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**Information letter to participants**

**Study 4**

**Effect of a neuromuscular electrical stimulation (NMES)/vibration-driven muscle strength training intervention on muscle force, physical function and health, and quality of life in people with a spinal cord injury**

Thank you for expressing your interest in this research. The purpose of this document is to explain the study that you may choose to participate in as a subject. Please read this document carefully, and do not hesitate to ask any questions.

**Project background information**

Neuromuscular electrical stimulation (NMES) is commonly applied to muscle (using stick-on pad electrodes) to improve muscle strength in people with spinal cord injuries (SCI), however a major problem associated with this electrical stimulation is that the muscles fatigue very quickly. The purpose of this study is to implement a novel exercise training method of electrical stimulation and examine physical health outcomes after the training period. In order to do this, you will perform some assessments before and after the training period. This research has been approved by the ECU Human Research Ethics Committee.

**Project aims**

To examine the effects of 12-week muscle strength training intervention using an electrical stimulation protocol based on the results of Study 2 (with or without tendon vibration), on muscle force production, symptoms of spasticity, functional capacity, physical health and quality of life in people with SCI.

**Methodology**

If you choose to participate in this study, you will be asked to attend the Physiology laboratory at ECU for 12 weeks, coming twice a week and you will complete the Physical Activity Readiness Questionnaire (PAR-Q) to ensure safe exercise participation, and you will need to refrain from vigorous exercise (for 48 h) and alcohol (for 24 h) and stimulant consumption (e.g. caffeine, energy drinks for 6 h) prior to testing. Also, you will not be able to participate if you have the flu, fever, are intoxicated or otherwise unwell on the day of testing.

We will explain the procedures, purposes and risks associated with this study to you, and ask for written informed consent. The study will be completed over 12 weeks; you will be attending the Walk On program for a 2-hour session and an additional half an hour will consist of this new method of electrical stimulation on your quadriceps (thigh muscles). In the first session, we will familiarise you with the test devices and you will perform the test procedures.

 Testing sessions: We will measure your body composition (using DEXA scan), your bone mineral density (using pQCT scan), blood lipids and anti-inflammatory markers (blood test from your arm), the area of muscle mass (using ultrasound), the amount of muscle force (using EMG), sit-to-stand test (using force plates), quality of life and spasticity subjective questionnaires and a pendulum test to objectively measure spasticity. These assessments will be done following an overnight fast over 1 or 2 sessions 4 weeks before starting the new intervention and immediately prior to starting the new intervention; then we will repeat the same tests at the end of the intervention period (12 weeks). These assessments will take approximately 2.5 hours but you can choose to do it in separate days if preferable.

Training sessions: You will sit on a test chair and two passive electrodes will be placed on the skin over your thigh muscles (quadriceps) and you will be given twitches of electrical stimulation to determine the peak twitch torque of the thigh muscle while your leg is held stationary by a testing machine (isokinetic dynamometer). The electrical stimulation (NMES) protocol will consist of repetitions of 2-s on 2-s off trains of NMES on each quadriceps femoris muscle performed alternately at the intensity required to elicit peak twitch torque (PTT-determined daily immediately prior to training). A vibratory device (DMS) will be held on the patella tendon simultaneously with the NMES. After 5 s of tendon vibration, repetitions of 2-s superimposed electrical stimulations (with no rest in between sets of 40 repetitions) will be applied to the muscle, while you will be attempting (regardless of success) to voluntarily contract the thigh muscle. Training will be finished once the torque reaches 50% of maximal peak twitch torque. All of these procedures are safe, and are commonly performed at Edith Cowan University.

**Eligibility**

You will be eligible for this study if:

* you are between 18 and 60 years old
* you have a spinal cord injury of any level and if have been involved in the “Walk On” program, it has to be for more than 14 weeks
* you have not any medical contraindications to use electrical stimulation and tendon vibration on your muscles

**Benefits of study participation**

You will receive free physical health assessments and you will be given 12 weeks of a novel method of electrical stimulation exercise training while being monitored by experienced researchers in the area of spinal cord injury research. The muscle (quadriceps femoris; thigh muscle) that we will examine in this study is one of the most important muscles in daily activities. Therefore, the information gained in this study will be reflective of your health status and functional ability. Importantly, you will see first-hand how this novel method of electrical stimulation exercise training can impact in your general health, physical function and quality of life. Most importantly you will be contributing to our efforts to help people with SCI to have access to better physical therapy techniques and have a better quality of life.

**Potential risks of study participation**

- Electrical stimulation procedures can be uncomfortable, but SHOULD NOT be painful; the researcher will ask for continuous feedback from you. Potential risks when using electrical stimulation include the development of autonomic dysreflexia (AD), which is a life-threatening situation, the development of spasticity, which is the sustained contraction of the muscle, hypotension, muscle damage and prolonged muscle fatigue. A trained Physiotherapist and an assistant will be looking after you during the whole time.

- The light skin abrasion performed immediately prior to the attachment of skin-based electrodes can increase the chance of skin infections. To further reduce this small risk, alcohol wipes will be applied to the skin after the abrasion as well as after the removal of the electrodes.

