PARTICIPANT INFORMATION SHEET

[INSERT QR CODE]

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

We would like to invite you to take part in a research study. Whether or not you wish to take part is entirely up to you. Before you decide it is important for you to understand why the research is being done and what it will involve. To help you decide please take time to read the following information carefully. Feel free to talk to others about the study if you wish. Ask us if there is anything that is not clear or if you would like more information.

Part 1 of this information sheet tells you the purpose of this research and what will happen to you if you take part.
Part 2 gives you more detailed information about the conduct of the research.

Part 1 – Overview of the Study

What is the purpose of the study?

Physical activity has many benefits for people with multiple sclerosis (MS) including reducing fatigue and disability, and improving quality of life. Despite the benefits of physical activity, many people with MS may not do very much physical activity and may spend a lot of time sitting (sedentary behaviour) because they do not receive sufficient support to be physically active.

We developed a new programme, called iStep-MS, to help people with MS to increase the amount of physical activity they do in their day-to-day lives. The iStep-MS programme uses different techniques to help people with MS increase the amount of physical activity they do and reduce the amount of time they spend in sedentary behaviours (e.g. sitting, watching TV). The programme was provided by physiotherapists and uses an adapted version of a handbook that is used by the NHS to help people change behaviours that cause ill-health. We adapted the handbook so that it provides specific support to people with MS to change their physical activity. As part of the programme, participants also monitor their steps and sedentary behaviour with a Fitbit Smartwatch.

In a previous study iStep-MS was delivered by physiotherapists at an MS Therapy Centre. We found that iStep-MS was safe, acceptable and easy to follow. It also increased stepping time, reduced fatigue and improved walking capability.

The aim of this study is to see how effective iStep-MS is for reducing fatigue when delivered by different healthcare professionals (like physiotherapists, physiotherapy assistants and occupational therapists) across different healthcare settings (like hospitals, community-based

NHS services and MS Therapy Centres). This would make iStep-MS more accessible as part of normal healthcare for people with MS.

Why have I been invited to participate?

You have been invited to take part in this study because you are a patient or member at one of the clinical services or centres that we are doing this research with. This information sheet has been sent to you through one of these services or centres. We are aiming to recruit 198 people with MS to take part in this study.

What to do if I want to take part?

If you want more information or decide to volunteer to take part then either (a) email the research team on istep@brunel.ac.uk, (b) visit this website [INSERT LINK TO EOI FORM], or (c) scan the QR code at the top of this sheet.

Who can take part in the study?

Any adult with MS can take part in the study if they:

- Aged ≥ 18 years
- Have not had a relapse for the past three months
- Can walk at least 20 metres (with or without a walking aid) without stopping for rests
- Have experienced some MS-related fatigue over the past four weeks
- Able to communicate in English
- Able to travel to one of the study sites or attend consultations online for the iStep-MS programme

You are not eligible to take part in the study if you:

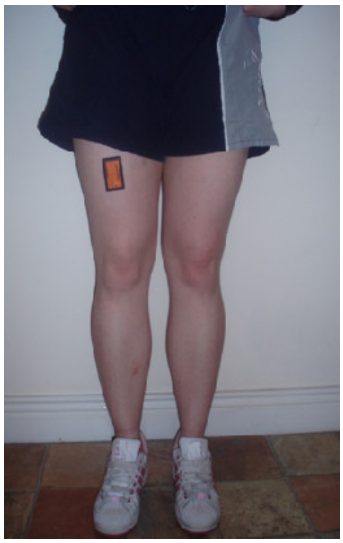
- Are pregnant
- Are taking part in another research study that involves a change in your treatment or receiving an intervention

Do I have to take part?

As participation is entirely voluntary, it is up to you to decide whether or not you wish to take part. If you do decide to take part we will ask you to sign a consent form. If you decide to take part you are still free to change your mind and withdraw at any time and without giving a reason. This will not affect the standard of the usual care you receive or your future medical care in any way.

What will happen to me if I take part?

Everyone who wishes to take part will receive a phone call or email from an iStep-MS study researcher who will give you more information about the study and check you are suitable to take part. If you are suitable to take part, you will be asked to complete a consent form and provide some information about your general health, your history of MS and symptoms. You will then be asked to complete a set of baseline measurements.



