PROTOCOL TITLE:

Comparison of a Hip Activation versus a Combined Hip Activation and Core Stabilization Program on Improving Lower Extremity Function.

PRINCIPAL INVESTIGATOR:

Daniel W. Flowers, PT, DPT, PhD
Assistant Professor of Physical Therapy
(318)-813-2958
Daniel.flowers@lsuhs.edu

VERSION NUMBER:

1

DATE:

12/7/23

Table of Contents

1.0 Objectives*

1.1 The purpose of this investigation is to compare the effects of a combined hip activation and core stabilization training home exercise program (HEP) versus a hip activation training HEP alone on lower extremity (LE) frontal plane mechanics in healthy individuals.

Specific Aim 1: To determine whether between- and/or within-group differences exist on the Forward Step-Down test (FSDT) when comparing a combined hip activation and core stabilization training HEP as compared to a hip activation training HEP.

Specific Aim 2: To determine whether between- and/or within-group differences exist on the peak external knee abduction moment when comparing a combined hip activation and core stabilization training HEP to a hip activation training HEP.

Specific Aim 3: To determine whether between- and/or within-group differences exist on gluteal and core muscle surface electromyography (sEMG) when comparing a combined hip activation and core stabilization training HEP to a hip activation training HEP.

Specific Aim 4: To determine whether a dose-response relationship exists between HEP compliance and change on the FSDT, peak external knee abduction moment, and sEMG.

1.2 Specific Aim 1:

H_0: There will be no between and/or within-group differences on the FSDT between the hip-activation group and the hip-activation-plus-core-stabilization group.

H_1: There will be between and/or within-group differences on the FSDT between the hip-activation group and the hip-activation-plus-core-stabilization group.

Specific Aim 2:

H_0: There will be no between and/or within-group differences on the peak external knee abduction moment during a drop landing task between the hip-activation group and the hip-activation-plus-core-stabilization group.

H_1: There will be between and/or within-group differences on the peak external knee abduction moment during a drop landing task between the hip-activation group and the hip-activation-plus-core-stabilization group.

Specific Aim 3:

H_0: There will be no between and/or within-group difference on the sEMG data between the hip-activation group and the hip-activation-plus-core-stabilization group.

H_1: There will be between and/or within-group differences on the sEMG between the hip-activation group and the hip-activation-plus-core-stabilization group.

Specific Aim 4:

H_0: There will be no dose-response relationship between HEP compliance and change on the FSDT.

H_1: There will be a dose-response relationship between HEP compliance and change on the FSDT.

H_0: There will be no dose-response relationship between HEP compliance and change on the peak external knee abduction moment during a drop landing task.

H_1: There will be a dose-response relationship between HEP compliance and change on the peak external knee abduction moment during a drop landing task.

H_0: There will be no dose-response relationship between HEP compliance and change on the sEMG.

H_1: There will be a dose-response relationship between e HEP compliance and change on the sEMG.

2.0 Background*

2.1 Knee injuries accounted for an estimated six and a half million visits to the emergency room between 1999 and 2008, and prevalence of knee pain has increased substantially over the last several decades with notably high incidence of patellofemoral pain.[1,2] A recent shift in the literature occurred regarding the treatment of persons with knee pain, particularly those diagnosed with patellofemoral pain syndrome (PFPS), with focus being more on hip activation programs for treatment.[3] Individuals with PFPS are known to exhibit hip and knee musculature weakness that most likely evolved from inactivity due to pain.[3] Treatment for PFPS previously involved targeting patella tracking abnormalities through the quadricep muscles.[4] While this may be the case during non-weight bearing activities in which the tibia is moving on a fixed femur, recent investigations have found proximal musculature plays a major role in distal LE mechanics in closed chain activities.[5,6] This data is enhancing the importance of clinicians to include assessments on the joints proximal and distal to the sites where injuries occur due to the closed chain nature of injury-prone activities and utilizing proximal musculature as an intervention for distal pathologies.[6]

Since it is known that proximal stability elicits distal mobility, having a core that can sustain high load in all three planes of motion is valuable for lower limb training.[6,7] Core stabilization is an important component of most gross motor activities, for compromised core stability creates an unstable proximal base.[8] This causes limitations in control and positioning of the LE for functional movements and increases injury risk.[7] Previous research suggests that core stabilization etiologies when left untreated can lead to injuries in the lumbar spine, hip and pelvis, shoulder, knee, and ankle.[8] Core stabilization programs have been shown to effectively improve physical function, and exercises utilizing isometric holds have been shown to improve recruitment of the hip muscles during weight bearing activities.[9]

Despite the considerable evidence that core musculature impacts LE function, there is a gap in research regarding the effects of core stabilization training versus core stabilization plus hip activation training to improve LE function.[7] Our aim is to determine whether differences exist between a combined core stabilization and hip activation HEP as compared to a hip activation HEP when trying to improve LE function.

