

# A self-management intervention aimed to increase an active lifestyle in persons with a long-term spinal cord injury to: the HABITS (Healthy active behavioural intervention in spinal cord injury) study

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		<input type="checkbox"/> Protocol
<b>Registration date</b> 07/09/2015	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 03/09/2015	<b>Condition category</b> Nervous System Diseases	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

The spinal cord is a bundle of nerve fibres which is encased in a bony column (known as the spine). It is the most important link between the brain and the other nerves in the body (peripheral nervous system). Damage to the spinal cord (spinal cord injury, SCI) can lead to serious consequences. SCI can range from mild to severe, and can cause a partial or total loss of movement, often leaving people with life-long disability. People with a SCI are often not very active, as they are usually confined to a wheelchair. This study is part of a research programme to help encourage people with a long-term SCI to become more physically active. The programme works by giving people the tools, skills and support to have a healthy and active lifestyle, as well as helping them to cope better with day to day life. The aim of this study is to find out whether a programme such as this can help people suffering from a long-term SCI to become more active and become more independent.

### Who can participate?

Adults who have been suffering from SCI for at least 10 years and are not very active.

### What does the study involve?

Participants are randomly allocated into one of two groups. Participants in the first group (intervention group) are enrolled in a 16 week self-management course designed to help them lead a more active lifestyle. These courses consist of one home visit, five group meetings, and five individual sessions and each participant is given a personal counselor to help them through the process. Participants in the second group (control group) are given information about how to have an active lifestyle in the form of one meeting and an information booklet. Levels of physical activity are measured using questionnaires at the start of the study, at the end of the intervention period (week 16), and six months after the intervention (week 42).

What are the possible benefits and risks of participating?

Participating in this study is beneficial as having an active and healthy lifestyle is important for good general health. The skills taught to participants will help them to maintain an active lifestyle long-term. There are not significant risks of participating, as all patients will still receive normal care. Participating will cost time and some physical effort for all patients in terms of the tests, questionnaires and keeping a diary.

Where is the study run from?

1. Rijndam Rehabilitation Centre (Netherlands)
2. De Hoogstraat Rehabilitation Centre (Netherlands)
3. Roessingh Rehabilitation Centre (Netherlands)
4. Adelante Rehabilitation Centre (Netherlands)

When is the study starting and how long is it expected to run for?

January 2011 to December 2014

Who is funding the study?

1. Netherlands Organisation for Health Research and Development (Netherlands)
2. Fonds NutsOhra (Netherlands)

Who is the main contact?

1. Ms Hedwig Kooijmans (Scientific)  
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2. Dr Johannes Bussmann (Scientific)

## Contact information

### Type(s)

Scientific

### Contact name

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## Additional identifiers

### Protocol serial number

N/A

## Study information

### Scientific Title

Randomized controlled trial of a self-management intervention aimed to increase an active lifestyle in persons with a long-term spinal cord injury: the HABITS (Healthy Active Behavioural Intervention in SCI) study

### Acronym

HABITS

### Study objectives

This intervention will show beneficial effects on:

1. A more active lifestyle
2. Self-management skills, such as proactive coping, problem-solving ability and self-efficacy
3. That participants with improvements in self-management skills will show more favourable effects on active healthy lifestyle than participants who do not improve in self-management skills.

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

Erasmus MC Medical Ethics Committee, 14/10/2011, ref: MEC-2011-225

### Study design

Double-blinded multi-centre randomized controlled trial

### Primary study design

Interventional

### Study type(s)

Treatment

### Health condition(s) or problem(s) studied

Spinal cord injury

### Interventions

Study participants were randomized to a 16 week self-management intervention consisting of one home-visit, 5 group-meetings, 5 individual sessions and a personal counselor in order to improve self-management skills that would facilitate behavior change towards an active lifestyle, or to a control group that only received information about an active lifestyle by one meeting and a booklet.

## **Intervention Type**

Behavioural

## **Primary outcome(s)**

1. Objectively measured physical activity, is assessed by the Physical Activity Scale for Individuals with Physical Disabilities (PASIPD), at baseline, 16 weeks and 42 weeks.
2. Subjectively measured physical activity is measured at baseline, 16 weeks and 42 weeks, by two accelerometer-based devices (ActiGraph GT3X+) [34]. One accelerometer attached at the wrist, the other to the spokes of one wheelchair wheel with special Velcro bands. Based on the results of the two accelerometers, a custom-made algorithm in MatLab differentiates between self-propelled wheelchair driving and other activities.

## **Key secondary outcome(s)**

1. Self-management skills (self-efficacy, proactive coping) are measured at baseline, 16 weeks and 42 weeks with two scales:
  - 1.1. The SCI exercise self-efficacy scale, measures self-reported self-efficacy for various types of physical exercise in individuals with SCI
  - 1.2. The Utrecht Proactive Coping Competence scale , which assesses an individual's experienced competency with regard to the various skills associated with proactive coping.
2. Stages of exercise change is measured at baseline, 16 weeks and 42 weeks using the Questionnaire University of Rhode Island continuous measure to assesses the six stages of change for regular exercise (based on the Trans-theoretical model)
3. Attitude, which is measured using the Exercise: Decisional Balance questionnaire at baseline, 16 weeks and 42 weeks. This questionnaire reflects the individual's relative weighing of the pros and cons of changing exercise behavior.

## **Completion date**

31/12/2014

## **Eligibility**

### **Key inclusion criteria**

1. Spinal cord injury (for at least 10 years)
2. Aged between 28-65 years
3. PASIPD score (Physical activity scale for individuals with physical disabilities) lower than the 75th percentile of a Dutch SCI population
4. Ability to use a hand-rim wheelchair

### **Participant type(s)**

Other

### **Healthy volunteers allowed**

No

**Age group**

Adult

**Sex**

All

**Key exclusion criteria**

1. Progressive disease or severe co-morbidities
2. Psychiatric problems that would interfere with the study
3. Insufficient knowledge of the Dutch language to understand the purpose of the study and the testing methods
4. No intention to change exercise behaviour in the next 6 months

**Date of first enrolment**

01/05/2012

**Date of final enrolment**

01/06/2014

**Locations****Countries of recruitment**

Netherlands

**Study participating centre****Rijndam Rehabilitation Centre**

Rotterdam

Netherlands

3015 LJ

**Study participating centre****De hoogstraat Rehabilitation Centre**

Utrecht

3583 TM

**Study participating centre****Roessingh Rehabilitation Centre**

Enschede

7500 AH

**Study participating centre**

**Adelante Rehabilitation Centre**  
Hoensbroek  
6432 CC

## Sponsor information

### Organisation

Netherlands Organisation for Health Research and Development (ZonMW)

### Organisation

Fonds NutsOhra

### Organisation

Netherlands Organisation for Health Research and Development

### ROR

<https://ror.org/01yaj9a77>

## Funder(s)

### Funder type

Research organisation

### Funder Name

Netherlands Organisation for Health Research and Development

### Alternative Name(s)

Netherlands Organisation for Health Research and Development

### Funding Body Type

Private sector organisation

### Funding Body Subtype

Other non-profit organizations

### Location

Netherlands

**Funder Name**  
Fonds NutsOhtra

## Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Other

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Study website</a>	Study website	11/11/2025	11/11/2025	No	Yes