**INFORMATION TO PARTICIPANTS INVOLVED IN RESEARCH**

**You are invited to participate**

You are invited to participate in a research project titled *“Investigating the effects of strength training with and without transcranial direct current stimulation on strength and function of the upper limbs of adults with spastic hemiplegic cerebral palsy”*

This project is being conducted by a student researcher *Jerusha Mather* as part of a *Doctor of Philosophy (PhD)* at Victoria University under the supervision of *Dr Jacqueline Williams, Dr Alessandra Ferri* from the *Institute of Health and Sport, Victoria University and Professor Wei Peng Teo* from the Institute of Education, Singapore*.*

**Project explanation**

Individuals with spastic hemiplegic cerebral palsy (SH-CP) face a decrease in functional ability between 10 and 35 years of age, limiting health and quality of life. Interventions that reduce this decline are critical. Though loss of strength has been linked to functional decline in SH-CP, strength training (ST) programs have proven ineffective in improving motor function and are limited by relatively small strength gains.

Effective movement requires a delicate balance between excitation and inhibition of the nervous cells in the brain which control movement. This balance is often disrupted in SH-CP. This imbalance may be a cause of the slower strength gains observed in SH-CP. This project includes two components that aim to explore this imbalance.

In the first session, we will use a non-invasive technique to measure brain activity (using near-infrared technology) while participants complete strength tests with the upper limbs. We will compare brain activity among individuals with SH-CP and adults without SH-CP.

In the second session, we will use a non-invasive, painless method of brain stimulation to look at whether we can alter the patterns of brain activity in adults with SH-CP and adult controls. After 20 minutes of stimulation, we will again look at brain activity while participants complete strength tests with the upper limbs. In this study, half of the participants in each group SH-CP (SH-CP and control) will receive the brain stimulation and the other half will receive a placebo form of stimulation. They will not know which type of stimulation they have received.

These studies have the potential to improve ST outcomes in SH-CP, which we hope will lead to greater improvements in function.

**COVID – 19**

The Victorian Government has eased restrictions in Victoria, which has made it possible for gymnasiums and other public venues to operate. It is proposed that research activities involving human participants may take place on campus. The purpose of this document is to highlight revised laboratory procedures to current practices to minimise the risk of any COVID-19 infections. It applies to all Exercise Physiology laboratories where human research trials are conducted within the Institute for Health and Sport (iHeS) at Victoria University (VU). This includes rooms PB145, PB151, PB152, PB153 and PB212, Building P, Footscray Park Campus (see room map on P.6).

Current evidence suggests COVID-19 most commonly spreads from droplets in the air and close contact with someone who is infectious. It can also spread from touching a surface that has recently been contaminated with the respiratory droplets (cough or sneeze) of an infectious person and then touching your eyes, nose or mouth. The most effective way to minimise the risk of infection with COVID-19 is to comply with physical distancing requirements and ensure staff and any visitors wear face masks and maintain good hygiene.

Each research area within iHeS has specific risks when returning to data collection in a COVID-19 environment. The key issues in Exercise Physiology are excessive expiration during exercise tasks, the inability to open windows to improve ventilation and exposure to biological materials (blood, tissue, saliva, and perspiration) and potentially contaminated items within the laboratory.

Controls will be put in place before the commencement of research trials to mitigate these risks and ensure a safe environment as far as reasonably practicable. These controls include

* Changes to Heating, Ventilating, and Air Conditioning (HVAC) system to improve ventilation
* Restricting the number of people in the laboratory to maintain social distancing
* Receiving approval from the Human Research Ethics Committee (HREC) and by Victoria University DVC-Research (or nominee) as per standard transition to Campus requirements
* Completing risk assessments and standard operating procedures with COVID-19 mitigating strategies in mind
* Researchers and participants we will be assigned to the most appropriate lab space when booking to ensure social distancing requirements are maintained
* Completing a COVID-19 screening questionnaire, attendance register and cleaning checklist
* Wearing a face mask and relevant personal protective equipment and
* Modifications to common laboratory procedures

**What will I be asked to do?**

Prior to participation, you will be asked to complete a screening questionnaire to ensure you are eligible to participate and that there are no safety concerns regarding your participation (this will include personal medical

questions). Information collected during this process will remain completely confidential.