2.2 Our participants will perform either a hip activation HEP or a hip activation and core stabilization HEP for eight weeks. This is the first investigation on this topic by three of the authors; however, two authors (DF and EM) have previously published articles utilizing the FSDT as a primary outcome measure, using the same methodology for assessment in this

study.[10] This study also builds on an unpublished clinical trial from the institution. Previous HEP protocols will be used for both groups to maintain interrater reliability.[4,11,12] The effects of a hip activation plus core stability HEP will be compared to the previously studied hip activation HEP utilizing the FSDT, the drop-landing task to observe peak knee abduction, sEMG data, and compliance of the HEP to determine a dose-response predictive correlation.

2.3 The FSDT is a functional outcome measure used to assess quality and control of frontal plane LE movement.[14] The FSDT can be used to determine how well an individual can ascend and descend stairs by observing eccentric quadricep action and overall balance and proprioception.[14,15] The FSDT has an established intrarater reliability for a visual movement assessment and provides a more accurate evaluation of function than bilateral tests while being simple and inexpensive to administer.[14,15]

The drop-landing task is an outcome measure that is utilized to evaluate neuromuscular control of the peak knee abduction moment in frontal plane landing mechanics.[16] It can be an efficient way of determining how the impact of the landing force can alter the knee biomechanics and put an individual at a greater risk of knee injuries.[16] The main component of the task is analyzing the rapid change in the knee abduction moment during initial contact via force plates.[16] Landing after jumping off a platform creates a ground reaction force (GRF) that is equal to bodyweight times velocity, a force that is greater than is sustainable for the knee.[17] On average, performing a drop landing task from a 0.3-meter box produces a peak vertical GRF of 4.5 times the individual's body weight.[17] This increased demand of force causes structures up the biomechanical chain to compensate in order to protect the knee joint.

Home-based programming is valuable for use with patients with barriers to attending in-clinic treatment and for maintenance plans for discharged patients. There is limited research involving home-based treatment as the primary intervention, perhaps because compliance with home programs can be affected by lack of accountability, psychological and environmental factors, and difficulty with verifying compliance.[18]

Compliance of the intervention protocol and the amount of change in the dependent variable pre- and post- intervention has been established as a reliable way to determine a dose-response relationship.[12] In this investigation, the authors aim to analyze the dose-response predictive relationship between compliance of the intervention sessions and altered FSDT scores, as well as changes in transversus abdominus (TA), gluteus maximus (GMax), and gluteus medius (GMed) activation via sEMG evaluation.

Our aim is it determine if an eight-week hip musculature activation and core stabilization HEP influences FSDT scores, the knee abduction moment via the drop-landing task, and sEMG of the TA, GMax, and GMed, and to assess whether a dose-response relationship exists between HEP compliance and changes in these measures over time.

As a result of the limited research, clinicians are continually challenged with best practices for assessing and training core stability and LE injuries.[7] This study will help build on the limited evidence to see if a core stabilization program plus hip activation will lead to optimal outcomes when designing a treatment plan for LE impairments.

3.0 Inclusion and Exclusion Criteria*

3.1 Screening will be performed synchronously with the written informed consent process through a self-reported assessment.

3.2 Inclusion: Participants will be current first- or second-year Doctor of Physical Therapy (DPT) students in the School of Allied Health Professions (SAHP) at LSU Health Shreveport over the age of 21.

Exclusion: Current pain or pathology in either LE which currently limits their ability to perform the FSDT or drop landing task, a history of low back pain in the last three months, known pregnancy, as pregnancy is a risk factor for diastasis rectus abdominis (DRA)[19] which may be exacerbated by participation in the intervention and could be a confounding variable, and current participation in other clinical trials.

3.3 Regarding the inclusion of persons at increased risk:

- Adults unable to consent: excluded due to not meeting inclusion criteria.
- Individuals who are not yet adults (infants, children, teenagers): excluded because this is not the target population.
- Pregnant women: excluded due to the risk of developing DRA[19] that may be exacerbated by the intervention, creating greater than minimal risk to this population.
- Prisoners: excluded due to not meeting inclusion criteria.

