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: ***The Effects of Core Activation and Stabilization Training on Gait Kinetics, Kinematics, and Speed, and Self-Perceived Function in Patients with Knee Osteoarthritis***

Sponsor: LSU Health-Shreveport Program in Physical Therapy

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

Contact Information: E-mail: dflowe@lsuhsc.edu Phone: 318-813-2958

Participant Name: _____

Participant ID Number: _____

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

(If you are being asked to give permission for another person (example: your child) to be in this research study, as you read this consent form, "you" always refers to that person.

You are being asked to participate because you are 40 years old or older and either have a diagnosis of knee osteoarthritis (OA) have been selected to participate in a control group without a diagnosis of knee OA.

What should you know about a research study?

- Your participation is completely voluntary.
- You can stop or leave at any time and your decision will not affect your relationship with this institution or your normal care.
- You will be told about any new information or changes in the study that could affect your health, welfare, or choice to stay in the research.
- You can ask all the questions you want before deciding if you want to be in this study.

Why is this research being done?

The purpose of this study is to find out whether activation or training of the abdominal muscles has an effect on the walking patterns of people with knee OA. The study will compare the walking patterns of participants with and without knee OA, then determine whether education on turning the abdominal muscles on while walking, and a six-week abdominal training program, improves the walking ability.

People with knee OA typically have abnormal mechanics while walking when compared to those who do not have the diagnosis. Additionally, previous research has indicated persons with knee OA also have thinning of their abdominal muscles when compared to those without knee OA. Previous research in young, active individuals has demonstrated that abdominal training can have a protective effect against knee injury, and that a lack of stability of the trunk can predict knee injury in young athletes. As a result, the investigators of this study wish to determine whether or not targeting the abdominal muscles can change the gait of patients with knee OA.

Potential benefits to others include the knowledge gained from this study telling physical therapists whether or not to include abdominal muscle exercises in their treatment of patients with knee OA in an effort to improve their walking mechanics and function.

How long will the research last?

We expect that you will be in this research study for about 8 weeks if you have knee OA, but only one day if you do not. For those with knee OA, about 10-12 hours total over the span of the 8 weeks will be required. The 8 weeks of participation will conclude after the end of the 6-week intervention program and the final walking assessment.

How many people will be in the research?

We expect about 50 people to participate in this research at our site. Approximately 50 people will participate in the entire study nationally, since this is the only site where participants will be recruited.

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

For those who decide they wish to participate, the extent of participation will depend on whether or not they have a diagnosis of knee OA. For both groups, all research activity will take place in the LSU Health-Shreveport School of Allied Health Professions (SAHP), located at 1450 Claiborne Ave, Shreveport, LA 71103.

The first step will be to perform a walking analysis in the Gait Lab. The investigators will first collect data on your body measurements, including height, weight, and other similar measurements. Then, markers will be placed on your pelvis and legs in order to allow the infrared cameras to track your movement. There will also be two video cameras used, along with force plates which will be walked on. All of this equipment will allow the investigators to analyze how you walk. You will be asked to walk across the room several times until the investigators have three good trials. At the same time, you will be wearing biofeedback electrodes on your waist to measure the activity of your abdominal muscles. There will be no electricity going into your body, as this device only reads electrical activity of muscles.

You will then be taught how to contract your abdominal muscles, with the same biofeedback device attached to your waist which will have an alarm, or an investigator giving you a cue, as to whether or not you are contracting the muscle correctly. You will then be asked to

repeat the walking activity while contracting your abdominal muscles just as before. You may be randomly selected to perform this second walking activity with the abdominal muscles activation, and the previously described trials without activation of the muscles second.

You will only have to interact with the two investigators, and the front desk staff in the clinic when you enter the building, unless you are a participant in with knee OA and choose to participate in an exercise group and/or exercise in the open gym during the 6-week training program.

The following information is only for those with a diagnosis of knee OA:

Those with knee OA will then enroll in a 6-week abdominal muscle exercise program. This will include two appointments per week with the investigator, which will last 30-45 minutes. It will also include a home exercise program, consisting of a few exercises to be performed 3 times per week. The training program will take place in the Rehabilitation Faculty Practice Clinic on the ground floor of the SAHP. You will be allowed to participate in a group or one-on-one, and in the open gym or in a private treatment room. At the end of this training program, you will be asked to return to the Gait Lab for one more session of the walking assessment as performed on the first day.

What are my responsibilities if I take part in this research?

For those without a diagnosis of knee OA:

You will be responsible for participating in a single walking assessment in the Gait Lab.

F*or those with a diagnosis of knee OA*:

You will be responsible for participating in two walking assessments in the Gait Lab, before and after the 6-week training program. You will be asked to attend 12 exercise sessions (two appointments per week), not missing more than 4 sessions in the 6-week training program. You will also be asked to perform your home exercises at 3 times a week but performing it at least once per week.

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 treatment for your knee OA. You are free to participate in other treatment activities without participating in this study.

Instead of being in this research, your choices may include treatment by a physician, surgeon, physical therapist, or other healthcare provider.

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 in order to maintain the integrity of the research. However, you can ask us to destroy any information that identifies you so that no one can tell the data belonged to you. Our contact information is below.

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 physical therapist 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, as a participant with a diagnosis with knee OA, you miss more than 4 sessions, and do not complete the home program at least once weekly.

What are the risks of being in this study?

One possible risk of participating in the study includes possible muscle soreness, or discomfort upon removal of adhesive markers due to hair on the skin of your legs or abdomen.

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.

What are the costs of being in the research?

Your medical condition requires that you receive certain standard medical tests and procedures. You and your insurance company will be charged for the health care services that you would ordinarily be responsible to pay. In some cases, insurance will not pay for services ordinarily covered because these services were performed in a research study. You should check with your insurance to see what services will be covered by your insurance and what you will be responsible to pay.

Tests and procedures done solely because you are in the research study are not considered ordinary care. The research specific costs will be at no charge to you or your insurance company.

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 improved walking mechanics and function after the 6-week intervention program for those with knee OA.

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.

After completion of your participation in the study, the data collected will remain stored for possible future used in the computer system in the Gait Lab, and in the investigators office. This data will be deidentified, except for this form. This will only be accessible to others, or the investigators themselves, with additional approval by the institution. The data on the computer system is password protected, and both the Gait Lab and the investigator's office are key accessible only. This data will be kept for a period of seven years.

What else do I need to know?

Participants can contact the investigators at (318) 813-2958 after completion of their participation if they would like to know the results of the study.

Who can I talk to?

If you have questions, concerns, or complaints, or think the research has hurt you, talk to the research team at (318) 813-2958 or dflowe@lsuhsc.edu.

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.

CONSENT TO PARTICIPATE IN A RESEARCH STUDY

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	