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

NCT: NCT03571971

Date: January 31, 2022

Approach:

Overview: **This pragmatic, feasibility randomized controlled trial (RCT) will consist of** up to **64 adult women and men** (ratio of approximately 4:1, respectively) **between the ages of 18 and 70 who are diagnosed with unilateral greater trochanteric pain syndrome (GTPS) during their initial physician evaluation** within the Jameson Crane Sports Medicine Institute physician clinics at The Ohio State University Wexner Medical Center (OSUWMC). All patients will have their standard clinical evaluation with their physician. The group of patients invited to participate in this study will be individuals who meet our clinical diagnostic criteria for GTPS who do not have systemic health or serious musculoskeletal disorders or recent treatment for their hip pain *(Table 1).* Members of the study team involved in recruitment and consenting will use a two-part process to ensure eligibility using the "Patient Screen Checklist" and the "Eligibility Criteria Checklist," described in detail in the Standard Operating Procedures document. The baseline study visit will occur immediately following the standard clinical examination with the physician.

Table 1. Eligibility Table

Inclusion Criteria	Exclusion Criteria
Ages 18-70, with a unilateral diagnosis of GTPS with: • Lateral hip pain, worst over greater trochanter, for ≥ 3 months • Pain with palpation over greater trochanter • Average pain intensity of ≥4/10 most days of the week	Any of the following treatments *within the last 3 months*: • corticosteroid injection in the affected hip • physical therapy or other skilled exercise intervention by a medical or rehabilitation professional
+ Single leg stance for 30 seconds (lateral hip pain reproduced: +LR of 12.2 for MRI-confirmed GTPS (Grimaldi 2017, BJSM), OR a*t least one of* the following clinical examination criteria: 1). + Hip FADER test (≥2/10 pain with 90° passive flexion, adduction, external rotation) 2). + Hip FADER-R (lateral hip pain reproduced with resisted internal rotation in FADER position) 3). + Passive hip adduction in sidelying (lateral hip pain reproduced with overpressure into hip adduction) 4). + Adduction with resisted isometric abduction (lateral hip pain reproduced with resistance in adduction position) 5). + FABER (lateral hip pain reproduced with flexion, abduction, external rotation)	Any of the following concomitant impairments or conditions: 1). Known or observed advanced spine, hip, knee, or ankle joint pathology, including: • Spinal or lower extremity surgery within the last 6 months • Imaging data showing Kellgren Lawrence grade ≥2 in any lower extremity joint with concurrent complaint ≥2/10 most days of the week. • Groin pain as the primary hip pain complaint ≥2/10 most days of the week. • <90 degrees of active hip and knee flexion bilaterally • <0 degrees of active ankle dorsiflexion 2). Systemic inflammatory diseases, or any systemic disease that affects the nervous or musculoskeletal system or uncontrolled diabetes, or active malignancy 3). Individuals who cannot tolerate or should not assume the positions required for the exercises for any reason other than hip discomfort

FADER, flexion adduction external rotation; FABER, flexion abduction external rotation

As part of the clinic-based testing for the study, participants will be asked to (1) complete online surveys with validated patient-reported questionnaires about their pain and function. The single-session of education and instruction (load modification vs standard exercise) will be performed by a licensed physical therapist immediately after the testing procedures are complete. Participants will undergo the same clinic-based testing protocol at the 4-week follow-up prior to their visit with the physician in the Jameson Crane Sports Medicine Institute at OSUWMC. For 4-weeks following the initial evaluation and clinic-based testing, participants will be asked to complete weekly online/telephone surveys to document their hip pain and function as well as their compliance with the prescribed home exercise program. Key variables of interest *(Table 2)* include the Global Rating of Change scale[18] and the Numeric Pain Rating Scale[18,33,34]. The other secondary variables of interest will help us more completely assess the effect of the proposed program hip function questionnaires, overall function,[35–37] activity level,[38] and self-efficacy.[39]