4.0 Study-Wide Number of Subjects*

4.1 N/A, not muti-institutional

4.2 N/A

5.0 Study-Wide Recruitment Methods*

5.1 N/A, not multi-institutional.

5.2 N/A, not multi-institutional.

5.3 N/A, not multi-institutional.

6.0 Multi-Site Research*

6.1 N/A, not multi-institutional.

6.2 N/A, not multi-institutional.

6.3 N/A, not multi-institutional.

7.0 Study Timelines*

7.1 The duration of an individual subject's participation in the study is ten weeks, consisting of one week of data collection to measure and record anthropometrics, sEMG, FSDT, Drop Landing Task, and teach the HEP, an eight-week intervention program, and one week of data collection to measure the FSDT, Drop Landing Task, and sEMG measurements after the intervention program. The estimated completion date for this study is August 2024.

8.0 Study Endpoints*

8.1 The primary study endpoint is the completion of data collection and intervention for all participants, which will be completed by May 2024. The secondary study endpoint is the completion of handling PHI, which will be completed August 2024.

8.2 Refer to 8.1.

9.0 Procedures Involved*

9.1 The study will be a single-blind randomized controlled trial utilizing a repeated-measures design, where all participants will perform the FSDT and Drop Landing Task for assessment pre- and post- HEP intervention. Concurrent to the functional movement assessment, sEMG data will be collected from the GMed, GMax, and TA, and kinetic/kinematic data will be collected via motion analysis. The investigator conducting the statistical analysis (DF) will not be involved in the randomization procedure and will be blinded to participant grouping. The participant key, which will denote group assignment will not be available to the PI, and group assignments will be provided to him to each participant number only for data analysis. Participants will be randomized into groups with opaque envelopes for allocation concealment as described by Clark et al.[20] The envelope will be sealed and have an additional security method of the person who created the envelope signing the back so it is obvious if it has been tampered with.[20] The person who creates the envelopes does not recruit any participants to prevent the ordering of participants into one treatment arm or another.[20] The hip activation HEP group will receive a combination of hip musculature activation exercises used by previous researchers that show an increase in hip muscle recruitment.[5,21] The hip activation plus core stabilization HEP group will receive the same hip exercises, plus core stabilization exercises used by previous researchers that showed a reduction in the external knee adduction moment.[10] In this design, the dependent variables are the scores on the FSDT, the peak external knee abduction moment as assessed during the Drop Landing Task, and sEMG (GMax, GMed, and TA), all on the dominant LE, and compliance with the HEP. The independent variable is the performance of the eight-week HEP. Three physical therapy students will perform the FSDT assessments and sEMG data collection (CB, TM, RS). Two faculty members will also assist with data collection (DF and EM). Prior to data collection and assessments, the three students (CB, TM, RS) will be educated by the primary investigator (DF), who is a board-certified orthopaedic clinical specialist and licensed physical therapist with eleven years of experience, on the FSDT protocol and on the Drop Landing Task protocol. The scoring guidelines of the FSDT will be reviewed and practiced prior to data collection.[15] The same methodology will be used from McCallister and Flowers[11] for scoring and reporting of the FSDT scores. The sEMG electrode placement will come from The ABC of EMG.[22] The procedure for collection of the maximum volitional isometric contraction (MVIC) of the GMed will follow the protocol used in a study by Harput et al.[23] The MVIC position of the GMax will follow the protocol used in a study by Selkowitz et al, with the knee flexed to 90^{o} in prone.[24,25] The MVIC position of the TA will follow the protocol used in a study by Okubo et al, at the elbow-toe with contralateral arm and leg lift in the quadruped position.[26] Once the participant has completed MVIC, reflected markers will be placed and they will perform a static then functional calibration on both LE. For the functional calibration, the participant will actively move their hip in space (hip flexion, 45-degree angle anterolateral, hip abduction, 45-degree angle posterolateral, and hip extension), flex and extend the knee, and dorsiflex, plantarflex, and perform ankle circles to calibrate appropriately for the dynamic task.

