

# Is muscle weakness in Multiple Sclerosis exacerbated with exercise?

## Participant Information sheet

**GU ethics approval reference: 2023/128**

### Who is conducting the research?

**Chief Investigator**

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**Chief Investigator**

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**Chief Investigator**

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**Medical Practitioner**

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### Why is the research being conducted?

Multiple sclerosis (MS) is a chronic and progressive demyelination disease of the central nervous system (CNS) that affects over 25 600 persons in Australia and more than 2 million worldwide. In MS, immune cells attack the insulating layer (myelin) around nerves residing in the CNS, resulting in the formation of scar tissue (sclerosis). Damaged nerves can impair the neural transmission that is essential for voluntary muscle contraction and muscle control from the CNS to the skeletal muscles. Impairment in neural transmission can be associated with muscle weakness and muscle fatigue, which are commonly reported symptoms in MS and can drastically impact the ability to perform work, exercise and day-to-day tasks. Despite the impacts that muscle fatigue can have on the quality of life in persons with MS, the mechanisms underlying muscle fatigue in the MS population remain poorly understood. This study will examine both the neural drive and muscle components, mechanisms that may potentially contribute towards the everyday muscle fatigue experienced in persons with MS.

### What you will be asked to do

If you agree to participate in this study, you will need to visit the Neural Control of Movement Laboratory (Griffith University, Gold Coast Campus) for a testing session lasting approximately 2.5 hours. At your first session you will need to complete a medical history questionnaire, the

Modified Fatigue Impact Scale (MFIS), and the Fatigue Severity Scale (FSS).

In your sessions, we will examine electrical activity in your muscles with a technique known as High-Density Electromyography to provide information about how well your nervous system activates your muscle. To do this, an adhesive electrode will be placed on the vastus lateralis muscle (part of your quadriceps) and you will be asked to contract your muscle by pulling against a strap attached to your ankle. Multiple contractions and contraction intensities will be required to assess your muscle contraction capacity. After we obtain your normal capacity to contract muscles, we will ask you to fatigue each muscle (similar to a workout at the gym) before we assess your muscle activity once again.

Following muscle activation studies with the use of high-density electromyography, you will be asked to participate in a walking test. The walking test requires you to walk as far as you can in 6 minutes up and down an indoor corridor. You will also be asked to complete a stair climb test, wall squat test and timed sit to stand test.

### **The basis by which participants will be selected or screened**

We are recruiting both healthy individuals and persons with relapsing remitting type multiple sclerosis. You can participate in the study if you are not pregnant, have no known neurological disorders (other than MS) and do not have an implanted medical device, such as a pacemaker.

You will not be eligible for this study if you have had any peripheral nerve pathologies and/or musculoskeletal injury affecting the upper arm, or if you have had an MS-related relapse within the last three months.

If you are not eligible to participate in the study, your relationship with the investigators and Griffith University will not be affected in any way. You will be asked to complete a medical history questionnaire, a Modified Fatigue Impact Scale and a Fatigue Severity Scale, so we can screen your suitability to undertake our study.

### **The expected outcomes of the research**

The primary benefit from this study is that we will be able to better understand the mechanisms involved in muscular fatigue in people with MS. Information of this nature has the potential to provide a tool for clinicians to i) objectively quantify the presence/severity of fatigue in the MS patients and ii) assist in discovering new treatments. Given that people with MS have reported that muscle fatigue interferes with their ability to perform work, exercise and day-to-day tasks, these outcomes from the study can positively impact the MS community by improving their quality of life and protecting their livelihood.

### **Risks to you**

It is unlikely that you will experience any adverse effects during the testing session whether you are healthy or have MS. Previous studies have shown that exercise testing is safe for people with MS and does not increase the rate of relapses. In the unlikely event that you do experience any adverse effects during the testing session, Dr Heshmat will be available to assist you either by telephone, at Griffith University, or at the Gold Coast University Hospital. If you still have specific questions related to the risk of experiencing a relapse while considering your participation in this study, you can also contact Dr Heshmat via the email on the front page.

There are no known complications for High-density Electromyography procedures, so the risks to you when undertaking this measurement is negligible. Please note that you will be asked to complete fatiguing exercises and a range of leg contractions. It is likely that you will be tired after the session and that your muscles may be sore the day(s) following participation. This is a normal symptom of exercise referred to as delayed onset muscle soreness (DOMS).

