

# Low-intensity wheelchair training in inactive people with a chronic spinal cord injury.

No registrations found.

<b>Ethical review</b>	Positive opinion
<b>Status</b>	Recruiting
<b>Health condition type</b>	-
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON27828

### Source

Nationaal Trial Register

### Health condition

Spinal cord injury  
Wheelchair  
Training  
Physical capacity

Dwarslaesie  
Rolstoel  
Training  
Fysieke capaciteit

## Sponsors and support

**Primary sponsor:** Prof. dr. C. Visscher

Center for Human Movement Sciences

Center for Rehabilitation

University Medical Center Groningen (UMCG)

University of Groningen

Antonius Deusinglaan 1, 9713 AV, Groningen

**Source(s) of monetary or material Support:** VSBFonds Nuts Ohra subsidieronde (ZonMw)

## Intervention

### Outcome measures

#### Primary outcome

The main study parameter is the physical capacity, measured by the peak power output. The peak power output is assessed during a peak exercise test in a wheelchair on a treadmill.

#### Secondary outcome

Secondary study parameters are:

(Sub)maximal capacity, propulsion technique, pain and functioning of the upper extremities, respiratory function, muscle strength, sprint capacity, wheelchair skills, independence (SCIM), metabolic syndrome, participation, quality of life and personal- and environmental factors.

## Study description

#### Background summary

This study is an evaluation of evaluate the short- and long-term effectiveness of low-intensity handrim wheelchair and regular intensity exercise training on physical capacity, daily (wheelchair)

activities, participation and quality of life, as well as on the risk of secondary complications (upper body overuse and cardiovascular risk factors) in three groups of individuals with a paraplegia (N=30, 3x10) and tetraplegia (N=30, 3x10), TSI>10y, age: 28-65y, dependent on a handrim propelled wheelchair, and without contra-indications.

The experimental groups will receive 16 weeks either low-intensity training (wheelchair: 2x30 min/week on 35% heart rate reserve (HRR) or hand cycle training (2x30 min/week on 70% HRR), while a control group will not receive training.

#### Study objective

People with a spinal cord injury are often dependent on a (hand rim) wheelchair and have an inactive lifestyle. Therefore, it is important to develop a good protocol for wheelchair training, which prevents overuse of the musculoskeletal system on one hand and improves the physical capacity and prevents the occurrence of secondary complications on the other hand. In the world of sport the training guidelines of the ACSM (ACSM, 1993, 1997) are often used. An intensity of 70-80%HRR, a frequency of 3-5x/week and a duration of 20-30 min. are in general accepted criteria to induce a training effect. However, Haskell (1994) proposed different training guidelines to improve physical fitness and health. According to Haskell,

exercise at a lower intensity (30-40%HRR) and with a more diverse pattern of light activities of different durations performed every day (like activities of daily living), might be more suitable for (extreme) inactive people. Additionally the risk for overuse injuries will be smaller. In 2006 a research project has been performed to study the effect of a 7-week low-intensity (30%HRR, 3x 70 min/week) wheelchair training in able-bodied subjects. The results showed that a low-intensity wheelchair training can improve the physical capacity and propulsion technique in healthy young men. The next step is to investigate the effect of this training in inactive people with a chronic spinal cord injury.

The primary objective is to evaluate the effectiveness of low-intensity hand rim wheelchair exercise training on physical capacity, daily (wheelchair) functioning, participation and quality of life in people with a spinal cord injury. Furthermore, the effect on secondary complications such as upper body overuse and cardiovascular risk factors in inactive people with a chronic spinal cord injury will be studied.

## **Study design**

### Screening:

Potential subjects are located through the databases of an interest organisation for persons with SCI and the rehabilitation centers (see 8.2) and are selected based on age (28-65y), TSI (>10y) and activity level (PASIPD score < 75th percentile of a Dutch SCI cohort (de Groot et al., 2010)).