9.2 Two investigators (CB, RS) will recruit the DPT class of 2025 in a group setting via word-of-mouth. During this time, the investigators will obtain informed consent of those students wishing to participate and who have self-reported that they meet the inclusion/exclusion criteria. If the required number of participants is not met ($N = 34$), the other investigator (TM) will recruit students from the DPT class of 2026 cohort via word-of-mouth about the investigation and obtain informed consent until the required number of participants are enrolled. After enrollment, each participant will sign up for a time to attend an initial data collection session in the Rehabilitation Faculty Clinic and the Motion Analysis Laboratory (Rm 2-217), both located in the SAHP at LSUHS. A randomization sequence will be created using Microsoft Excel by inputting 17 entries for each group and using the functions to sort by random array. The sequence will be printed on paper inserts. The inserts will be placed in sequentially numbered opaque envelopes and sealed by TM, who will then sign on the back of the envelope over the seam. Participants will meet in the Rehabilitation Faculty Clinic and age, sex, height, weight, BMI, and dominant LE will be recorded by DF or EM. The dominant LE is defined as the leg that they usually use to kick a soccer ball.[11] Participants will take the elevator to the second floor and report to 2-217 for sEMG, FSDT, and Drop Landing Task force plate data collection. Additional anthropometrics consisting of leg length, knee width, and ankle width will be obtained for accurate motion capture. Then, sEMG electrodes ("Self-adhesive Ag/AgCl Dual Electrodes" by Noraxon) will be applied to the GMax, GMed, and TA of the side of the dominant leg, following the placement criteria from The ABC of EMG by EM (for female participants) or DF (for male participants) and an MVIC for each muscle will be performed and recorded, with resistance by RS.[22,24,25] Motion capture markers will be placed on participants by a single student investigator at the following locations bilaterally: ASIS, PSIS, lateral epicondyle at the knee, lateral thigh, lateral shank, lateral malleolus, calcaneus, and head of the second metatarsal. Plug-in-Gait (PiG) static calibration and functional calibration for the knee joint will be performed before performing outcome measures. Participants will be instructed on the procedure for the FSDT by RS prior to completing the test. The FSDT consists of five consecutive repetitions of a forward step down from a 20 cm step, with one score given for the whole set of five repetitions.[15] Two student investigators (TM, RS) will score via a score sheet and average the number between the scores.[15] The Drop Landing Task will be instructed by TM and consist of three trials of dropping from a 30 cm box to land on the force plate for the average knee abduction moment across the trials.[27] sEMG data, FSDT scores and motion, and Drop Landing Task force plate and motion capture data will be collected before and after the 8-week HEP. After the initial FSDT and Drop Landing Task are completed, CB will draw the next sequentially numbered envelope and escort the participant to another room to open the opaque envelope, educate the participant on the HEP, and explain the compliance chart to the participant. Each participant will demonstrate the exercises of the HEP to ensure proper form and will be informed on the proper progression of the exercises. A compliance chart will be given to the participants to track every time they perform the HEP. Previous authors have used compliance charts to measure this variable in preparation for a dose-response analysis for activation programs.[10] The participants will take home their HEP, a compliance chart, and resistance bands. The participants will complete either the hip activation and

core stabilization HEP two days a week for eight weeks described by Flowers et al.[12] or the hip activation HEP alone described by Cannon et al.[13] for two days a week for eight weeks, with at least two rest days between sessions, and document the completion of the session on the compliance chart. At the end of the 8-week period, each participant will be scheduled to return for post-completion anthropometics data collection and to room 2-217 to turn in their compliance sheet and perform a follow-up sEMG, FSDT, and Drop Landing Task using the same procedures as before.

9.3 Table of events that lists each procedure or test and how often the procedure or test will occur.

Written Informed Consent	1
Eligibility Screening	1
Anthropometric Assessment (height, sex, weight, BMI)	2
FSDT	2
sEMG	2
Drop Landing Task	2
HEP education	1
Compliance chart education	1
HEP	16
Compliance chart documentation	16

9.4 To reduce the risk of muscle soreness, participants will be educated on proper performance of the exercises, to space sessions at least two days apart, and to progress to a resistance band once they can perform all exercises for one consecutive minute on the dominant LE. An informed consent document with participant identification numbers will be used to obtain consent from the participants. A participant identification number key will be made to match the participant's name to their assigned number to maintain confidentiality. A sign up for the anthropometric data collection and pre- and post-HEP sEMG and FSDT data collection will be created, allowing the participants to sign up with their identification number. A Microsoft Excel sheet (shared among the investigators on SharePoint and password protected) to collect data will be used by the investigators. A compliance chart for the participants to track their exercise sessions will be created. A paper copy of the HEP will be given to the participants. All hardcopy informed consents and grading sheets will be maintained in the PI’s office (SAHP Rm 2-234) in a locked cabinet.

9.5 Data collected will consist of participant age, sex, height, weight, BMI, and MVIC (GMax, GMed, and TA), in addition to the following pre- and post- intervention: FSDT, peak external knee abduction moment, sEMG from GMax, GMed, and TA, recorded FSDT video, and recorded drop landing task video. The data from the compliance chart will only be collected post-intervention.

9.6 N/A

9.7 N/A

10.0 Data and Specimen Banking*

10.1 N/A

10.2 N/A

10.3 N/A

11.0 Data Management and Confidentiality*

11.1 Descriptive statistics will be provided for the demographic data to compare age, sex, height, weight, BMI, dominant LE, and MVIC of the TA, GMax, and GMed.