Table 2. Variables of Interest

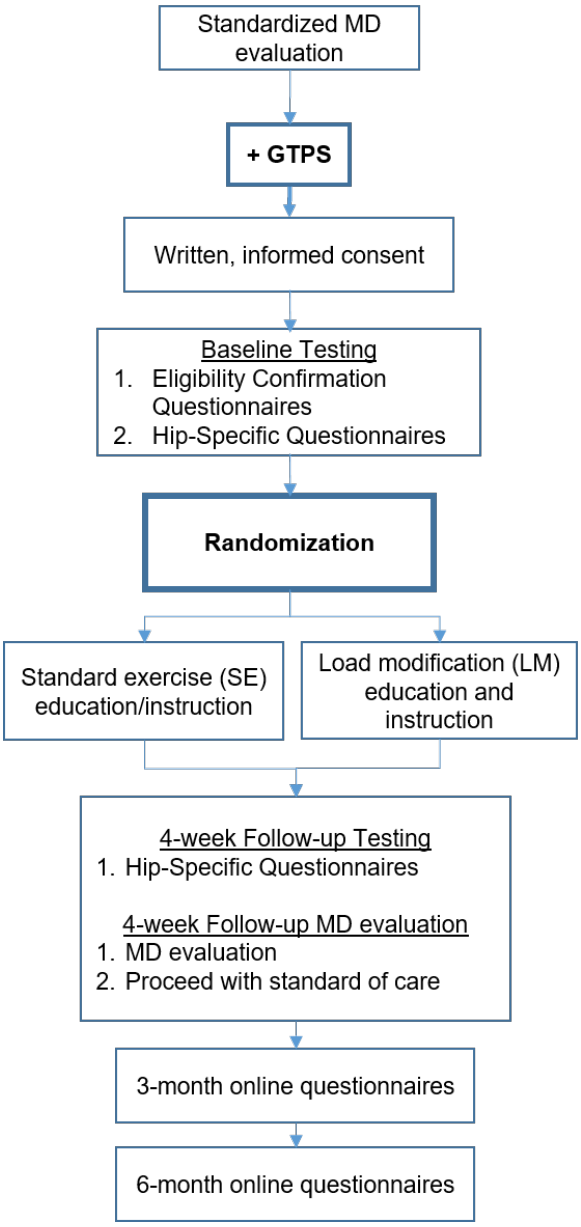
Primary VOIs	Secondary VOIs
Global Rating of Change (GROC) (Mellor 2016)	Frontal plane kinematics of the trunk, pelvis, hip, and knee during a single leg squat
Numeric Pain Rating Scale (NPRS) (Farrar 2010, Fearon 2017, Mellor 2016)	Victorian Institute of Sport Assessment for Greater trochanteric pain syndrome (VISA-G) (Fearon 2014)
	Pain Self-Efficacy Questionnaire (PSEQ) (Nicholas MK 2007)
	Patient Acceptable Symptomatic State question (PASS) (Levy 2016, Chalal 2015)
	Patient Reported Outcomes Measurement Information System (PROMIS) Bank v2.0 Physical Function
	Tegner Activity Level Scale (TALS) (Mohtadi 2012)

A. Sample size estimation:

To inform our sample size estimation for this feasibility randomized controlled trial, we used the available literature which reported a 7% treatment success rate at 4-weeks following a single, standard exercise session (ie. non-load modifying)[6] and the hypothesized 70% treatment success rate following an 8-week to a supervised load modification program.[18] Conservatively, we estimated that the standard exercise (SE) group and load modification (LM) group would have a 20% and 50% success rate, respectively. **With one-side type I error=0.1, power=80%, and allocation ratio is 1:1, we will need 22 participants in each group (total N=44). We will recruit 64 individuals with GTPS to account for up to 30% attrition over the course of the study due to drop-out.** To fully recruit the study after proper regulatory approval is in place and staff are trained, we anticipate a 15-month recruitment time-frame for the 60 participants. This factors in a recruitment rate of 5 participants per month (see Letters of Support/Collaboration), from an eligible 10 (minimum 50% recruitment rate).

