LOUISIANA STATE UNIVERSITY HEALTH SCIENCES CENTER in Shreveport
Institutional Review Board (IRB) for the Protection of Human Research Subjects

CONSENT TO PARTICIPATE IN A RESEARCH STUDY

Title of research study: Does a Hip Muscle Activation Home Exercise Program Change Patient Performance on the Forward Step-Down Test?

Sponsor: Louisiana State University Health Shreveport, School of Allied Health Professions, Program in Physical Therapy

Investigator: Daniel W. Flowers, PT, DPT, PhD

Contact Information: (318) 813 - 2958

Participant Name: _____

Participant ID Number: _____

DETAILED INFORMATION

Why are you being invited to take part in a research study?

You are being asked to participate because you are a first or second year Doctor of Physical Therapy (DPT) student in the School of Allied Health Professions (SAHP) at LSU Health Shreveport (LSUHS) without current knee pain or pathology in your dominant leg.

Why is this research being done?

The purpose of this study is to determine if a specific type of exercise program focused on activation of the hip muscles improves your movement during a step-down task. It is currently unknown if an activation training exercise program can change movement on this sort of task, so we are hoping to see if our exercise program can influence your movement on the task.

How long will the research last?

We expect that you will be in this research study for a total of 3 ½ hours. One hour of this will be split into two 30-minute sessions before and after the eight-week exercise program. Across the eight-week exercise program, you will spend a total of approximately 2 ½ hours.

How many people will be in the research?

We expect about 35 people to participate in this research study.

What happens if I say yes, I want to be in this research?

There will be two in person study visits. Each will be 30 minutes. The investigators will first collect personal information, including your age, sex, height, weight, body mass index, and determine your dominant leg. You will then have adhesive electrodes placed on your hip and buttocks on the dominant limb by an investigator of the same sex. You will perform a step-down task five times, while your form and muscle activation data are collected. This same procedure will occur before and after the exercise program.

There will be an exercise program for you to complete at home twice a week for eight weeks. You will be educated on this program after the first data collection session. There will be a chart for you to fill out every time you complete an exercise session. Once complete, you will return to LSU for your second data collection session.

Participating in this study will not affect your grades/academic standing at this institution.

Will I definitely receive the experimental drug?

There are no experimental drugs being used in our study.

What are my other options if I do not want to be in this research?

You do not have to be in this study. If you decide not to be in the research now or later, it will not affect your usual care and it won't be held against you.

You do not have to be in this study to receive an exercise program focused on hip muscle activation. You are welcome to pursue formal physical therapy with any provider of your choice.

Instead of being in this research, your choices may include performing hip muscle exercises on your own or receiving assistance from certified personal trainers or physical therapists.

What happens if I say yes, but I change my mind later?

You are free to leave the study at any time. There are no penalties and you do not lose any benefits to which you are otherwise entitled. Data that we have already used will stay in the

study database and cannot be removed to maintain the integrity of the research. All data will be deidentified.

As with all exercise programs, there is a chance of some muscle soreness in the muscles that are being trained. To minimize this, the exercise program has specific guidelines you will need to follow. You will be educated on these during your educational session.

If you decide to stop, we may ask you if we can contact you for safety reasons or to follow your health. We may also ask you if we can collect data from your medical records and your routine medical care.

Can I be removed from the research without my OK?

The investigators in charge of the research study or the sponsor can take you out of the study even if you do not ask to leave. This may happen if an unrelated injury occurs during the study that doesn't allow you to complete the exercise program or testing after the program. This would result since you may no longer fit the inclusion criteria of the study.

What are the risks of being in this study?

- Muscle soreness
- Loss of privacy/confidentiality

Regarding possible muscle soreness, the investigators have provided dosing guidelines for the home program to minimize any potential soreness that may arise.

For breach of confidentiality, one of the risks of being in this study is that your personal information could be lost or exposed. This is very unlikely to happen, and we will do everything we can to make sure that your information is protected. All data will be deidentified, and your name will only be present on documents that are under lock and key in the investigator's office.

If you become pregnant during the study, you should tell the study investigators. You will be removed from the study, as you will no longer meet the inclusion criteria.

What are the costs of being in the research?

Taking part in this research study may lead to added costs to you by requiring transportation to the study site twice during the study. Otherwise, there are no costs associated with participating in this research study.

Will being in this study help me in any way?

We cannot promise any benefits to you or others from your taking part in this research. However, possible benefits include an improvement in activation of the hip muscles and in movement on a step-down task. There is also a potential benefit to the science of physical therapy given any findings related to the investigation.

Will my information collected for the research remain confidential?

Efforts will be made to limit the use and disclosure of your personal information, including research study and medical records, to people who have a need to review this information. We cannot promise complete privacy. Organizations that may inspect and copy your information include the LSUHSC-S HRPP and other representatives of this organization.

The data will be kept for up to one year after the completion of the data analysis in case the research will be continued. The only people to have access to this information will be the research investigators. Hardcopy data will be stored in a locked drawer and office of the primary investigator. Electronic data will remain on Sharepoint.

What else do I need to know?

Medical treatment for an injury or illness related to your participation in this study will be made available to you by LSU Health Sciences Center at Shreveport and Ochsner LSU Health Shreveport Academic Medical (Ochsner LSU Health Shreveport St. Mary Medical Center) and/or Ochsner LSU Health Monroe Medical Center. Generally, this care will be billed to you, your insurance, or other third party. We have no program to pay for medical care for research-related injury.

Who can I talk to?

If you have questions, concerns, or complaints, or think the research has hurt you, talk to the principal investigator, Dr. Daniel Flowers, at (318) 813 – 2958.

This research has been reviewed and approved by the LSUHSC-S IRB which is a group of people who help protect your rights and welfare as a research participant. You may also talk to them at (318) 813-1350 about:

- Questions, concerns, or complaints that are not being answered by the research team.
- Concerns if you cannot reach the research team.

- The need to talk to someone besides the research team.
- Any questions about your rights as a research subject.
- The desire to get more information or provide input about this research.

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Signature Block for Capable Adult

Your signature documents your permission to take part in this research.

Signature of subject	Date/Time (AM or PM)
Printed name of subject	
Signature of person obtaining consent	Date/Time (AM or PM)
Printed name of person obtaining consent	
Signature of witness to subject's signature	Date/Time (AM or PM)
Printed name of person witnessing subject's signature	