FSDT

The FSDT data will be analyzed using a 2 x 2 mixed ANOVA to evaluate for between- and within-group differences.

sEMG

Data processing: Raw sEMG signals will be bandpass filtered between 10-500 Hz. The signal will be rectified, then smoothed using the Root Mean Square method with a 50ms window. The signal will be normalized to the MVIC obtained during the MVIC testing.

Data analysis: Following MVIC normalization, the mean EMG activation and peak EMG activation for each trial will be recorded. Each step-down repetition will be analyzed as a separate trial, and an average taken of all 5 trials to provide the data for each muscle pre- and post-test. The same procedure will take place for all three Drop Landing Task trials. The mean data for each sEMG data point will be analyzed via a 2 x 2 mixed ANOVA for each outcome variable.

Drop Landing Task force plate: Data processing: Motion capture data will be processed in Vicon's Nexus2 software using the PiG model. Gaps will be filled using the appropriate gap fill strategy. External knee abduction moment will be extracted from the kinetic data.

Data analysis: A 2 x 2 mixed ANOVA will be used to evaluate for between- and within-group differences on the peak knee abduction moment during the Drop Landing Task.

Regression analysis: Regression analyses will be performed to determine whether a dose-response analysis exists between the HEP compliance and the dependent variables.

11.2 G*power (Heinrich-Heine-University Düsseldorf, Düsseldorf, Germany) software was used to perform an a priori power analysis to determine the required *N* for this investigation. Data was obtained from McCallister and Flowers (2020),[11] which showed a significant within-groups difference pre-exertion and five minutes post-exertion change on the FSDT (r = .27). Pearson's coefficient was converted to Cohen's d (d = .56). An *N* of 28 was calculated to achieve significant results, with beta = .80 and alpha = .05 for a two-tailed hypothesis from a 2 x 2 mixed ANOVA analysis. We assumed an attrition rate of 20% given the repeated-measures design of the investigation. Therefore, a final *N* of 34 will be recruited for the successful completion of this study.

11.3 See 9.4.

11.4 The student investigators (TM, RS, and CB) will be educated on the proper procedures of the FSDT, Drop Landing Task, sEMG data collection, force plate data collection, and the HEP by the primary investigator (DF) and co-investigator (EM). The FSDT will be analyzed and scored by two student investigators (TM and RS). TM and RS will record and average their scores following the completion of five repetitions to improve the quality of

the data.[11] The sEMG electrodes will be placed on the female participants by EM and on the male participants by DF. RS will provide the pressure for the MVIC and explain the FSDT procedure to every participant. TM will explain the drop landing task procedure to every participant. CB will draw the next sequentially numbered envelope and escort the participant to another room to open the envelope, explain the HEP, and explain the compliance chart to the participant. The primary investigator (DF) is a board-certified orthopedic physical therapist with 11 years of experience, who has published research on this test.[11] The co-investigator (EM) is also a board-certified orthopedic physical therapist with 6 years of experience, who also published research on this test with the primary investigator.[11]

11.5 The data that will be collected during the entire study includes: participant number, age, height, weight, BMI, sex, MVIC of GMax, GMed, and TA, leg dominance, FSDT pre and post HEP, recorded FSDT video, sEMG from GMed, GMax, and TA on the side of the dominant leg during FSDT pre and post HEP, peak external knee abduction moment during the Drop Landing Task pre and post HEP, recorded Drop Landing Task video, and compliance. Data storage will follow the guidelines in section 9.4. The data will be stored for the duration of the study and throughout the following semester while analyzing and finalizing data for presentation. The data will be kept up to one year after the completion of the data analysis in the event that the research wants to be continued. The only people to have access to this information will be the primary investigator, the co-investigator, and student investigators (DF, EM, CB, TM, RS). All investigators are responsible for the receipt and transmission of the data. Data will be manually transported to DF office room 2-234 in the SAHP at LSUHS. Electronic data will remain on SharePoint.

12.0 Provisions to Monitor the Data to Ensure the Safety of Subjects*

12.1 N/A

13.0 Withdrawal of Subjects*

13.1 Non-study related injury that alters participant ability to complete HEP or FSDT post intervention.

13.2 If the participant notifies any investigator that they do not wish to participate any longer or if they no longer meet the inclusion/exclusion criteria, the investigators will notify the participant that they have been withdrawn from the study and document the reason for the withdrawal and date. The participant will provide the returned compliance sheet to the investigators.