**Session 1**

We would like you to attend Victoria University (Footscray Park) for session lasting approximately 90 minutes. You will work with an accredited exercise physiologist and the PhD candidate. We will use functional near-infrared spectroscopy to measure activity in your brain, while you perform strength tests with your affected arm (SH=CP) or dormant arm (controls). We will also use electromyography to measure the activity of your arm muscles. These techniques are explained below.

*Functional near-infrared spectroscopy (fNIRS)*

This is a non-invasive and painless method of measuring activity in cells in the brain. It requires you to wear a snug-fitting cap with a strap under your chin. We will connect some electrode cables to the cap, over the area of the brain controlling movement. Some of the electrodes disperse near-infrared light painlessly through the scalp, while others absorb this light back into the fNIRS system. The amount of light that is reabsorbed gives us an indication of how much oxygen that area of the brain was using at the time. The amount of oxygen being used is a good indicator of brain activity. While this technique is painless, there can sometimes be discomfort when the cap is being fitted. This is because we sometimes need to push hair aside to get a clear signal. There is a small risk of eye damage if you were to look directly into the near-infrared lights, so we will ensure these are kept away from your eyes. The probability is really low, because the electrodes that send the light will be switched on once on the head, and switched off before the cap is removed

*Surface electromyography*

This is a non-invasive and painless way to measure the electrical activity in the muscle. Electrodes (2.5cm diameter) will be taped over your bicep and tricep muscles of your affected arm, after the area has been cleaned with some alcohol swabs.

*Strength Tests*

You will be asked to sit in a special reclined chair called a Cybex. We will use a seatbelt across your body and pelvis to reduce body movement. You will be asked to perform 3 different types of strength exercise:

1. You will be asked to perform a flexion of your elbow to produce as much force as you can against a stationary resistance.

2. You will be asked to perform a flexion of your elbow to produce as much force as you can at a set speed determined by the Cybex.

3. You will be asked to repeat the exercise in (1), but this time, you will contract your muscle with less intensity (50% of the maximum amount you produced in exercise 1) but for a longer time period (20 seconds)

For safety reasons, researchers will be asked to wear masks, face shields, gloves, and gowns when conducting research activities. There will be perplex barriers between participant and researcher where possible. We will ensure adequate air exchange and refresh rates are maintained in facilities. We will also ensure adequate sanitation of research equipment. Participants will be asked to always wear masks.

An COVID Screening Assessment will be administered to the participants a day prior to attending the testing site (over the phone) and the day of testing.

**Session 2**

If you choose to continue to participate in session 2, you will be asked to remain at Victoria University for an additional 45 mins. During this time, we will use the non-invasive brain stimulation method described below. After this, you will be asked to complete the same movement tasks as in session 1 (while still wearing the fNIRS cap).

*Non-invasive brain stimulation – transcranial direct current stimulation (tDCS)*

This is a painless and non-invasive technique that delivers a constant, low level of electrical current over your scalp. The cells in the brain can be activated by this electrical current, altering the balance of brain activity. It involves two electrode pads being placed over the scalp, held on by a headband. A battery-powered device is connected to the electrode pads and will deliver the electrical stimulation. You will initially feel some tingling over the area where the pads are placed, but otherwise should not experience any pain. Half of our participants will receive real stimulation and the other half will receive a placebo stimulation. You will not be able to tell the difference. You will be asked to remain seated for 20 mins while you receive this stimulation. Following this, we will remove the device and ask you to complete the strength-based tasks again. Some people may experience short-term side effects from tDCS. These include tingling or burning sensations, headaches, sleepiness, or itching. We will ask you regularly if you are experiencing any of these effects. If you answer yes, we will stop the session immediately, and follow-up within 24 hours to ensure this has resolved.