Recruitment and Informed Consent *(Figure 1)*: Prior to enrollment, written informed consent will be obtained from all potential participants after information about the purpose, methods, and demands of the study is provided both verbally and in writing (via the consent documentation) to the participant. The participants for this trial will be recruited from the Jameson Crane Sports Medicine Institute physician clinics at OSUWMC during their on-site medical visit. Once the treating physician confirms GTPS diagnosis through our standardized and validated clinical examination process (Table 1, Inclusion Criteria),[18,31] the study recruiter will then discuss the study opportunity with the patient and proceed with the consenting process when appropriate.

All participants will be provided verbal and/or written information (depending on preference) detailing the purpose of the study, type of testing and treatment involved, and potential risks and benefits of participation. Participants will be given time to ask questions and determine their interest in participation without coercion. Patients will be informed during the recruiting process, that if they consent to study participation, they cannot receive a corticosteroid injection that day or during the 4 weeks of the trial. A 4-week follow-up visit to the physician is standard of care for patients with GTPS seen in the Jameson Crane Sports Medicine Institute. This allows physicians to evaluate the effects of common treatments like medication, injections, 'wait and see' advice, and/or physical therapy; at that time, they determine next step interventions based on the initial treatment response. Our research will work within this same 4-week 'trial' period during their regularly scheduled doctor's visits to provide one of two different types of exercise education.



Patients who refuse to forgo injections for 4 weeks will be excluded from the study. Individuals who, for medical reasons, cannot tolerate or should not assume the positions required for the exercises for any reason other than hip discomfort will be excluded. Patients must enroll on the same day as the visit with their physician in order to receive the intervention; however, they do not have to complete the REDCap questionnaires during that visit. All participants will have the option to complete their questionnaires via a unique link to their personal survey or verbally by phone; the online link be sent to them via email to be completed at their earliest convenience. The participants will be required to sign the IRB-approved consent and HIPAA forms prior to participation in the study.

B. Randomization, concealed allocation, and blinding: A randomization list will be generated and secured with the study biostatistician prior to the start of the study. It will contain study-specific unique identifiers (ie. GTPS1, GTPS2, etc) and a binary code for treatment group (ie. 0 or 1). A copy of this list will be provided to the Sports Medicine Clinical Research Manager who provides administrative support to all clinical trials in the Sports Medicine Institute. The Manager will determine the group assignment (e.g. 0 = LM, 1 = SE) independent of the biostatistician and the PI. The PI will put together 30 concealed envelopes for each treatment group that contain the group assignment and the appropriate exercise program instructions (SE vs LM) and provide these to the

Manager. The Manager will then label, seal, and place them in a drawer in the physician. The Manager will not be involved in the recruitment, testing, or analysis involved with this trial. She will be the only person with the UID, randomization order, and treatment allocation data all in one place. These data will be stored under lock and key in the private office of the Manager, and in a password-protected file, accessible only to the Manager.

After consent, participants will proceed with testing by a blinded tester. Randomization and group allocation will occur immediately following testing. After testing, the tester will inform the treating physical therapist of group (e.g. 0 vs 1). The drawer with the concealed/sealed envelopes will be accessible to the treating physical therapist and the physicians. The treating physical therapist will select the next available envelope from the appropriate group (0 vs 1) and proceed with the assigned treatment; only when she or he breaks the envelope seal will she or he know the group assignment (LM vs SE).

C. Blinding: Investigators involved in the participant testing and statistical analysis of the outcome variables of interest will be blinded to group allocation. The treating physicians, physical therapist interventionists and patients cannot feasibly be blinded to treatment arm. Participants will not be informed of the study hypotheses and unblinded investigators will not share group allocation information with the blinded investigators. All references to group assignment in other research documentation (ie. REDCap™, video data collection form) will be coded (ie. '0' and '1') to maintain blinding. One trained tester will consent and perform baseline and 4-week follow-up testing. At the 4-week follow-up, the physician will re-evaluate the participant with the clinical diagnostic criteria and discuss their compliance and response to the home exercise program. As is consistent with standard of care, the physician and patient will determine the next course of treatment. The treatment plan will be entered using custom coding (ie. 'smart phrases') to allow discrete data to be queried. Statistical analysis will be performed by the blinded study biostatistician with input from the PI (see Statistical Analysis Plan). After the physician finishes his/her visit with the participant, the tester will proceed with the 4-week follow-up testing and will remind the participant she or he is blinded to treatment and cannot receive any information about the group to which they have been assigned.

