



South West Impact of Multiple Sclerosis (SWIMS) Project – a Study of Multiple Sclerosis in the South West Peninsula

INFORMATION SHEET

Invitation to participate

We would like to invite you to take part in a research project. Before you decide whether or not to participate, it is important for you to understand why the research is being done and what it will involve. This information sheet explains the background and aims of the project. Please take time to read it carefully and discuss it with family and friends or your own doctor if you wish. If there is anything that is not clear or if you would like more information, please ask us. Your participation in this project is entirely voluntary.

Why have I been chosen?

Everybody in Devon and Cornwall who has a diagnosis of multiple sclerosis (MS) will be invited to participate in this project. In addition, anyone in the area who has had a single episode of inflammation of one part of the brain or spinal cord (known as "clinically isolated syndrome") will also be invited to participate. The key to the success of the study is being able to identify every single case of MS and clinically isolated syndrome in the area and then to follow up the patients over a number of years. If you have had just one isolated episode of inflammation (e.g. a temporary problem with your vision, a problem with muscle strength, balance or coordination, or pain, numbness or tingling in your limbs) then **you do not have MS**. However, it is important for us to include you in the project if possible.

What is the overall aim of the project?

MS is the commonest cause of neurological disability in young adults. Current treatments are aimed either at controlling specific symptoms or are designed to target the immune system in the early stages of relapsing-remitting MS. As yet few treatments have been effective in primary or secondary progressive disease.

Clinical trials in MS cost large amounts of money. If better treatments are to be developed then it is important that trials use the best way of measuring the usefulness of current and new treatments. However, in order that we may evaluate such treatments it is very important to understand how MS affects people over time, from the very first sign of a neurological problem. This is known as the *natural history* of the disease.

The aim of this project is to study the natural history of the local MS population. This will enable us to view the disease over time and try to develop better ways of assessing treatments in clinical trials. The project will be confined to people with MS and clinically isolated syndrome in Devon and Cornwall, but the information gained will help to improve treatments for everyone with MS and act as a resource for many years to come.

What will the project involve?

The first objective of this project is to identify everyone in the local area who has MS, and to collect some baseline information from them. The project will also attempt to identify and collect baseline information from people with clinically isolated syndrome (i.e. just one episode of inflammation). It is important for us to include people with clinically isolated syndrome in our research since a proportion of this group may go on to develop MS at a later stage in life.

Secondly, we will use postal questionnaires to collect follow up information from all participants. If you have MS, you will receive a questionnaire booklet approximately every six months, which will ask about your current health status and the impact of MS on your everyday life. The questionnaires are specifically designed to measure the effects of disease in different ways and will help us to develop new ways of measuring the impact of MS. This information can be used later in designing clinical trials. Participants who have clinically isolated syndrome will simply be asked to complete a general health questionnaire booklet once a year. All the information gathered will form a natural history database which we will store on computer and add to over the coming years.

Finally, we would like to record the date and results of any investigations you may have had to support your diagnosis (e.g. MRI scan, lumbar puncture or nerve conduction studies). The study team will be able to check this information on your behalf from your medical notes, so it does not matter if you cannot remember the exact dates.

What would I have to do if I took part?

Initially we want to collect some baseline information. This will include your name and address, age, a description and start date of your first MS symptoms (or clinically isolated syndrome), and if applicable, what type of MS you have and the date your diagnosis was confirmed. If you decide to participate in this project then you can provide this information straight away by completing the Baseline Record Form.

Secondly, we will invite you to complete regular postal questionnaires, as described above. Freepost envelopes will be provided. All questionnaires will involve filling in tick boxes or circling answers and should be very straightforward to complete. However, if you have any difficulties you can telephone the coordinating centre and a member of the research team will be pleased to help. If you decide to take part in this project then we will send you your first questionnaire within the next few months.

IMPORTANT: If you decide to participate in this project, you must complete and sign the enclosed Consent Form and return it to us in the FREEPOST envelope provided. Please also complete the Baseline Record Form and return it in the same envelope. If you have any questions about giving your consent, please call us on 0800 015 3430.

Do I have to take part?

No. Participation in this project is entirely voluntary and if you decide not to take part your usual medical care will not be affected in any way.

Will the project involve taking any new medication?

No. We will not change your existing medication or prescribe any new treatments for you. You should continue to take all your usual medicines as prescribed.

Will I have to make any extra visits to the hospital or to my GP?

No. You will provide most of the information that we need by completing the questionnaires that we send to you. If you have MS, the study team will need to confirm details of your diagnosis and test results directly from your hospital or GP notes, but you will not normally be required to attend any extra appointments yourself.

How long will the project last?

At present we hope that the project will last for at least ten years. In this way we can build up an extensive local database which will be invaluable in helping us to develop better ways of assessing treatments in MS. Naturally we would like participants to be involved in the project over several years, but if you decide to take part then you are free to withdraw at any stage in the future.

Will my records be confidential?

All information collected about you during the project will be kept strictly confidential. You will be allocated a project number at the beginning of the project and we will use this number and your initials on all postal questionnaires rather than your full name or other identifying details. All information that we collect on you will be stored on our computer database. Your name and address will be stored separately from the other information you supply during the project so that you cannot be immediately identified from your study records. Doctors, nurses and other members of the research team will have access to your project records at the Plymouth coordinating centre and all information will be handled in compliance with the Data Protection Act (1998).

What are the benefits of taking part in this project?

Whether you have MS or not, allowing us to monitor your health over time will enable you to be actively involved in helping to develop new and improved ways of measuring the impact of MS on people with the disease. This population-based project will also help us to design future clinical trials that will improve treatments for everyone with MS.

Who is organising the project?

The project is being organised by the Clinical Neurology Research team at the Peninsula Medical School in Plymouth and is being led by Professor John Zajicek. If you decide to take part we will inform your GP.

What will happen to the results of the project?

The project is intended to provide the research team with ongoing information over a period of several years. As such, there will not necessarily be any single final result, but you will be informed of any significant advances or outcomes as they occur.

Your rights

Your participation in this project is entirely voluntary. You may withdraw at any time without it affecting your current or future medical treatment in any way. If you agree to take part in this project, you will need to sign the enclosed consent form.

Contact for further information

If you require any further information about this project, or have any questions please contact the Clinical Neurology Research office on **0800 015 3430** (FREEPHONE) during office hours and a member of the project team will be able to help you.
