ISRCTN99826269 https://doi.org/10.1186/ISRCTN99826269

Efficacy of aerobic training of people with neuromuscular diseases

Submission date
19/07/2012

Recruitment status
No longer recruiting

Registration date
19/07/2012

Overall study status
Completed

Last Edited
08/04/2019

Condition category
Nervous System Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
This study aims to investigate how aerobic exercise training can help people with two common neuromuscular diseases (NMD): Charcot-Marie-Tooth disease (CMT) and Inclusion Body Myositis (IBM). These diseases cause muscles to become weaker over time which often leads to disability and risk of other disease due to inactivity. Exercise is important to maintain general health but may also help to improve symptoms of NMD. We will therefore study how aerobic training changes fitness levels, muscle strength, walking abilities and general well-being. In addition, we will monitor the safety of training and how practical it is for people to take part in this type of exercise. Motivation, confidence and barriers to exercise will also be explored. Both IBM and CMT will be investigated concurrently with the same methods but will be analysed and reported as separate studies. This is because people with different NMDs may respond to exercise in different ways.

Who can participate?
Participants aged 18 to 75 will be recruited from the clinics and research databases at our centre. Potential participants need to live less than 2.5 hours travel time from the centre because of the need for several visits and for the physiotherapist to travel to the gym where the person is exercising.

What does the study involve?
Participants will be randomly allocated to either the intervention group or the control group. The intervention group will participate in aerobic exercise on a seated exercise bike in a local gym, three times a week for 12 weeks. The control group will continue with their usual activities for 12 weeks (i.e. no extra exercise over and above what they would normally do). After an 8-week break the two groups will then swap over (i.e., patients in the control group will exercise and those in the intervention group will continue with their usual activities). Measurements will be taken by researchers who will not know whether the person has been training or not. A research physiotherapist will visit twice and participants will be monitored regularly by gym fitness instructors.

What are the possible benefits and risks of participating?
Results from the study will be used to plan further research with the ultimate aim of developing NHS exercise prescriptions for people with NMD.

Where is the study run from?
The Centre for Neuromuscular Diseases at the National Hospital for Neurology and Neurosurgery, London, UK

When is the study starting and how long is it expected to run for?
Recruitment started in June 2011 and the study is expected to run for three years.

Who is funding the study?
National Institute for Health Research (NIHR) (UK)

Who is the main contact?
Dr Gita Ramdharry
g.ramdharry@ucl.ac.uk

Contact information

Type(s)
Scientific

Contact name
Dr Gita Ramdharry

ORCID ID
http://orcid.org/0000-0001-9344-0301

Contact details
MRC Centre for Neuromuscular Disease
National Hospital for Neurology and Neurosurgery
Box 102
8-11 Queen Square
London
United Kingdom
WC1N 3BG
+44 (0)20344 82455
g.ramdharry@ucl.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
12167

Study information

Scientific Title
Efficacy of aerobic training of people with neuromuscular diseases: a randomised cross-over study

Study objectives
The aim of this current study is to investigate the effect of aerobic training in two common neuromuscular diseases (NMD): Charcot-Marie-Tooth (CMT) and Inclusion Body Myositis (IBM). Both diseases result in progressive muscle wasting with substantial morbidity and disability. The study proposes to systematically examine the effect of aerobic training on fitness levels, muscle strength and function. This study will also monitor the safety, feasibility and impact on quality of life of this type of exercise training in these groups.

Sixty subjects will be recruited from the neuromuscular clinics at Queen Square (30 from each disease group, aged between 18-75). The disease groups will be investigated concurrently with the same methods but will be viewed and analysed as separate studies. A crossover design will be used with training and control periods. For the training intervention, participants will train in selected local gyms and train on a bicycle ergometer. The trial will span three years with each subject participating for a 34 week period. Maximum aerobic capacity during exercise testing will be the primary outcome. There will also be measures of muscle strength, body composition, and activity levels. In addition the study will investigate non-motoric effects of exercise such as mood, motivation, sleep and fatigue.

Ethics approval required
Old ethics approval format

Ethics approval(s)
London Surrey borders, 23/09/2011, ref:11/LO/0760

Study design
Randomised; Interventional; Design type: Treatment

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

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

Topic: Neurological; Subtopic: Neurological (all Subtopics); Disease: Nervous system disorders

Interventions
There are two arms to this study: a control arm and an intervention arm. Because the trial has a cross-over design, all participants will take part on both arms in a random order with an 8 week wash out period in between.

