

Exercise Intervention for Multiple Sclerosis: the Sheffield ExIMS trial

Submission date 16/10/2008	Recruitment status No longer recruiting	☐ Prospectively registered ☒ Protocol
Registration date 05/02/2009	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 05/12/2017	Condition category Nervous System Diseases	☐ Individual participant data

Plain English summary of protocol

Background and study aims

Multiple sclerosis (MS) is one of the most common diseases of the central nervous system (brain and spinal cord) in young adults. Healthy nerves are coated in a fatty casing (myelin sheath) which helps messages to travel quickly and smoothly along them. When a person is suffering from MS, the immune system, which normally helps to protect against infection, attacks and gradually destroys the myelin sheath (demyelination). This means that messages cannot travel along the nerves effectively causing a range of disabilities. A number of recent studies have shown that exercise is an effective way of improving functioning and mobility in people suffering from MS. The aim of this study is to investigate the effectiveness of a 12-week exercise programme in patients with mild to moderate MS.

Who can participate?

Adults with MS who are able to walk a distance of 10 meters.

What does the study involve?

Participants are randomly allocated to one of two groups. Those in the first group take part in a 12 week exercise programme. This involves two supervised and one home-based session per week for six weeks and then one supervised and two home-based sessions per week for six weeks. The sessions take place in small groups and involve short bouts of low to moderate intensity exercise. Those in the second group continue with their normal support alone during the study. At the start of the study and then again after 12 weeks and a further six months, participants in both groups complete a walking test to assess their abilities and complete a number of questionnaires in order to find out if their quality of life and other MS symptoms have improved.

What are the possible benefits and risks of participating?

Not provided at time of registration

Where is the study run from?

Centre for Sport and Exercise Science, Sheffield Hallam University (UK)

When is the study starting and how long is it expected to run for?

January 2009 to January 2012

Who is funding the study?

Multiple Sclerosis Society (UK)

Who is the main contact?

Dr John Saxton

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Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

Protocol serial number

Version 1: 15/08/08

Study information

Scientific Title

The effects of a pragmatic exercise therapy intervention on physical activity and important health outcomes influencing maintenance in people with multiple sclerosis (PWMS)

Acronym

ExIMS

Study objectives

1. People with multiple sclerosis (PWMS) who are randomised to pragmatic exercise therapy will have improved functional and health outcomes in comparison to usual care only controls at three-months and six-months of follow-up
2. PWMS who are randomised to pragmatic exercise therapy will have increased structured exercise and free living physical activity levels in comparison to usual care only controls at three-months and six-months of follow-up

3. Inclusion of a pragmatic exercise therapy intervention in the patient care pathway is a more cost-effective treatment strategy than current medical care alone in PWMS

Ethics approval required

Old ethics approval format

Ethics approval(s)

South Yorkshire Research Ethics Committee, 28/10/2008 (ref: 08/H1310/69)

Study design

Randomised controlled trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Multiple sclerosis

Interventions

Exercise Group:

A 12-week intervention period is planned for the exercise group, with a more frequent contact phase during the first 6-week block (two supervised exercise sessions at the centre and one home-based session a week), and reduced contact during the second 6-week block (one supervised session and two home-based sessions a week). Sessions will be conducted in small groups (up to 3 PWMS) and will consist of short bouts (e.g. 5 x 3-min, with 2-minute rest intervals) of low to moderate intensity exercise (50 - 69% maximum heart rate). In accordance with recent recommendations the intervention will be stage-adapted and participants will be encouraged to exercise within their own capabilities.

Usual Care:

The usual care group will continue with their normal support during this time period.

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

1. Physical activity levels
2. Six-minute walking test

All outcome measures will be taken at baseline, 12-weeks and at 6-months follow-up.

Key secondary outcome(s)

1. Neurological impairment and clinical functional mobility
2. Quality of life
3. Fatigue

- 4. Focus groups and interviews
- 5. Immunological analysis

All outcome measures will be taken at baseline, 12-weeks and at 6-months follow-up.

Completion date

01/01/2012

Eligibility

Key inclusion criteria

1. Clinical diagnosis of MS with an Expanded Disability Status Scale (EDSS) score of between 1.0 - 6.5, and able to walk 10 m distance
2. Aged 18 - 65 years, either sex
3. Participants must have been clinically stable for at least 4 weeks prior to entering the study
4. Participants on disease modifying therapy (interferon and glatiramer acetate) must have been stable on this treatment for at least 3 months prior to entering the study
5. Physically able to participate in some form of exercise three times per week
6. Able to provide written informed consent

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Key exclusion criteria

1. Failure to meet any of the above inclusion criteria
2. Experiencing illness that impairs their ability to be physically active three times per week
3. Not willing to be randomised to either the exercise intervention or usual care control group
4. Living more than 20 miles from the trial centre
5. Already engaged in purposeful structured exercise or brisk walking exercise for equal to or greater than three times per week for equal to or greater than 30 minutes per session and have been so on a consistent basis during the previous six months

Date of first enrolment

01/01/2009

Date of final enrolment

01/01/2012

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Centre for Sport and Exercise Science

Sheffield Hallam University

Collegiate Campus

Sheffield

United Kingdom

S10 2BP

Sponsor information

Organisation

Sheffield Teaching Hospitals NHS Foundation Trust (UK)

ROR

<https://ror.org/018hjpz25>

Funder(s)

Funder type

Charity

Funder Name

Multiple Sclerosis Society (UK)

Alternative Name(s)

mssocietyuk, MS Society UK, Multiple Sclerosis Society UK, Multiple Sclerosis Society of Great Britain and Northern Ireland, The MS Society, MS Society

Funding Body Type

Private sector organisation

Funding Body Subtype

Associations and societies (private and public)

Location

United Kingdom

Results and Publications

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	15/10/2015		Yes	No
Protocol article	protocol	01/03/2013		Yes	No