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**PLAIN LANGUAGE STATEMENT AND CONSENT FORM**

TO:

**Plain Language Statement**

Date:

Full Project Title: Blood Flow Restriction Exercise: The Physiology and Outcomes of Training

**Principal Researcher: Dr. Stuart Warmington**

**Student Researcher: Mr. Matthew Clarkson**

**Associate Researcher(s): Louise Conway, Anthony Barnett**

You are invited to take part in this research project, which will investigate the effect of blood flow restriction during walking training. This Plain Language Statement contains detailed information about the research project. Its purpose is to explain to you as openly and clearly as possible all the procedures involved in this project before you decide whether or not to take part in it.

Please read this Plain Language Statement carefully. Feel free to ask questions about any information in the document. You may also wish to discuss the project with a relative or friend or your local health worker. Feel free to do this. Once you understand what the project is about and if you agree to take part in it, you will be asked to sign the Consent Form. By signing the Consent Form, you indicate that you understand the information and that you give your consent to participate in the research project.

You will be given a copy of the Plain Language Statement and Consent Form to keep as a record.

Purpose

This is a student project contributing to a Bachelor of Exercise and Sport Science (Honours) degree.

The purpose of this project is to investigate the application of blood flow restriction during exercise, and the training effects that result. There is a body of evidence that demonstrates benefits in muscle size and strength following low-intensity blood flow restriction training, equivalent to that of high-intensity exercise without the blood flow restriction. Studies have utilised several modes of exercise: walking, cycling, and resistance training and a large proportion of this research involves younger, apparently healthy participants, while research into its application in older adults is lacking.

It is likely that the benefits would be similar in older adults, and that this would directly improve performance in functional outcome measures representative of improved everyday function. Training with blood flow restriction cuffs at a low-intensity can produce these functional benefits while eliminating the intimidation, potential risk and negative stigma that surrounds high-intensity exercise in populations unlikely to adhere to it, such as older adults and frail adults.

This study will utilise functional outcome measures to gauge improvements in lower limb muscle strength following a 6-week blood flow restriction walking program.

Methods

Participants will be asked to complete one of the two trials (walking with blood flow restriction to the lower limbs, or walking without restriction).

Participants will be required to complete 4 supervised training sessions per week over a 6-week period, for a total of 24 sessions. The initial session will be familiarisation with the equipment and protocol, as well as the initial testing session for the baseline outcome measures. The following sessions will be training sessions with a re-testing session following the third and sixth weeks.

The outcome measures utilised in the testing sessions will include common outcomes measures: Timed Up and Go (stand up from a chair, walk 3m, turn, walk back and sit down), Six Minute Walk Test (6 minute continuous walking, trying to cover as much distance as possible), Sit-to-Stand Test (moving from sitting in a chair to standing upright and back as many times as possible in 30 seconds), and Queen's College Step Test (3 minute repeated step-ups at a pace of 22-24 steps per minute and step height of 41.83cm).

During the familiarisation session for those in the blood flow restriction group, blood flow will be restricted to the lower limbs using an automatic tourniquet system at the top of each thigh. Blood flow restriction will be applied for a practice walking bout of the same duration as the training sessions (10-minutes) and released at the conclusion of this time.

The cuff pressure will be pre-determined separately for each limb prior to any physical tasks while the participant is standing, which is representative of the level of the heart to the cuff height during the walking tasks. With the restriction cuffs in place on the limb, a clip on device will be applied to the second toe of the appropriate foot. Following a 5 min rest period the automated measurement of the point at which blood flow to the limb stops will be performed using an inbuilt function of the machine where the restriction cuffs gradually inflate to produce a continuous rise in pressure until blood flow to the tissues is no longer detected at the toe. This pressure measurement will be conducted twice on each limb and deemed acceptable if within 20 mmHg. The average will then be used to set the cuff pressure for the walking. If more than 20 mmHg, the average of three tests will be used.

During training sessions, participants in the group that have the pressure cuffs fitted will walk at a continual pressure equivalent to 70% of their pre-determined limb occlusion pressure. This allows for some limb blood flow during the walking exercise.

Training sessions will involve one of two set walking courses that will be repeated each training session over the course of the 6-week program. The walking will be done continuously, with participants in both groups (with blood flow restriction and without) walking at the set pace of 4km/h for 10 minutes. There will be a primary course located in the local park area on the public walking track, and a secondary course in the walkway located on the ground floor of building B at Deakin University, Burwood, which provides a viable contingency for poor weather. This indoor track is commonly used for other walking protocols by students and clients of the Deakin Clinical Exercise Learning Centre.

Following the initial walk protocol participants from each group will be required to complete a 5 minute gentle walk as recovery (no blood flow restriction during this time).

Demands

You will be required to be screened for eligibility and provide consent. You must also be able to commit the necessary time for testing four times per week for six consecutive weeks. Expected time per session is 15-20 minutes (approximately 30 minutes for testing sessions).

You will need to keep all exercise outside of that conducted in the study to a minimum in order to attribute outcomes to the study protocol. The study may provide motivation to increase your physical activity beyond the study, and researchers can provide advice on this, but this must only be on conclusion of the study.

Risks

There are no foreseeable medical risks to participation in this project. During training sessions, if you are wearing the pressure cuffs may experience a certain level of discomfort, similar to that of having blood pressure taken, but this does not pose a risk of causing pain. Due to the volume of training, previously inactive participants may experience some level of muscular fatigue. This is not expected to limit your ability to perform normal daily activities, but you should be aware that any initial soreness should dissipate within 2-3 days.

