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Personalized Blood Flow Restriction for Anterior Cruciate Ligament Rehabilitation

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UNIVERSITY OF WASHINGTON
CONSENT FORM

Personalized Blood Flow Restriction for Anterior Cruciate Ligament Rehabilitation

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Researchers' statement

We are asking you to be in a research study. The purpose of this consent form is to give you the information you will need to help you decide whether to be in the study or not. Please read the form carefully. You may ask questions about the purpose of the research, what we would ask you to do, the possible risks and benefits, your rights as a volunteer, and anything else about the research or this form that is not clear. When we have answered all your questions, you can decide if you want to be in the study or not. This process is called "informed consent." We will give you a copy of this form for your records.

PURPOSE OF THE STUDY

Weakness of the muscles around the knee is regularly seen in the months and years after anterior cruciate ligament (ACL) reconstruction surgery. This has been linked to future joint problems such as osteoarthritis. During the rehabilitation process, one of the main aims is to restore the strength and function of the knee, however this can be challenging due to the limits on the stress that can be put on the joint. Personalized blood flow restriction is an exercise technique that works by using a pressure cuff to reduce the amount of blood flow to the muscles being tested. It has been suggested that it can help to build strength while performing exercises that don't require heavy weights. In this study, we aim to test if personalized blood flow restriction is suitable for patients undergoing rehabilitation for ACL reconstruction, and to see how it affects the exercise being performed.

STUDY PROCEDURES

We will ask you to come to a motion analysis laboratory for testing. Here, we will take measurements of your height and weight and ask you to complete a short questionnaire relating to the function and pain of your knee. You will be asked to wear shorts and a t-shirt for the testing.

We will attach a number of reflective markers to your body and place some sensors over your thigh muscles. A pressure cuff, similar to the cuff that is placed around your upper arm when measuring blood pressure, will be placed around your thigh and calibrated so that we can control the amount of blood flow to the muscles around your knee. You will be asked to perform step up and step-down exercises while different levels of pressure are applied by the system. For four different blood flow conditions, you will be asked to do a set of 30 repetitions, then a 30 second break, then 3 sets of 15 repetitions with 30 seconds rest. We will record your movements and the forces generated while you perform the exercises. You will be asked to rate the discomfort and difficulty of the exercise after each condition is complete.

The whole procedure should take no longer than 90 minutes. At any point during the study you may refuse to answer questions, or do an exercise, or withdraw from the study completely.

RISKS, STRESS, OR DISCOMFORT

The physical risk for the exercises we will ask you to do is about the same as doing a workout in your local gym. A qualified sports physiotherapist will be present for the session and will provide instructions for how to perform the exercises safely. The sessions will not exceed 4 periods of 6 consecutive minutes of exercise, and you will be encouraged to rest in between. You will not be asked to continue if you find the exercises too difficult. We will encourage you to stretch and warm up prior to testing.

The blood flow restriction cuff applies a pressure around the thigh and this may cause some discomfort that resolves quickly when the cuff is removed. The amount of time the cuff is inflated for will be minimized, and you can stop testing at any time if you find it becoming too uncomfortable.

The use of reflective markers and muscle sensors may cause some skin irritation which is usually minor and resolves quickly.

ALTERNATIVES TO TAKING PART IN THIS STUDY

The alternative is not to take part in this study.

BENEFITS OF THE STUDY

There are no direct benefits to you. The system being tested may prove to be a useful tool for helping to assess people who are recovering from knee surgery.

CONFIDENTIALITY OF RESEARCH INFORMATION

The researchers will keep the study information confidential. We will label your research information with a study number, not your name. We will keep your name, address, telephone number, and other information that might identify you separate from the research information in a secure location. We will destroy these records at the end of the record retention period.

Government or university staff sometimes review studies such as this one to make sure they are being done safely and legally. If a review of this study takes place, your records may be examined. The reviewers will protect your privacy. The study records will not be used to put you at legal risk of harm.

OTHER INFORMATION

You may refuse to participate, and you are free to withdraw from this study at any time without penalty or loss of benefits to which you are otherwise entitled.

RESEARCH-RELATED INJURY

If you think you have a medical problem related to this research, contact Joshua Gellert, DPT (Co-Investigator- 206.520.5000), right away. He will treat you or refer you for treatment.

Subject's statement

This study has been explained to me. I volunteer to take part in this research. I have had a chance to ask questions. If I have questions later about the research, or if I have been harmed by participating in this study, I can contact one of the researchers listed on the first page of this consent form. If I have questions about my rights as a research subject, I can call the Human Subjects Division at (206) 543-0098 or call collect at (206) 221-5940. I will receive a copy of this consent form.

Printed name of subject	Signature of subject	Date

Copies to: Researcher
Subject