Non-invasive Brain Stimulation to Improve Quadriceps Muscle Function After Anterior Cruciate Ligament Reconstruction

NCT #: ID not assigned yet

7/23/20

Consent Form for Participation in a Research Study
Determining the neural mechanisms involved in quadriceps muscle dysfunction after ACL reconstruction

You are being invited to participate in a research study. This consent form tells you about the study including its purpose, what you will be asked to do if you decide to take part, and the risks and benefits of being in the study. Please read the information below and ask us any questions you may have before you decide whether or not you want to participate.

WHAT IS THE PURPOSE OF THIS STUDY?

This study is being conducted at Arcadia University. The purpose of this study is to compare quadriceps muscle strength and function between athletes that underwent ACL reconstruction and athletes without a history of knee injury, and to examine the effects of a type of electrical stimulation delivered over your scalp on quadriceps strength. This study consists of 2 sessions that will each take approximately 3 hours to complete. This study will involve approximately 30 participants without a history of significant knee injury or surgery and 30 participants with a history of ACL reconstruction. All participants will be between the ages of 18 and 55 years.

Exclusion criteria for this study include: (1) currently on anti-epileptic medication or have a history of epilepsy or seizures (2) have a first-degree family member with a history of epilepsy (3) had a prior head injury that required hospitalization or concussion in the past 6 months (4) have any metal in the head, eyes, neck or face (with the exception of dentures) (5) have a history of brain surgery (6) have skull abnormalities or fractures (7) have implantation of electrical devices such as (but not limited to) cardiac pacemaker, cardiac defibrillator, cochlear implants or nerve stimulators (8) history or recurring or severe headaches/migraines (9) known neurological disorders or muscle diseases (10) pregnancy (11) lower extremity botulinum injections in past 6 months (12) baclofen pumps (13) taking any medications that act on the central nervous system.

Your participation in this study is voluntary, and you may decline to participate without penalty. You may also withdraw from this study at any time without any consequences. If you choose to withdraw during the study, your data collected up to that point will be destroyed. If you decide to withdraw after completing this study, you may contact the student researcher or faculty advisor. Moreover, you can skip any questionnaire items that you do not wish to answer without penalty. The research team retains the right to stop testing if he determines that any aspect of the protocol puts the participant at more than minimal risk.

WHAT WILL YOU BE ASKED TO DO?

Overview

This study consists of 2 sessions that each last about 2.5 hours. The 2 sessions will be the same with one difference. During one session, you will receive active electrical stimulation over your scalp during stationary bike riding. During the other session, you will receive sham electrical stimulation over your scalp during stationary bike riding. The strength and lab testing will be performed at the beginning and end of each session.

Strength Testing

The test will measure the strength of the quadriceps muscle (the muscle on the front of your thigh) and hamstring muscle (the muscle in the back of your thigh). You will be seated in a device that resists your kicking motion, and measures how much force your muscle can exert. Each test will require a series of practice and recorded contractions. Trials will be repeated (up to a maximum of 4 trials) until a maximum contraction is achieved for both legs.

Lab Testing

Participants Initials_____

Transcranial magnetic stimulation (TMS) will be used to examine your nervous system while you sit on a strength measuring device. TMS is described in more detail below.

TMS Testing

Magnetic Stimulation will be delivered through a coil placed on your head. The coil will be moved around the head in order to find the optimal site for stimulating the muscles around your knee. Short pulses of stimulation will occur about every 3-4 seconds while you activate muscles in your thigh and lower leg. Each pulse feels like a light tap on your head and may cause a twitch in muscles throughout your legs. The intensity of the stimulator will be adjusted based on your response.

Intervention (bike riding with transcranial electrical stimulation)

You will be asked to ride a stationary bike for a total of 20 minutes. The first 5 minutes and last 5 minutes will serve as a warmup and cool down with light resistance. The middle 10 minutes will be performed at moderate resistance. During the stationary bike riding, we will apply low intensity electrical stimulation over your scalp. This stimulation is called transcranial direct current stimulation (tDCS). It is not invasive. It consists of applying a small amount of electrical stimulation to your head using a system powered by two 9-volt batteries. This will go on during the bike riding. While it is happening, you may or may not temporarily feel a small amount of tingling, itching, or burning over the scalp. If the stimulation bothers you too much, please let us know and we will stop. After tDCS, we will examine your scalp.

Self-Report of Function Questionnaires

After both sets of testing and the intervention, you will complete a questionnaire asking you to rate how well your knee is doing currently and to monitor symptoms related to the intervention.

