PARTICIPANT INFORMATION SHEET

Changing physical activity behaviour in people with MS: the iStep-MS trial

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.

Please take time to decide whether you wish to take part

Part 1 of this leaflet 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 because they do not receive sufficient support to be physically active. A new approach is required to help people with MS to increase the amount of physical activity they participate in in their day-to-day lives.

We have developed a programme that uses evidence-based techniques to help people who have MS to increase the amount of physical activity they do and reduce the amount of time they spend in sedentary behaviours (e.g. sitting and lying). The programme is provided by physiotherapists and uses an adapted

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version of a handbook that is used by the NHS to help people change a variety of behaviours that cause ill-health. We've adapted the handbook so that it provides specific support to people who have MS to change their physical activity behaviour. As part of the programme the physiotherapists will provide participants with a small device called a pedometer to monitor how many steps they take each day. Although we believe that this programme may help people with MS to increase the amount of physical activity they do and reduce the amount of time they spend in sedentary behaviours we need to conduct this research to determine if it is a feasible approach. This study aims to determine if the programme is safe, enjoyable and easy to follow.

Why have I been invited to participate?

You have been invited to take part in this study because you are registered on a database at the Berkshire MS therapy Centre. This letter has been sent to you through the Centre. The iStep-MS research team did not have access to your contact information. 60 people with MS will be asked to take part in this study.

Who can take part in the study?

Men and women with MS can take part in the study if they:

- Have not had a relapse for the past three months
- Can walk independently in the home environment (with or without a walking aid)
- Do not have an unstable illness (e.g. unstable angina)

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

- Are pregnant
- Are taking part in another research study

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.

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What will happen to me if I take part?

Everyone who wishes to take part will receive a phone call from an iStep-MS trial researcher. The researcher will give you more information about the study and also check you are suitable to take part. If you are suitable to take part, the researcher will invite you to a baseline assessment. This assessment can take place in the Berkshire MS Therapy Centre or, if you prefer, it can take place at your home.

At this assessment, you will be asked to sign a consent form. The researcher will answer any questions you have and ensure you understand what the study involves before you are asked to sign it. The researcher will gather some information about your general health, your history of MS and symptoms. You will then be asked to complete a range of questionnaires. These questionnaires will ask you about a number of different things from how physically active you currently are and how many hours you sit during the day to how fatigue impacts you.

During this time you will be given two monitors that measure how much activity you do and instructions on how they work. The first monitor, called an Actigraph (Fig. 1), will measure the amount of steps you take and record the intensity of your physical activity. The Actigraph is worn around your waist. The second monitor, an *activ*PAL (Fig. 2) is a small matchbox-sized device that you attach to your thigh. It measures how much time you spend sitting down, standing up or lying. Both devices are small and comfortable and are worn with your usual daily clothes. You will be asked to wear these activity monitors and record when you wear them in an activity diary for seven days in a row so we can see on average how active you are over a week. This assessment will take about two hours to complete. You can take as many breaks as you would like during this time.

Fig 1. Actigraph acclerometer

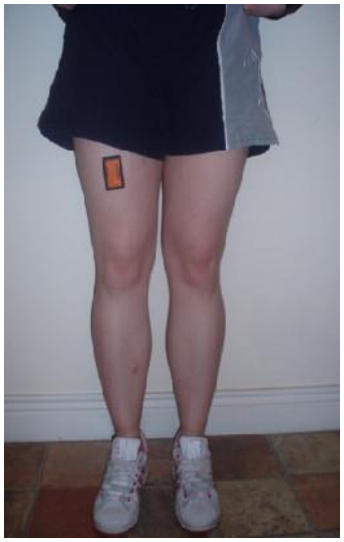

Fig 2. activPAL acclerometer

What happens after the assessment visit?

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 assessment 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 assessment.

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 physiotherapist over 3 months. Each session will be up to 45 minutes long. At each session the physiotherapist will discuss topics such as the benefits of increasing physical activity, how you feel about trying to increase your activity levels, how you plan to increase your walking 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. Everyone who takes part in the iStep-MS programme will be given a handbook to help them to set goals and plan when and where they will do activity. You will also be given a device called a pedometer to measure the number of steps you do each day and a physical activity diary to record your activity. Your physiotherapist will discuss how to use the pedometer and support you in planning your goals.

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.

