UNIVERSITY of GUELPH

COLLEGE OF BIOLOGICAL SCIENCE
Department of Human Biology and Nutritional Sciences

Participant Information and Consent Form

Project Director: Dr. Jamie Burr**,** University of Guelph
Co-Investigator: Dr. Geoffrey Power, Dr. Stephen Brown, Brenda Scott-Thomas (PT)
University of Guelph
Students: Courtney White

Project Title: The use of blood flow restriction for augmenting training response to rehabilitative and preventative training for strength, stability and balance.

Part 1: Information relevant to the research project

Lower body soft tissue injuries, from rolling one's ankle or otherwise mis-stepping often require medical, paramedical or physiotherapy intervention to return to full function. Time-lost to injury can have an effect on functions of daily living, occupational performance and physical training abilities. The typical mode of treatment (whether rehabilitative – after an injury- or preventive) is muscle strengthening exercises. If methods to speed recovery or augment prevention, the human cost of time-lost could be greatly decreased.
Recent evidence from muscle strength training literature has shown that relatively light load exercise (as would be performed for rehabilitative/pre-habilitative training) becomes significantly more effective when blood flow to those muscles is restricted temporarily through the use of an inflated blood pressure cuff. Literature to date, however, has only used light resistance training with weights, and whether the same effects would occur using other common modalities in rehab (i.e. balance training, or electrical muscle stimulation) have yet to be tested. As such, our goal is to examine if functional changes in balance, stability or muscle strength result from using blood flow restricted training as compared with traditional training without blood flow restriction.

If you choose to take part in this study, you will be asked to participate in a 4 week training study in the Animal Science and Nutrition Building at the University of Guelph (Exercise lab rm 383). Prior to any physical testing, we will ask that you complete a PARQ+ safe exercise screening form, to ensure that there is no reason to believe you might be at risk of an adverse event related to normal physical exertion. Testing will be performed at the beginning of the study (baseline), 2 weeks into training, and then at the completion of the 4 week protocol. Testing will take up to approximately 2 hours per test (total 6 hours) and training will be done in the lab 5 times per week for approximately 30 min each time (150min/week, for 4 weeks).

For the testing session, we will examine your ability to balance under a variety of conditions while standing on a force plate that measures your centre of pressure. The conditions will include single leg standing (while moving or not moving your arms), double leg standing on a soft surface, and jumping using one or both legs. We will also measure the strength of your muscles and their contractile properties using standard strength tests and electrically induced muscle

contractions (see set up in the picture, below). While doing these tests, which require you to contract against our exercise machine, we will measure the electrical activity of your muscles using electrodes on the surface of your skin. This allows us to understand what is happening to your muscles and how strong the contractions are.

Figure 1: Experimental set-up for the neuromuscular testing session. Note the participant secured within the Cybex dynamometer with feedback on the computer monitor. Electromyography is being collected from the tibialis anterior muscle (muscle lateral to your shin bone) and the stimulator is being used to activate the fibular nerve which causes contraction in that muscle. (Stimulator probe is taped to the leg below the knee and controlled through the beige box with orange buttons).

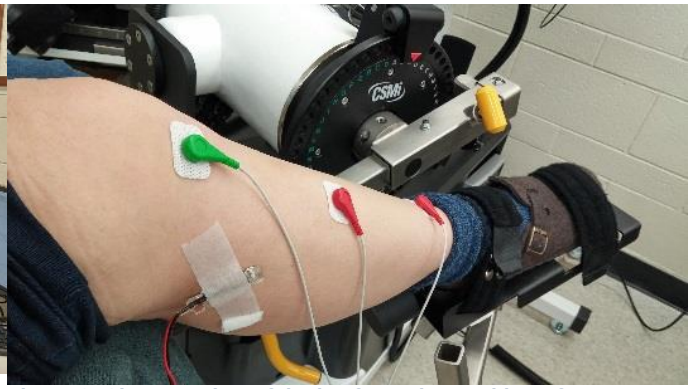

Figure 2: Close-up view of the leg from above with surface electrodes and the stimulator probe present on the prepared leg.