Before the first test, participating subjects will be screened by a physician on cardiovascular or musculoskeletal contraindication. Anthropometric measurements will be performed and, based on a questionnaire and the subject's history and medical chart, information on demographics, lifestyle habits and secondary complications will be recorded (Haisma et al., 2007). In addition, a wheelchair check-up will take place, which will include recording of wheelchair specifications and maintenance status.

In each week of testing, blood samples and saliva samples will be taken in the morning, when subjects are in fasting state, to determine the components of the metabolic syndrome.

### Exercise testing - wheelchair:

Subjects of all three groups will conduct the handrim wheelchair exercise and skill tests with their own wheelchair. A set of wheels providing biofeedback and other parameters on propulsion technique (Optipush), e.g. force and cadence, will replace that of the subject's wheelchair.

**Maximal isometric strength test.** The maximal isometric wheelchair push test will be conducted to determine the subject's maximal force on the handrim. This is a wheelchair-specific strength test in which subjects, while sitting in their wheelchair, push themselves

forward as hard as possible. The wheelchair remains stationary due to a cable, which is attached to a force transducer and to the wheel axle.

After the isometric strength test there will be a resting period of eight minutes. Then there will be a three minutes warming up period. After warming up there is a three minutes rest period before starting the 30 s sprint test.

**Sprint power test.** A 30s sprint test will be performed. Peak forces and peak and mean power output will be recorded. After a 10 minutes resting period the submaximal test starts.

**Submaximal performance test.** Consists of two times three minutes wheelchair propulsion on two different workloads (power out (PO)) and a constant velocity; workload and velocity both depend on baseline capacity. A 2-min rest period will be between the two blocks. LPD and RPE will be recorded.

The gross mechanical efficiency (ME) will be calculated from the energy expenditure ( $E_n$ ) and PO according to:  $ME = PO (W) \cdot E_n^{-1} \cdot 100\%$ .

After a 2-min rest interval, the graded exercise test (GXT) will be performed.

**Maximal aerobic capacity test: GXT.** consists of 1-min exercise blocks in which the velocity of the treadmill belt is held constant and in which the workload will be increased every step by adding extra resistance ( $F_{add}$ ) through a pulley system (Valent et al., 2007b). The test will be ended when the subject can no longer maintain his or her position on the belt as a consequence of exhaustion, or when the subject indicates that he/she wants to stop. A separate drag test will be performed to determine the drag force ( $F_{drag}$ ) of the wheelchair-user system using the protocol of Van der Woude et al. (1986). Power output will be calculated from  $F_{drag}$ , added load ( $F_{add}$ ) and the velocity of the belt ( $v$ ) according to:  $PO = (F_{drag} + F_{add}) \cdot v$ .

**Exercise testing – hand cycle:**

Hand cycle (sub)maximal performance tests. These tests will only be performed by the hand cycle group and are necessary for eliciting correct exercise intensity during the hand cycle training (see 4.5). The same protocol will be followed as during the (sub)maximal wheelchair performance tests.

### Wheelchair skills:

The Wheelchair Circuit (Kilkens et al., 2004, Kilkens et al., 2002) is a test to assess manual wheelchair skill performance. It consists of 8 different standardized tasks that will be performed in a fixed sequence on a floor surface and on a motor-driven treadmill. The tasks are (1) figure-of-8 shape, (2) crossing a doorstep (height, 0.04m), (3) mounting a platform (height, 0.10m), (4) 15-m sprint, (5) 3% slope, (6) 6% slope, (7) wheelchair propulsion (3 minutes), and (8) transfer. Performance in a stationary and dynamic (10m) wheelie task will give insight in the overall wheelchair skill of the participant (Cowan et al., submitted 2010). All subjects will use their own wheelchair, only for the 15m sprint it will be instrumented with Optipush wheels (see footnote c above). During circuit performance, the ability to perform the test items, performance times of the figure-of-8 shape and 15-m sprint, and peak heart rates during the 3% and 6% slope items on the treadmill will be recorded. Heart rate (in beats/min) will be registered with a Polar sport tester Vantage NVE at a 5-second storage interval.

