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The effect of cycling using active-passive trainers on spasticity, cardiovascular fitness, function and quality of life in people with multiple sclerosis

Submission date
03/12/2016

Recruitment status
No longer recruiting

Registration date
07/02/2017

Overall study status
Completed

Last Edited
10/05/2019

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
Multiple sclerosis (MS) is one of the most common diseases of the central nervous system (brain and spinal cord). Healthy nerves are coated in a fatty casing (myelin sheath) which helps messages to travel quickly and smoothly along nerves. When a person is suffering from MS, the immune system, which normally helps to protect against infection, attacks the myelin sheath, stripping it from the nerves (demyelination). This demyelination means that messages cannot travel along the nerves effectively, causing a range of symptoms including problems with balance and coordination, weakness in the arms or legs and spasticity (where muscles feel stiff, heavy and difficult to move). Some people have a form of MS called progressive MS, which is where symptoms become worse overtime, without periods of recovery. Some evidence suggests that exercise can help to delay the worsening of symptoms. The aim of this study is to find out whether daily limb cycling can improve the symptoms associated with MS and improve patient's ability to exercise.

Who can participate?
Adults with progressive MS who are disabled and have spasticity in their legs.

What does the study involve?
30 people with Multiple Sclerosis are recruited from an inpatient rehabilitation unit and randomly allocated to one of two groups. Those in the first group receive 30 minutes of assisted cycling (2 minutes passive warm up, 26 minutes active cycling and 2 minutes passive cool down), five days per week for 4 weeks, in addition to their usual care. Those in the second group receive their usual care only for the duration of the study. At the start of the study and then again after four weeks, spasticity, cardiovascular fitness, function and quality of life are measured using questionnaires. In addition, for those who take part in the assisted cycling, the symmetry, distance cycled and power are measured following each session.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
Physically Disabled Rehabilitation Unit, Queen Elizabeth University Hospital (UK)

When is the study starting and how long is it expected to run for?
September 2015 to July 2017

Who is funding the study?
CSP Charitable Trust Awards (UK)

Who is the main contact?
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Contact information

Type(s)
Public

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Additional identifiers

ClinicalTrials.gov (NCT)
NCT02737904

Protocol serial number
GN15PY148

Study information

Scientific Title
The effect of cycling using active-passive trainers on spasticity, cardiovascular fitness, function and quality of life in people with multiple sclerosis (MS)

Study objectives

The aim of this study is to determine if daily lower limb cycling improves symptoms associated with multiple sclerosis (MS) and improves exercise tolerance.

Ethics approval required
Old ethics approval format

Ethics approval(s)
West of Scotland Research Ethics Service, 26/04/2016

Primary study design
Interventional

Study design
Randomised controlled feasibility study

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Multiple Sclerosis

Interventions
Thirty pwMS admitted to the PDRU will be randomly assigned to intervention (APT+usual care) or control (usual care) groups. The sample size for this pilot study was a pragmatic decision based on the number of people who would be admitted to PDRU during the study period.

In this pragmatic study both groups (intervention and control) will receive four weeks of conventional in-patient rehabilitation (usual care) and in addition the intervention group will receive four weeks of cycling on the APT (see below).

In the intervention group, participants will be seated on a chair or wheelchair in front of a Motomed APT, with their feet strapped into the pedals, such that they can comfortably cycle with a maximum of 120° of knee flexion. Each exercise session will begin with a 2 minute warm up consisting of passive cycling, where the legs of the participant are moved passively by the APT at 10 revolutions per min (rpm). Next the participant will cycle for up to 26 minutes, at 60rpm, in this phase the participant is required to actively cycle and to maintain a symmetrical pattern of movement using the feedback on the display. If the participant is unable to actively cycle at any point during the 26 minute exercise period, or if they have a spasm, the Motomed APT will revert to the passive mode. The final phase is a cool down where participants again will have 2 minutes of passive cycling at 10rpm. Participants will receive visual feedback on their speed, the distance they have cycled and their symmetry (i.e. a comparison of the work done by the right versus left legs) on the display panel which is approximately 1.5 metres in front at eye level.

For both groups, at baseline, demographic details will be recorded; age, sex, type of MS, time since diagnosis, EDSS, social circumstances, use of walking/mobility aids. Medications will be recorded and any changes in medication during the study period noted. Outcome measures will be taken, by a blinded assessor, before and after the four week treatment period. It would have been preferable to have a follow up period however participants are likely to be discharged home at that point.

Intervention Type
Other

Primary outcome(s)
Effect of spasticity on aspects of daily life will be measured using the Multiple Sclerosis Spasticity Scale at baseline and 4 weeks

Key secondary outcome(s)
1. Spasticity will be measured using The Modified Ashworth Scale (MAS) at baseline and 4 weeks
2. Cardiovascular fitness will be measured using the oxygen uptake efficiency slope (OUES) at baseline and 4 weeks
3. Function will be assessed by the Functional Independence Measure (FIM) and the Timed 25-foot walk test (T25FW) at baseline and 4 weeks
4. Quality of Life will be measured with the MSQOL-54 at baseline and 4 weeks
5. Symmetry, distance cycled and power will be recorded using data collected from the active passive trainer (APT) following each cycling session (intervention group only)

Completion date
31/07/2017

Eligibility

Key inclusion criteria
1. Confirmed diagnosis of progressive MS
2. Aged over 18 years
3. Have an Expanded Disability Status Scale (EDSS) of between 6.5 (Requires two walking aids - pair of canes, crutches, etc - to walk about 20m without resting) and 8.5 (Essentially restricted to bed much of day. Has some effective use of arms retains some self care functions) and spasticity in their lower limbs (self reported).

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
1. Cognitive impairment (cannot understand instructions)
2. Other co-morbidities which would preclude them taking part in exercise
3. Visual impairment (such that they cannot see the screen on the APT)

Date of first enrolment
01/07/2016

Date of final enrolment
01/05/2017

Locations

Countries of recruitment
United Kingdom

Scotland

Study participating centre
Physically Disabled Rehabilitation Unit (PDRU)
Queen Elizabeth University Hospital
1345 Govan Road
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Sponsor information

Organisation
NHS Greater Glasgow & Clyde

ROR
https://ror.org/05kdz4d87

Funder(s)

Funder type
Charity

Funder Name
CSP Charitable Trust Awards

Results and Publications

Individual participant data (IPD) sharing plan

Participant data will be made anonymous; coding will be used to identify participants within the data set. Any information pertaining to the participant's identity will be stored in a locked filing cabinet in a locked room at the study site. Anonymised data will be stored on an NHS password protected computer Only the research team and regulatory authorities will have access to the data collected for the study.
Following completion of the study the anonymised data will be stored on a data storage device, this will be labelled and stored in a locked filing cabinet in a locked room within the clinical site for 10 years.

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Abstract results	abstract	01/12/2017	10/05/2019	No	No