The STEMS Project

Patient Information Sheet

Full study title: The Scottish Treatment in Multiple Sclerosis Project pilot study

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We would like to invite you to take part in this research study. This is a new research project run by a collaboration between the NHS and the University of Dundee. Before you decide whether or not to participate, we need to be sure that you understand firstly why we are doing the study and secondly what it would involve if you agreed to take part. The ultimate aims of this project are to learn more about how multiple sclerosis (MS) affects the people of Scotland, how it is being treated, and to see if we can track the course of MS using a web-based approach.

This information sheet describes the STEMS Project pilot study in more detail. This pilot study is designed to help us understand how to engage participants and collect accurate data. It is important you understand why this research is being done and what it involves, so please read this carefully before signing up to the study. If you want, discuss it with others. We will do our best to explain and provide any further information you may ask for now or later. You do not have to make an immediate decision. If you are interested in helping with this research, please go to the website where you can sign up for the study.

If you have questions, please contact the study team on the above number or email us.

What is the STEMS Project pilot study?

Although research into multiple sclerosis happens all over the world, we still need to learn more about this condition. For example, multiple sclerosis is more common in Scotland than in most other countries, but we do not know why this is. The fact that MS is more common here means that it is important for us to understand how it affects the Scottish population, including discovering exactly how many people have the diagnosis. It is also important to try to understand more about the way it affects the lives of people in this country, and how it is treated and managed. New treatments have become available for MS over recent years. These might change the landscape of multiple sclerosis in the future and it is vital that we can learn about these changes.
We have designed the Scottish Treatment in MS (STEMS) Project to tackle some of these issues. We would like to be able to describe how MS affects the population of Scotland more fully. We are running a pilot of this study in Tayside and North Fife, before we consider expanding it to other parts of Scotland. This study uses a website for participants to submit information about themselves and their condition so that this information can be used for research.

We will check a lot of this information against health records (including hospital notes and test results), which will allow us to learn how useful this sort of information can be. A lot could be learned about MS using the information that is already collected during the normal process of caring for patients in the NHS, but it is even more useful if patients are involved too. The European Medicines Agency have agreed upon the sort of information which a useful MS research database should contain. No databases are widely used in Scotland which gather this information currently.

In summary, the STEMS Project is a new internet-based research study which aims to understand how MS affects the population of Scotland. This project will allow us to learn more about how common MS is and how it is being treated. In the future, we hope that further research into all aspects of MS might be possible using the STEMS Project.

If I take part what will it involve?
The STEMS Project pilot study has two main parts: a questionnaire study directly involving patients with MS who tell us about themselves using a new website, and MS research using anonymised patient information. We are planning to run this pilot study for 12 months.

To be involved in the questionnaire study, you will need to read all of the information and give your consent to take part. A summary of what the study involves is given in the diagram below.
When a patient consents to take part, we will ask them to tell us about themselves and their MS using questionnaires. We will also ask for permission to use the clinical records that are collected as part of their care to study how MS affects patients.

After you create an account on the website, you can sign in and complete the initial sign-up information. The first set of forms might take roughly an hour to complete, but it may be possible to complete this more quickly. You do not need to do them all at one time. We ask about how you were diagnosed with MS and how it affects you, as well as your MS treatment. If you have other health problems, and if you are on other medications, we will ask you to record them. Some of the forms that we use have been used in MS research in the past, whilst some are new for this study.

Once you have completed the set of forms on sign up, we will ask you to complete some of these questionnaires again every 3 months for as long as you agree to take part in the study. We expect these will take 10 to 20 minutes to complete. You can also update some details whenever you wish.

If you consent to take part in the STEMS project, consent will be valid for 5 years from the last date you signed into the website or until you withdraw from the study.

Certain members of the research team will have access to the accounts of study participants. This allows the study team to help update some parts of your account if needed.
Most of the information you submit to the website will be visible to you at any time. For some of the MS questionnaires, we will display the results to you after you complete the questionnaire alongside previous results.

When you consent to join the STEMS project, you will also give permission for the research team to review your clinical records and the data you have submitted. This will allow the study team to understand how things like test results (for example MRI scans or clinical examinations performed in the clinic) relate to the results from the questionnaires. We will collect some of this data in a database.