HOW WILL CONFIDENTIALITY BE MAINTAINED? WHO MAY KNOW THAT YOU PARTICIPATED IN THIS RESEARCH?

All patients will be identified by a case number. Only the investigators will have access to the data. Neither your name nor any identifying information will be used in publication or presentation resulting from this study. Data will be archived indefinitely.

The confidentiality of your records will be protected to the extent permitted by law. Your research records may be viewed by Arcadia University's Institutional Review Board, which is a committee formally designated to approve, monitor, and review biomedical and behavioral research involving humans.

WHAT ARE THE POSSIBLE RISKS AND DISCOMFORTS?

Strength testing: You may experience temporary local muscle soreness and fatigue for approximately 2-3 days after the test.

Hop Testing: Subjects with ACL injury could experience a loss of balance or fall during hop testing, however your other leg is free to touch down to provide support and prevent loss of balance. Upon request, the tester can stand close to you during the hops, providing a hand for support to prevent loss of balance.

TMS testing: There is a very rare chance TMS may result in a mild headache after a full session of simulation. During testing there is a sensation of tapping and if you feel any discomfort we will change the setting and/or take frequent breaks to minimize the discomfort. During a pulse of TMS there is also a loud click that occurs. While very rare, there is a risk of this affecting hearing. If the sound bothers you, we will provide ear plugs to minimize this noise. There is a very small risk of fainting during TMS. If you experience any signs of dizziness or fainting we will immediately stop testing and place you in a position of comfort until the symptoms

Participants Initials_____

resolve. Finally, there is a extremely small risk of seizure during TMS. People with certain medical conditions have increased risk of seizures. We have already screened your history to make sure you do not have any of these conditions.

Intervention (transcranial direct current stimulation): Although very unlikely, you may experience minor skin irritation from the wet pads used for tDCS. This should disappear within 1-2 days. Rubbing the area with lotion will help with any discomfort. You may also experience itching, tingling, headache or a burning sensation during the intervention. We will monitor these symptoms during and after each session. Permanent side effects have never been reported after this type of electrical stimulation. While it is extremely unlikely, if you get an injury during the study that requires medical attention, we will direct you to your physician. You or your insurance will pay for the care you receive.

WHAT ARE THE POTENTIAL BENEFITS?

All participants will receive results of their strength assessment. For participants in the ACL group, the results of the strength assessment will provide objective data that can help to determine progression through rehabilitation.

WILL THERE BE ANY COSTS TO YOU FOR PARTICIPATING IN THIS RESEARCH?

There will be no costs to you for participating in this study.

WILL YOU RECEIVE ANY COMPENSATION FOR PARTICIPATION?

All participants will receive $100 for participation after completion of both sessions.

WHO SHOULD YOU CALL IF YOU HAVE QUESTIONS OR CONCERNS?

If you have any questions about this study, please contact the Principal Investigator, Ryan Zarzycki at (215) 572-8527 or zarzyckir@arcadia.edu, or Shailesh Kantak (co-investigator) at kantaks@arcadia.edu.

This study has been approved by the Arcadia University Institutional Review Board (IRB). To ensure that this research continues to protect your rights and minimizes your risk, the IRB reserves the right to examine and evaluate the data and research protocols involved in this project. If you wish to know more about your rights, please contact the Office for the Committee for the Protection of Research Subjects at (267) 620-4111.

I have read the above description of the study and my participation in it, and have had my questions and concerns addressed by the researcher. I agree to participate in this study and acknowledge that I have received a personal copy of this consent form.

Participant's Printed Name: _____

Participant's Signature: _____ Date: _____

Researcher's Signature: _____ Date: _____

Participants Initials_____

<u>OPTIONAL</u> CONSENT FOR ADDITIONAL USES OF VIDEO RECORDINGS/PHOTOGRAPHS

I voluntarily give my permission for the researchers in this study to use videos and photographs of me collected as part of this research study to be used in publications, presentations, and/or for educational purposes. I understand that no identifying information beyond that contained in the video recording and/or photographs will be provided to educational/scientific audiences; however my facial features (and/or those of child) may be seen.

_____ _____
(Signature of Participant) (Date)

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<u>OPTIONAL</u> CONSENT TO BE CONTACTED FOR FUTURE STUDIES:

Do we have your permission to contact you regarding participation in future studies? Please write your initials next to your preferred choice.

_____ YES _____ NO

Participants Initials_____