Queen Mary
University of London
Barts and The London

Patient information sheet (online)

You are being invited to take part in a research study. Before you decide it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with friends, relatives, your MS team and/or your GP if you wish. Ask us if there is anything that is not clear if you would like more information. Take time to decide whether or not you wish to take part.

We are asking people who have MS and are currently pregnant to take part in this study. This study is being carried out by researchers from across the UK. The Chief Investigator is Dr Ruth Dobson, who is based at Queen Mary University. This study is being done in collaboration with the UK MS Register, who will be responsible for storing the information that is collected about you and your baby during this study.

What is the purpose of this study?

We are conducting a study to look at MS and pregnancy. At the moment, we know that MS seems to become less active during pregnancy, but then may flare up (rebound) in the first 3 months after a childbirth. However, most of this information comes from women with MS who are not taking any disease modifying therapy (DMT).

We don't yet have enough information about the safety of many of the newer DMTs in pregnancy, nor do we fully understand the effect of DMT on MS disease activity during pregnancy. This means that when we talk to women with MS about DMT in pregnancy there are a lot of questions that they have that we currently can't answer properly. It also means that women are getting different advice from different people, which can be very confusing.

We don't know what decisions women with MS are making about breastfeeding, and also what is influencing these decisions. Added to this, we have very little information about the supplements that women with MS take during pregnancy and after having a baby. Importantly, it seems that women with MS have an increased chance of experiencing changes in their mood after having a baby, but there is very little information about this for either women with MS or their healthcare teams. We don't know where women with MS who are experiencing these mood changes turn to for help, or whether they are able to get the help that they need.

We have set up a study (the UK MS Pregnancy Register) to try to help researchers to answer some of these questions, using information about both mothers with MS and their babies. To do this we will collect information on all pregnancies occurring in women with MS, whether or not MS DMT are being taken.

What does taking part in this study involve?

If you decide to take part, we will ask a series of questions both during your pregnancy, and in the first year after you give birth. We will ask you to complete a questionnaire at around 15 weeks pregnant, 24 weeks pregnant, and then 3 months and 12 months after you give birth. The information that we will be asking you for will include personal details (including name and date of birth), details on your MS and MS treatments, and expected date of delivery. We will also ask for information from your pregnancy scans. After you have given birth, we will also ask you questions

about your baby, as well as questions about your mood, how you feed your baby (breastfeeding and formula feeding), and what has influenced these choices.

We will also ask for the details of your GP and MS team, and any other doctors who are involved in your care during this pregnancy or the care of your baby in the first year of its life (for example obstetricians, paediatricians). We may contact these doctors to get extra medical information about you, your pregnancy, and/or your baby. All information is strictly confidential and will not be made available by us to anyone other than healthcare practitioners who are directly involved with your care. If you tell us that you are having particular difficulties with your mood we will let your GP know, as this is important clinical information that they should be aware of.

We will be asking you these questions online, via a secure website. If you find it tricky to use the website for any reason, you are free to ask someone to help you. At the moment, we do not have facilities to allow people to take part in this study using any other means. We are sorry if this stops you from being able to take part, and would be interested to hear if this is the case, so that we can take this into account as we develop the study.

We are also asking for your permission to get in touch with you in the future, so that we can tell you about other studies that follow on from this study, and to see if you want to take part in these studies. Any such studies would need to have ethical permission to get in touch with you in this way before making any contact. We need to keep your contact details in order to allow us to do this. If you do not want us to get in touch with you in this way in the future then please let us know.

It is up to you to decide whether or not to take part. If you do decide to take part you will be asked to complete a consent form before providing any personal details or answering any study questions. If you decide to take part, you are still free to withdraw at any time and without giving a reason. This will not affect the medical care you receive.

As part of this study your information will be stored on UK MS Register systems, as part of the UK MS Register. The UK MS Register may ask for your permission to link to your medical records held on national systems; this will be done in person via your MS team.