The measurements will involve you completing online questionnaires at home about your health, like how fatigue affects you, your walking capability and quality of life. You will also be sent a tape measure to measure your waist circumference and a monitor, called an activPAL (see image), to measure the number of steps you take and how much time you spend sitting down, standing up or lying. The activPAL is a small device that you attach to your thigh and is worn comfortably with your usual daily clothes. You will be asked to wear the activPAL and complete a short sleep and wake time diary for seven days in a row so we can see on average how active you are over a week. This device will be loaned to you but the researchers take responsibility for any loss or damage. If a device becomes faulty or lost, please contact the research team.

What happens after the baseline measurements?

When we don't know the best medical or physiotherapy treatment to provide to people, we need to compare a new treatment to treatment as usual, or "usual care". Following the baseline measurements, everyone who agrees to take part in this study will be randomly allocated to one of two groups; one group of people will receive the iStep-MS programme and the other group will continue to receive their usual care. The group you are in will be chosen completely at random by a computer programme. The computer programme uses a process of randomisation, which is similar to tossing a coin in order to decide which group the next person is in. This means that you will have an equal chance of being allocated to either of the groups. The research team won't know what group you are in until after you have completed the baseline measurements.

To be able to test how well the iStep-MS programme works for improving health, we need to repeat the measurements taken at baseline. A member of the research team will ask you to do this at approximately 3 months after your baseline measurements, and again 6 months later. The measurements taken will be compared between the two groups to find out if the programme works. We may also ask you to take pat in a focus group face-to-face at Brunel University or online to find out about your experiences of taking part in the study.

What will happen if I am in the iStep-MS programme group?

If you are allocated to the iStep-MS group you will receive four sessions with a healthcare professional over 3 months. Each session will be up to 45 minutes long and will take place in-person or online depending on your preference. Your travel expenses for attending any in-person sessions will be reimbursed. At each session the healthcare professional will discuss topics such as the benefits of increasing physical activity and reducing sedentary behaviour, how you feel about trying to increase your activity levels, how you plan to increase your walking and reduce sitting, and your beliefs about achieving this. You will make an action plan together, set some

achievable goals and try to come up with some strategies to help you overcome any problems you think might come up. We may record some of the sessions so the research team can monitor how they are being delivered by the healthcare professionals.

Everyone who takes part in the iStep-MS programme will be given a handbook to help them set goals and plan when and where they will do activity. You will also be given a Fitbit Smartwatch to keep (see image) to measure your daily physical activity, or you may be able to use your own Smartwatch if you already have one. Your healthcare professional will discuss how to use the Smartwatch and support you in planning your goals. This device will be given to you to keep. If a device becomes faulty or lost, please contact the research team.

What happens if I am in the usual care group?
If you are allocated to the usual care group, you will continue with your normal routine for the duration of the study. Once the study has ended, we will provide you with the iStep-MS handbook and a Fitbit Smartwatch to keep so you can benefit from using these.

What are the possible disadvantages?
Choosing to take part or not to take part will not disadvantage you in any way and will not impact on your current or future medical care. The study will take up some of your time, which might be an inconvenience. There are no other likely disadvantages.

What are the possible benefits of taking part?
We cannot promise that taking part will benefit you but the study will give you an opportunity to increase your physical activity and to easily access support designed to help you gradually increase your walking. You may feel better as a result of doing more physical activity and spending less time in sedentary behaviour. We hope the information we get from this study will help improve the treatments for people with MS in the future.

As a thank you for taking part, we will provide you with a £20 shopping gift voucher after each of the three study assessment sessions.

What are the possible risks associated with taking part?
A member of the research team will ask you about your medical history to make sure it's safe for you to take part in the study. However, if you are finding any problems with the level of activity that you are engaging in, you should get in touch with a member of the research team or your iStep-MS deliverer to discuss this.

There is a small risk that people may find completing the questionnaires tiring or distressing. If this happens then please take a break and then continue if you are happy to. Participation is voluntary and you may withdraw at any point without this decision affecting your normal care.

