Menstrual cycle and MS-related symptom tracking: App Development

Participant Information Sheet

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You are being invited to take part in this research study. We've created this leaflet to help you understand why the study is being carried out and what it will involve.

Reading this leaflet, discussing it with others or asking any questions you might have will help you decide whether or not you would like to take part. The research team are more than happy to answer any questions, and contact details are provided on the final page.

What is the purpose of this study?

Multiple sclerosis (MS) is a disease that affects three times as many females as males. Despite this, little is known about how hormones such as oestrogen influence the disease. More is known about how pregnancy and the menopause affect MS-related symptoms and disability, but less is known about how the menstrual cycle alters the lives of females with MS.

Individuals with MS often experience unpredictable changes in disease-related symptoms such as fatigue, muscle weakness, poor balance and co-ordination. Previous research in females with MS has suggested that these symptoms have the potential to be worsened at key points of the menstrual cycle. Specifically, just before or during menstruation, these symptoms tend to be worse. Despite the research done so far, no research has looked in detail at how different symptoms change across the menstrual cycle.

This project aims to develop a mobile phone application that people with MS can use to report their symptoms daily. This will use validated clinical questionnaires, to see which symptoms change across the menstrual cycle, and how much they change by. To achieve this, we will use a co-design approach. This means the researchers will work alongside those with MS, clinicians and app developers to create an app that is easy to use.

Why have I been invited?

You have been invited to take part in this study because you are either:

- A woman with MS who is not using any hormonal contraceptives (e.g., the pill, implant, injection).
- A woman with MS who is using a form of hormonal contraceptives.
- A man with MS.
- A clinician involved in the care of people with MS.
- An app developer.
- An academic who is researching MS.

Do I have to take part?

Your participation is voluntary. This information sheet is to help you make that decision. If you decide to take part, you can stop participation at any point without any need for explanation. You are completely free to decide whether or not to take part, or to take part and then leave the study before it ends.

What will happen if I take part?

The app development will take place in three phases. You will be involved at each stage, with the opportunity to provide feedback throughout the process. This three-phase approach has already been used by the research team to develop apps for people with Parkinson's Disease.

Phase 1: Development

This phase involves attending a focus group (approximately 1 hour, hosted online via Microsoft Teams or Zoom). During this the research team will outline the concept of the app and present their plans and drawings. During the focus group there will be a chance to ask questions and provide feedback. You will also be given an offline version of the app to look at in your own time. After 1-2 weeks of the focus group, we will ask you to write down any extra feedback you might have about the look, the language, and the layout of the app. Following this, your feedback will be used to build the prototype of the app. The research team will respond to your comments explaining how we have adapted the app from your comments. If you have more comments or suggestions we will continue to revise the app until everyone is happy with its contents.

Phase 2: Implementation

The next phase involves those with MS downloading the app to their phone and using it for one full menstrual cycle (or one-month equivalent time period). If you do not have a compatible device with Android as the operating system, the research team will send you a suitable smartphone and step-by-step instructions. The research team will contact you once per week for the duration of this phase to provide support if required. Each day, you will be prompted by the app to report your MS-related symptoms and menstrual cycle or hormonal contraceptive cycle-related symptoms (women only). If you forget to report symptoms for three days in a row, a member of the research team will contact you to remind you or help to solve any technical issues.

Phase 3: Evaluation

Following the one cycle/month reporting period, you will be asked to evaluate the app in two ways: First, the research team will send you a 'System Usability Scale' questionnaire, which asks you to rate the following statements on a scale of 1 (strongly disagree) to 5 (strongly agree):

1. I think I would like to use the app frequently
2. I found the app unnecessarily complex
3. I thought the app was easy to use
4. I think that I would need the support of a technical person to be able to use the app
5. I found the functions of the app were well integrated
6. I thought there was too much inconsistency in the app
7. I would imagine people would learn to use the app very quickly
8. I found the app to be very awkward to use
9. I felt very confident using the app
10. I needed to learn a lot of things before I could get going with the app

After everyone has completed the questionnaire, you will be asked to attend an online follow-up focus group to provide feedback on your use and experience of the app (approximately one hour). We will ask questions that allow us to assess the usability of the app, the user experience, and its clinical implications. Once the focus group has been completed, the research team and app developers will use this feedback to adjust the app for the final time, once again sending you an update explaining how your feedback has been used.

