

# A preliminary study investigating if muscle stimulation as an exercise therapy for people with multiple sclerosis helps strengthen muscles, improves walking, helps with tiredness, and reduces spasms

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## Plain English summary of protocol

### Background and study aims

Multiple sclerosis (MS) is a condition where the body mistakenly attacks the brain and nerves, causing damage. MS is a lifelong condition that can worsen over time, leading to muscle tiredness, weakness, and balance problems, which can make walking difficult. Exercise can help, but many people with MS find it challenging due to tiredness, balance issues, needing help, and lack of confidence.

Muscle stimulation might help people with MS exercise more easily. It can be done at home using sticky pads on the skin that send painless electrical signals to make muscles contract, similar to exercising with weights. This could help prevent worsening muscle weakness, improve walking ability, increase physical activity, and reduce tiredness, helping people stay independent for longer.

The aim of this study is to gather information to plan a larger study to see if muscle stimulation can strengthen muscles, improve walking, reduce tiredness, and decrease muscle spasms in people with MS.

### Who can participate?

People with MS can participate in this study if they:

- Have any form of MS
- Have problems with walking but can walk at least 20 meters without resting (with or without walking aids)

### What does the study involve?

The study will involve 50 people with MS from two hospital clinics in Liverpool and Wolverhampton. Half of the participants, chosen randomly by a computer, will receive muscle stimulation along with their usual care. They will use the muscle stimulation equipment at home on their legs for 12 weeks. The other half will continue with their usual care.

Participants will have their muscle strength, walking ability, muscle spasms, and levels of tiredness measured at the start, after 3 months, and after 6 months. Both groups, along with their carers and clinicians, will be asked about their experiences with the study and reasons for not participating.

What are the possible benefits and risks of participating?

Benefits:

There are no guaranteed direct benefits, but participants will help gather information to plan a future study. The future study aims to see if muscle stimulation can help people with MS improve walking, get stronger, and feel less tired.

Risks or disadvantages:

Participants may not be placed in the group they prefer, which can be disappointing.

The skin may become red or irritated from the sticky pads, but this usually goes away quickly once stopped.

Some people might find the sensation uncomfortable at first but usually get used to it.

Participation requires time for visits and completing questionnaires.

Where is the study run from?

The study is being conducted at two hospital clinics in Liverpool and Wolverhampton.

When is the study starting and how long is it expected to run for?

November 2024 to October 2027

Who is funding the study?

The study is funded by the National Institute for Health and Care Research (NIHR207134) (UK)

Who is the main contact?

Dr Fraser Philp, [f.philp@liverpool.ac.uk](mailto:f.philp@liverpool.ac.uk)

## Contact information

### Type(s)

Public, Scientific, Principal Investigator

### Contact name

Dr Fraser Philp

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# Additional identifiers

## EudraCT/CTIS number

Nil known

## IRAS number

341925

## ClinicalTrials.gov number

Nil known

## Secondary identifying numbers

CPMS 61577, NIHR 207134, Protocol number: UoL001907

# Study information

## Scientific Title

A randomised controlled feasibility study investigating surface neuromuscular STIMulation as an exercise therapy versus usual care in people with multiple sclerosis to help improve lower limb strength, walking and fatigue (STIM-MS)

## Acronym

STIM-MS

## Study objectives

As this is an acceptability and feasibility study there is no null or alternative hypothesis.

## Ethics approval required

Ethics approval required

## Ethics approval(s)

Approved 28/02/2025, North West - Greater Manchester South Research Ethics Committee (2 Redman Place, Stratford Cross, London, E20 1JQ, United Kingdom; +44 (0)2071048065; gmsouth.rec@hra.nhs.uk), ref: 25/NW/0039

## Study design

Randomized controlled feasibility study comparing surface neuromuscular electrical plus usual care versus usual care only with a nested qualitative study

## Primary study design

Interventional

## Secondary study design

Randomised controlled trial

## Study setting(s)

Community, Hospital

## Study type(s)

Prevention, Quality of life, Treatment

## **Participant information sheet**

### **Health condition(s) or problem(s) studied**

Multiple Sclerosis (MS)

### **Interventions**

Randomisation lists will be generated using block randomisation with random variable block length, stratified by site and multiple sclerosis type, and a 1:1 randomisation ratio. Lists will be produced by an independent statistician.

