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**Do interventions targeting proprioceptive feedback and exercise improve functional gait and reduce falls and falls risk in people with multiple sclerosis?**

**PARTICIPANT INFORMATION STATEMENT**

**What is this study about?**

You are invited to take part in a research study of exercise interventions to improve walking and reduce falls and falls risk in people with Multiple Sclerosis (MS).

We, the investigators, hope to learn whether the addition of interventions targeting sensory feedback about movement (proprioception) during exercise can improve mobility, safety, and reduce falls in people with MS.

**Who is being invited to participate in this research?**

You have been invited to participate in this study because you registered your interest in the study by responding to one of our advertisements, and you meet the following inclusion criteria:

You are aged between 18-65

You have been diagnosed with multiple sclerosis

You have not had any recent major injuries or surgeries to your upper or lower limbs

You can walk independently (with or without the use of an assistive device)

You have not had a relapse within the last 3 months

You have not had corticosteroid treatment within 28 days of the study commencement

You have been cleared by your doctor to engage in exercise

To your knowledge, you are not pregnant

This Participant Information Statement tells you about the research study. Knowing what is involved will help you decide if you want to take part in the research. Please read this sheet carefully and ask questions about anything that you do not understand or want to know more about.

Participation in this research study is voluntary.

By giving your consent to take part in this study you are telling us that you:

* Understand what you have read.
* Agree to take part in the research study as outlined below.
* Agree to the use of your personal information as described.

You will be given a copy of this Participant Information Statement to keep.

The study is being carried out by the following researchers:

Dr David Kennedy – Lecturer, Discipline of Physiotherapy, Faculty of Health Sciences, University of Sydney

Dr. Phu Hoang - Senior Research Officer, Neuroscience Research Australia

Associate Professor Colleen Canning - Discipline of Physiotherapy, Faculty of Health Sciences, University of Sydney

Professor Stephen Lord - Senior Principal Research Fellow, NHMRC; Conjoint Professor, UNSW, Neuroscience Research Australia

Sylvia Mai – Honours Student, Discipline of Physiotherapy, Faulty of Health Sciences, University of Sydney

This study is being funded by MS Research Australia.

**What will the study involve for me?**

This study examines an intervention that provides additional sensory feedback during exercise. We are investigating the effectiveness of home-based whole-body vibration training to improve mobility outcomes and reduce prospective falls and or falls risk compared to standard exercises in people with MS.

**The use of whole body vibration during exercise to reduce falls and improve mobility**

Whole body vibration involves the transfer of vibrations from a vibrating platform to the body via the feet. This study uses whole body vibration training, which involves performing exercises while standing on a vibrating platform. This is thought to improve sensory feedback during the exercise and may increase muscle activation. If you elect to participate you will be randomly allocated to one of two exercise groups. One group will perform exercises on a whole body vibration platform while the other group will perform the exercises on the ground. The WBV platform (supplied by SaunaGem Australia) will be placed in your home at no cost to you for the duration of the 10-wk study.

There will be an initial 45-minute assessment session to measure your walking abilities and falls risk. We will also collect basic demographic details from you such as your age, gender, severity of your multiple sclerosis, and mobility status. None of this information will be published or disclosed to anyone outside the research team. All testing sessions will be held at the University of Sydney Cumberland Campus or at Neuroscience Research Australia.

The tests you will be asked to perform are listed below and you will be given sufficient rest between each test.

1. The Physiological Profile Assessment will be used to test your visual acuity, walking, coordination, sensation, and strength to determine your falls risk
2. The Timed Up and Go Test will be used to measure the times it takes you to get up from a chair, walk 3m, turn around and return back to sitting in the chair again.
3. The choice stepping reaction time (CSRT) which requires participants to stand on a portable rubber mat and step quickly and accurately onto four targets for a total of 20 steps while being timed.
4. The 9-Hole Peg Test (9HPT) which consists of moving pegs from a box into holes on a peg-board then back again.
5. The symbol-digit test (SDMT). This test requires participants to pair specific numbers with given geometric figures in 90 seconds.
6. The 10 Metre Walk test will measure the time it takes you to safely walk 10 metres
7. The 6 Minute Walk Test will measure the distance you can walk safely in 6 minutes

We will use the 9HPT, the SDMT, and the 10-meter Walk test to determine the multiple sclerosis functional composite (MSFC) score. The MSFC provides a composite score that relates to mobility and disability levels.

You can choose to return for a second assessment 1 week after the initial assessment using the same tests. You can elect to participate in the second assessment by ticking the box on the Consent form under *Additional Assessment*.

After the initial assessment (or the second assessment if you choose to do so) you will be randomly assigned to one of two exercise groups and asked to commit to a 10-week home-based exercise program consisting of four exercises that will take approximately 20-30 min to complete and to keep a falls diary to track any falls or near falls during and for 10 weeks after your participation in the exercise program. A trained research assistant (either a physiotherapist or exercise physiologist) will make a home visit to teach you the exercises before you start the program. For those allocated to the whole body vibration group, whole body vibration platforms will be installed during the home visit and you will be taught how to use them properly. This home visit should take up no more than 1 hour of your time.