D. Clinic-based testing: Baseline testing and treatment will occur in the clinic, immediately following the physician evaluation and confirmation of GTPS diagnosis, for all patients who consent to participate in the study. The clinic-based testing sessions will occur at baseline (immediately after randomization) and at the 4-week clinical visit by a blinded tester. These testing sessions will take about 10 minutes for the questionnaires. Clinic-based testing will include patient-reported questionnaires using Research Electronic Data Capture (REDCap™) survey. REDCap™ is a secure, web-based application that supports data capture, auditing, and exporting[40] to gather baseline data with regard to their pain and level of function[41] and is hosted at The Ohio State University. Participants will be given the option to complete the survey on either our research handheld tablet (iPad) or laptop or desktop provided by the researcher.

E. Intervention: The single physical therapy educational and instructional session will occur at baseline, immediately following the clinic-based testing. This session will be administered by the unblinded physical therapist interventionists who is trained to administer these protocols. **Participants will receive either (1) standard exercise education and instruction (SE) or (2) load modification education and instruction (LM), based on their treatment group** randomization. Standard exercise education includes exercises currently prescribed by physical therapists, like stretching and strengthening activities. Participants randomized to the load modification group will undergo approximately 5 additional minutes of education and instruction about their posture and movement modifications and will also be provided an information sheet with text and pictures (see Appendix: Supplements). Both groups will be instructed to perform the home exercise program once per day, performing Level 1 activities for the first two weeks and Level 2 activities for the last two weeks. (see Appendix. Supplements - Home exercise programs for both groups). Both groups will receive handouts with pictures and detailed instructions for each of their exercises.

a. Home exercise program (HEP): Both protocols were modelled after current literature for a standard lower extremity exercise program for GTPS and a load modification program. The load modification program from Mellor and colleagues (2016) was further adapted to include exercise dosage shown to be effective in

patellar tendinopathy trials.[29,30] The HEP will be instructed and guided by the physical therapist, in combination with practice by the patient, and demonstration by the therapist, if needed. It is expected that program instruction will take about 15-20 minutes in both groups and that the home programs themselves will take between 15-20 minutes. The physical therapist will provide standardized cueing to optimize technique. Participants will be provided opportunities to ask questions during the session and provided a written home program with text and pictures for the patient to follow. These instructions, including the pictures will be made available online through REDCap™, along with instructional videos to provide the participant an additional resource to clarify technique.

b. Activity modifications instructions for the load modification group: This instruction will take approximately 5 additional minutes based on our use of this handout in our physical therapy clinic with patients with GTPS for the past 2 years.

i. **Posture and movement handouts**: The physical therapist will share the handout (Appendix 2. Supplements – Lateral Hip Pain Activity Modifications) with the participant, asking them to identify any of the movements or postures (ie. sitting with legs crossed, iliotibial band stretching) that are common to their daily activities. Patients will be educated as to how each contributes to increased pressure on the lateral structures of hip and can cause pain. The physical therapist will review, demonstrate, and provide feedback on all items relevant to the participants' daily routine.

ii. **Using pain as a load modification guide**: Participants in the load modification group will be instructed not to exceed 5 out of 10 on the NPRS during the exercises, and proceed with training as long as this pain intensity during exercise does not increase their pain in within the next 24 hours.[13]

iii. **Changes to activity level**: participants in the load modification group who report >5/10 pain with exercise that does not change or is worse the next day will be advised to reduce their physical exercise activity (ie. walking, hiking, running).[13] Participants in the load modification group will also be instructed to modify activity level as needed to avoid increasing pain or stiffness each week. Participants randomized to the standard exercise group will be instructed to avoid the painful physical exercise activity for the duration of the 4-week program (ie. "If it hurts, don't continue to do it. Focus on these few exercises for the 4 weeks). Activity level will be monitored using the Tegner Activity Level Scale on a weekly basis over the 4-week intervention.[43]