Intervention group - surface neuromuscular electrical stimulation (SNMES) and usual care  
Following baseline measurements and randomisation, participants will be provided with the SNMES device (commercial constant current two channel electrical stimulator) and instructed how to use it at home. They will be advised to continue with their normal exercise and physical activity routines and will continue to receive their usual care.

The bilateral thigh (quadriceps and hamstrings) and shank (triceps surae and tibialis anterior) muscles will be stimulated. Each session will involve stimulating at least two muscle groups e.g. the quadriceps and hamstrings or triceps surae and tibialis anterior. The total session will last no more than 30 minutes and each muscle group will undergo a total of 45 contractions at a maximum tolerated intensity. Participants' limbs will be in a standard lower limb brace to ensure a maximum tolerable isometric contraction.

Stimulation parameters will be

- Frequency: 50Hz
- Pulse duration: 450µs
- ON:OFF time 5:10 secs
- Intensity: maximum tolerated

They will progressively work towards 3 to 4 sessions per week over a 12-week period for a maximum of 30 minutes across both legs.

Control group - usual care

The control group will continue to receive their usual care provided by their multiple sclerosis team. Participants will attend the clinic for baseline measurements and will complete the same outcome measures and assessments at equivalent timepoints to those in the SNMES arm

Both groups will receive a booklet diary that contains information about usual care, a diary for recording either use of the stimulator or usual care received, and contact details for support from the study team. They will also receive a phone call during weeks 1 and 6 to see how they are getting on.

### **Intervention Type**

Device

### **Pharmaceutical study type(s)**

Not Applicable

### **Phase**

## Phase II

### Drug/device/biological/vaccine name(s)

Commercially available, constant current two channel electrical stimulation device.

### Primary outcome measure

As this is an acceptability and feasibility study there is no primary outcome measure. An objective of this study is to collect data on candidate outcome measures to determine the primary outcome for the future trial and enable sample size calculations based on this.

### Secondary outcome measures

1. Levels of functional disability measured using Expanded disability status scale (EDSS) at screening, 3 and 6 months.
2. Disease and demographic characteristics at baseline (age, sex, ethnicity, height, weight, disease subtype, years since diagnosis, annual relapse rate).
3. Number of relapses (total).
4. Level of impairment measured using type and number of walking aids used
5. Muscle function/balance measured using Timed up and Go (TUG) at baseline, 3 and 6 months.
6. Exercise tolerance measured using 2 minute walk test (2MWT) at baseline, 3 and 6 months.
7. Spasm frequency measured using Penn spasm frequency scale (PSFS) at baseline, 3 and 6 months.
8. Quality of life measured using Multiple Sclerosis Impact Scale (MSIS- 29) at baseline, 3 and 6 months.
9. Energy and drive (fatigue) measured using the fatigue severity scale (FSS) at baseline, 3 and 6 months.
10. Impact of fatigue on cognitive, physical and psychosocial function measured using Modified Fatigue Impact Scale – 5-item version (MFIS-5) at baseline, 3 and 6 months.
11. Measure of disability measured using World Health Organization Disability Assessment Schedule 2.0 - 36 version (WHODAS 2.0) at baseline, 3 and 6 months.
12. Health-related quality of life measured using European Quality of Life 5 Dimensions 5 Level Version (EQ-5D-5L) at baseline, 3 and 6 months.
13. Health resources and accessed measured using the Modular resource-use measure (ModRUM) at 3 and 6 months.
14. Lower limb pain measured using a numerical rating scale (lower limb pain) at baseline, 3 and 6 months.
15. Muscle stiffness measured using the Modified Ashworth Scale (MAS) at baseline, 3 and 6 months.
16. Lower limb range of movement ROM (Knee and ankle) measured at baseline, 3 and 6 months.
17. Lower limb strength measured using MRC Oxford strength assessment (Knee and ankle) measured at baseline, 3 and 6 months.

### Overall study start date

01/11/2024

### Completion date

01/10/2027

## Eligibility

### Key inclusion criteria

People with multiple sclerosis (MS):

1 Adults with primary progressive, secondary progressive or relapsing-remitting multiple sclerosis.

2. Expanded disability status scale score  $\geq 4.0$  and  $\leq 6.5$ .

4= Significant disability, self-sufficient and up and about some 12 hours a day. Able to walk without aid or rest for 500m.

6.5= Requires two walking aids to walk about 20m without resting).