You will not be able to know if you are in the placebo or stimulation group until the conclusion of the entire project.

For safety reasons, researchers will be asked to wear masks, face shields, gloves, and gowns when conducting research activities. There will be perplex barriers between participant and researcher where possible. We will ensure adequate air exchange and refresh rates are maintained in facilities. We will also ensure adequate sanitation of research equipment. Participants will be asked to always wear masks.

An COVID Screening Assessment will be administered to the participants a day prior to attending the testing site (over the phone) and the day of testing.

**What will I gain from participating?**

Although we can promise no specific benefit to you, you may gain a sense of satisfaction from helping others with their research from participating in this study.

**How will the information I give be used?**

This is a double-blind study protocol. It means that in, you will be randomly allocated to either the real or placebo tDCS group. Double-blind means that neither you, nor the researchers working with you, will be aware of which group you have been allocated to. Dr Williams (the study lead) will be responsible for randomly allocating you into a group and programming the stimulator with either the real or placebo stimulation and your allocation will not be shared with the researchers working directly with you.

The information you give us will be de-identified. This means that we will remove your name and give the information a special code number. Only the research team will be able to break the code to match your name to your code number.

All information will be stored securely in a locked filing cabinet in the Institute for Health and Sport at Victoria University. Your information will also be stored on a password-protected computer database.

Information will be used in a PhD thesis, journal publications, and will be presented at conferences. We will keep the information for fifteen years following the completion of the project. After this time, we will destroy the information by shredding documents and/or deleting computer files.

Sometimes individual data will be reported, yet all data are not associated to the name, so no one can identify you as participant.

**What are the potential risks of participating in this project?**

There are very low risks associated with fNIRS, however eye care is imperative as fNIRS use lasers, it is important that participants do not look directly into the lasers.

The tDCS procedure is non-invasive and safe. There are some common minor adverse effects reported in previous studies, which typically stop when tDCS is ceased or within a 24-hour period. These effects may include tingling, headache, sleepiness, burning, and itching. In rare cases, seizures may occur. We will carefully screen you prior to participation to ensure you are eligible to undergo tDCS. We will be monitor you throughout each session and ask you to report any untoward effects. If you report any of such effects, the session will be stopped immediately. It is normal to experience some tingling from the tDCS initially, but it should subside after 20-30 secs. If the tingling persists for more than 1 minute and/or over 2 sessions, we will exclude you from further participation in the study. As part of your participation, we will ask you to complete an adverse event questionnaire immediately after testing and again 24-48 hours later.

**How will this project be conducted?**

We aim to recruit 24 participants with SH-CP and 24 participants without SH-CP, aged 18-35 years, for each of the studies described here. All participants, after screening, will complete the assessments described above (this may vary depending upon which studies are consented to). The assessments and interventions will be conducted at Victoria University Footscray Park Campus at a time convenient for the participant and the research team.

After all participants have been assessed, group data will be analysed to determine whether there are significant differences among adults with SH-CP and those who do not.

**Who is conducting the study?**

This study is being conducted within the Institute for Health and Sport at Victoria University.

Dr Jacqueline Williams is the Principal Researcher for this project. Dr Williams works within the Institute for Health and Sport. Her expertise is in motor skill development and impairment. You can contact Dr Williams 03 9919 4025 or Jacqueline.Williams@vu.edu.au.

Any queries about your participation in this project may be directed to the Chief Investigator listed above.

If you have any queries or complaints about the way, you have been treated, you may contact the Ethics Secretary, Victoria University Human Research Ethics Committee, Office for Research, Victoria University, PO Box 14428, Melbourne, VIC, 8001, email researchethics@vu.edu.au or phone (03) 9919 4781 or 4461.