ISRCTN41541516 https://doi.org/10.1186/ISRCTN41541516

Exercise Intervention for Multiple Sclerosis: the Sheffield ExIMS trial

Submission date
16/10/2008

Recruitment status
No longer recruiting

Registration date
05/02/2009

Overall study status
Completed

Last Edited
05/12/2017

Condition category
Nervous System Diseases

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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
j.m.saxton@shu.ac.uk

Contact information

Type(s)
Scientific

Contact name
Dr John Saxton

Contact details
Centre for Sport and Exercise Science
Sheffield Hallam University
Collegiate Hall
Collegiate Crescent Campus
Sheffield
United Kingdom
S10 2BP
+44 (0)114 225 4414
j.m.saxton@shu.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

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

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 measure
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.

Secondary outcome measures
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.

Overall study start date
01/01/2009

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
120

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
England

United Kingdom

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)

Sponsor details
Research and Development Department
Third Floor, Pegasus House
463a Glossop Road
Sheffield

England
United Kingdom
S10 2QD

Sponsor type
Hospital/treatment centre

Website
http://www.sth-research.group.shef.ac.uk

ROR
https://ror.org/018hjpz25

Funder(s)

Funder type
Charity

Funder Name
Multiple Sclerosis Society (UK)

Alternative Name(s)
Multiple Sclerosis Society of Great Britain and Northern Ireland, The MS Society, MS Society UK, Multiple Sclerosis Society UK, MS Society

Funding Body Type
Private sector organisation

Funding Body Subtype
Associations and societies (private and public)

Location
United Kingdom

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