

Group exercise therapy for mobility and balance in people with multiple sclerosis

Submission date 27/03/2008	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 17/10/2008	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 21/10/2010	Condition category Nervous System Diseases	<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title

Group exercise therapy for mobility and balance in people with multiple sclerosis: a randomised controlled trial

Study objectives

To determine whether group exercise therapy can improve mobility, balance, self-efficacy and quality of life in people with multiple sclerosis (MS).

Ethics approval required

Old ethics approval format

Ethics approval(s)

NHS Office for Research Ethics Committees Northern Ireland (ORECNI), approved in 2007 (ref: 07/N1R01/5)

Study design

Single-blind, randomised, single-centre trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Treatment

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 with balance and mobility problems

Interventions

The exercise group will attend an exercise class twice per week for 6 weeks. The exercises will consist of 8 different stations and will be staged according to ability. Each class will last approximately 90 minutes with 10 minutes warm up, 3 minutes per exercise, 3 minutes rest in between and a cool down period/discussion time at the end.

There is no intervention for the control group. At the end of the study period they will be offered 1-2 workshops (as necessary) at the end of the trial to teach them the exercises that were offered to the experimental group.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

Rivermead Mobility Index, assessed at baseline, immediately after the 6 weeks of intervention, and 3 and 6 months following discharge from the intervention. Analysis will be conducted on an intention to treat basis.

Secondary outcome measures

The following will be assessed at baseline, immediately after the 6 weeks of intervention, and 3 and 6 months following discharge from the intervention:

1. Berg Balance Scale
2. The Multiple Sclerosis Impact Scale (MSIS-29)
3. Multiple Sclerosis Walking Scale-12
4. Barthel Index
5. MS Self-efficacy Scale

Analysis will be conducted on an intention to treat basis.

Overall study start date

01/03/2008

Completion date

01/06/2011

Eligibility**Key inclusion criteria**

1. Confirmed diagnosis of MS
2. Male or female, over 18 years of age
3. In a stable phase of their MS
4. Cognitively they must have a Score of 6 or more in the 10-point mini mental score (Hodkinson, 1972)
5. A minimum score of 14 on the Rivermead Mobility Index

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

160

Key exclusion criteria

1. The Expanded Disability Status Scale (EDSS) >7.00
2. Serious other medical or surgical condition

Date of first enrolment

01/03/2008

Date of final enrolment

01/06/2011

Locations**Countries of recruitment**

Northern Ireland

United Kingdom

Study participating centre**Senior Lecturer**

Northern Ireland

United Kingdom

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Sponsor information**Organisation**

University of Ulster (UK)

Sponsor details

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Sponsor type

University/education

Website

http://www.ulster.ac.uk

ROR

https://ror.org/01yp9g959

Funder(s)

Funder type

Government

Funder Name

The Research and Development Office, Northern Ireland Health and Social Services Central Services Agency (United Kingdom) (grant ref: RRG 8.5-RRG/3277/05)

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?
Abstract results	Pilot study presented at 'World Physical Therapy ' Abstract can be found on page 325	02/06/2007		No	No