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

Submission date
06/10/2011

Recruitment status
No longer recruiting

Registration date
12/12/2011

Overall study status
Completed

Last Edited
28/10/2013

Condition category
Nervous System Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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, Germnay

Who is the main contact?
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Contact information

Type(s)
Scientific

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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?
Results article	results	01/03/2014		Yes	No