

PATIENT INFORMATION SHEET

Version 1.2

Study Title: Life-style, Exercise and Activity Package for People living with Multiple Sclerosis (LEAP-MS) - Feasibility study – Intervention testing

Why am I being contacted?

You are being contacted because you have expressed an interest in taking part in research which relates to multiple sclerosis.

We would like to invite you to participate in the following study.

What is the study about?

Our aim is to design and test an intervention to help people with progressive multiple sclerosis (PwPMS) to be as physically active as possible.

So far, we have interviewed PwPMS and physiotherapists and asked them about their views on the barriers to and facilitators of physical activity. We have brought PwPMS, friends and family and physiotherapists together for a 'co-production' day to think about what type of intervention PwPMS think would help support them to be physically active.

We have used what we learned from the interviews and the co-production event to develop a personalised intervention to support PwPMS with ongoing physical activity and a training package for physiotherapists.

In the next phase of the study we aim to evaluate (test) this intervention and to do this we need the help of PwPMS. In total, 21 adult (18 years and over) PwPMS will take part in this study for 6 months.

What has been developed?

The intervention developed for this study is made up of two parts. The first part is a coaching session with a physiotherapist (via a secure web video conferencing system or where possible, in person at your home) to help you identify what types of physical activity might work best for you and how you can build activity into your daily life.

During the coaching sessions we will work with you using our purpose developed website that provides:

- support to set aims and challenges for yourself
- activity ideas
- information about MS and exercise
- facilities to help you track your activity levels
- messaging services to help you communicate with your physiotherapist.

What will I be asked to do?

You will speak to a member of the LEAP-MS team who will talk about the study in more detail. You will be asked to complete a consent form and some short online questions which will help to determine whether you are eligible to take part.

If the answers you give match the eligibility criteria for this stage of the study you will be given access to the LEAP-MS website. The website includes information on topics such as: MS and physical activity, managing fatigue and using equipment. It provides ideas for activities to do on your own or with your friends and family. The website lets you select activities that focus on particular abilities you have or directs you to specific areas you might want to work on such as strength, flexibility, balance or co-ordination. Importantly the website will help you to set your own aims and plans, personalised to your own requirements.

Following this, we will arrange an online consultation (via a secure web video conferencing system) or, where possible, a home visit for you with a trained physiotherapist who will provide coaching and support in the use of the website and help you to choose the best activities for you. With your permission, we would like to record online consultations. When you meet with one of the study physiotherapists they will look at your answers to the online questions and confirm whether or not you are eligible to carry on with the study. During this consultation, there may be a small chance that the physiotherapist will identify some reason which might mean you are unable to continue in the study.

If you are able to continue in the study, you will be asked to use the website and record the activities you do for an initial 3 month period. During this time you will have access to a physiotherapist for advice and support or via a messaging system through the website and can request up to a further 5 online or, where possible home-based consultations. How you use the web-based tool, when you use it, the information you add and the communication you have with your physiotherapist will be removed and stored securely in a research database at Cardiff University for researchers to analyse as part of the study.

After 3 months, you will be asked to complete a series of short questionnaires and be interviewed by a LEAP-MS study team member. The interview will take place over the phone or in your home. In the interview you will be asked about your experiences of using the website alongside the physiotherapist and any suggestions you may have to improve the intervention. With your permission we would like to audio record this interview.

You will then be able to access the website for a further 3 months and invited to continue to use it for this time to support your physical activities. The team will record your use of the website to find out how people use the tool over the whole 6 month period (in the initial 3 month period and the additional 3 month period).

At the end of the additional 3 month period you will be asked to complete a final set of short questionnaires.

If I am struggling to be physically active can I still participate in the research?

Yes. If you are struggling to be physically active, you are just the type of person we want to be involved. It's important that we have a broad understanding of how different people use the intervention and what their experiences of using it are.

If you are physically active, then we equally want you to participate – so we can better understand what is helping you to be active and what you think of the intervention.

What are the benefits in taking part?

We don't yet know whether using the LEAP-MS intervention might lead to specific health benefits. This early stage of the research focusses on how usable and acceptable it is. Future research could use what we learn in this study to further develop the intervention and test for any benefits.

By taking part in the study you will have the support of a physiotherapist to develop and review personalised physical activity plans.

You will have access to a website to give you ideas about the types and range of activities that you might like to do and to find supporting information about being active with MS.

You may benefit from the research by broadening your physical activities and learning about how to make changes to your own physical activity in partnership with health professionals.

Are there any risks?

