Outcome measures

### Primary outcome

The primary outcome is the ventilatory anaerobic threshold (VAT). The VAT will be determined as the averages from two independent raters. The VAT can be determined by (1) the point where the V'E/V'O2 reaches its minimum or starts to increase without an increase in the V'E/V'CO2; (2) the point at which the partial pressure of end-tidal oxygen tension (PETO2) reaches a minimum or starts to increase without a decline in the partial pressure of end-tidal carbon dioxide tension (PETCO2); and, (3) the point of deflection of V'CO2versus V'O2 (V-slope method). Oxygen uptake during the ST is assessed with the Cortex Metamax B3 (Cortex Biophysik GmbH, Leipzig, Germany) measuring gas exchange while subjects perform the ST.

### Secondary outcome

VO2max (ml.kg-1.min-1), defined as a plateau in VO2 or a Respiratory Exchange Rate (RER) of *1.05 for 50-64 year olds and RER *1.0 for those 65 years and older for both males and females as recommended by Edvardsen et al.
in addition we will determine the respiratory compensation point or secondary ventilatory threshold (RCP). The RCP can be determined by: (1) the minimal value or nonlinear rise of V'E/V'CO2; (2) the point that PETCO2 starts to decline; and (3) the point of deflection of V'E versus V'CO2.

time walked during the test, measured by stopwatch

adverse events during the test

# Study description

**Background summary**

Each year 47.000 people in the Netherlands suffer a stroke for the first time, in total 129 people per day. In 2011 the costs of care for stroke survivors were estimated to be 970 million euro for males and 1.3 billion for females (top 10 of most expensive conditions). Rehabilitation of stroke survivors is aimed at gaining as much independence as possible in their own environment. After discharge from the hospital stroke survivors need to stay or become physically active to keep or regain their aerobic capacity as an important part of integration into society.
Research shows that almost 80% of the stroke survivors has reduced strength and an aerobic capacity between 12-20 ml/kg/min. According to Shephard a minimum VO2max of 15 ml/kg-1/min-1 is needed to perform functional activities for independent living. Cardiopulmonary capacity (i.e., aerobic capacity or VO2max) is defined as the highest rate at which oxygen can be taken up and consumed by the body during intense exercise18. Obtaining a valid measure of aerobic capacity in stroke survivors is important for the purpose of determining exercise capacity, training prescription, treatment efficacy evaluation, and/or investigation of exercise-induced adaptations of the oxygen transport/utilization system. The current gold standard for the assessment of aerobic capacity is considered to be the maximal cardiopulmonary exercise test (CPET) with measurements of ventilation and gas exchange, for direct assessment of maximal oxygen uptake (VO2max). VO2max is the accepted indicator of aerobic capacity and reflects the limits of the cardiorespiratory system to respond to exercise.
The assessment of aerobic capacity in persons after stroke is more challenging than in healthy subjects because they present with stroke-specific impairments such as muscle weakness, fatigue, poor balance, contractures and spasticity, which can compromise CPET outcome. Marzolini et al. for instance, reported that at the start of an exercise training intervention only 68.4% of CPETs (n=98) provided information sufficient to prescribe exercise intensity in persons with chronic stroke, suggesting that many persons after stroke do not reach the limits of their cardiopulmonary system before training. In the search for a CPET protocol that allows persons after stroke to reach the limits of their cardiopulmonary system, a multitude of different protocols have been developed using treadmill, body weight supported treadmill, (recumbent) leg cycle ergometry and recumbent stepper exercise. However, the majority of subjects did not reach the limits of their cardiopulmonary system in these protocols. Given the reported difficulty of measuring VO2max in persons after stroke, we may need to consider an alternative, for instance, the determination of the ventilatory threshold, or respiratory compensation point (RCP). The RCP is recommended as an appropriate target intensity level for the prescription of exercise as it is an effort independent measure and maximum testing is not

