Study Title: Load Modification Versus Standard Exercise to Inform Treatment for Individuals With Greater Trochanteric Pain Syndrome.

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The Ohio State University Combined Consent to Participate in Research and HIPAA Research Authorization

Study Title: Load modification versus standard exercise to inform treatment for individuals with greater trochanteric pain syndrome

Principal Investigator: Stephanie Di Stasi Roewer

Sponsor: Foundation for Physical Therapy

- **This is a consent form for research participation.** It contains important information about this study and what to expect if you decide to participate. Please consider the information carefully. Feel free to discuss the study with your friends and family and to ask questions before making your decision whether or not to participate.
- **Your participation is voluntary.** You may refuse to participate in this study. If you decide to take part in the study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you and you will not lose any of your usual benefits. Your decision will not affect your future relationship with The Ohio State University. If you are a student or employee at Ohio State, your decision will not affect your grades or employment status.
- **You may or may not benefit as a result of participating in this study.** Also, as explained below, your participation may result in unintended or harmful effects for you that may be minor or may be serious depending on the nature of the research.
- **You will be provided with any new information that develops during the study that may affect your decision whether or not to continue to participate.** If you decide to participate, you will be asked to sign this form and will receive a copy of the form. You are being asked to consider participating in this study for the reasons explained below.

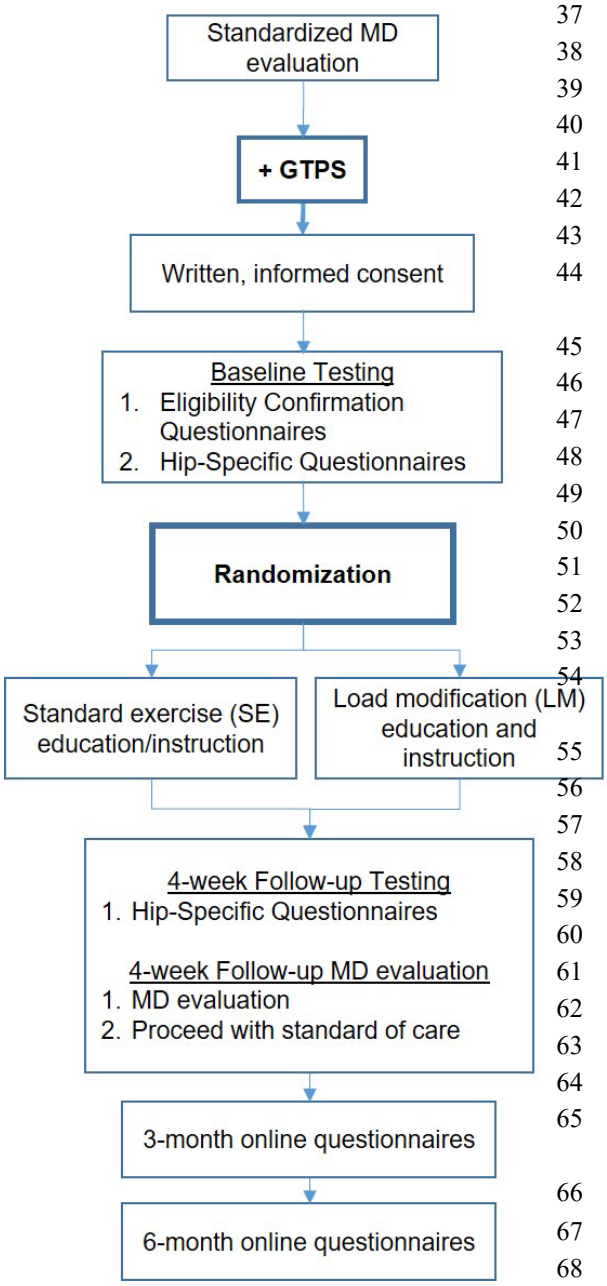
1. Why is this study being done?

The purpose of this study is to compare the effects of two different physical therapy programs on pain and function in individuals diagnosed with greater trochanteric pain syndrome (GTPS). You are being asked to participate in this study because your physician has confirmed that you have a diagnosis of GTPS (also known as lateral hip pain). Physical therapy is a common treatment option, but has mixed results. We are trying to understand what the most effective program is for optimizing function and reducing pain for the majority of individuals with GTPS.

