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Changing physical activity and sedentary behaviour in people with MS to reduce fatigue: the iStep-MS study

Submission date
08/04/2025

Recruitment status
Recruiting

Registration date
01/05/2025

Overall study status
Ongoing

Last Edited
20/06/2025

Condition category
Nervous System Diseases

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Physical activity has many benefits for people living with multiple sclerosis (MS) including improvements in physical, mental and social wellbeing. Despite these benefits, the majority of people with MS don't do very much physical activity and spend a lot of their day sitting.

The aim of this project is to test how effective a new physical activity intervention is, called iStepMS, for improving fatigue in people with MS.

Participants will have a range of measurements taken before the intervention, then 3 and 9 months later. After the first measurements, participants will be randomly entered into the intervention group or a usual care control group.

Who can participate?
We will do the study with 198 people living with MS. We will recruit participants from an MS therapy centre, a hospital and community health service.

What does the study involve?
The 99 participants in the control group will be asked to continue what they are doing as normal. The 99 people in the intervention group will receive the iStep-MS intervention. iStep-MS will involve four physical activity consultations over 3 months with a qualified healthcare team member at a hospital, community NHS service or charity-funded MS centre. The consultations will be in-person or online and use techniques known to support more physical activity and less sitting. Participants will receive the iStep-MS handbook that provides readings and tasks to do before the consultations and provides guidance on setting goals and planning when, where and how to do physical activity and reduce sitting. They will also be given a Smartwatch activity tracker to monitor their physical activity, set goals and receive reminders to move.

To test if the programme is effective, we will see if the following measurements change: physical activity, steps, sitting time, fatigue, walking capability, pain and quality of life. We will also use focus groups to find out about the experiences of participants and staff delivering iStep-MS.

What are the possible benefits and risks of participating?
We cannot promise that taking part will lead to benefits, but the study will give participants an opportunity to increase their physical activity and to easily access support designed to help them gradually increase their physical activity. Participants may feel better as a result of doing more physical activity and spending less time sitting. We hope the information we get from this study will help improve the treatments for people with MS in the future.

There is a small risk that people may find completing the questionnaires tiring or distressing. If this happens they can take a break and then continue if they are happy to. A very small number of people are sensitive to the adhesive tape used for the activity monitoring, which is similar to that on a sticking plaster. If this happens, we will advise participants to remove the tape and attach the monitor to the other thigh or to stop wearing it. Participation is voluntary and participants may withdraw at any point without this decision affecting their normal care.

Where is the study run from?
Brunel University of London (UK)

When is the study starting and how long is it expected to run for?
March 2025 to February 2027

Who is funding the study?
Multiple Sclerosis Society (UK)

Who is the main contact?
Dr Daniel Bailey, daniel.bailey@brunel.ac.uk

Contact information

Type(s)
Public, Scientific, Principal Investigator

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Dr Daniel Bailey

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number
335169

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 60234

Study information

Scientific Title
Effectiveness and cost-effectiveness of the iStep-MS physical activity and sedentary behaviour intervention in people with MS: A randomised controlled trial

Acronym
The iStep-MS study

Study objectives
Primary Objective: To investigate the effect of the iStep-MS intervention on fatigue in adults with MS at 9 months.

Secondary Objectives: To investigate the effect of the iStep-MS intervention on the following outcomes at 3 and 9 months:
1. Fatigue (at 3 months)
2. Stepping time and number of steps per day
3. Standing time
4. Daily sitting and prolonged sitting time
5. Quality of life
6. Walking capability
7. Pain
8. Self-efficacy
9. Cost per quality adjusted life year
10. Cost per change in fatigue

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 29/04/2025, London – Bloomsbury NHS Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 207 104 8384; bloomsbury.rec@hra.nhs.uk), ref: 25/LO/0272

Study design
Interventional randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Community, Hospital

Study type(s)
Treatment

Participant information sheet
See study outputs table

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

Interventions
The intervention will be delivered alongside usual care. The intervention will consist of four physical activity consultations (online or in person) delivered over 12 weeks by a qualified healthcare staff member. The consultations will be supported by a handbook. A Smartwatch will also be provided for use throughout the intervention to support self-monitoring of physical activity and sedentary behaviour, in addition to goal setting. The initial consultation (intervention start) will take place within approximately two weeks following randomisation. Subsequent consultations will take place approximately 2, 6 and 10 weeks following intervention start. Prior to each consultation the participant will be encouraged to complete a pre-reading section in the handbook. They will also be asked to record their activity prior to each consultation using the Smartwatch provided. Each physical activity consultation is expected to last for up to 45 minutes. During each consultation the participant's progress and individual physical activity goals will be reviewed. Topics such as the benefits of increasing activity, participant's feelings about increasing their walking, how participants plan to increase their physical activity and reduce sedentary behaviour, and their beliefs about achieving this will be discussed. The intervention deliverer and participant will work together to develop an action plan, set achievable goals and develop strategies to overcome any problems that may arise.