After 5-weeks of the home-based exercise program, a second home visit will be made to progress your exercises and check your technique. A final home visit will be made at the completion of the 10-week exercise program to collect whole body vibration platforms from those allocated one. The completed falls diary will need to be mailed back to our research facility each month.

**Do I have to be in the study? Can I withdraw from the study once I've started?**

**Being in this study is completely voluntary and you do not have to take part. Your decision whether to participate will not affect your current or future relationship with the researchers or anyone else at the University of Sydney, Neuroscience Research Australia, or your doctors.**

If you decide to take part in the study and then change your mind later, you are free to withdraw at any time. You can do this by signing the Revocation of Consent form at the end of the Information and Consent form.

If you decide to withdraw from the study, we will not collect any more information from you. Any information that we have already collected, however, will be kept in our study records will be included in the study results. This is because the study is designed to give us the most definitive answer to whether the intervention was effective or not and that includes partial results. You can elect to have your results withdrawn by ticking the box on the Revocation of Consent form.

**Are there any risks or costs associated with being in the study?**

As a participant you may experience mild discomfort and/or fatigue during and after the testing and exercise sessions. Some people may develop mild soreness in some muscles one to two days after exercise. You will also be taught how to safety perform the exercises and use equipment to minimise any risk.

**What happens if I suffer injury or complications as a result of the study?**

If participation in the study results in any adverse effects we will ensure that you receive appropriate medical care. If you experience an adverse side effect please inform us, the investigators, immediately so that appropriate medical care can be provided and the study terminated if required. This document also includes contact details of the investigators and details of emergency services available in case any side effects occur after you have left the institute.

You may have a right to take legal action to obtain compensation for any injuries or complications resulting from the study. Compensation may be available if your injury or complication is caused by the procedures, or by the negligence of any of the parties involved in the study. If you receive compensation that includes an amount for medical expenses, you will be required to pay for your medical treatment from those compensation monies.

If you are not eligible for compensation for your injury or complication under the law, but are eligible for Medicare, then you can receive any medical treatment required for your injury or complication free of charge as a public patient in any Australian public hospital.

**Are there any benefits associated with being in the study?**

We cannot and do not guarantee or promise that you will receive any benefits from this study.

**What will happen to information about me that is collected during the study?**

By providing your consent, you are agreeing to us collecting personal information about you for the purposes of this research study. Your information will only be used for the purposes outlined in this Participant Information Statement, unless you consent otherwise.

Your information will be stored securely and your identity/information will be kept strictly confidential, except as required by law. Study findings may be published, but you will not be individually identified in these publications.

Any information that is obtained in connection with this study and that can be identified with you will remain confidential and will be disclosed only with your permission or except as required by law. If you give us your permission by signing this document, the combined results of the whole study will be used for research purposes, however your individual results will not be released to any person, including medical practitioners, except as required by law. Your data will be identified through subject ID numbers. Data forms will be held within a locked laboratory at University of Sydney. If you do participate in future studies with these researchers, data from this study may be used and thus, needs to be stored in potentially re-identifiable form. We plan to publish the results in the form of scientific journal articles and conference presentations. In any publication, information will be provided in such a way that you cannot be identified.

**What will happen to my treatment when the study is finished?**

For both projects, you will have been instructed in home exercise interventions that you will be able to continue independently if you choose.

**Can I tell other people about the study?**

Yes, you are welcome to tell other people about the study.

**What if I would like further information about the study?**

When you have read this information, Dr. Phu Hoang will be available to discuss it with you further and answer any questions you may have. If you would like to know more at any stage during the study, please feel free to contact Dr. David Kennedy at 61 2 9351 9589 or by email at david.kennedy@sydney.edu.au.

**Will I be told the results of the study?**

You have a right to receive feedback about the overall results of this study. You can tell us that you wish to receive feedback by contacting Dr. David Kennedy at 61 2 9351 9589 or by email at david.kennedy@sydney.edu.au. A summary of research findings will be offered to research participants at the completion of the study. We will email you a plain language summary of the findings. In addition, you may wish to receive a summary of your personal results collected during the assessment sessions. If you wish to receive this information, please tick the relevant box on the consent form.

**What if I have a complaint or any concerns about the study?**

Research involving humans in Australia is reviewed by an independent group of people called a Human Research Ethics Committee (HREC). The ethical aspects of this study have been approved by the HREC of the University of Sydney [INSERT protocol number]. As part of this process, we have agreed to carry out the study according to the National Statement on Ethical Conduct in Human Research (2007). This statement has been developed to protect people who agree to take part in research studies.

If you are concerned about the way this study is being conducted or you wish to make a complaint to someone independent from the study, please contact the university using the details outlined below. Please quote the study title and protocol number.

The Manager, Ethics Administration, University of Sydney:

Telephone: +61 2 8627 8176

Email: ro.humanethics@sydney.edu.au

Fax: +61 2 8627 8177 (Facsimile)

This information sheet is for you to keep