necessary. Measuring RCP in persons after stroke is feasible for the majority of subjects as evidenced by the reports of 5 studies. Recent studies have found the determination of RCP to have reasonably good reliability (ICC3,1 = 0.77 (95% CI 0.24, 0.87) in persons after stroke. Since CPET requires expensive equipment and trained personnel, not available to many clinicians, there is an urgent need for a valid and reproducible field test to assess at least the RCP and if possible, VO2max. In clinical settings field tests of walking ability are often used. These usually comprise a self-paced test in which the patient walks as far as possible in either six or twelve minutes. Despite the wide use in stroke rehabilitation, the 6MWT requires a long walking track, it can only be performed on an individual basis, and participants may be influenced by self-paced walking speed, motivation, and encouragement that cannot be standardized and might influence the level of exertion. Their very simplicity, however, limits the information that can be obtained from them about the physiological and symptomatic changes that occur during exercise. Therefore, the Shuttle Walk Test, initially developed for persons with COPD, may be of more use. The protocol was modified from that of a progressive, externally paced 20 meter shuttle running test, widely used as a field test of functional capacity in athletes. The protocol has been adapted or modified for patients with a variety of chronic diseases for adults and children and has been found to be safe and have acceptable psychometric properties. A systematic review reported the correlations between distance walked in the SWT and VO2peak to range from 0.67 to 0.95 ($p<0.01$) for criterion validity. ICCs for test retest reliability ranged from 0.76 to 0.99. To date the SWT has not been tested or applied in subjects after stroke. For many adults with physical disabilities, the original 20-m shuttle test is not suitable, because the starting speed (8 km/h) and increase (0.5 km/h) every minute are beyond their capabilities. A continuous progressive exercise lasting between 6 and 17 minutes is optimal for achieving a maximal effort.
Verschuren et al. developed a modified Shuttle Test (ST) for children with cerebral palsy, which, compared with the original SWT, uses smaller increments in walking or running speed over a 10-m course. There are 2 protocols available for this 10-m shuttle test. The Level I shuttle test (ST-I) starts at 5 km/h. The Level II shuttle test (ST-II) starts at 2 km/h. Speed is increased 0.25 km/h every level (minute) for both tests. These protocols might be a more suitable functional walk/run test for individuals with motor deficits, including subjects after stroke.
Since most subjects after stroke that participated in the SUSTAIN study (n=60) walked less than 3.5 km/hr during a 6 minute walk test, we will investigate the validity and reproducibility of the ST-II test (that starts at 2 km/hr) for measuring cardiopulmonary capacity.

## Study objective

Primary Objective: to investigate the validity and reproducibility of the ST for measurement of cardiopulmonary capacity in stroke survivors.
Secondary Objective(s): To establish 1. the reproducibility of the exercise

time during the ST, 2. safety of the ST in stroke survivors, 3. possible differences in the reproducibility and validity of the ST between patients with subacute stroke and patients with chronic stroke.

### Study design

This is a test-retest study.
Subjects will be asked to perform the Shuttle Test (ST) twice, about one week apart. After the ST and appropriate rest a validation procedure will be performed lasting 3 minutes.

### Study burden and risks

We will ask people after stroke to come 2 x 1 hour for testing. We will exclude subjects at risk for potential problems with maximal exercise testing (such as fall prone subjects and subjects with severe cardioascular disease. During the test the researcher accompanies the subject. We therefore estimate the burden and risks associated with participation as low.This study will provide insight into the validity and reproducibility of the ST for people after stroke. This field test has the potential to provide information on a subject*s exercise capacity, to be used to determine exercise intensity and treatment outcomes. The individual subjects will get insight into their exercise capacity and will be given a report on their exercise capacity to share with their attending physical therapist and/or physician if they should wish to do so.

## Contacts

**Public**
Hogeschool Utrecht

Heidelberglaan 7
utrecht 3584CS
NL
**Scientific**
Hogeschool Utrecht

Heidelberglaan 7
utrecht 3584CS
NL

# Trial sites

## Listed location countries

Netherlands

# Eligibility criteria

**Age**
Adults (18-64 years)
Elderly (65 years and older)

## Inclusion criteria

* Stroke according to the WHO definition
* Age over 18
* Able to walk 10 m with supervision (Functional Ambulation Categories * 3)
- Be close to completion of the in-patient rehbailitation stay (for patients in the Hoogstraat)

## Exclusion criteria

* Severe cognitive disorder (Mini Mental State Examination <24 points)
* Severe communicative disorder (Utrecht Communication State < 4 points)
* Be a recurrent faller, defined as more than two falls in a six*month period. Falls are defined as *an unexpected event in which the participants come to rest on the ground, floor, or lower level.*
- contraindication for maximal exercise test, such as severe cardiovasculair disease.

# Study design

## Design

**Study type:** Observational non invasive

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| Masking: | Open (masking not used) |
| Control: | Uncontrolled |
| Primary purpose: | Treatment |

### Recruitment

NL

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| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 04-09-2017 |
| Enrollment: | 30 |
| Type: | Actual |

## Ethics review

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| Approved WMO Date: | 24-05-2017 |
| Application type: | First submission |
| Review commission: | METC Universitair Medisch Centrum Utrecht (Utrecht) |
| Approved WMO Date: | 31-08-2017 |
| 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 | NL60836.041.17 |