# The effect of 16-week low-intensity wheelchair training on functions, activities, and participation in inactive people with a spinal cord injury.

Published: 04-06-2008
Last updated: 15-05-2024

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,...

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| **Ethical review** | Approved WMO |
| **Status** | Recruitment stopped |
| **Health condition type** | Spinal cord and nerve root disorders |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON37191

**Source**
ToetsingOnline

**Brief title**
Wheelchair training after a chronic spinal cord injury

### Condition

- Spinal cord and nerve root disorders

**Synonym**
paralysis, spinal cord injury

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Rijksuniversiteit Groningen

**Source(s) of monetary or material Support:** ZonMW

## Intervention

**Keyword:** physical capacity, spinal cord injury, training, wheelchair

## 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

Secundary 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

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 ACMS (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 divers 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 healty young men. The next step is to investigate the effect of this training in inactive people with a chronic spinal cord injury.

**Study objective**

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**

A controlled randomized trial

**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.

**Study burden and risks**

Subjects will participate in a 10-months research project executing a 16 week wheelchair or handbike training-program on a treadmill, 2 days/week 30 min on 35%HRR (wheelchair) or 30 min on 70%HRR (handbike).
Measurements will be performed at 4 different time slots.
Subject may experience some discomfort and/or muscle soreness after the peak exercise test or training. Furthermore, the risks during training and testing sessions are relatively low because of thorough screening prior to participation, use of skilled and licensed therapists and safety precautions throughout training and testing. The expected beneficial training effects in combination with the limited risks would justify execution of the proposed study.

# Contacts

**Public**
Rijksuniversiteit Groningen

Antonius Deusinglaan 1
9713 AV Groningen
NL
**Scientific**
Rijksuniversiteit Groningen

Antonius Deusinglaan 1
9713 AV Groningen
NL

# Trial sites

## Listed location countries

Netherlands

# Eligibility criteria

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

## Inclusion criteria

Spinal cord injury
Wheelchair-dependent
28 - 65 years
Time since injury > 10y

## Exclusion criteria

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
Musculoskeletal complaints of the upper extremities, neck or back.

Progressive disease
Psychiatric problem
Not having enough knowledge of the Dutch language to understand the purpose of the study and the testing methods.
Plans to start another lifestyle (e.g. more physical active, diet) in the months that the experiment is going on.

# Study design

## Design

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|---|---|
| Study type: | Interventional |
| Intervention model: | Parallel |
| Allocation: | Randomized controlled trial |
| Masking: | Open (masking not used) |
| Control: | Active |
| Primary purpose: | Treatment |

## Recruitment

NL

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|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 01-09-2008 |
| Enrollment: | 60 |
| Type: | Actual |

# Ethics review

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| Approved WMO Date: | 04-06-2008 |
| Application type: | First submission |
| Review commission: | METC Amsterdam UMC |
| Approved WMO Date: | 05-04-2011 |
| Application type: | Amendment |
| 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

ID: 27828
Source: Nationaal Trial Register
Title:

## In other registers

| Register | ID |
|---|---|
| CCMO | NL21812.029.08 |
| OMON | NL-OMON27828 |