The proposed walking course provides minimal risk as it is a fine gravel track. It will be monitored for pot holes and any areas of uneven footing prior to each session which will be either filled or avoided. The local park land is also a public space and a no-lead dog zone, and while there is minimal risk of incident as a result of this, it is worth noting. Neither of these issues provides risk to a level that surpasses what you may face regularly in any public setting.

Benefits

Benefits of this study to you, particularly if you have wanted to increase your physical activity level, may include improved functional strength, improved performance of daily functional activities, as well as potential improvements in energy levels and feelings of personal wellbeing that are often linked to increased physical activity levels.

While there are no direct benefits to the wider community, this research provides important insight into a potential clinical alternative for improving functional strength and performance in the older adult population. The results of this research may demonstrate that low-intensity exercise using blood flow restriction protocols from this study is a viable alternative to more demanding high-intensity exercise whilst producing similar outcomes.

Privacy and Confidentiality

Identifiable data from testing sessions will be recorded on a basic form representing quantitative measures of performance during the outcome measures. This data will then be transferred to a digital format for analysis and only the researchers will have access to this information. Any information obtained in connection with this project that can identify you will remain confidential. No personal, identifying information will be presented or published in relation to the research.

Dissemination and Publication of the Results

Upon completion of the project the results will be published in the Honours Thesis of Matthew Clarkson, and submitted for potential peer-review and journal publication in the field of exercise science. The results will also be presented at the Deakin University Fourth Year Research Conference. If you would like a copy of the abstract for this thesis/presentation, please make this known to the researchers.

You will be notified by email if the project is accepted for peer reviewed publication, and can be provided with a copy of the publication at that time if you so request.

Monitoring

As principal researcher and supervisor, Dr Warmington is responsible for monitoring overall conduct and progress of the research project. He will serve both these responsibilities through regular communication with student researcher Mr Clarkson. All researchers will meet on a bi-weekly basis (at a minimum) to discuss the progress of the research project.

Any payments to participants

You will not receive any payment.

The amounts and sources of funding for the research

The project will be funded by the Deakin University School of Exercise and Nutritional Sciences.

Right to Withdraw from the Study

Participation in any research project is voluntary. **If you do not wish to take part you are not obliged to.** If you decided to take part and later change your mind, you are free to withdraw from the project at any stage. Any information obtained from you to date will not be used and will be destroyed.

Your decision whether to take part or not to take part, or to take part and then withdraw, will not affect your relationship with Deakin University.

Before you make your decision, a member of the research team will be available to answer any questions you have about the research project. You can ask for any information you want. Sign the Consent Form only after you have had a chance to ask your questions and have received satisfactory answers.

If you decide to withdraw from this project, please notify a member of the research team or complete and return the Revocation of Consent Form attached. This notice will allow the research team to inform you if there are any health risks or special requirements linked to withdrawing.

Contact details of the researchers

**Matthew Clarkson**

School of Exercise & Nutrition Sciences, Faculty of Health,
Deakin University, Burwood 3125, Australia.

Tel: 0400 225 116

Email: mclarks@deakin.edu.au

**Stuart Warmington, Lecturer in Exercise Physiology**

Centre for Physical Activity and Nutrition Research (CPAN),
School of Exercise & Nutrition Sciences, Faculty of Health,
Deakin University, Burwood 3125, Australia.

Tel: +61 3 9251 7013

Email: [stuart.warmington@deakin.edu.au](https://services.exchange.deakin.edu.au/owa/redir.aspx?C=792b1be031464e6a8822c958d6c9db95&URL=mailto%3astuart.warmington%40deakin.edu.au)

Complaints

If you have any complaints about any aspect of the project, the way it is being conducted or any questions about your rights as a research participant, then you may contact:

The Manager, Research Integrity, Deakin University, 221 Burwood Highway, Burwood Victoria 3125, Telephone: 9251 7129, research-ethics@deakin.edu.au

Please quote project number [201X***-***XXX]***.***

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 **PLAIN LANGUAGE STATEMENT AND CONSENT FORM**

**TO:**

**Consent Form**

**Date:**

Full Project Title: Blood Flow Restriction Exercise: The Physiology and Outcomes of Training

**Reference Number:**

I have read, or have had read to*,* and I understand the attached Plain Language Statement*.*

I freely agree to participate in this project according to the conditions in the Plain Language Statement.

I have been given a copy of the Plain Language Statement and Consent Form to keep.

The researcher has agreed not to reveal my identity and personal details, including where information about this project is published, or presented in any public form.

Participant’s Name (printed) ……………………………………………………………………

Signature ……………………………………………………… Date …………………………

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**PLAIN LANGUAGE STATEMENT AND CONSENT FORM**

**TO:**

**Withdrawal of Consent Form**

*(To be used for participants who wish to withdraw from the project)*

**Date:**

Full Project Title: Blood Flow Restriction Exercise: The Physiology and Outcomes of Training

**Reference Number:**

I hereby wish to WITHDRAW my consent to participate in the above research project and understand that such withdrawal WILL NOT jeopardise my relationship with Deakin University*.*

Participant’s Name (printed) …………………………………………………….

Signature ………………………………………………………………. Date ……………………

**Please mail or email this form to:**

 **Dr** **Stuart Warmington**

Centre for Physical Activity and Nutrition Research (CPAN),
School of Exercise & Nutrition Sciences, Faculty of Health,
Deakin University, Burwood 3125, Australia.

Email: [stuart.warmington@deakin.edu.au](https://services.exchange.deakin.edu.au/owa/redir.aspx?C=792b1be031464e6a8822c958d6c9db95&URL=mailto%3astuart.warmington%40deakin.edu.au)