- Ultrasound scanning does not involve any notable risks. If you have any questions about the risks to you, please ask us immediately.

- The small electrical signals emanating from the muscles during the strength training tests will be recorded using small skin-based recording electrodes; the light abrasion of the skin in preparation for the procedure can pose a small risk of infection, which will be minimised further by the application of alcohol to the area before and after electrode use. Some of these procedures may be uncomfortable and unpleasant depending on your sensory threshold levels, but under no circumstances should they be painful. *We will remind you to tell a researcher immediately if you experience any pain during these procedures*

- Blood sampling from the antecubital vein (near the crease at the front of the elbow) can sometimes leave a small bruise and on rare occasions may be sore to touch for several days. The trained (certified) researcher performing the procedure will use sterile procedures to ensure the risk of infection is negligible.

- DEXA and the pQCT scans emit radiation when performed. This will expose you to very low-level radiation. DEXA scanning is routinely performed in the clinical setting, and produces exceedingly low levels of radiation dosages per scan. To assist your understanding, a single DEXA scan produces 1 – 6 µSv and the CT scan is less than this; a standard flight from Perth to Darwin generates 16 µSv, and daily radiation levels (at sea-level) expose us to 12 – 16 µSv. *If you have any questions about the risks to you, you should ask a researcher immediately*.

- Sit-to stand test will be performed with a harness and inside parallel for safety reasons and a trained researcher and clinician will be with you at all times.

- A trained clinician will perform the pendulum test and it does not involve any notable risks.

**Participant rights**

Participation in this study is completely voluntary. You retain the right to withdraw from the study or refuse single measurements at any time, and without the need to give a reason for your decision. There will be no consequences for your withdrawal or refusal of single measurements. Reporting of the study findings will be done with complete confidentiality and your identity will not be disclosed to anyone outside of the study at any time. You have the right to receive information regarding your own data/results at any time during the study from a member of the research team.

**The research team**

This research project is being undertaken as part of the requirements of a PhD candidature (Exercise and Health Sciences) at Edith Cowan University (ECU).

PhD candidate: Vanesa Bochkezanian (v.bochkezanian@ecu.edu.au) 6304 3972

Supervisor: A/Prof. Anthony Blazevich (a.blazevich@ecu.edu.au) 6304 5472

Co-supervisor: Prof. Rob Newton (r.newton@ecu.edu.au) 6304 3443

Further details of supervisors and the School of Exercise and Health Sciences are available at: http://www.sebhs.ecu.edu.au

**Data collection and storage**

The responsible researchers (Ms. Vanesa Bochkezanian, A/P Anthony Blazevich and Prof. Rob Newton) will store data securely so that personal information cannot be accessed by those external to the study. Data collection sheets (paper versions) and back-up copies on hard disk drive will be safeguarded by storage in a locked cabinet and/or protected by the research team on password-protected computers.

**Use of the study’s results**

The results of this study will be used as the basis for a subsequent study as a part of Ms Vanesa Bochkezanian’s research. In addition to this, results will be used for publication in Journals and presentations at Conferences, but confidentiality and anonymity will be maintained at all times.

**Contact details**

For more information on the project, please contact the research leader, Ms. Vanesa Bochkezanian: Building 21.501, School of Exercise and Health Sciences, Edith Cowan University

Phone: 0421166741

Email: v.bochkezanian@ecu.edu.au

If you would like to talk to an independent person regarding any aspect of this research, please contact the Research Ethics Support Officer at ECU:

Office of Research & Innovation, Edith Cowan University, 270 Joondalup Drive, Joondalup

Phone: 6304 5122

Email: research.ethics@ecu.edu.au

**The information above should be kept safe so you can refer to it if you need to.**

**The following page will be detached and kept by the research team.**

**Effect of a neuromuscular electrical stimulation (NMES)/vibration-driven muscle strength training intervention on muscle force, physical function and health, and quality of life in people with a spinal cord injury**

Informed consent form

Ms. Vanesa Bochkezanian and the research team

**Participant consent to the study**

* I confirm that I have read the above information form, which has described the purpose, methodology (including possible risks) and participant rights.
* I have had an opportunity to discuss the procedures with the lead researcher and have had any questions answered to my own satisfaction.
* I agree to the experimental protocol as explained to me and give consent to participate in the testing program.
* I will not participate if I: have flu, fever, am intoxicated or otherwise unwell.
* I will not participate if I have done the following: vigorous exercise (for 48 h) or alcohol (for 24 h) or stimulant consumption (e.g. caffeine, energy drinks for 6 h) prior to testing.
* I can withdraw from the project or refuse to participate in single measurements at any time without reason for my decision.
* My results may be used in scientific reports (e.g. in peer-review publication) and presentations, in which my personal data or identity will remain anonymous.
* My blood samples may be stored and kept for re-analysis (confidentiality will be retained).
* **I will ask for a copy of this signed form if I wish to retain one for my records**.

Emergency contact information:

Date Participant name and signature

Date Researcher name and signature