A Multidisciplinary Study of Cognition in Multiple Sclerosis

Information Sheet

Why is this study being done?

You are being invited to take part in a research study to be carried out at Beaumont Hospital, under the supervision of Prof. Orla Hardiman, Principal Investigator and Consultant Neurologist. Changes in cognition (thinking and memory) are common in people with Multiple Sclerosis (MS) and can interfere with daily functioning and quality of life. However, these changes remain poorly understood. There is also a need for better and more reliable measurements of cognitive processing in people with MS. Because of this, it is difficult to design treatments that can improve cognitive performance in those affected.

This study aims to improve our understanding of the cognitive changes in MS to better understand the needs of patients.

Why am I being asked to take part?

We are asking individuals 18 years or older with a diagnosis of MS to take part in this study.

What will happens to me if I agree to take part?

If you are interested in taking part in this study, we will firstly explain the study in greater detail over the phone and, if you are willing to participate, you will be invited to sign the consent form (sent to you via post).

This study involves completing a brief cognitive questionnaire which will assess your thinking (approx. 10 mins to complete). This will be posted to you to complete at home. A stamped and addressed envelope will be provided for you to return the questionnaire to the research team.

You may also be invited to complete additional cognitive tests that will assess your thinking in greater detail. These paper and pencil tests will take approximately 2 hours to complete. To ensure the safety of all participants**,** these tests will be completed through a virtual appointment using a secure video-link (T-Pro). This will allow you to complete the tests from the comfort of your home.

As part of this study, you may also be invited to take part in EEG recording sessions, which lasts approximately 2.5 hours and will be carried out at St. James's Hospital – Clinical Research Facility. We will reimburse you for any reasonable and vouched travel expenses up to a value of €50 for this visit. There will be no other costs associated with your participation in this study.

You don't have to take part in this study. You can change your mind about taking part in the study any time you like. Even if the study has started, you can still opt out. You do not have to give us a reason.

What are the benefits?

While there is no direct and immediate benefit to you in participating, this study is hoping to benefit people with MS by increasing our understanding of the cognitive changes that take place over the course of the disease.

What are the risks?

There are minimal risks anticipated from taking part in this research study, as the procedure and devices are safe and commonly used.

If you do become fatigued while completing the cognitive tests and questionnaires you will be offered to take refreshment breaks at any time.

In terms of the EEG recordings, in the unlikely event that you show allergic reactions to the gels, the experiment will stop and we will provide medical advice to treat the reaction. There may also be discomforts for you during the recordings, as you may find the EEG session to be boring, tiring and fatiguing as it includes sitting in a chair for 1-2 hours.

If at any time you feel that your participation in this study has become unduly stressful, you are free to discontinue. This will not affect in any way the quality of care that you receive.

There is no intention to look for diseases using the recorded data. In the unlikely case of incidental findings in the EEG recordings that may be an indirect sign of a previously unknown disease, you will be asked for permission to discuss the findings with a neurologist, your GP or other appropriate doctor.

Confidentiality and Data Protection

All information which is collected about you during the course of the research will be kept strictly confidential. Only members of the research team, under the approval and supervision of Prof. Orla Hardiman, Principal Investigator will have access to research participants' information. Procedures for this study are carried out in accordance with Article 6 and 9 of the General Data Protection Regulation (GDPR) 2016.

Where can I get further information?

If you are interested in participating, or have any questions about the study, please contact the researcher listed below:

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