PROTOCOL TITLE:

Does a Hip Muscle Activation Home Exercise Program Change Patient Performance on the Forward Step-Down Test?

PRINCIPAL INVESTIGATOR:

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VERSION NUMBER:

1

DATE:

10/31/22

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1.0 Objectives*

1.1 The purpose of this study is to determine if activation training of the hip musculature affects muscle activation and frontal plane mechanics in healthy individuals.

Specific Aim 1: Determine whether performance on the forward step-down test (FSDT) changes after an eight-week home exercise program (HEP) focused on hip musculature activation in healthy individuals.

Specific Aim 2: Determine whether surface electromyography (sEMG) hip musculature changes following an eight-week HEP focused on hip musculature activation in healthy individuals.

Specific Aim 3: Determine whether a dose-response relationship exists between compliance on the HEP and changes in FSDT scores in healthy individuals.

Specific Aim 4: Determine whether a dose-response relationship exists between compliance on the HEP and sEMG changes in hip musculature activation in healthy individuals.

1.2 Specific Aim 1:

H_0: There will be no significant change in FSDT scores after an eight-week hip musculature activation HEP in healthy individuals.

H_1: There will be a significant change in FSDT scores after an eight-week hip musculature activation HEP in healthy individuals.

Specific Aim 2:

H_0: There will be no significant change in sEMG data of hip musculature after an eight-week hip musculature activation HEP in healthy individuals.

H_1: There will be a significant change in sEMG data of hip musculature after an eight-week hip musculature activation HEP in healthy individuals.

Specific Aim 3:

H_0: There will be no significant dose-response relationship between HEP compliance and FSDT scores in healthy individuals.

H_1: There will be a significant dose-response relationship between HEP compliance and the FSDT scores in healthy individuals.

Specific Aim 4:

H_0: There will be no significant dose-response relationship between HEP compliance and sEMG data of hip musculature in healthy individuals.

H_1: There will be a significant dose-response relationship between HEP compliance and sEMG data of hip musculature in healthy individuals.

2.0 Background*

2.1 Over the past 10 years, there has been a shift in the literature regarding treatment for individuals with frontal plane abnormalities and altered lower extremity biomechanics, especially in the case of individuals with patellofemoral pain syndrome (PFPS). Originally, the treatment focused on the knee joint itself and strengthening the quadriceps musculature.[1] Current literature suggests that the focus of treatment for individuals with PFPS should be on the proximal hip joint.[2–5] There is evidence that pain is reduced in individuals with PFPS after hip and knee muscle strengthening compared with knee muscle strengthening alone.[3] While it is necessary to rule out true tibiofemoral and patellofemoral joint issues in individuals with PFPS, it is important to not neglect the transverse and frontal plane movements of the hip and ankle joints.[5] Women are more likely to suffer from PFPS syndrome because they have a lower rate of torque development in the hip extensors, leading to an earlier activation of the hip and knee extensors[6], emphasizing the importance of focusing treatment on the proximal hip joint and surrounding musculature. It is important to remember that the muscles of the lower extremity are all connected via the lumbo-pelvic hip complex, which is why the recent literature focuses on more proximal musculature rehabilitation while treating more distal pathologies.

Weakness of the hip abductors, external rotators, and extensors has been shown to lead to increased frontal and transverse plane motions at the hip.[3] There is evidence to suggest that there are improvements in pain and overall function after a hip abductor and external rotation strengthening program.[5] However, strength training has been unable to generate movement changes in women with PFP.[3] In a case report on two separate patients with patellofemoral pain, muscle recruitment exercises, endurance training exercises, and core stability exercises were used to treat their pain, function, strength, gait, and biomechanical abnormalities. A combination of hip muscle activation and strengthening decreased the symptoms in these patients and improved their overall function, including stair navigation.[2] In other areas of the body, activation training vs strength training has been compared to see what yields better outcomes.[7] There is a current hole in the literature regarding whether activation

training alone of the hip musculature can alter frontal plane movements of the lower extremity. There is evidence to support that activation training of certain muscles may lead to better performances of the muscle during more advanced training programs.[8] Increasing core activation during exercises focused on the hip musculature, such as clam shells, side-lying hip abduction, and prone hip extension, was shown to overall increase muscle activation of the LE.[9] As for dosing of these exercises, one minute isometric holds have been shown to improve recruitment of the hip muscles during weight bearing activities.[10] Hip muscle activation training is an area of treatment which needs more research to see the overall benefits, but it has been explored in core musculature[11], so we hope to examine if similar results will occur at the hip joint.