To be able to assess the effect of the iStep-MS programme we need to repeat the questionnaires and measurements taken at your baseline assessment. A member of the research team will ask you to come back for follow-up at approximately 12 weeks after you have joined the study, and again 6 months later. Measurements taken will be compared between the two groups to find out if the programme works. After each assessment you will be asked to take home and wear the Actigraph and *activ*PAL to measure your physical activity for 7 days. Like the baseline assessment, the second and third assessments will be conducted at the Berkshire MS Therapy Centre, or if you prefer, a researcher can come to your home to do it.

Your travel expenses (public transport, car mileage) to the Berkshire MS Therapy Centre for research assessments will be reimbursed.

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 or participation at the MS centre. The study will take up some of your time, which might be an inconvenience. You will have to cover your own travel expenses to attend the Berkshire MS centre for the intervention sessions. There are no other likely disadvantages.

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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 daily 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 trial will help improve the treatments for people with MS in the future.

What are the possible risks associated with taking part?

A member of the research team will ask you about your medical history to ensure it's safe for you to take part in the programme. 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 to discuss this.

There is a small risk that people may find the data collection procedures, in particular some aspects of the questionnaires that discuss fatigue or quality of life tiring or distressing. If this situation were to occur the researcher collecting the data will ask if you if you would like to take a break and if are happy to continue. At all points during the study you will be reminded that participation is voluntary and that 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 *activ*PAL, 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 with this.

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. Paper copies of personal data will be stored in a locked filing cabinet, with access only to the members of the research team who

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require the use of this data. All information will be securely stored for ten years after the study has ended and then be destroyed.

Responsible members of Brunel University London 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. All will have a duty of confidentiality to you as a research participant.

There is one important exception to the guarantee of confidentiality. If you tell us something that suggests that you or others are being placed at risk of significant harm, we are obliged to pass this information on. We will talk to you about the procedures involved before the information is shared.

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 and Brunel University London and may be published in recognised medical journals. In any report or publication, we will not use your name or give any information that could identify you. If you wish you can request a summary of the results when the study is complete. Your height, weight and physical activity results from the assessment will be made available to you on request at the end of the study.

What would happen if I don't want to continue with the study?

You can withdraw from the study at any point, without giving reason. If you choose to withdraw you would be asked which type of withdrawal you would prefer – you can choose between leaving the study and allowing the information already given to be used by the study team OR leaving the study and asking for the information already given by you to be destroyed. If you withdraw from the study it will not affect your future participation at the MS centre in any way.

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Who is organising and funding the research?

The research is being organised by Dr Jennifer Ryan and Dr Meriel Norris from the Department of Clinical Sciences in Brunel University London. The research is funded by the MS society. Brunel University London is acting as the sponsor. All postal costs of this letter have been funded by the project grant. A donation to the Berkshire MS centre has been made from the research grant.

What if something goes wrong?

If you are harmed by taking part in this research project, there are no special compensation arrangements. If you are harmed due to someone's negligence, then you may have grounds for a legal action but you may have to pay for it.

What are the indemnity arrangements?

Brunel University London holds insurance policies which apply to this study. If you can demonstrate that you experienced harm as a result of your participation in this study, you may be able to claim compensation. Please contact Prof Peter Hobson, the Chair of the University Research Ethics committee (Peter.hobson@brunel.ac.uk) if you would like further information about the insurance arrangements which apply to this study.

Who has reviewed the study?

This research has been reviewed at by independent group of people, called a Research Ethics Committee which is there to protect your safety, rights, wellbeing and dignity. This study has been reviewed and given a favourable opinion by Brunel University London College of Health and Life Sciences REC.

Contact for further information and complaints

For general information

If you would like any further details about this study, would like to ask us any questions, or would like to express your interest in taking part then please do not hesitate to contact a member of the iStep-MS trial team. You can call or text the team on 07393949575 or email istep-ms@brunel.ac.uk or visit the trial website www.istep-ms.com.

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For complaints and questions about the conduct of the Research

Professor Peter Hobson, Chair of the University Research Ethics committee (Peter.hobson@brunel.ac.uk)

Passage on the University's commitment to the UK Concordat on Research Integrity

Brunel University is committed to compliance with the Universities UK Research Integrity Concordat. You are entitled to expect the highest level of integrity from our researchers during the course of their research.

If you have decided that you would not like to participate we would ask that you consider completing a questionnaire. The purpose of this questionnaire is to help identify the reasons why people are not participating in the study. We hope that this information will help us to tailor and improve future research studies. This survey will take approximately 5 minutes to complete and can be accessed through the following link goo.gl/GpPl1D

If you have received this invitation and we do not hear from you, we will send you one further invitation.

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