13.3 N/A

14.0 Risks to Subjects*

14.1 Risks associated with this study include:

• Physical risks: muscle soreness is a potential side effect that may occur with exercise. This will be minimized via the progression principles previously outlined in section 9.4. This is likely to happen but will be minimized via progression principles that will be taught to you at the first study visit. The magnitude of this risk is minor. Another risk is skin irritation and/or a rash from wearing or removing the electrode patches that stick to the skin for sEMG and for 3D Motion Capture markers. If participants become pregnant during the study, they should tell the study investigators. They may be removed from the study

due to risk of developing separation of the abdominal muscles called diastasis recti. It is not expected that the baby's health or mother's health will need to be followed.

• Privacy/confidentiality risks: participants' personal information could be lost or exposed. This is very unlikely to happen, and all hardcopy data will be locked in the PI's office. Digital data is password protected. Given the nature of the personal information collected, the magnitude of this risk is minor.

• Modesty: participants' buttocks will be exposed for the placement of the electrode stickers. An investigator of each participants' same sex will drape them to minimize exposure and will place the electrode stickers on their buttocks.

14.2 N/A

14.3 N/A

14.4 N/A

15.0 Potential Benefits to Subjects*

15.1 The potential benefits that an individual may experience from taking part in this investigation are improved frontal plane trunk and LE mechanics, improved GMed, GMax, and TA activation.

15.2 N/A

16.0 Vulnerable Populations*

16.1 N/A

17.0 Community-Based Participatory Research*

17.1 N/A

18.0 Sharing of Results with Subjects*

18.1 Participants will not receive their individual results.

19.0 Setting

19.1 This study will recruit potential subjects from the LSUHS DPT cohorts of 2025 and 2026 in Shreveport, LA. Recruitment will take place via the procedures outlined in section 9.2. Procedures for research will be performed in the SAHP at LSUHS. Anthropometric data will be collected in the Rehabilitation Faculty Clinic. The motion analysis lab, room 2-217, will be used for the sEMG data collection, FSDT, and education of the HEP. There is no composition or involvement of any community advisory board. The research will not be conducted outside of the organization or its affiliates.

20.0 Resources Available

20.1 The three student investigators (TM, RS, CB) are DPT students in the 2025 cohort at LSUHS. They will be educated on the procedures of the FSDT, described in Park et al,[15] procedures of the Drop Landing Task, described in Fan et al,[27] sEMG electrode placement,[21,22,24,25] and data collection and interpretation[21] by the primary investigator (DF), who is a board-certified orthopedic physical therapist with 11 years of experience and the co-investigator (EM), who is a board-certified orthopedic physical therapist with 6 years of experience. The primary (DF) and co-investigator (EM) will assist the student

investigators as needed throughout the study, including assisting with data collection and analysis.

20.2 The total number of first- and second-year DPT students enrolled in the SAHP at LSUHS is 71. Given the required $N = 34$, there are enough potential participants to successfully complete this investigation. The student investigators (CB, TM, RS) are enrolled in an independent study for the Fall 2023 semester to receive IRB approval. In the spring of 2024, the data collection portion of the study will begin and be concluded by May 2024. The investigators will be enrolled in Research IV during this semester to allow time to begin working on the poster presentation. Drs. Flowers and McCallister will each provide 5% FTE for their involvement in the study. During the summer semester of 2024, the student investigators will begin analyzing the data and disseminating the findings. All data analysis will be concluded by August 2024. The motion analysis lab, room 2-217 in SAHP at LSUHS has a treatment mat, sEMG materials and technology, in addition a large open space used for motion analysis. The Rehabilitation Faculty Clinic is located on the ground floor of the SAHP at LSUHS and is where the anthropometric data will be collected. Our study has less than minimal risk. The PI will complete the DOA, including the assigning of roles and responsibilities, and educate each investigator at the time of signing.

21.0 Prior Approvals

21.1 Dr. Edward Mahoney will need to provide approval for the study to commence since he serves as Chair of the Physical Therapy Department.

22.0 Recruitment Methods (Local)

22.1 Two investigators (CB, RS) will inform the 2025 DPT cohort in a classroom at LSUHS via word of mouth. During this time, the investigators will obtain informed consent. If the required number of participants is not met ($N = 34$), the other investigator (TM) will recruit students from the 2026 DPT cohort via word-of-mouth about the investigation and obtain informed consent until the required number of participants are enrolled.

22.2 The subjects will be either 1st or 2nd year DPT students in the SAHP at LSUHS.

22.3 Potential subjects will first be identified from DPT class of 2025 by entering a classroom at the SAHP at LSUHS. If more participants are needed, the remainder will be recruited via word of mouth from the DPT class of 2026 cohort.