2. How many people will take part in this study?

Up to 64 subjects will participate in this study.

3. What will happen if I take part in this study?



The figure to the left provides details of the testing and treatment involved in this study. If you choose to participate, you will be randomly assigned one of two physical therapy treatment groups, standard exercise education or load modification education. You have an equal chance of being assigned to either of the two treatment groups.

Standard exercise education includes exercises currently prescribed by physical therapists, like stretching and strengthening activities. Load modification education also includes exercises currently prescribed by physical therapists, like stretching and strengthening activities, but will also include education on common daily postures and movement patterns that may increase load and stress on the muscles and tendons around your hip.

You will know which exercise group you have been assigned, but the individual testing you will not and cannot know to which group you have been assigned. Each time you see the individual testing you, he/she will remind you they cannot know to which group you have been assigned and to avoid discussing any details of your exercise program with that person. If the individual testing you learns to which group you have been assigned, it could influence or invalidate the results of the study.

Participants in BOTH groups will:

- *complete questionnaires related to current pain level and level of function*. You will be asked to complete these questionnaires at baseline, and 4 weeks, 3 months, and 6 months after your initial study visit. During your 4-week home program, you will also be asked to complete weekly questionnaires about compliance with and response to your home program and your activity level.
- *consult with an on-sight physical therapist with an expertise in hip rehabilitation*. The physical therapist will provide verbal and written education regarding the assigned treatment.

You will complete all of your questionnaires online. On the days of your visit with the physician, you can complete your questionnaires in the office on the computer desktop or tablet made available to you. For the questionnaires we ask you to complete weekly during your 4-week home program, a unique link will be sent to your email address or a study personnel will contact you verbally via telephone each week. This will allow you to access your weekly survey at your convenience from your home computer, smartphone or telephone.

In order to assess the effectiveness of the physical therapy treatments, you cannot receive other treatment (ie. corticosteroid injections, surgery, other types of physical therapy) during the 4 week exercise period. This 4-week 'wait period' is consistent with recommended waiting periods after receiving a corticosteroid injection, another common treatment for GTPS.

A 4-week follow-up visit with your physician is standard of care for patients with GTPS at Ohio State Sports Medicine. This allows you, with your physician, to evaluate the effects of common treatments like medication, injections, 'wait and see' advice, and/or physical therapy. Our research will work within this same 4-week 'trial' period during your regularly scheduled doctor's visits to provide one of two different types of exercise education. As with any standard of care doctor's visit, you (and your insurance company) will be billed for the costs. There is no additional cost to participate in the research; your time with the physical therapist during these two sessions is not billed to you or your insurance company.

After the 4 week initial study period, you can pursue any other treatment of their choice, including treatment provided to the other group. At the standard of care 4-week follow-up, you can request the exercise program of the other group. There will be no additional cost associated with this education session.

Through your 3 month and 6 month questionnaires, we will ask you to provide information about other treatments you have had since enrollment into the study. You will automatically receive a link via email to your questionnaires at 3- and 6- months. We may follow-up with you again by email or by phone if your questionnaires are not completed within one week of the automated message. You are not required, as part of this study, to attend any physician follow-ups.

4. How long will I be in the study?

Your total time commitment to the study will be approximately 2 hours.

You will spend about 3-5 minutes with study personnel reviewing your health history in order to determine your eligibility. If they determine you are not eligible, your time in the study is complete.

If you are eligible, you will then spend approximately 30 additional minutes during their baseline visit to complete consent paperwork, online surveys/questionnaires, and the treatment. During their 4-week follow-up, participants will spend about 8-10 minutes completing online questionnaires. Online or telephone questionnaires will be completed weekly over the first 4 weeks (8-10 minutes each), and at 3 and 6 months post-baseline (10-15 minutes each). If you

choose to complete the home program as instructed (daily), you will spend about 15-20 minutes each day for 4 weeks performing home exercises, regardless of which exercise education program you were assigned.