Following testing, you will be assigned (randomly) to one of two groups for the 4 weeks of training. Both groups will have different levels of blood flow restriction applied to each leg (one tight, one loose), and will perform the method of rehabilitative style training assigned to their group with both legs. Group 1 will do traditional balance type exercises. This will include standing and balancing on one leg, using soft (less stable surfaces underfoot), moving other body parts to disturb normal balance and catching throwing drills. Group 2 will use a passive model of training, wherein participants will sit in a chair, and their leg muscles will be stimulated to twitch via electrodes placed on the skin. The set-up will look very similar to the picture above, and will also mimic the testing in this regard. The contractions of the muscles will be very light (about 10% of maximal) and will thus not be uncomfortable.

Potential risks during test sessions

The use of electrical stimulation during testing is necessary to allow us to compare results in each of our participants. While the sensation is not painful, it might be uncomfortable since it is not a familiar feeling for many people. Electrical stimulation during training will be a much lower stimulus, and thus will be even less likely to be uncomfortable.
People with sensitive skin might have a minor skin reaction to adhesives used in this experiment.

As you will be performing muscle exertions and experiencing balance perturbations, you may experience fatigue. You will be given rest breaks throughout the testing session to ensure that fatigue is minimized. You may request additional rest periods during the test sessions at any time. During these evaluations there is a minimal risk of injury and falling during the balance tests and training sessions. All sessions will be monitored by a member of our research team, and the difficulty of the maneuvers will be matched individually to the progress of each

participant. You might experience some mild muscle soreness for 1-3 days after the initial testing or training sessions, similar to the slight muscle soreness a few days following a hard work-out. This muscle soreness is normal, and will self-resolve within approx. 72 hr.

Blood flow restriction has been shown to be safe and is commonly employed as a training methodology in other parts of the world. There is a possibility that particularly stressful exercise can lead to excessive muscle trauma and breakdown, leading to a serious condition known as rhabdomyolysis. **This condition is extremely rare, only occurs with extensive effort far beyond that which will be employed in the current investigation**. However, should you ever notice that you have intense muscle pain and/or a noticeable darkening of your urine, you should inform the researchers and seek medical attention. There is also a very low risk of an inappropriate change in blood pressure or a blood clot (deep vein thrombosis), which theoretically could dislodge and travel to the smaller vasculature causing embolism. Persons with known vascular disease, or diabetes might be at higher risk of rupturing an unstable vascular plaque, and should not participate as this could lead to an adverse cardiovascular event.

You can withdraw from the experiment at anytime without penalty even after you have given consent to participate. Your personal safety is important to us.

Remuneration
We will be offering a $25 gift card to each participant

Confidentiality
Subject codes will be used in data analysis; your name will not be used.

Any information obtained from these records will be kept confidential in the laboratory and secured in a cabinet in a locked room. <u>This information will be used strictly for research and teaching purposes only.</u> The data collected during your tests sessions will be stored electronically on a password-protected computer and made available only to the research team.

Feedback
Please contact the researchers listed on this form should you have any concerns about the protocol or have felt any lingering adverse symptoms post testing.

After the completion of the test session, a discussion between yourself and the researchers will give you the opportunity to ask any questions you may have about the research project. The researchers will debrief you at this time and provide details as to the expected findings of this research. Following data analysis and project completion, a feedback letter will be given to you summarizing the findings of the project and contact information if you have any questions as to these findings.

**This study has been reviewed and has received ethics clearance through the University of Guelph Research Ethics Board. If you have any questions regarding the use and safety of human subjects in this research you may contact S. Auld, University of Guelph Research Ethics Officer, 519-824-4120 (extension 56606), sauld@uoguelph.ca).*

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Part 2: Participant Consent Form

I _____have read and understood the information provided as to the purpose of the project, the protocol to be conducted and the risks involved with participating in the above study. I have been informed as to the nature of the feedback to be provided upon completion of the trial itself and upon the completion of the project.

I understand that if I have any questions or concerns resulting from my participation in this study, I may contact the above people.

I understand that information obtained from my testing sessions will be used strictly for research and teaching purposes and that my name will be kept confidential in data presentations resulting from this research.

I am aware that I may withdraw from the study at any time *without penalty* even after my consent has been given and the project has commenced. With full knowledge of all forgoing I agree, of my own free will, to participate in this study.

_____	_____	_____
Subject Name (printed)	Participant Signature	Date
_____	_____	_____
Witness Name (printed)	Witness Signature	Date

Persons responsible for project:

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