The information that you submit will not be used to change your treatment or care, for MS or any other health conditions. It is important that you understand that you will not be able to contact your healthcare providers through the website.

Finally, the Tayside pilot of the STEMS Project has been designed as a basic platform which we hope we can improve over time. We will be seeking feedback from participants to understand how it can be improved. As part of this, we may notify you of changes periodically, update the consent form or change the questionnaires. If appropriate, any changes will be approved by research governance and ethics committees.

**Why have I been contacted about the STEMS project pilot?**
The STEMS project pilot is a collaboration between the University of Dundee and local NHS multiple sclerosis services in NHS Tayside. We are writing to patients who are believed to have a diagnosis of MS under the care of an MS specialising neurology consultant, inviting them to join the study.

**Do I have to take part in the STEMS Project?**
It is up to you to decide to take part in the STEMS Project. Participation in this study is entirely voluntary and you are free to refuse to take part or to withdraw from the study at any time without having to give a reason and without this affecting your future medical care or your relationship with medical or nursing staff looking after you.

We plan to write to everyone up to twice to ensure as many people are given the option to join the study as possible. If you do not want to take part you do not need to do anything further in response to any letter from us. However, if you contact us to tell us you do not want to be involved, we can ensure that you will not be contacted a second time.

**What if something goes wrong?**
If you have any concerns about your participation in the study you have the right to raise your concern with a researcher involved in conducting the study or a doctor involved in your care.
If you have a complaint about your participation in the study, you should first talk to a researcher involved in the study. However you have the right to raise a formal complaint.
You can make a complaint to a senior member of the research team or to the Complaints Officer for NHS Tayside.

Complaints and Feedback Team
NHS Tayside
Ninewells Hospital
Dundee DD1 9SY
Freephone: 0800 027 5507
Email: feedback.tayside@nhs.net

In the event that you think you have suffered harm as a result of your participation in the study there are no automatic financial compensation arrangements. However, you may have the right to make a claim for compensation. Where you wish to make a claim, you should consider seeking independent legal advice but you may have to pay for your legal costs.

Insurance
The University of Dundee and Tayside Health Board are Co-Sponsoring the study. The University of Dundee maintains a policy of public liability insurance which provides legal liability cover in respect of damages, costs and expenses arising out of claims.

Tayside Health Board is a member of the NHS Scotland Clinical Negligence and Other Risks Insurance Scheme (CNORIS) which provides legal liability cover of NHS Tayside in relation to the study.

As the study involves University of Dundee staff undertaking clinical research on NHS Tayside patients, such staff hold honoray contracts with Tayside Health Board which means they will have cover under Tayside’s membership of the CNORIS scheme.

You should be aware that if you apply for health, life, travel or income protection insurance you may be asked questions about your health, including medical history, pre-existing medical conditions, if you have had any genetic test or your participation in this study. It is not anticipated that your involvement in the study will adversely affect your ability to purchase insurance but some insurers may use this information to limit the offer of cover, apply exclusions or increase any premium. If you have a diagnosed medical condition, even where the condition is diagnosed as part of a research study, the insurer may take this in to consideration when deciding whether to offer insurance to you.

I do not have a computer, can I still take part?
If you have access to a computer at a library or one belonging to a friend then it is fine for you to use this to take part in the study, as long as you are permitted to use the computer in this way. It is also possible to take part using mobile devices to access the internet, such as a tablet or smart phone.

This study is designed to run through the website, but you can still take part without the use of a computer. There is the option to complete a consent form on paper. This will allow you to provide consent for the study. Please contact us using the details at the end to discuss how this can be arranged.
I do not have an email address; can I still take part?
Without an email address, it is difficult for us to maintain regular contact with you. There are a number of free email services that can be accessed on the internet. However, you can take part in some aspects of the study by post. Please contact us to discuss this further.

What sort of information will you ask for?
We are using online questionnaires to gather information about MS. There are questions about you, including basic information like date of birth and address. We will also collect information about how MS affects you, including general things about your diagnosis and the type of MS you have, or if you have relapses. We also use online versions of questionnaires which are used in MS research more widely.

You can update the basic information about you at any time during the study. We will contact you to ask you to update MS related information every 3 months. The study team may be able to submit information on your behalf.