Any results from the study will be presented only in a way that does not allow you, or anyone else who takes part in the study, to be identified.

If you decide to take part, you and/or your child will not be required, as part of this study, to make any additional visits to any clinics or to have any additional tests or procedures. If, in the future, we are taking part in other studies that may be of interest to you, we may send you relevant information by email or post so that you can decide whether or not you wish to take part. You are under no obligation to take part in any such studies. If you wish to contact us for any further information, contact details are as given at the bottom of this page.

What are the benefits of taking part in this study?

There are no direct benefits to you for taking part in this study. However, we hope that information from this study will improve the care of women with MS considering pregnancy in the future.

What are the risks of taking part in this study?

There are 2 main risks of taking part in this study. The first is that you may find some of the questions upsetting. We appreciate that asking personal questions about pregnancy may be very upsetting in some cases, and where this may be the case you do not need to answer any or all of the questions that we are asking you. We have provided information about charities that are able to provide support in some of these cases.

The other risk is that information about you, and that allows you to be identified, may leave the secure environment where it is stored. This is a risk whenever information is stored electronically. We are using the highest level of encryption, and storing information that could identify you separately from all other information about you in order to minimise the chances of this happening.

Do I have to take part in this study?

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.

If you have any concerns about taking part in this study, please first contact the study team.

What if I want to make a complaint about this study?

If you want to complain about how researchers have handled your information, you should contact the research team in the first instance. If you are not happy after that, you can contact Barts Health PALS by telephone on 0203 594 2040 or via email on RLHpals.bartshealth@nhs.net. If your complaint is about how your information has been handled, you can also contact the QMUL Data Protection Officer by emailing data-protection@qmul.ac.uk

If you are not happy with their response or believe they are processing your data in a way that is not right or lawful, you can complain to the Information Commissioner's Office (ICO) (www.ico.org.uk or 0303 123 1113).

What will happen to information about me as part of this study, and will my taking part in this study be kept confidential?

We will follow ethical practice and all information about you will be handled in confidence. We will need to use information from you, from your medical records, your GP, and other people involved in the care of your MS and the care of your child (where relevant) for this research project. This information will include your and your childs' name, date of birth, contact details, and NHS number. This information will be used to do the research and/or to check your records to make sure that the research is being done properly.

We will keep all information about you safe and secure. All the information collected as part of this study is stored on secure servers with the highest levels of encryption. Where we collect identifiable data, this is stored separately from any other information about you. Identifiable data is information that could identify you, such as your name, date of birth, or NHS number. People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.

Your individual data will not leave the MS Register servers. If these is an occasion where we want to move your data away from these servers will we contact you to seek your permission to do this. We hope that if this study is successful to keep the data collected as part of this study as a research database; if this is the case we will email you to tell you that we are doing this, and give you the option to withdraw your data from this database.

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

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 tell us or inform your MS team.

What are my choices about how your information is used?

You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have. We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you. If you agree to take part in this study, you will have the option to take part in future research using your data saved from this study.

If you choose to stop answering questions as part of this study, we would like to continue collecting information about your health from central NHS records, your hospital, your GP, and any other healthcare providers you have told us about. If you do not want this to happen, tell us and we will stop.

Where can you find out more about how your information is used?

You can find out more about how we use your information

- At https://www.hra.nhs.uk/information-about-patients/
- At http://www.arcs.qmul.ac.uk/governance/information-governance/data-protection/
- By asking one of the research team
- By sending an email to data-protection@qmul.ac.uk

Where can I find the results of this study?

Regular reports on the progress of the project are sent to our funders - the Horne Family Trust – and to the XXX Ethics committee. We will also share any results and updates about this study via the blog on the homepage.

Who has reviewed this study?

The study has been reviewed and been given approval by Central Bristol Research Ethics Committee, an independent NHS Research Ethics Committee in order to protect your safety, rights, wellbeing and dignity.

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 in some hospitals. 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 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.