

# Group-based multidisciplinary rehabilitation for outpatient clients with multiple sclerosis

<b>Submission date</b> 06/10/2017	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 20/10/2017	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 19/10/2017	<b>Condition category</b> Nervous System Diseases	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Multiple sclerosis (MS) is a condition that affects the brain and/or spinal cord, causing problems with vision, arm or leg movement, sensation or balance. A two-year multi-professional group-based out-patient rehabilitation program has been developed for people with MS based on themes of energy conservation, cognition, mood and body control. The aim of this study is to test the effect of this rehabilitation model on the participation and daily life of people with MS. The study also tests the Impact on Participation and Autonomy (IPA) measure, which was translated into Finnish during the study, and aims to find out which factors are associated with participation and autonomy of people with MS.

### Who can participate?

People with MS aged between 18 and 65

### What does the study involve?

Participants take part in group-based rehabilitation every two weeks. The sessions last 3-6 hours. Carers of the participants are involved in the part of the sessions. A comparison group of 19 people with MS receive typical rehabilitation for people with severe disabilities which contains mainly physiotherapy. In addition to test the IPA questionnaire more data is collected from people with MS during an in-patient rehabilitation period of 1-3 weeks at Masku Neurological Rehabilitation Center. The rehabilitation model is evaluated with questionnaires for rehabilitees, their families, service providers and co-operation partners on four occasions and with focus-group interviews with the rehabilitees. Rehabilitees' participation restrictions, occupational performance and rehabilitation goal attainment are measured.

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

Participants may benefit from the group-based rehabilitation by improving their participation in everyday life and also become more conscious about their perceived participation in everyday life. The study carries low or no risk of harm to the participants.

### Where is the study run from?

The Social Insurance Institution of Finland

When is the study starting and how long is it expected to run for?  
August 2010 to September 2013

Who is funding the study?  
The Social Insurance Institution of Finland

Who is the main contact?  
Maarit Karhula

## Contact information

**Type(s)**  
Public

**Contact name**  
Mrs Maarit Karhula

**Contact details**  
Mäntyharju  
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52700

## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
Social Insurance Institution of Finland reports nro 131

## Study information

**Scientific Title**  
Group-based multidisciplinary rehabilitation for outpatient clients with multiple sclerosis improving participation, occupational performance and goal attainment

**Study objectives**  
Group-based multidisciplinary rehabilitation for outpatient clients with multiple sclerosis improves participation, occupational performance and goal attainment.

**Ethics approval required**  
Old ethics approval format

**Ethics approval(s)**  
1. The Ethics Committees of the Finnish Social Insurance Institution, 02/09/2010  
2. The Hospital District of Southwest Finland, ref: 45/180/2012

**Study design**

Mixed methods study

**Primary study design**

Interventional

**Secondary study design**

Non randomised study

**Study setting(s)**

Community

**Study type(s)**

Treatment

**Participant information sheet**

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

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

Multiple sclerosis

**Interventions**

Group-based multidisciplinary rehabilitation targeting to energy saving, cognition, mood and body control.

The multicentre, cross-sectional study involved 80 participants, of whom 38 persons participated in rehabilitation based on medical rehabilitation services for persons with severe disabilities and 42 based on discretionary rehabilitation services for people with disabilities. In addition 6 persons participated in the rehabilitation but not in the post measures. A comparison group of 19 persons with MS received typical rehabilitation based on medical rehabilitation services for persons with severe disabilities. Total duration of treatment was 21 months.

In addition to evaluate the psychometric properties of the IPA and factors that predict participation and autonomy of persons with MS additional data was collected from persons (n=89) with MS in 2012–2013 during an in-patient rehabilitation period of 1-3 weeks at Masku Neurological Rehabilitation Center in order to receive a larger sample.

The functionality of the rehabilitation model was evaluated with questionnaires for rehabilitees, their families, service providers and co-operation partners on four occasions during the rehabilitation project and with focus-group interviews with the rehabilitees. Primary outcome measures were rehabilitees' participation restrictions, occupational performance and rehabilitation goal attainment.

**Intervention Type**

Other

**Primary outcome measure**

1. Autonomy and participation, measured using the Impact on Participation and Autonomy measure

2. Self-perceived problems in everyday activities and participation, measured using Canadian Occupational Performance Measure
3. Goal attainment during rehabilitation, measured using Goal Attainment Scaling  
Measured at baseline, 12 months and 21 months

### **Secondary outcome measures**

1. Quality of life, measured using WHOQOL-BREF
2. Perceived impact of disease, measured using Multiple Sclerosis Impact Scale  
Measured at baseline, 12 months and 21 months

### **Overall study start date**

01/02/2010

### **Completion date**

31/05/2017

## **Eligibility**

### **Key inclusion criteria**

1. Age between 18 and 65 years (inclusive)
2. A confirmed diagnosis of MS
3. Ability to fill in questionnaires independently or with the help of an assistant

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

Patient

### **Age group**

Adult

### **Lower age limit**

18 Years

### **Sex**

Both

### **Target number of participants**

Altogether 194 persons, for rehabilitation study 105 persons and in addition 89 persons for the evaluation of the IPA measure

### **Key exclusion criteria**

Participants were excluded if they were not capable of expressing their own choices or answering questions in the questionnaires

### **Date of first enrolment**

01/05/2010

### **Date of final enrolment**

30/09/2013

## **Locations**

## **Countries of recruitment**

Finland

## **Study participating centre**

The Social Insurance Institution of Finland

Helsinki

Finland

00056

## **Sponsor information**

### **Organisation**

The Social Insurance Institution of Finland

### **Sponsor details**

PL 450

Helsinki

Finland

00056

### **Sponsor type**

Other

### **ROR**

<https://ror.org/057yw0190>

## **Funder(s)**

### **Funder type**

Other

### **Funder Name**

The Social Insurance Institution of Finland

## **Results and Publications**

### **Publication and dissemination plan**

The report of the project is available: <https://helda.helsinki.fi/handle/10138/42945>  
Other publications are planned to published in high-impact peer reviewed journals during 2018 and 2019

### Intention to publish date

31/12/2019

### Individual participant data (IPD) sharing plan

The data consisting of filled measure forms and informed consent of participants were stored in the archive of Social Insurance Institution of Finland. The data will be stored for 10 years after data collection.

### IPD sharing plan summary

Stored in repository

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	01/03/2013		Yes	No
<a href="#">Results article</a>	results	01/03/2014		Yes	No
<a href="#">Results article</a>	results	01/11/2017		Yes	No