Once all three phases have been completed, the research team will apply for ethical approval to run the larger scale study where 90+ people with MS will report their symptoms daily. This larger scale study is separate from this app development study, and you are under no obligation to take part in this.

What are the possible disadvantages of taking part?

Aside from the time commitment required to participate, for which we are extremely grateful and will remunerate you in accordance with NHS guidelines (see below), there are relatively few disadvantages. Monitoring and reporting your symptoms daily might result in your becoming more aware of your experience of MS, and to those unfamiliar with this process, this could result in some negative thoughts or feelings. The questions that the app will ask you are based on validated clinical questionnaires, meaning that the language used is intended to be neutral and not cause any distress. However, if the process does cause any negative emotional consequences, or concerns about your symptoms, you are free to withdraw from the study at any time and would be advised to contact your local MS support team (e.g., MS nurses) to discuss this.

What are the possible benefits of taking part?

Historically, women's health wasn't the focus of much MS research. So there is a lot we don't know about how and why MS affects women differently. Your participation in this study will be crucial in developing the tools used in future research that aims to gain a better understanding of how the menstrual cycle influences a woman's experience of MS.

Additionally, in accordance with National Institute for Health and Care Research (NIHR) guidance for public involvement in research, we will provide you with a payment of £75 for your involvement in this study. This aligns with the NIHR's policy for involvement in a task or activity where preparation is required and which equates to approximately half a day's activity (e.g., 2 one-hour focus groups).

Finally, the research team intend to publish a scientific paper describing the process and its key findings, with the intention of encouraging other research groups to take this co-design approach to developing clinical tools. Because of the key role you will play in developing these clinical tools, we would like to include you as a co-author on this publication. This is completely optional, and you are under no obligation to be listed as a co-author.

How can I withdraw from the study?

If you do wish to withdraw then you can do so without any judgement or negative consequences. Simply email any of the research team informing us that you do not wish to continue with testing. You do not have to give any reason.

Will my taking part in this study be kept confidential and anonymous?

All data will be dealt with under the strictest of guidelines and according to the Data Protection Acts of 1984 and 1998, and General Data Protection Regulation (GDPR) 2016. All data you provide (e.g., questionnaire responses, written feedback, and focus group discussions) will not be attributed to you (i.e., linked to your name). However, as mentioned above, we would like to list you as a co-author on any eventual publications that arise from the study. This means that your involvement in the study would not be confidential, but to ensure that your individual responses are not linked directly to you, we will summarise feedback into 'key themes' that generalise your comments. You will also have the opportunity to provide feedback and ask for adjustments to any eventual publications that arise from your involvement in the study if you are not satisfied with how your data has been represented.

How will my data be stored?

All data will be stored in accordance with University guidelines, the Data Protection Act and General Data Protection Regulation. Data will be stored on a password protected computer and backed up onto a password protected cloud storage service that will only be accessible to the researchers. As the data subject, you have the right

to access your own data at any time, and request it to be removed from the study, if you wish. If you are unsatisfied with how your data has been handled, you can lodge a complaint with the Information Commissioner's Office (ICO).

How will my data be processed?
We will store your data according to the section above, and we will process your data under Article 9(2)(j) GDPR, which permits processing that is necessary for scientific or historical research purposes, providing we have appropriate security safeguards in place. Your personal data will not be exported outside of Northumbria University, and only the research team will handle this information.

Who is organising and funding the study?
This study is organised by researchers at Northumbria University, under the supervision of the Principal Investigator (Dr Paul Ansdell). The study is funded by the MS Society (registered charity: 1139257/SC041990), as part of the research grant titled 'Menstrual-related worsening of multiple sclerosis: when and why?' (reference number: C005-24.1). The study is also supported but not funded by MS Together (registered charity: 1200565).

What will happen to the results of the study?
As mentioned above, the findings from this study will be used to develop tools that the research team will use in future research. In addition, the research team might present the findings at academic conferences, and write a scientific paper describing the study for publication.

Who has reviewed this study?
This study has received ethical approval from the Northumbria University Faculty of Health and Life Sciences Research Ethics Committee (reference ID: 9764). This involves independent review by researchers to assess that what we are asking of you is appropriate and ethically sound, followed by approval from the Department Ethics Lead (Dr Claire Thornton). If you require confirmation of this, please contact Dr Thornton (claire.thornton@northumbria.ac.uk).

For further information…
If you have any questions about this study or this information sheet, please contact either of the lead investigators:

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