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Effective exercise for people with Multiple Sclerosis

Submission date	Recruitment status	[X] Prospectively registered
17/10/2007	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
15/11/2007	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
11/10/2011	Nervous System Diseases	

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
Effective exercise for people with Multiple Sclerosis: a single-blind randomised non-controlled trial

Study objectives
To examine the effect of three different forms of exercise delivered over a three-month period. Three exercise groups will perform the same amount of exercise within sessions but it will be delivered in different ways:
1. Shorter and hard (anaerobic)
2. Longer and easy (aerobic)
3. A combination of both aerobic and anaerobic exercises

Please note that as of 11/02/2009 this record was updated to include amended trial dates. The initial trial dates at the time of registration were:
Initial anticipated start date: 01/11/2007
Initial anticipated end date: 01/07/2009

Ethics approval required
Old ethics approval format

Ethics approval(s)
Added 11/02/2009: National Research Ethics Service, Oxfordshire REC A gave approval on the 7th May 2008 (ref: 08/H0604/3)

Study design
Single-blind randomised non-controlled trial

Primary study design
Interventional

Secondary study design
Non 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

Interventions
Three exercise groups will perform the same amount of exercise within sessions delivered in different ways:
1. Shorter and hard (anaerobic)
2. Longer and easy (aerobic)
3. A combination of both aerobic and anaerobic exercises

Total duration of treatment will be the same for each treatment arm. Each participant will have 20 minute exercise sessions 3 x per week for 12 weeks (36 sessions). The total relative work performed (determined from baseline fitness assessment) at each exercise session will be the same for each exercise group but the intensity and delivery of the exercise with be different. An assessment will take place at week 24 (12 weeks after end of intervention).

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Two-minute walk distance, measured at baseline, week 6 (half-way intervention), week 12 (end intervention) and week 24 (follow up).

Secondary outcome measures
1. Questionnaires:
1.1. Barthel Index of independence in activities of daily living
1.2. Fatigue Severity Scale (FSS): self reported fatigue levels
1.3. Physical Activity Questionnaire in the Elderly (PASE): self reported activity levels in home, work and social environments
1.4. General Health Status questionnaire - 36-item Short Form health survey (SF-36): Patient-completed health status measure
1.5. Short Orientation Memory Concentration scale (SOMC): measure of orientation, memory and concentration
1.6. Subjective vitality individual difference scale: self reported energy levels scale
1.7. Self efficacy scale: confidence to take complete exercise scale
2. Anthropodmetry: weight (kg), height (m) and leg-length (cm) (anterior superior iliac spine to med. Malleolus)
3. Muscle performance: extensor leg power - measurement of leg extension power in sitting
4. Mobility:
4.1. Step count during 8 days measured with a Step Activity Monitor (watch sized device worn on ankle)*
4.2. Timed up and go test (sit to stand from chair and walk 5 metres)
4.3. During 2 minute walk test (walking characteristics (step time and length) recorded with a small accelerometer worn on back)
5. Hydration status: urine analysis
6. Blood test: of neurotrophic factors (proteins associated with brain function) and immune markers*
7. Fitness test:
7.1. Heart Rate (HR): heart rate monitor
7.2. Blood pressure: arm cuff measure
7.3. Rating of perception of effort and symptoms (Breathing and Leg effort): self report

7.4. Enjoyment S-bipolar scale: self report
7.5. Rate of oxygen consumption (metabolism): measurement of expired air
7.6. Muscle response to exercise (blood lactate levels): finger prick (capillary) blood samples
8. Qualative analysis of focus group meetings and interviews

Secondary outcome measures will be measured at baseline, week 6 (half-way intervention), week 12 (end intervention) and week 24 (follow up).

*Neurotrophic factors, immune markers and step activity will only be measured at baseline and end intervention

Overall study start date
01/06/2008

Completion date
01/10/2009

Eligibility

Key inclusion criteria
1. Adults (over 18 years, either sex) with Multiple Sclerosis (MS)
2. Able to sit and pedal on a cycle ergometer and complete 60 seconds unloaded exercise
3. Ambulatory with/without a walking aid

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
60

Key exclusion criteria
1. Serious medical condition or complication that would preclude safe exercise
2. Sudden change/relapse in MS
3. Cognitively unable to consent

Date of first enrolment
01/06/2008

Date of final enrolment
01/10/2009

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Movement science group
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Sponsor information

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Sponsor type
University/education

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ROR
https://ror.org/04v2twj65

Funder(s)

Funder type
Charity

Funder Name
Multiple Sclerosis Society (UK) (grant ref: 840/06)

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?
Results article	results	01/05/2011		Yes	No