As well as the information that you submit to the study, with your permission, data will be collected from NHS health records, such as hospital notes and computer records. We will be collecting a very specific set of information from health records. This will be used to check and compare with the information that you have told us. Also, we will collect some specific healthcare information to make sure that the STEMS database has the minimum information which the European Medicines Agency suggests an MS database should hold. This includes some specific laboratory tests and basic information about MRI scan results. We may also use other records to follow your health status, including data from the General Register Office, the Office for National Statistics and death certificates.

The information gathered by the researchers will be stored in the database that only the research team can access.

Is the information I submit secure and safe?
Identifiable information about you and your collected study data will be stored locally and designated members of the research team will have access to this information. For data management purposes, your identifiable information and coded study data data will also be securely stored on a password-protected database(s) in MEMO Research, within the University of Dundee. Specified members of the data management team will also have access to your identifiable information.

Your data will be archived securely for five years after the end of study, after which it will be destroyed. Identifiable information about you will not be published or otherwise shared. Your anonymous study data may be shared with other researchers in the UK.

If you need any further information about the study confidentiality and security, please get in touch.

Will you contact me about anything else during the study?
If you agree to take part in the study, we will contact you to keep you informed about the progress of the study or any specific news which we think you might be interested in.
relating to the study. We will do this by emailing a newsletter. We hope to do further studies using the STEMS Project, about other aspects of MS or treatment. We will contact you to invite you to take part if such studies become available.

**What happens when the study stops?**
The pilot study will last for 12 months. During this time, we will look at what works and if anything needs to be changed, before deciding how to do the STEMS Project in the longer term. We will contact you at around this time to let you know what will happen in the future.

When the study does end we will contact you, and you will be required to have no further involvement.

**What are the possible benefits of taking part?**
The main benefit of taking part in the STEMS Project pilot study is in contributing to improving our understanding of MS, and how it affects the population of Scotland.

**What are the possible disadvantages and risks of taking part?**
The main disadvantage from taking part is that it may take some time to complete the questionnaires. After you first log in it can take some time to complete the first set of questionnaires. After that, only the questionnaires about how MS affects you will be requested every 3 months.

**How is the STEMS Project pilot study funded?**
This study is being sponsored by the University of Dundee and NHS Tayside. The pilot study is funded by the charity Tenovus Scotland to start off the STEMS Project in Tayside. The project is also supported by the NHS Tayside Multiple Sclerosis Endowment Fund. Further funding will be sought to continue the project in the longer term if the pilot is successful. The study has been organised by Dr. Kerr Grieve, Clinical Research Fellow, MEMO Research.

**Has this study received ethical approval?**
The West of Scotland Research Ethics Service, which has responsibility for scrutinising all proposals for research on humans, has examined the proposal and has raised no objections from the point of view of research ethics. It is a requirement that your records in this research, together with any relevant medical records, be made available for scrutiny by monitors from the University of Dundee and NHS Tayside, whose role is to check that research is properly conducted and the interests of those taking part are adequately protected.’

**How would taking part in the STEMS Project pilot affect my multiple sclerosis care?**
Being involved with the STEMS Project pilot does not affect your clinical care in any way. The project involves collaboration with MS care teams to identify possible participants, but you do not have to indicate to them that you are taking part. You should continue to raise any concerns about your MS care with your MS nurse or doctor. If you have questions about the study, please contact us using the details at the top of this page.

**How much time will participation in this research take?**
When you first log into your account after you have consented to join the STEMS Project pilot study, there are a few questionnaires to complete. You do not need to do all of these at one time though. In total, we expect they will take less than an hour.

After the first questionnaires are finished, we will contact you in 3 months to ask you to fill in some of the questionnaires again. These are shorter, and we expect they will take 10-20 minutes to complete. You do not need to complete all the questionnaires at one time, so you can log back in later to finish them if you would prefer to break it up.

If you would prefer not to fill in regular questionnaires for a while, you can ask us to stop sending you reminder emails. This option is easy to access within the web portal, and you can switch it on and off whenever you like.

**Can I withdraw from the STEMS Project pilot study at any time?**

Yes. You can withdraw at any time. The best way to do this is to use the website to withdraw. Please log in to your account on the website or contact us. If you contact us directly, we will be able to withdraw you.