F. Weekly online/telephone surveys: Participants will be asked to complete a REDCap™ survey (Appendix 2. Supplements – Weekly Survey) each week until their follow-up visit to the Jameson Crane Sports Medicine Institute for study testing and their clinical visit. This weekly survey will include the GROC, the NPRS, and home exercise program compliance questions. It will also include questions about any treatment they have received or injuries they have had that may affect the outcomes of interest.

Though not the primary focus of this feasibility trial, we will invite all participants to complete follow-up REDCap™ surveys at 3 and 6 months post initial intervention to gather information about current pain level, function, and activity level. Participants will not be asked to complete any home exercise program compliance data or report changes to their care or any new injuries. With IRB approval, we will obtain information regarding subsequent treatments and procedures from the participants' electronic health record with the goal of providing us relevant preliminary data to inform the variables of interest for the future clinical trial.

Safety stopping rules:

We anticipate a small proportion of the participants in each group (<15%) may experience an increase in symptoms with participation in this trial. Thus, we will employ safety stopping rules as described in detail in the Human Subjects document.

G. Data management

a. **Personal Health Information (PHI):** The participant's medical chart information, REDCap™ data, and 2D videos all contain PHI. All PHI relevant to the patient's hip condition is collected and maintained within the participant's medical chart (IHIS). These PHI data are accessible only by the approved, unblinded researchers who have undergone IHIS training within OSUWMC. REDCap™ data is encrypted and sits behind OSUWMC's firewall. Data will be coded with a unique-identifier (UID) and the file which links the UID to the patient's personal

health information (PHI) will be kept on a secure server behind the OSUWMC firewall and password-protected. Only research team members with user privileges (approved by the PI) have access to this database via username and password. When REDCap™ data are exported to files for analysis, they will be exported without PHI data unless the analysis requires it and the PI approves. These files will be maintained on our secure laboratory server behind OSUWMC firewall; it is accessible only to members of the research team. 2D video will be collected with a GoPro. All videos will be transferred within 24 hours from the GoPro to the (1) laboratory server within a separate, password-protected folder on our server, accessible only to investigators blinded to treatment group, and (2) REDCap. 2D videos will be deleted from the GoPro after successful transfer to the server. As part of the 2D video collection, we will use REDCap to document NPRS scores with the matching video recordings with each task.

Post collection data storage and analysis: A blinded study team member will be responsible for 2D video quality control and creating trial clips for subsequent analysis. Video analysis will begin after the last participant completes their 4-week follow-up. These data will be used to determine measurement variability (intraclass correlation coefficients, standard error of the measurement, and minimal detectable change values) and provide information with regard to changes in movement patterns as a result of program participation. Frontal plane kinematics (peaks and excursions) of the trunk, pelvis, hip, and knee will be calculated (Kinovea version 0.8.15) for each task. Analysis will include the double and single leg static starting postures and peak frontal plane motion (as identified using the joint position tracking function). Lines will be drawn through the long axes of the bones for the shank and thigh, through the ASIS for the pelvis, and from the sternum to the midpoint of the ASIS line (Figure 2). Horizontal and vertical 'lab axes' will be applied to the image to allow calculations relative to pure horizontal (ie. pelvic drop) and pure vertical (ie. trunk lean). Angles will also be calculated with respect to the proximal segment.

Statistical analysis plan:

An intention to treat approach is planned for all analyses, using all participants who were randomized who have available data at 4 week follow-up. Where appropriate, normality will be assessed and non-parametric approaches will be used when assumptions are violated. Demographics and clinical characteristics (ie. age, sex distribution, BMI, baseline pain scores, etc) will be summarized for SE and LM groups, respectively, and compared between the groups using two-sample t-test for continuous outcomes or Fisher's exact test for discrete outcomes.