22.4 N/A

22.5 N/A

23.0 Local Number of Subjects

23.1 At least 34 participants will be recruited locally.

23.2 N/A

24.0 Provisions to Protect the Privacy Interests of Subjects

24.1 Individuals participating in the study will be given an identification number to protect their personal identity. Participants will only be expected to interact and provide personal information to the investigators on the study.

24.2 There will only be the investigators in the room during data collection, and any questions will be asked individually with the investigators. If another participant is to be in the room

learning the HEP, the view will be obstructed with a divider to ensure confidentiality. Any written data will refer to the participants with numbers, not actual names. No previous medical history will be entered into the data collection.

24.3 Any information about the subjects will be verbally reported to investigators.

25.0 Compensation for Research-Related Injury

25.1 It does not involve greater than minimal risk.

25.2 N/A

26.0 Economic Burden to Subjects

26.1 There will be no economic burden to the participants. Any required materials will be provided. The only thing the participants will be responsible for is transportation to the facility where study is conducted.

27.0 Consent Process

27.1 The consent process will take place in classrooms at the SAHP at LSUHS. There is no waiting period between informing the prospective subject and obtaining the consent. Continued verbal consent will be given during the FSDT/sEMG/Drop Landing Task process both before and after HEP. We will be using "SOP: Informed Consent Process for Research (HRP-090)."

Non-English-Speaking Subjects

- N/A

Waiver or Alteration of Consent Process (consent will not be obtained, required information will not be disclosed, or the research involves deception)

- N/A

Subjects who are not yet adults (infants, children, teenagers)

- N/A

Cognitively Impaired Adults

- N/A

Adults Unable to Consent

- N/A

Adults Unable to Consent

- N/A

28.0 Process to Document Consent in Writing

28.1 We will be using "SOP: Written Documentation of Consent (HRP-091)."

28.2 Our research does not involve more than minimal risk.

28.3 See attached completed informed consent form submitted with this protocol. *

29.0 Drugs or Devices

- N/A

References:

1. Gage BE, McIlvain NM, Collins CL, Fields SK, Comstock RD. Epidemiology of 6.6 million knee injuries presenting to United States emergency departments from 1999 through 2008. *Acad Emerg Med.* 2012;19(4):378-385. doi:10.1111/j.1553-2712.2012.01315.x
2. Nguyen US, Zhang Y, Zhu Y, Niu J, Zhang B, Felson DT. Increasing prevalence of knee pain and symptomatic knee osteoarthritis: survey and cohort data. *Ann Intern Med.* 2011;155(11):725-732. doi:10.7326/0003-4819-155-11-201112060-00004
3. Bolgla LA, Boling MC, Mace KL, DiStefano MJ, Fithian DC, Powers CM. National Athletic Trainers' Association Position Statement: Management of Individuals With Patellofemoral Pain. *J Athl Train*. 2018;53(9):820-836. doi:10.4085/1062-6050-231-15
4. Powers CM. The influence of abnormal hip mechanics on knee injury: A biomechanical perspective. *J Orthop Sports Phys Ther*. 2010;40(2):42-51. doi:10.2519/jospt.2010.3337
5. Mascal CL, Landel R, Powers C. Management of Patellofemoral Pain Function : 2 Case Reports. *J Orthop Sport Phys Ther*. 2003;33(11):647-660.
6. Leetun DT, Ireland ML, Willson JD, Ballantyne BT, Davis IM. Core stability measures as risk factors for lower extremity injury in athletes. *Med Sci Sports Exerc*. 2004;36(6):926-934. doi:10.1249/01.mss.0000128145.75199.c3
7. Huxel Bliven KC, Anderson BE. Core stability training for injury prevention. *Sports Health.* 2013;5(6):514-522. doi:10.1177/1941738113481200
8. Leetun DT, Ireland ML, Willson JD, Ballantyne BT, Davis IM. Core stability measures as risk factors for lower extremity injury in athletes. *Med Sci Sports Exerc*. 2004;36(6):926-934. doi:10.1249/01.mss.0000128145.75199.c3