5. Can I stop being in the study?

You may leave the study at any time. If you decide to stop participating in the study, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled. Your decision will not affect your future relationship with The Ohio State University.

6. What risks, side effects or discomforts can I expect from being in the study?

After you enroll in the study, a study team member will review with you your health history in order to confirm your eligibility to participate. This will take approximately 3-5 minutes. If they determine you are not eligible, you will be withdrawn from the study and will not complete any of the testing. At this time, you can ask to receive the exercise handouts provide to participants. You will not be asked to complete any follow-up testing.

The tasks associated with this study, including a physical examination and performance of exercises, have typical risks associated with any physical exertion, including post-activity soreness or in rare cases, muscle strains. All activities in this study are considered standard of care and have no greater risks associated with them than typical exercise or physical therapy evaluation and treatment.

7. What benefits can I expect from being in the study?

You may experience pain relief and/or improved function as a result of study participation. Your participation may also improve our understanding of the most effective treatment of individuals with GTPS.

8. What other choices do I have if I do not take part in the study?

You may choose not to participate without penalty or loss of benefits to which you are otherwise entitled.

9. What are the costs of taking part in this study?

There are no direct costs associated with taking part in this study; however, your insurance will be billed as it typically would for medical care for physician and physical therapy appointments.

10. Will I be paid for taking part in this study?

You are eligible to receive $60 in gift cards over the course of the study. You will receive a gift card after completion of the questionnaires, both at the initial visit after the intervention ($20) and the 4-week follow-up visit ($20). You will receive an additional $20 gift card if you

complete all of the weekly online/telephone surveys between the initial and follow-up visits. You will not receive compensation for the 3- month and 6- month questionnaires. By law, payments to subjects are considered taxable income.

11. What happens if I am injured because I took part in this study?

If you suffer an injury from participating in this study, you should notify the principal investigator of this study as soon as possible. The principal investigator will determine if you should obtain a medical evaluation.

The cost for this treatment will be billed to you or your medical or hospital insurance. The Ohio State University has no funds set aside for the payment of health care expenses for this study.

12. What are my rights if I take part in this study?

If you choose to participate in the study, you may discontinue participation at any time without penalty or loss of benefits. By signing this form, you do not give up any personal legal rights you may have as a participant in this study.

You will be provided with any new information that develops during the course of the research that may affect your decision whether or not to continue participation in the study.

You may refuse to participate in this study without penalty or loss of benefits to which you are otherwise entitled.

An Institutional Review Board responsible for human subjects research at The Ohio State University reviewed this research project and found it to be acceptable, according to applicable state and federal regulations and University policies designed to protect the rights and welfare of participants in research.

13. Will my study-related information be kept confidential?

All information related to your study eligibility will be retained in a locked file drawer, accessible only to approved study personnel. If you are eligible to complete the surveys, we will work to make sure that no one sees your survey responses without approval. But, because we are using the Internet to collect your surveys, there is a chance that someone could access your online responses without permission. In some cases, this information could be used to identify you. Your data will be protected with a code to reduce the risk that other people can view the responses.

Efforts will be made to keep your study-related information confidential. However, there may be circumstances where this information must be released. For example, personal information regarding your participation in this study may be disclosed if required by state law.

Also, your records may be reviewed by the following groups (as applicable to the research):

- Office for Human Research Protections or other federal, state, or international regulatory agencies;
- U.S. Food and Drug Administration;
- The Ohio State University Institutional Review Board or Office of Responsible Research Practices;
- The sponsor supporting the study, their agents or study monitors; and
- Your insurance company (if charges are billed to insurance).

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search the website at any time.

14. HIPAA AUTHORIZATION TO USE AND DISCLOSE INFORMATION FOR RESEARCH PURPOSES

I. What information may be used and given to others?

- Past and present medical records;
- Research records;
- Records about phone calls made as part of this research;
- Records about your study visits;
- Information that includes personal identifiers, such as your name, or a number associated with you as an individual;

- Information gathered for this research about:
  - Physical exams
  - Diagnostic imaging
  - Diaries and questionnaires
- Records about any intervention you received including, but not limited to:
  - Corticosteroid injection
  - Prescription pain medication
  - Physical Therapy
  - Surgery

II. Who may use and give out information about you?

Researchers and study staff may use information about you. The information you provide as part of this study is accessible only to trained research staff with approved access to your data. Only deidentified data (ie. data that cannot be traced back to you) would be given out. Primarily, this is done in the form of research or educational presentations or publications.

