

# Aerobic exercise to improve fitness, walking ability and cognitive function in multiple sclerosis: a randomized controlled trial

<b>Submission date</b> 06/10/2011	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 12/12/2011	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 28/10/2013	<b>Condition category</b> Nervous System Diseases	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims:

Several studies have shown that fitness training can increase well-being and quality of life in patients with multiple sclerosis. However, most of the available studies have included patients during the early phase of disease with mild to moderate disability. In this study, we investigated if standardized fitness training is possible for patients with progressive disease and which training form may be most suitable for this group. In addition, we will explore if exercise can enhance physical fitness, walking ability and cognitive function (e.g. memory).

### Who can participate?

Male or female patients aged 30-60 years with secondary-progressive multiple sclerosis and an Expanded Disability Status Scale (EDSS) between 4 and 6.

### What does the study involve?

The patients were randomly allocated to one of three different groups of fitness training or to a wait list control group (where these patients would have to wait to receive the fitness training). All patients in the three fitness training groups will exercise for approximately 30-45 minutes, 2 or 3 times a week, for 8 weeks. The intensity of the training was adjusted to their individual fitness level which was assessed at the initial fitness evaluation at the Department of Sports Medicine. The patients in the wait list control group will be offered an 8 week exercise training program of their choice free of charge after the study is completed.

### What are the possible benefits and risks of participating?

Participants could increase their level of physical fitness under medical supervision. However exercise may lead to an increase of some symptoms of multiple sclerosis due to increases in body temperature while exercising.

### Where is the study run from?

University Hospital Hamburg-Eppendorf, Hamburg, Germany

When is the study starting and how long is it expected to run for?  
The study started in August 2010 and ended in January 2012.

Who is funding the study?  
University Hospital Hamburg-Eppendorf, Germany

Who is the main contact?  
Prof Christoph Heesen  
heesen@uke.de

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Prof Christoph Heesen

**Contact details**  
Martinistrasse 52  
Hamburg  
Germany  
20246  
heesen@uke.de

## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
PV3689

## Study information

**Scientific Title**  
Hamburg Pilot Trial on Exercise in Secondary Progressive Multiple Sclerosis (HAPITEX-SPMS)

**Acronym**  
HAPITEX-SPMS

**Study objectives**  
The aim of the study is to investigate the safety and feasibility of exercise in multiple sclerosis (MS) patients with advanced disability. We will also test the potential of standardized exercise interventions to improve physical fitness, enhance cognitive function and decrease fatigue and depression in MS patients with progressive disease.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Medical Board Hamburg, Germany, 1 August 2011, ref: PV3689

**Study design**

Randomised controlled trial with wait list control group

**Primary study design**

Interventional

**Secondary study design**

Randomised controlled trial

**Study setting(s)**

Hospital

**Study type(s)**

Quality of life

**Participant information sheet**

Not available in web format, please use the contact details below to request a patient information sheet

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

Multiple Sclerosis

**Interventions**

Subjects are randomly assigned to one of four conditions (biased coin randomization):

1. Bicycle ergometry
2. Hand ergometry
3. Rowing
4. Waitlist control

The goal is to have 10 subjects in each group, 8 weeks with 2-3 sessions per week

**Intervention Type**

Other

**Phase**

Not Applicable

**Primary outcome measure**

Physical fitness pre and post intervention as determined by a standardized ergometer test

**Secondary outcome measures**

1. Walking ability (6-minute walk test)
2. Cognitive function (assessed by a neuropsychological battery including learning and memory, attention, executive function and processing speed)

- 3. Depression (IDS-30R)
- 4. Fatigue (MFIS)

Assessed pre and post intervention.

**Overall study start date**

01/08/2011

**Completion date**

31/01/2012

## **Eligibility**

**Key inclusion criteria**

- 1. Patients with secondary-progressive multiple sclerosis (MS)
- 2. Disease duration <20 years
- 3. Expanded disability status scale (EDSS) 4-6

**Participant type(s)**

Patient

**Age group**

Other

**Sex**

Both

**Target number of participants**

40

**Key exclusion criteria**

- 1. Immunomodulatory therapy in the last 3 months
- 2. Steroid therapy in the last 4 weeks
- 3. Relapsing-remitting or primary progressive MS
- 4. Laboratory markers of liver and kidney function outside of the normal range
- 5. Immunodeficiency or other serious medical illnesses (based on the judgement of the physician)
- 6. Hepatitis B or hepatitis C infection or other chronic liver diseases
- 7. Patients taking psychoactive medication (benzodiazepines, neuroleptics, antidepressants)

**Date of first enrolment**

01/08/2011

**Date of final enrolment**

31/01/2012

## **Locations**

**Countries of recruitment**

Germany

**Study participating centre**  
**Martinistrasse 52**  
Hamburg  
Germany  
20246

## **Sponsor information**

### **Organisation**

Institute for Neuroimmunology and Clinical Multiple Sclerosis Research (Germany)

### **Sponsor details**

Falkenried 94  
Hamburg  
Germany  
20251

### **Sponsor type**

Research organisation

### **Website**

<http://www.zmnh.uni-hamburg.de/martin/main.php>

## **Funder(s)**

### **Funder type**

University/education

### **Funder Name**

Institute for Neuroimmunology and Clinical Multiple Sclerosis Research, University Hospital  
Hamburg-Eppendorf (Germany)

## **Results and Publications**

### **Publication and dissemination plan**

Not provided at time of registration

### **Intention to publish date**

### **Individual participant data (IPD) sharing plan**

## IPD sharing plan summary

Not provided at time of registration

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	01/03/2014		Yes	No