The intervention arm will consist of community based aerobic exercise on a seated static bicycle in a local gym, 3 times a week for 12 weeks. The intensity of training will be set as a target training heart rate increased every 4 weeks from 60% heart rate reserve to 80% heart rate reserve.

The control arm involves continuing with your usual activities prior to starting the trial for 12 weeks (i.e. no extra exercise over and above what you would normally do).

Intervention Type
Behavioural

Primary outcome measure
Maximal oxygen uptake (VO2 max); Timepoint(s): baseline, 12 weeks, 20 weeks and 32 weeks

Secondary outcome measures
Impairment measures
1. Total Work (Watts/sec) and maximum power output (Watts) during exercise testing: measured from bicycle ergometer
2. Body composition and body mass index
3. Blood pressure and lung function (spirometry)
4. Fatigue severity: using the modified Fatigue Severity Scale (mFSS)
5. Disease severity: CMT Exam Score; IBM Functional Rating Scale
6. Lower limb muscle strength measures (isokinetic & isometric dynamometry)

Functional measures
1. Walking speed: using a Timed 10m Walk Test at normal and maximal speeds
2. Six Minute Timed Walk Test: change in maximal walking distance in 6 minutes and peak heart rate
3. Perceived exertion during the Six Minute Timed Walk Test: using the Borg 15-point scale
4. Heart rate and Physiological Cost Index (PCI) during the Six Minute Timed Walk Test: using a heart rate monitor
5. Physical Activity monitoring over 7 days[1]

Self reported measures
1. Gait performance: Walk12 scale
2. Fatigue using the mFSS
3. Self-efficacy for Management of Chronic Diseases Scale
4. Health related QOL: Short Form 36 scale
5. Barriers to Activity and Exercise: modified Barriers to Physical Activity and Disability Survey
6. International Physical Activity Questionnaire (IPAQ)
7. Sleep and Sleepiness using PSQI and ESS respectively

Safety and monitoring
1. Blood plasma creatine kinase measurement

2. Pain: using the visual analogue scale (VAS)
3. Fatigue using the mFSS
4. Diary: to monitor mood and participation in the training regime

Overall study start date
01/05/2012

Completion date
30/04/2014

Eligibility

Key inclusion criteria
1. Clinical diagnosis of CMT or IBM
2. Male and female, aged 18 to 75 years
3. Able to walk for 30m with or without a walking aid or orthotic devices
4. Ability to safely mount/dismount an exercise bike unaided or standby assistance 5. Signed informed participant consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 60; UK Sample Size: 60

Key exclusion criteria
1. Presence of other significant neurological disorders (such as multiple sclerosis, cerebrovascular diseases, movement disorders), or major comorbidities (e.g. definite cognitive impairment, psychiatric disease, heart or lung failure, orthopaedic or rheumatological disorders)
2. Limb surgery during the six months prior to screening (or planned before final assessment)
3. Failure to pass the screening assessment outlined in the standardized operating procedure for exercise testing
4. Concurrent involvement in another intervention trial
5. People already participating in moderate to vigorous aerobic exercise more than three times per week
6. Aged over 75 or under 18 years
7. Women of child-bearing age onlyif they are pregnant at the inclusion into the study or plan to become pregnant during the study

Date of first enrolment
01/05/2012

Date of final enrolment
30/04/2014

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
MRC Centre for Neuromuscular Disease
London
United Kingdom
WC1N 3BG

Sponsor information

Organisation
UCL and UCLH Clinical Research Facility (UK)

Sponsor details
235 Euston Road
London
England
United Kingdom
NW1 2BU
+44 (0)20 3447 2929
RandD@uclh.nhs.uk

Sponsor type
Hospital/treatment centre

Website
http://www.uclh.nhs.uk/Research/CRF/Pages/Home.aspx

ROR
https://ror.org/02jx3x895

Funder(s)

Funder type
Research council

Funder Name
Medical Research Council (MRC) (UK)

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Funder Name
Research for Patient Benefit Programme

Alternative Name(s)
NIHR Research for Patient Benefit Programme, RfPB

Funding Body Type
Government organisation

Funding Body Subtype
National government

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	09/04/2019	08/04/2019	Yes	No