



* Participant Information Leaflet

We would like to invite you to take part in the UK MS Register.

Before you decide, you need to understand why this research is being done and what it would involve for you. Please read the following information carefully to decide whether or not you wish to take part.

Take the time to talk to others about the study. Please ask us if there is anything that is not clear or if you would like further information.

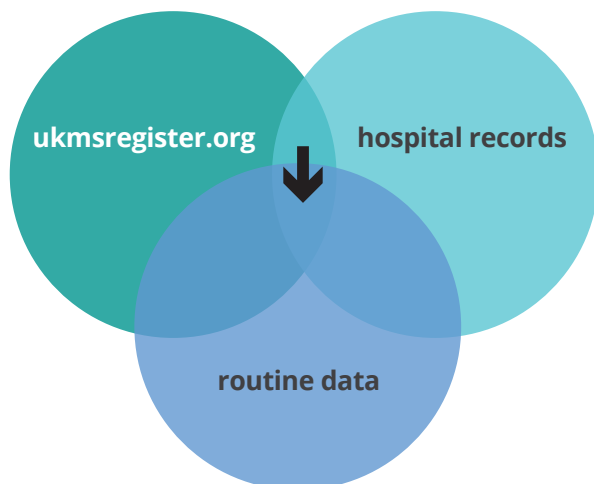
Why have I been invited?

Recruitment for the MS Register is being carried out at a number of Neurology centers across the UK. All people with a confirmed diagnosis of MS who attend your neurology clinic are being invited to join the Register.

What is the purpose of the study?

The purpose of the MS Register is to capture better, higher quality information about living with MS in the UK today. More data needs to be gathered about the physical, environmental and social effects for people and carers affected by the condition. Capturing and analysing this data will help provide better information to improve care and treatments. As can be seen below, Register data is captured from 3 main areas:

- * Having these linked sources provides the richest data



Who is organising and funding this research?

Swansea University College of Medicine is organising this research with a grant from the MS Society.

What are the benefits in taking part?

We cannot promise that the study will help you personally, but the information we obtain will help improve the care and treatment of people with MS.

Research from this study has already contributed to a number of articles published in peer reviewed journals, an updated list of these is always available at blog.msregister.org. This is the best place to keep up to date with the activities of the MS Register.

We send out regular newsletters updating you on the research that the Register is currently undertaking and summaries of the findings so far.

Do I have to take part?

No you don't have to take part. Participation is entirely voluntary, if you do decide to participate, you will still be free to withdraw at any time, without giving a reason. Once withdrawn any identifiable data will be removed but the anonymised aggregate clinical data will be retained.

This will not affect the care you receive in any way.

What will happen to me if I take part?

If you take part, information that is collected during your visit to the neurology clinic will be anonymised and included on the MS Register. You will also be encouraged to visit the MS Register website to provide your own views and experiences. This information will also be anonymised before it is included.

Everything that you provide will be safeguarded and protected to ensure your privacy. The anonymous information on the Register will be used to carry out research studies and service planning to help people with MS. The use of anonymously linked datasets is of immense value in chronic health condition research.

Will my taking part in the study be kept confidential?

Yes. We will follow ethical practice and all information about you will be handled in confidence. Your identifiable information (name, address and date of birth) will be stored separately from the Register. The Register team will, from time to time, contact you by post, email or telephone, to collect more data about you and your health condition. In the future, other researchers might want to contact you, to ask you to take part in some research.

The Register team will not pass on your contact details to anyone else, without asking your permission first.

Who has reviewed the study?

The study has been reviewed and been given approval by South West – Central Bristol Research Ethics Committee (16/SW/0194), an independent NHS Research Ethics Committee in order to protect your safety, rights, wellbeing and dignity.

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

It is your right to withdraw from the study at any time. This will not affect your clinical care in any way. To withdraw from the study, simply inform your clinician.



What if I have a query or a concern?

Should any issue arise during the study that you are unhappy with please do not hesitate to contact us. We will do our best to answer your questions. If you remain unhappy and wish to complain formally, you can do this by contacting Rod Middleton by email at:

r.m.middleton@swansea.ac.uk

or by post via:

Data Science Building,
Swansea University
Medical School,
Swansea, SA2 8PP

What will happen to the results of the project?

Regular reports on the progress of the project are sent to our funders - the MS Society and the South West Central Bristol Ethics committee.

Updates on activity about the MS Register can always be found at blog.msregister.org

We have also published a number of articles in peer reviewed journals. We present at conferences and meetings.

The knowledge we gain from this study will fuel campaigns for fair, relevant policy and improved healthcare for people living with MS.

The detail

All the information collected by the MS Register is stored on secure servers with the highest levels of encryption. Where you give your consent for us to collect identifiable data, this is stored separately from the clinical data.

What do we mean by identifiable information?

Identifiable information is that data that specifically identifies you: name, date of birth, gender, postcode and identifying numbers such as NHS Number or a National Insurance number. In the context of the Register such information never forms part of your Register 'record' and will never be published in any format.

The identifiable part is used to create an anonymous identifier which we can then use to link to other records, which are also anonymous.

Identifiable information is stored separately from the main Register record in the event that we want to contact you.

What do we need from your medical notes?

Every time you visit your health care professional they keep a record of what happened at that visit. These records are primarily kept on paper. As computerised systems within the NHS become more common more data will be held on them, but for the moment the medical notes remain the first document of entry. It's possible that we will need to have access to these notes to capture some data that is not recorded within a clinical system.



What are Health Related Records?

These are records from outside of your neurology department that primarily exist on other electronic systems. So examples of these would be MRI scans or data that exists on laboratory systems such as Biochemistry or Haematology. We may also approach your General Practitioner to capture related data from their systems and this may also include routine sources of data such as Hospital Episode Statistics (HES for English data or Patient Episode data for Welsh data).

What is Data Linkage?

Data linkage is the merging of two or more separate data sets (e.g. General Practice information and outpatient data about the same person) for research purposes.

The Register does this by deleting anything identifiable within your neurology record and replacing it with a unique code. Data from any other related clinical records are also anonymised in the same way and replaced with the same code. This code lets us link these records together so we can perform wider analysis. The anonymisation is carried out by a trusted NHS third party so we are unable to re-identify any individuals after this process has been carried out.

Other MS researchers

It has long been recognised that the lack of information about living with MS in the UK affects both people with MS and the MS research community. It makes sense that the information that we collect via the Register be accessible to more than the Register team.

Should a researcher approach us with appropriate ethical permissions and should they pass the appropriate governance measures that the Register has in place they could be granted access to a small selection of the anonymised data to carry out their own research.

What will I have to do?

There are two main ways that you can get involved with the Register:

- 1) By signing the consent form within this pack you can agree to take part in the clinical element of the UK MS Register study. Once you do this your clinician will securely transmit relevant portions of your clinical data to the MS Register.
- 2) If you, a carer or a member of your family have access to the internet via computer, tablet or smartphone you can also add your experiences to the data collected. If you join up at ukmsregister.org you will be given the opportunity to complete questionnaires covering a variety of topics related to living with MS in the UK today. New questionnaires are added regularly so we will keep in touch with you by email regarding updates.



For further information about the MS Register please contact:



01792 606354



contact@ukmsregister.org



facebook.com/UKMSRegister



twitter.com/UKMSRegister



UK MS Register
Data Science Building,
Swansea University
Medical School,
Swansea, SA2 8PP



Swansea University
Prifysgol Abertawe