To evaluate the effect of treatment group allocation on dichotomized treatment success (Aim 1, Hypothesis 1), defined as either: 1) at least 'moderately better' on the Global Rating of Change scale or 2) ≥2 point decrease on the Numeric Pain Rating Scale, we will use Fisher's exact test to compare the success rate between SE and LM group. Frontal plane kinematics are a secondary variable of interest (Aim 1, Hypothesis 2). With the available 2D data set, we will compare change scores between groups using independent t-tests and/or effect sizes. These data may serve as preliminary data for future grant applications.

To evaluate study retention rates and treatment adherence (Aim 2) we will use descriptive statistics. We will calculate the number of participants in each treatment group who report completing the home program "most (4+) days of the week" and "mostly as directed" on each of the four (4) follow-up REDCap™ surveys. The retention rate and compliance rate will be calculated with 95% confidence interval using exact binomial for each treatment at each follow-up.

H. Feasibility: We will evaluate the feasibility of a future clinical trial to determine the efficacy of load modification exercises and education in improving post-operative function in patients with GTPS by quantifying:
   1. The proportion of recruited participants from the total number (a) screened and (b) eligible
   2. Participant adherence as measured by: (1) number of weekly surveys completed (ie. number of surveys completed/total number of surveys, (2) weekly home exercise program compliance (self-reported) over the duration of the study, (3) participation retention/attendance at the 4-week follow-up session, and (5) reasons for drop-out and when it occurred (e.g. participant moved out of the area prior to 4-week follow-up)

I. Potential Problems/Alternative Strategies

1. MRI will not be used to confirm gluteal tendinopathy. Grimaldi and colleagues (2017)[31] performed a diagnostic utility study of 65 individuals with GTPS that showed pain during a 30 second single limb stance was strongly associated with MRI-confirmed gluteal tendinopathy (+LR = 12.2). Importantly, literature also confirms the high prevalence of MRI-confirmed gluteal tendinopathy in asymptomatic individuals,[31,44,45] highlighting the absence of a strong association between imaging-identified tissue pathology and the clinical syndrome of GTPS. For the aims of this study, this and other validated clinical tests will be used to identify individuals with GTPS. We accept that a small, but insignificant proportion of enrolled participants with clinical indicators of GTPS may not have radiologically-confirmed gluteal tendinopathy. We do not anticipate this will affect the results of this study.
2. Treatment success is no different between groups (ie. equally effective or ineffective). Compressive forces of the gluteal tendons onto the greater trochanter increase with poor frontal plane control of the hip and pelvis. If is unexpected that modification of these loads through postural and activity modifications and targeted exercises would not be significantly more effective than exercises that disregard this mechanism. However, the lack of effect may indicate the need for more frequent, supervised intervention. If both groups demonstrate equal success, these data would still support our proposed model of a 'physical therapy first' approach.
3. Hip abduction weakness is a clinical feature of GTPS and strength gains may be a critical metric of program success. Hip abduction strength will not be measured, but is associated with poor frontal plane pelvic and hip control during a squatting task. We concede that movement changes may be associated with strength improvements, but contend that improvements in strength do not ubiquitously translate to better movement. Thus, we opted to evaluate movement in this preliminary efficacy and feasibility trial.
4. We may be underpowered to see an effect over the 4 week period. The 4-week follow-up period is consistent with clinical practice and the approach to previous studies[6,22] evaluating the effect of corticosteroid injections. Further, we modelled our treatment approach on robustly designed RCTs[14,29,30] in other lower extremity tendinopathy that suggest this 4-week period is enough time to see an effect if one exists.

Benchmarks for success

The first benchmark will be full participant enrollment (N=60) within the first 15 months of the study The second benchmark will be to maintain 80% 4-week follow-up retention rate; we will assess this at the midpoint of recruitment and testing (N=30) and again at final testing of all participants. Finally, our third benchmark of success will be to have <15% adverse events rates as defined per GROC (see Protection of Human Subjects section)

Citations (in order of appearance)

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