A very small number of people are sensitive to the adhesive tape used for the activPAL, which is similar to that on a sticking plaster. If this happens to you, we will advise you to remove the tape and attach the activPAL to the other thigh or to stop wearing the activPAL. Again, you should get in touch with a member of the research team using the contact details below if you have any problems.

Part 2 – Further Information

This section details the organisation of the study and complaint procedures if you are not happy with the conduct of the study.

Will my taking part in this study be kept confidential?

All information which is collected about you during the research will be kept strictly confidential. Responsible members of Brunel University of London or regulatory authorities may be given access to data for monitoring and/or audit of the study to ensure the study is being carried out correctly and complying with regulations. Access to paper and electronic files would be given to authorised people, which would be set up on a limited basis for the duration of the monitoring/audit period. These people will have a duty of confidentiality to you as a research participant.

Will I be recorded, and how will the recording be used?

If you take part in one of the focus groups, this will be recorded using the recording feature on a smartphone or tablet device, using Microsoft Teams and/or an encrypted Dictaphone. The recording will be saved onto a University password protected laptop. The recording will be typed up word for word and a fake name will be used to protect your identity. Following this, the recordings will be deleted.

What will happen to the results of the research study?

The results of the study will be written up in reports for the MS Society who are funding this research. The results of the study may be published in scientific journals and presented at conferences so we can share the findings with other researchers and healthcare professionals. We will also send a summary of the findings to you by email if you consent to this.

What will happen if I don't want to carry on with the study?

If you wish to leave the study, then you are free to do so and without giving a reason. There will be no disadvantage or detriment to you if you withdraw. If you choose to withdraw, data you have already provided will continue to be used in analysis of the study results.

Who is organising and funding the research?
The research is being sponsored by Brunel University of London and is funded by the MS Society.

What if there is a problem?
If something goes wrong, then please contact the research team as soon as possible to explain the problem. We will work with you to find a resolution. If you would like to discuss the problem with someone outside of the research team then please contact Chair of the Research Ethics Committee: Professor Christina Victor (christina.victor@brunel.ac.uk).

What are the indemnity arrangements?
Brunel University of London provides appropriate insurance cover for research which has received ethical approval. In the event of a claim for which negligence cannot be demonstrated, the claimant may need to take legal action for which they would need to pay.

Who has reviewed the study?
This study has been reviewed and given favourable opinion by the [INSERT REC NAME] NHS Research Ethics Committee and the College of Health, Medicine and Life Sciences Research Ethics Committee at Brunel University of London.

Research Integrity
Brunel University of London is committed to compliance with the Universities UK Research Integrity Concordat, which is a national framework for good research. You are entitled to expect the highest level of integrity from the researchers during the course of this research.

How will we use information about you?
We will need to use information from you for this research project.

This information will include your:

- name
- contact details
- age
- gender
- ethnicity
- employment status

People will use this information to do the research or to check your records to make sure that the research is being done properly. People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.

We will keep all information about you safe and secure by:

- storing your data in line with General Data Protection Regulation (GDPR) guidance
- storing paperwork in locked filing cabinets
- storing electronic files on password protected laptops and secure servers

How will we use information about you after the study ends?
Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

We will keep your study data for a maximum of 10 years. The study data will then be fully anonymised and securely archived or destroyed.

What are your choices about how your information is used?

- You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have
- You have the right to ask us to access, remove, change or delete data we hold about you for the purposes of the study. You can also object to our processing of your data. We might not always be able to do this if it means we cannot use your data to do the research. If so, we will tell you why we cannot do this
- If you agree to take part in this study, you will have the option to take part in future research using your data saved from this study

Where can you find out more about how your information is used?
You can find out more about how we use your information

- our leaflet www.hra.nhs.uk/patientdataandresearch
- by asking one of the research team
- by sending an email to data-protection@brunel.ac.uk
- by ringing us on 01895 274000

Contact for further information and complaints
For general information
Principle Investigator: Dr Daniel Bailey, Email: daniel.bailey@brunel.ac.uk

For complaints and questions about the conduct of the research
Professor Christina Victor, Chair of Brunel University of London Research Ethics Committee, Email: christina.victor@brunel.ac.uk

Thank you for taking the time to read this and considering taking part in this study.