Carers or people who help look after people with MS who were involved in the study:

- This includes provision of informal or formal care, assistance with activities related to the study including attendance of hospital visits, use of the surface neuromuscular electrical stimulation device, recording of information related to healthcare visits, physical activity or exercise.

Healthcare practitioners and staff involved in the study:

- Healthcare practitioners and staff (clinical and non-clinical) who were involved in the set-up or delivery of the study.

### **Participant type(s)**

Patient, Health professional, Carer

### **Age group**

Adult

### **Lower age limit**

18 Years

### **Sex**

Both

### **Target number of participants**

64 in total. Total 50 people with MS in the randomised controlled trial of SNMES plus usual care (n=25) versus usual care only (n=25) . Nested qualitative study involving interviews for people with MS involved in randomised controlled trial and carers (n=15 to 20 total anticipated, maximum of 10 new participants (carers)) and interviews with healthcare practitioners involved in the study (n=6 to 8).

### **Key exclusion criteria**

People with Multiple Sclerosis:

1. Clinically isolated syndrome.

2. People with multiple sclerosis in an active relapse or <8-weeks since a relapse.

3. Lower-limb peripheral nerve injury.

4. Fixed lower-limb contractures.

5. Contraindications to surface neuromuscular electrical stimulation i.e.

5.1. Pregnancy

5.2. Uncontrolled Epilepsy

5.3. Any of the following in the lower limbs:

i) Peripheral nerve injury

ii) Unstable fractures or orthopaedic condition affecting the lower limb

iii) Cancer (malignancy) in the areas of the electrode placement

iv) Skin infection / devitalised skin at the electrode placement site

6. Unable to apply and control surface neuromuscular electrical stimulation device or braces

independently or with carer assistance.

7. Other co-morbidities that could affect mobility/additional underlying condition e.g. stroke.

Cardiac pacemaker/history of cardiac problems will not be a reason for exclusion but recruitment will be subject to cardiologist approval.

Carers of people with MS who were involved in the randomised controlled trial:

1. Carers of people who help look after people with MS but were not involved in the study will not be eligible.

Healthcare practitioners and staff involved in the study:

1. Healthcare practitioners or staff not involved in setting up or delivering the study

**Date of first enrolment**

11/08/2025

**Date of final enrolment**

01/10/2026

## **Locations**

**Countries of recruitment**

England

United Kingdom

**Study participating centre**

**The Walton Centre NHS Foundation Trust**

The Walton Centre

Lower Lane

Fazakerley

Liverpool

United Kingdom

L9 7LJ

**Study participating centre**

**The Royal Wolverhampton NHS Trust**

West Park Rehabilitation Hospital

Park Road West

Wolverhampton

United Kingdom

WV1 4PW

## **Sponsor information**

**Organisation**

University of Liverpool

**Sponsor details**

4th Floor Thompson Yates Building  
Faculty of Health and Life Sciences  
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+44 7717 863747  
sponsor@liverpool.ac.uk

**Sponsor type**

University/education

**Website**

<http://www.liv.ac.uk/>

**ROR**

<https://ror.org/04xs57h96>

**Funder(s)****Funder type**

Government

**Funder Name**

National Institute for Health and Care Research

**Alternative Name(s)**

National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

**Funding Body Type**

Government organisation

**Funding Body Subtype**

National government

**Location**

United Kingdom

**Results and Publications**



**Publication and dissemination plan**

A dissemination strategy and materials will be developed working closely with the Patient and Public Involvement and Engagement group to ensure our work and formats are accessible and inclusive. These include videos, presentations and written materials distributed through relevant charities and clinical networks, social media, newsletters and websites. We will also leverage public engagement resources and events available through the research teams institutions, as well as academic publications and presentations at scientific conferences.

**Intention to publish date**

01/10/2027

**Individual participant data (IPD) sharing plan**

The datasets analysed during the current study will be stored in a publicly available repository: <https://datacat.liverpool.ac.uk/>

**IPD sharing plan summary**

Stored in publicly available repository

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Participant information sheet</a>	Carers version 1.1		08/07/2025	No	Yes
<a href="#">Participant information sheet</a>	Easy read info version 1.1		08/07/2025	No	Yes
<a href="#">Participant information sheet</a>	Healthcare professionals version 1.1		08/07/2025	No	Yes
<a href="#">Participant information sheet</a>	Key facts version 1.0		08/07/2025	No	Yes