Intervention Type
Behavioural

Primary outcome measure
Fatigue measured using the Modified Fatigue Impact Scale at baseline, 3 months and 9 months.

Secondary outcome measures
1. Stepping time and number of steps per day using the activPAL activity monitor measured at baseline, 3 months and 9 months
2. Standing time using the activPAL activity monitor measured at baseline, 3 months and 9 months
3. Daily sitting and prolonged sitting time using the activPAL activity monitor measured at baseline, 3 months and 9 months
4. Quality of life using the EQ-5D-5L measured at baseline, 3 months and 9 months
5. Walking capability using the 12-item Multiple Sclerosis Walking Scale measured at baseline, 3 months and 9 months
6. Pain using the EQ-5D-5L pain scale measured at baseline, 3 months and 9 months
7. Self-efficacy using the Multiple Sclerosis Self-Efficacy Scale measured at baseline, 3 months

and 9 months
8. Cost per quality-adjusted life year based on the EQ-5D-5L measured at baseline, 3 months and 9 months
9. Cost per change in fatigue based on the Modified Fatigue Impact Scale measured at baseline, 3 months and 9 months

Overall study start date
01/03/2025

Completion date
28/02/2027

Eligibility

Key inclusion criteria
1. Diagnosis of MS.
2. Experiencing MS-related fatigue over the past four weeks as indicated by a score of ≥ 38 on the Modified Fatigue Impact Scale (MFIS).
3. Relapse free for the past 3 months; a relapse will be defined as 'the appearance of new symptoms, or the return of old symptoms, for a period of 24 hours or more, in the absence of a change in core body temperature or infection'.
4. Expanded Disability Status Scale (EDSS) score of 1.0 "no disability, very small sign that one function isn't normal" to 6.5 "you can walk 20 metres with two aids (crutches, sticks or frame etc) without stopping for rests"; this range allows inclusivity across different disability levels, in line with the iStep-MS feasibility study.
5. Free of contraindications to participate in physical activity as defined by the local site criteria.
6. Free of unstable medical conditions e.g. unstable angina.
7. Able to communicate in English to a standard sufficient to provide informed consent and take part fully in the study protocols.
8. Able to travel to a study centre or attend online consultations for the intervention.

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
Planned Sample Size: 198; UK Sample Size: 198

Key exclusion criteria
1. EDSS score ≥ 7.0 "Unable to walk beyond approximately 5m even with aid. Essentially restricted to a wheelchair; though wheels a standard wheelchair and able to get in and out alone. Up and about in wheelchair some 12 hours a day".
2. Currently pregnant or become pregnant during the study.

3. Already participating in an interventional clinical trial (in order to minimise the impact of potential confounding variables on the study outcomes).
4. Do not have capacity to provide informed consent.

Date of first enrolment
15/07/2025

Date of final enrolment
28/02/2026

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
The Hillingdon Hospitals NHS Foundation Trust
Pield Heath Road
Uxbridge
United Kingdom
UB8 3NN

Study participating centre
Milton Keynes Neuro Conditions Service
Milton Keynes Community Health Services, Neuro Rehab Services, Bletchley Community Hospital, Whalley Drive, Bletchley
Milton Keynes
United Kingdom
MK3 6EN

Study participating centre
Harrow MS Therapy Centre
Harrow School Farm, Watford Road
Harrow
United Kingdom
HA1 3TS

Study participating centre
Bedford MS Therapy Centre
155 Barkers Lane
Bedford

United Kingdom
MK41 9RX

Study participating centre
Camden Neurological and Stroke Service
St Pancras Hospital, 4 St Pancras Way
London
NW1 0PE

Study participating centre
Neurophysiotherapy Service, Royal Free London NHS Foundation Trust
Royal Free Hospital, Pond Street
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United Kingdom
NW3 2QG

Sponsor information

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Brunel University of London

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Sponsor type
University/education

Website
https://www.brunel.ac.uk

ROR
https://ror.org/00dn4t376

Funder(s)

Funder type
Charity

Funder Name
Multiple Sclerosis Society

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
Planned publication in a peer-reviewed journal

Intention to publish date
28/02/2028

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a publicly available repository: https://brunel.figshare.com/. Raw quantitative data will be made available following data analysis and will be available for a minimum of 10 years.

IPD sharing plan summary
Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 1.0	10/04/2025	09/05/2025	No	Yes