In the unlikely event that you require medical treatment due to our testing procedures, you will be immediately attended by the supervising researcher who will administer first aid and manage your care. For serious events, an ambulance will be called and you will be taken to the emergency department of the hospital as directed by the paramedical staff and all the associated expenses will be covered as per university policy. Specifically, if an adverse event occurs, insurance cover for this study is via the Griffith University public liability policy under the 'legal liability for personal injuries to a third party caused by an event in connection with our business.' In the case of any event, one of the chief investigators of the study or a doctor associated with the university will write a letter for you to present to your general practitioner advising them of the findings.

### **Your confidentiality**

The investigators listed on the front page will be the only people with access to your records. All of your data and documents will be de-identified. This will be done by allocating a number to you (01, 02, 03 etc.) based on when you are enrolled into the study. Your informed consent document and medical history questionnaire will be stored in a lockable filing cabinet in the Neural Control of Movement Laboratory at Griffith University (G02\_2.12). This room is secure and can only be accessed by swipe card by a small number of staff and students approved to work in the laboratory. Electronic data pertaining to muscle activity will be stored in the Griffith University Research Storage Drive. The testing laboratory currently has secure password protected account for this system, where the data from the current study can only be accessed by the investigators on this application. Personal information will be stored for 5 years following the completion of the study to meet with requirements of State and Commonwealth governments. Following this period all data will be destroyed via approved and safe mechanisms at Griffith University.

### **Your participation is voluntary**

It is important that you freely volunteer to take part in this study. Your involvement in the study does not give you added benefits with Griffith University or the allied health practice that displayed the recruitment flyer for this study. You are free to withdraw from the study at any time, and of course, there will be no penalty if you choose to do so. Any decision to withdraw from the study will not impact on your relationship with the university or the allied health practice that displayed the recruitment flyer for this study.

### **Feedback to you**

If you would like a summary of your results, you are welcome to contact Marc Bruneau via email ([m.bruneau@griffith.edu.au](mailto:m.bruneau@griffith.edu.au)). He will then provide a short document in plain language which describes how your results fit into the context of the study.

### **Questions or further information?**

If any aspect of the study concerns you, or you have other questions regarding the investigation, please do not hesitate to contact one of the chief investigators whose contact details appear on the front page.

### **The ethical conduct of this research**

This project has been approved by the Griffith University Human Research Ethics Committee (GU Ref No: 2023/128). Griffith University conducts research in accordance with the *National Statement on Ethical Conduct in Human Research*. If you have any concerns or complaints about the ethical conduct of the research project you should contact the Manager, Research Ethics on 3735 4375 or [research-ethics@griffith.edu.au](mailto:research-ethics@griffith.edu.au).

### **Privacy Statement**

The conduct of this research involves the collection, access and use of your identified personal information. As outlined elsewhere in this information sheet, your de-identified personal information may appear in publications arising from this research. This is occurring with your consent. Any additional personal information collected is confidential and will not be disclosed to third parties without your consent, except to meet government, legal or other regulatory authority requirements. A de-identified copy of this data may be used for other research purposes. However, your anonymity will at all times be safeguarded, except where you have consented otherwise. For further information consult the University's Privacy Plan at <http://www.griffith.edu.au/about-griffith/plans-publications/griffith-university-privacy-plan> or telephone (07) 3735 4375.

**Thank you for your assistance in this research project**

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**Medical Practitioner**

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Department of Neurology, Gold Coast  
University Hospital  
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This project has been approved by the Griffith University Human Research Ethics Committee (GU Ref No: 2023/128). By signing below, I confirm that I have read and understood the information package and in particular have noted that:

- I understand that my involvement in this research will include a visit to the Neural Control of Movement Laboratory (G02 room 2.12).
- I have had any questions answered to my satisfaction;
- I understand the risks involved;
- I confirm I do not have any of the exclusion criteria listed on the participant information sheet;
- I understand that there will be no direct benefit to me from my participation in this research;
- I understand that my participation in this research is voluntary, and I understand that my decision to participate in no way impacts upon the service I receive from Griffith University or the Investigators of this project;
- I understand that if I have additional questions I can contact the research team;
- I understand that I am free to withdraw at any time, without explanation or penalty;
- I understand that I can contact the Manager, Research Ethics, at Griffith University Human Research Ethics Committee on 3735 4375 (or [research-ethics@griffith.edu.au](mailto:research-ethics@griffith.edu.au)) if I have any concerns about the ethical conduct of the project; and
- I agree to participate in the project.

**Signature:** \_\_\_\_\_

**Name:** \_\_\_\_\_

**Date:** \_\_\_\_\_