III. Who might get this information?

- Authorized Ohio State University staff not involved in the study may be aware that you are participating in a research study and have access to your information;
- If this study is related to your medical care, your study-related information may be placed in your permanent hospital, clinic or physician's office record;

IV. Your information may be given to:

- The U.S. Food and Drug Administration (FDA), Department of Health and Human Services (DHHS) agencies, and other federal and state entities;
- Governmental agencies in other countries;
- Governmental agencies to whom certain diseases (reportable diseases) must be reported; and
- The Ohio State University units involved in managing and approving the research study including the Office of Research and the Office of Responsible Research Practices.

V. Why will this information be used and/or given to others?

- To do the research;
- To study the results; and
- To make sure that the research was done right.

VI. When will my permission end?

This permission will be good until 3 years after the last participant completes their 6 month survey/questionnaires.

VII. May I withdraw or revoke (cancel) my permission?

Yes. Your authorization will be good for the time period indicated above unless you change your mind and revoke it in writing. You may withdraw or take away your permission to use and disclose your health information at any time. You do this by sending written notice to the researchers. If you withdraw your permission, you will not be able to stay in this study. When you withdraw your permission, no new health information identifying you will be gathered after that date. Information that has already been gathered may still be used and given to others.

VIII. What if I decide not to give permission to use and give out my health information?

Then you will not be able to be in this research study and receive research-related treatment. However, if you are being treated as a patient here, you will still be able to receive care.

IX. Is my health information protected after it has been given to others?

There is a risk that your information will be given to others without your permission. Any information that is shared may no longer be protected by federal privacy rules.

X. May I review or copy my information?

Signing this authorization also means that you may not be able to see or copy your study-related information until the study is completed.

15. Who can answer my questions about the study?

For questions, concerns, or complaints about the study, or if you feel you have been harmed as a result of study participation, you may contact

Stephanie Di Stasi: phone (614) 685-9779; email: stephanie.distasi@osumc.edu
Kate Martin: phone: (614) 293-2385; email: kathryn.martin4@osumc.edu

For questions related to your privacy rights under HIPAA or related to this research authorization, please contact **the HIPAA Privacy Officer: Address: Suite E2140, 600 Ackerman Road, Columbus, OH 43210; Phone: (614) 293-4477**

For questions about your rights as a participant in this study or to discuss other study-related concerns or complaints with someone who is not part of the research team, you may contact Ms. Sandra Meadows in the Office of Responsible Research Practices at 1-800-678-6251.

If you are injured as a result of participating in this study or for questions about a study-related injury, you may contact:

Stephanie Di Stasi: phone (614) 685-9779; email: stephanie.distasi@osumc.edu

Signing the consent form

I have read (or someone has read to me) this form and I am aware that I am being asked to participate in a research study. I have had the opportunity to ask questions and have had them answered to my satisfaction. I voluntarily agree to participate in this study.

I am not giving up any legal rights by signing this form. I will be given a copy of this combined consent and HIPAA research authorization form**.**

Printed name of subject	**Signature of subject**
	AM/PM
	Date and time
Printed name of person authorized to consent for subject (when applicable)	**Signature of person authorized to consent for subject (when applicable)**
Relationship to the subject	**AM/PM** **Date and time**

Investigator/Research Staff

I have explained the research to the participant or his/her representative before requesting the signature(s) above. There are no blanks in this document. A copy of this form has been given to the participant or his/her representative.

Printed name of person obtaining consent	**Signature of person obtaining consent**
	AM/PM
	Date and time

Witness(es) - *May be left blank if not required by the IRB*

Printed name of witness	**Signature of witness**
	AM/PM
	Date and time
Printed name of witness	**Signature of witness**
	AM/PM
	Date and time