### Lung function:

Flow-volume curves will be made with an Oxycon (Viasys) to assess respiratory function. Three repeated curves will be made and if the resultant curve does not have its characteristic shape, an extra measurement will be made. The FVC (in liters) and FIV1 and FEV1 (in liters) for each subject will be additionally expressed as a percentage of what that subject was expected to score in comparison with an age, sex, and height-matched able-bodied population.

### Muscle strength:

To determine the strength of the upper extremities, the shoulder abductors, internal and external rotators, elbow flexors and extensors, and wrist extensors in both arms will be tested with the manual muscle test (MMT). The strength is rated on a scale ranging from 0 to 5 (Haisma et al., 2006). The scores of the 12 muscle groups give a MMT sum score (maximum is 60).

The muscle groups (with exception of the wrist extensors) that scored 3 or greater on the MMT will be tested with handheld dynamometry (HHD) according to a standardized protocol (Haisma et al., 2006). The maximum force (in Newton) of the 10 muscle groups will be summated.

### Daily activity monitoring:

In the week preceding each measurement session, a lightweight odometer installed on the

subjects' wheelchair will be used to measure the number of wheel revolutions. In addition, subjects are asked to keep a daily activity diary on each of the days that the odometer is installed.

### Questionnaires:

Questionnaires will be filled out at home in the week before each designated measurement session(s), in order to determine functional status and independence (FSS, SCIM (filled out by investigator in rehabilitation center), pain and complaints of the upper extremity (WUSPI, questionnaires wrist- and other musculoskeletal complaints), physical activity (PASIPD, EAMQ), life satisfaction (HADS), health-related quality of life (a brief version of WHOQOL), participation (USER-P), illness cognition (ICQ), self-efficacy (ESES, SEWMS), and – only before the pre-test – social support (SSL-12), and wheelchair satisfaction (D-QUEST). This will take approximately 1 hour. After each test and training session a complaints diary will be filled out to monitor the occurrence of musculoskeletal problems.

### Intervention

The experimental groups will receive 16-week low-intensity wheelchair exercise training (35%HRR; 2x30min/week) or handcycling training (70%HRR, 2x30 min/week) while the control group will not receive any training.

## Contacts

### Public

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## Eligibility criteria

### Inclusion criteria

Patients, aged > 28 yrs, with a chronic spinal cord injury (>6y), and an inactive lifestyle (lowest 75% of normscore of spinal injury patients on physical activity questionnaire 'PASIPD').

### Exclusion criteria

1. Cardiovascular contra-indications for testing according to the American College of Sports Medicine (ACSM) guidelines, or a resting diastolic blood pressure above 90 mm Hg or a resting systolic blood pressure above 180 mm Hg;
2. Musculoskeletal complaints of the upper extremities, neck or back;
3. Progressive disease;
4. Psychiatric problem;
5. Not having enough knowledge of the Dutch language to understand the purpose of the study and the testing methods;
6. Plans to start another lifestyle (e.g. more physical active, diet) in the months that the experiment is going on.

## Study design

### Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial

Masking:	Open (masking not used)
Control:	Active

## Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	01-09-2011
Enrollment:	60
Type:	Anticipated

## IPD sharing statement

**Plan to share IPD:** Undecided

## Ethics review

Positive opinion	
Date:	25-08-2011
Application type:	First submission

## Study registrations

### Followed up by the following (possibly more current) registration

ID: 37191  
Bron: ToetsingOnline  
Titel:

### Other (possibly less up-to-date) registrations in this register

No registrations found.

## In other registers

Register	ID
NTR-new	NL2891
NTR-old	NTR3037
CCMO	NL21812.029.08



**Register**

ISRCTN

OMON

**ID**

ISRCTN wordt niet meer aangevraagd.

NL-OMON37191

## Study results

**Summary results**

N/A