Muscle soreness and fatigue

Risks associated with taking part in this study are largely connected to any physical activities you chose to do. Managing any risks around the activities you choose can be discussed with your physiotherapist at your consultation.

You may experience some minor muscle soreness, muscular strain or increased fatigue in the few days following the initiation of a new exercise program or increased physical activity. Ordinarily this should resolve spontaneously and research evidence suggests that regular physical activity can reduce MS related fatigue.

If you do experience any adverse effects by using the LEAP-MS intervention, you will be asked to inform the study team and your physiotherapist. You will be shown how to communicate this during your first consultation with your physiotherapist.

Pregnancy

Exercise and physical activity are not contra-indicated in pregnancy, but there may be additional considerations when the person with MS is pregnant. At this early stage of intervention development, we are unable to provide detailed and specific advice for pregnant women with progressive MS. Should you become pregnant during the study you will need to inform the study team and you will be unable to continue with the study. With your permission, all the data you have contributed up until the point of pregnancy would be kept and contribute to the study findings and we would invite you to be interviewed about your experiences of the LEAP-MS intervention up until that point.

Do I have to take part?

No. It is your choice whether or not you take part. If you do decide to take part but later decide you do not want to continue, you are free to withdraw at any time. Not taking part, or deciding to stop, will have no impact or influence on your care. If you participate and then decide that you want to withdraw from the study you will be asked about which parts of the study you wish to withdraw from.

What will happen to my information and who is responsible for looking after it?

Cardiff University is the sponsor for this study, based in the United Kingdom (UK). Cardiff University will be using information from you in order to undertake this study and will act as the data controller for this study. This means that Cardiff University are responsible for looking after your information and using it properly.

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible.

Cardiff University will use your name and your contact details to contact you about the research study, to make sure that where relevant, information about your participation in the study is recorded in your medical notes and to oversee the quality of the study. Individuals from Cardiff University and regulatory organisations may look at research records to check the accuracy of the research study. The only people in Cardiff University who will have access to information that identifies you will be people working directly on the LEAP-MS study, people who need to contact you to collect data, audit the data collection process, complete follow up assessments, analyse the data, write up the research findings or send you results of the study.

All information that you give to us will remain confidential, and we will store it securely (in locked cabinets, or secure computers). Study data stored at the research centre at Cardiff University will be kept separate from personal information (names, addresses, and phone numbers). Audio recordings will be transcribed (a record will be typed up) by a member of the study team. In some instances it may be sent to an external transcription company used by Cardiff University. Any external transcription company that we may use is required to treat all data confidentially and will adhere to General Data Protection Regulation (GDPR). Once the audio files are transcribed the recording and transcript are deleted by the external company and held only by the study team on university secure computers.

We may use quotes from your interview in reports, presentations or publications. If we do this, you will not be identified and we would change all names or places that you mention so that it is not possible for someone to identify you.

Cardiff University will keep identifiable information about you from this study for a minimum of 15 years after the study has finished. This is in line with Cardiff University policies. You can find out more about how we use your information here: <https://www.cardiff.ac.uk/public-information/policies-and-procedures/data-protection>

What will happen to the results of the research study?

You will be sent a summary of the study findings. A report of the research results will be completed and submitted to the Multiple Sclerosis Society who are funding the study. Results will also be published in scientific journals and presented at conferences. You will not be identified in any report, publication or presentation; all results will be completely anonymous.

Who is doing the study?

The study is funded by the Multiple Sclerosis Society. It is being organised by Cardiff University working in partnership with Cardiff and Vale and Cwm Taf Health Boards.

Who has reviewed this study?

This study has been approved by Wales Research Ethics Committee 6 who agreed this study is being conducted in an appropriate manner.

Raising concerns

There are no special compensation arrangements in place for this study. The normal NHS complaints mechanisms will still be available to you. If you have any concerns about the study, you can speak with the study manager Christy Barlow in the first instance, or, if you would like to speak to someone who is not involved in the project, please contact Dr James White (details below).

What happens next?

If you feel you *might* like to take part in this study, please go to www.leapms.org and complete the expression of interest form. The form will be sent to the study team electronically. Once the LEAP-MS study team have received your expression of interest form, they will be in touch to discuss the study further.



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If you use a communication aid, and you are unable to communicate over the phone, please indicate this on the expression of interest form and provide an email address and/or include details about how you communicate and what aid you use.

Thank you very much for considering taking part in this study.

The LEAP-MS team

LEAP-MS Study team contact details:

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For concerns or complaints only please contact:

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