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**Information letter to participants**

**Study 2**

**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 look into different protocols of electrical stimulation as well as tendon vibration to find a better and safer method to use in people with SCI. In order to do this, we will test different protocols of electrical stimulation and tendon vibration in people with SCI, based on a previous study with healthy people. This information will be essential to the preparation of a subsequent intervention study in people with SCI. This research has been approved by the ECU Human Research Ethics Committee.

**Project aims**

The main aim is to quantify the amount of force your thigh muscles produce during different protocols of electrical stimulation and tendon vibration. Also, we will identify which electrical stimulation and tendon vibration protocols produce less muscle soreness and less spasticity in the following days. Another aim of this study is to identify which electrical stimulation protocol elicits higher levels of muscle oxygenation.

**Methodology**

If you choose to participate in this study, you will need to attend the ECU laboratory on three separate days with at least three days between each session and you will be asked to complete the Physical Activity Readiness Questionnaire (PAR-Q) to ensure safe exercise participation. 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. In the first session, we will familiarise you with the test devices and you will perform the test procedures. You will perform the same tests in the following sessions. All procedures will take approximately two hours on each day.

Test sessions: You will perform a 5-minute cycle warm-up before the tests. You will then sit on a test chair and will be given twitches of electrical stimulation of the thigh muscle while your leg is held stationary by a testing machine (isokinetic dynamometer). Two passive electrodes will be placed on the skin over your stronger thigh muscle (quadriceps) and you will be given one of the electrical stimulation protocols. After the end of the session we will test for indication of minor muscle damage measure (which is commonly measured after strength training sessions) using muscle ultrasound, imaging your thigh muscle, palpation of the muscle and a measure of the blood flow and muscle oxygenation through the skin. We will also ask you to fill a spasticity questionnaire following the session and in the next 3 following days. 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
* you have not any medical contraindications to use electrical stimulation and tendon vibration on your muscles

**Benefits of study participation**

You will receive information regarding your own physical performance if you wish. The muscle (quadriceps femoris; thigh muscle) that we will examine in this study is one of the most important muscles in daily activities and for sports performance. Therefore, the information gained in this study will be reflective of your health status and functional ability. Importantly, you will see first-hand how ultrasound imaging works and how research is done in the exercise science field.

Most importantly you will be contributing to our efforts to help people with SCI to have access to better physical therapy techniques 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 in people with SCI are the development of autonomic dysreflexia (AD), which is a life-threatening situation, the development of spasticity, which is the sustained contraction of the muscle and 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 and measure of the blood flow through the skin do not involve any notable risks. If you have any questions about the risks to you, please ask us immediately.

**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 (Sport and Exercise 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.
* **I will ask for a copy of this signed form if I wish to retain one for my records**.

Date Participant name and signature

Date Researcher name and signature