

Group-based multidisciplinary rehabilitation for outpatient clients with multiple sclerosis

Submission date 06/10/2017	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 20/10/2017	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 19/10/2017	Condition category 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
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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?
Results article	results	01/03/2013		Yes	No
Results article	results	01/03/2014		Yes	No
Results article	results	01/11/2017		Yes	No