9. Kim B, Yim J. Core Stability and Hip Exercises Improve Physical Function and Activity in Patients with Non-Specific Low Back Pain: A Randomized Controlled Trial. *Tohoku J Exp Med*. 2020;251(3):193-206. doi:10.1620/tjem.251.193
10. Flowers DW, Brewer W, Mitchell K, Ellison J, Frilot C. The Effect of Core Stabilization Training on Improving Gait and Self-Perceived Function in Patients with Knee Osteoarthritis: A Single-Arm Clinical Trial. *Pathophysiolog*y. 2022;29(3):495-506. Published 2022 Sep 1. doi:10.3390/pathophysiology29030040
11. McCallister E, Flowers D. Can the Forward-Step-Down Test Be Used Reliably in the Clinical Setting to Assess Movement Changes Resulting from Maximal Exertion? A Pilot Study. *Internet* Journal of Allied Health Sciences and Practice. Published online 2020. doi:https://doi.org/10.46743/1540-580x/2020.1931
12. Flowers DW, Brewer W, Ellison J, Mitchell K, Frilot C. Transversus abdominis activation does not alter gait impairments in patients with and without knee osteoarthritis. *Clin Biomech (Bristol, Avon)*. 2021;82:105270. doi:10.1016/j.clinbiomech.2020.105270
13. Cannon J, Weithman BA, Powers CM. Activation training facilitates gluteus maximus recruitment during weight-bearing strengthening exercises. *J Electromyogr Kinesiol*. 2022;63(August 2021):102643. doi:10.1016/j.jelekin.2022.102643
14. Loudon JK, Wiesner D, Goist-Foley HL, Asjes C, Loudon KL. Intrarater reliability of functional performance tests for subjects with patellofemoral pain syndrome. *J Athl Train*. 2002;37(3):256-261.
15. Park KM, Cynn HS, Choung SD. Musculoskeletal predictors of movement quality for the forward step-down test in asymptomatic women. *J Orthop Sports Phys Ther*. 2013;43(7):504-510. doi:10.2519/jospt.2013.4073
16. Ishida T, Koshino Y, Yamanaka M, et al. The effects of a subsequent jump on the knee abduction angle during the early landing phase. *BMC Musculoskelet Disord.* 2018;19(1):379. Published 2018 Oct 20. doi:10.1186/s12891-018-2291-4
17. McNair PJ, Prapavessis H. Normative data of vertical ground reaction forces during landing from a jump. *J Sci Med Sport.* 1999;2(1):86-88. doi:10.1016/s1440-2440(99)80187-x
18. Argent R, Daly A, Caulfield B. Patient Involvement With Home-Based Exercise Programs: Can Connected Health Interventions Influence Adherence?. *JMIR Mhealth Uhealth.* 2018;6(3):e47. Published 2018 Mar 1. doi:10.2196/mhealth.8518
19. Cavalli M, Aiolfi A, Bruni PG, et al. Prevalence and risk factors for diastasis recti abdominis: a review and proposal of a new anatomical variation. *Hernia.* 2021;25(4):883-890. doi:10.1007/s10029-021-02468-8
20. Clark L, Dean A, Mitchell A, & Torgerson DJ. Envelope use and reporting in randomised controlled trials: a guide for researchers. *Research Methods in Medicine & Health Sciences.* 2021;2(1):2-11. doi:10.1177/2632084320957204
21. Selkowitz DM, Beneck GJ, Powers CM. Which exercises target the gluteal muscles while minimizing activation of the tensor fascia lata? Electromyographic assessment using fine-wire electrodes. *J Orthop Sports Phys Ther.* 2013;43(2):54- 64. doi:10.2519/jospt.2013.4116
22. Konrad P. The ABC of EMG: A Practical Introduction to Kinesiological Electromyography. Noraxon U.S.A.; 2006.
23. Harput G, Ulusoy B, Akmese R, Ergun N. Comparison of muscle activation levels and knee valgus between individuals with medial patellofemoral ligament reconstruction and healthy individuals during fatiguing step down task. *Clin Biomech.* 2020;78(May):105067. doi:10.1016/j.clinbiomech.2020.105067

24. Selkowitz DM, Beneck GJ, Powers CM. Which exercises target the gluteal muscles while minimizing activation of the tensor fascia lata? Electromyographic assessment using fine-wire electrodes. *J Orthop Sports Phys* Ther. 2013;43(2):54- 64. doi:10.2519/jospt.2013.4116
25. Selkowitz DM, Beneck GJ, Powers CM. Comparison of electromyographic activity of the superior and inferior portions of the gluteus maximus muscle during common therapeutic exercises. *J Orthop Sports Phys* Ther. 2016;46(9):794-799. doi:10.2519/jospt.2016.6493
26. Okubo Y, Kaneoka K, Imai A, et al. Electromyographic analysis of transversus abdominis and lumbar multifidus using wire electrodes during lumbar stabilization exercises. *J Orthop Sports Phys Ther.* 2010;40(11):743-750. doi:10.2519/jospt.2010.3192
27. Fan B, Xia H, Xu J, Li Q, Shull PB. IMU-based knee flexion, abduction and internal rotation estimation during drop landing and cutting tasks. *Journal of Biomechanics*. 2021;124:110549. doi:https://doi.org/10.1016/j.jbiomech.2021.110549