

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

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		<input type="checkbox"/> Protocol
<b>Registration date</b> 07/02/2017	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
<b>Last Edited</b> 10/05/2019	<b>Condition category</b> Nervous System Diseases	<input type="checkbox"/> 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?

Miss Alison Barclay

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## Contact information

### Type(s)

Public

### Contact name

Miss Alison Barclay

### Contact details

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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

NCT02737904

Secondary identifying numbers

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

### **Study design**

Randomised controlled feasibility study

### **Primary study design**

Interventional

### **Secondary study design**

Randomised controlled trial

### **Study setting(s)**

Hospital

### **Study type(s)**

Treatment

### **Participant information sheet**

No participant information sheet available

### **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 measure**

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

### **Secondary outcome measures**

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)

### **Overall study start date**

01/09/2015

### **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

### **Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

30 patients

**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**

Scotland

United Kingdom

**Study participating centre**

**Physically Disabled Rehabilitation Unit (PDRU)**

Queen Elizabeth University Hospital

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## **Sponsor information**

**Organisation**

NHS Greater Glasgow & Clyde

**Sponsor details**

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**Sponsor type**

Hospital/treatment centre

**ROR**

<https://ror.org/05kdz4d87>

## **Funder(s)**

**Funder type**

Charity

**Funder Name**

CSP Charitable Trust Awards

## **Results and Publications**

**Publication and dissemination plan**

As this is a small scale study, if the results are positive, it is likely that a larger trial will be performed before the benefits of APT's for people affected by MS can be stated for certain. However the data from this pilot study will help to inform the definitive RCT.

Participants will be sent a lay summary of the findings. Findings will also be presented at appropriate conferences, such as CSP Conference or MS Frontiers, and the local Best Practise Study Days and publish the findings in a relevant scientific journal so that other health care professionals can use the findings to guide how they advise pwMS to use the APTs.

**Intention to publish date**

31/07/2018

**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?
<a href="#">Abstract results</a>	abstract	01/12/2017	10/05/2019	No	No