There is a brief questionnaire after withdrawal. This is not compulsory but it will help us understand the reason why you did not want to continue in the study.

If you decide you want to rejoin the study after you have withdrawn then that is okay. If you want to rejoin the study you will need to read the information and provide consent again. To do this please contact the study team before you rejoin so that the database can be prepared.

You may not need to withdraw fully, but you can allow us to continue to track your health events using your health records. In this case, we will no longer contact you with questionnaires to fill in. You can change your mind about this at any time, and you can rejoin the study in the future if you do decide to withdraw. You can select whether you receive questionnaire reminders or not on your account on the website.

**I am already taking part in another study. Can I still take part in this project?**

Yes. You might need to check with the other research team that they are happy for you to join the STEMS Project pilot study. You can also join other studies in the future as you please.

**Data Protection Privacy Notice**

**How will personal information be used?**

We will use your personal data for the purpose of conducting this clinical trial/research study.
University of Dundee/NHS Tayside is the sponsor for this study based in the United Kingdom. We will be using information from you and your medical records in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. University of Dundee/NHS Tayside will keep identifiable information about you for 5 years after the study has finished.

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.

You can find out more about how we use your information at http://www.ahspartnership.org.uk/tasc/for-the-public/how-we-use-your-information and https://www.dundee.ac.uk/information-governance/dataprotection/ and at http://www.nhstayside.scot.nhs.uk/YourRights/PROD_298457/index.htm or by contacting Research Governance, Tayside Medical Science Centre (TASC), 01382 383900 email tascgovernance@dundee.ac.uk. If you wish to complain about the use of your information please email dataprotection@dundee.ac.uk or, informationgovernance.tayside@nhs.net or, you may wish to contact the Information Commissioner’s Office.

NHS will collect information from you and your medical records for this research study in accordance with our instructions.

NHS will use your name, CHI number and contact details to contact you about the research study, and make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study. Individuals from University of Dundee/NHS Tayside and regulatory organisations may look at your medical and research records to check the accuracy of the research study. The study team will pass these details to University of Dundee/NHS Tayside along with the information collected from you and your medical records. The only people in University of Dundee/NHS Tayside who will have access to information that identifies you will be people who need to contact you to for the purpose of this research study or audit the data collection process. The people who analyse the information will not be able to identify you and will not be able to find out your name, CHI number or contact details.

NHS Tayside/University of Dundee will keep identifiable information about you from this study for 5 years after the study has finished.

University of Dundee/NHS Tayside will collect information about you for this research study from your clinical records and national databases. This information will include your name, CHI number, contact details and health information, which is regarded as a special category of information. We will use this information to conduct the research study.

Lawful basis for processing
The University/NHS Tayside asserts that it is lawful to process your personal data for the purposes of the clinical trial/research study. The legal basis on which we process your information is that processing is necessary for the performance of a task (research) carried out in the public interest or in the exercise of official authority vested in the University of Dundee/NHS Tayside.

The University/NHS Tayside asserts that it is lawful to process your sensitive personal data (if applicable) for the purposes of the clinical trial/research study. With respect to sensitive personal information such as data concerning health, the basis on which we process this information is that processing is necessary for scientific research purposes. We are obliged to ensure processing is subject to appropriate safeguards that ensure technical and organisational measures are in place to respect your rights.

If you have any questions about the STEMS Project now or in the future, please contact the study team preferably by email on stemsproject@dundee.ac.uk, or by telephone on 01382 383119.

Abbreviations:

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<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
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<tbody>
<tr>
<td>MS</td>
<td>Multiple sclerosis</td>
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<tr>
<td>STEMS</td>
<td>Scottish Treatment in MS (Project)</td>
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<tr>
<td>NHS</td>
<td>National Health Service</td>
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<tr>
<td>CHI</td>
<td>Community Health Index (number)</td>
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Contact details for further information.

Thanks for taking time to read this information and for considering participating in this study. If you would like more information or want to ask questions about the trial/study please contact the study team using the contact details above. You can contact us Monday – Friday between 09:00-17:00. Or email at any time (we will respond to emails as soon as possible during working hours). Outside of those hours, if you are taking part in the study, and need advice you can contact your out of hours GP service/NHS24 via 111.