2.2 Our participants will execute the hip activation intervention via an 8 week home exercise program (HEP). This is the first study on this topic by the authors; however, two of the authors have previously published work using the FSDT as an outcome measure, using the same procedures for assessment as in this investigation.[12] The study will evaluate the effects of a hip activation training program via HEP on the FSDT, as well as compliance measures of the HEP to analyze a dose-response predictive relationship.

2.3 The FSDT is a relevant outcome measure for people with altered frontal plane movements after an activation training program because activation training has been shown to alter corticomotor excitability of the gluteus maximus and hip biomechanics.[13] The FSDT has been shown to assess neuromusculoskeletal control of the hip[14], because treating the proximal musculature has been shown to be beneficial for outcomes.[15,16] Intrarater reliability has been established for the FSDT in individuals with PFPS and has been shown to relate to changes in pain levels.[17] Interrater reliability for the FSDT has also been established with good agreement of the quality and distinguishing of movements between raters.[12,18] Validity has been established for the use of the FSDT on individuals with altered frontal plane mechanics.[14]

Compliance measurements of the intervention sessions and the amount of change in the dependent variable pre- and post-intervention have been shown as a reliable way to predict a dose-response relationship.[11] In this study, the authors aim to analyze a dose-response predictive relationship between compliance of the intervention sessions and altered FSDT scores, as well as change in gluteus medius and maximus activation via sEMG data.

We are aiming to determine if a hip musculature activation training HEP has any affect on FSDT scores and sEMG measures of activation and to see how compliance affects the FSDT and muscle activation.

3.0 Inclusion and Exclusion Criteria*

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

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

Exclusion: current knee pain or pathology in the dominant leg, and women with known pregnancy.

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 our target population
- Pregnant women: excluded due to creating greater than minimal risk
- Prisoners: excluded due to not meeting our inclusion criteria

4.0 Study-Wide Number of Subjects*

4.1 N/A, not multi-institutional.

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 220 minutes or 3.66 hours. It will take 30 minutes to measure and record anthropometrics, sEMG, FSDT, and teach the HEP. The FSDT and sEMG measurements will be taken again at the end of the intervention program. The HEP should take a maximum of 10 minutes a session, therefore 20 minutes total are allotted each week. The duration anticipated to enroll all study subjects is 15 minutes. The estimated completion date for the study is August 2023.

8.0 Study Endpoints*

8.1 The primary and secondary study endpoints are the completion of data collection and intervention for all participants, which will be completed by May 2023.

8.2 Refer to 8.1.

9.0 Procedures Involved*

9.1 The study will utilize a repeated-measures design, where all participants will perform the FSDT for assessment pre- and post-intervention via an HEP while sEMG data is being collected from the gluteus medius and gluteus maximus. All of the activities listed above will be performed on the dominant LE. The HEP will be a combination of hip musculature activation exercises used by previous researchers that show an increase in hip muscle recruitment.[2,10,19,20] Core activation via a side plank will be added to the clam exercise and the side-lying hip abduction exercise.[9]In this design the dependent variables are the scores on the FSDT pre- and post-HEP, sEMG pre-and post-HEP, and compliance with the HEP. The independent variable is the performance of the eight-week HEP. Two physical therapist students will perform the FSDT assessments and sEMG data collection (CH and MS). Two faculty members will also assist with data collection (DF and EM). Prior to data collection and assessments, the two students (CH and MS) will be educated by the primary investigator (DF), who is a board-certified orthopedic clinical specialist physical therapist with ten years of experience, on the FSDT protocol. Scoring guidelines of the FSDT will be reviewed according to the study by Park *et al*[18] and practiced prior to data collection. The sEMG electrode placement will come from *The ABC of EMG.*[21] The procedure for collection of the maximum volitional isometric contraction (MVIC) of the gluteus medius will follow the protocol used in a study by Harput *et al.*[22] The MVIC of the gluteus maximus will follow the protocol used in a study by Selkowitz *et al*, with the knee flexed to 90º in prone.[19] The same methodology will be used from McCallister and Flowers for scoring and reporting of the FSDT scores.[12]

9.2 One investigator (CH) will inform one PT cohort in room 1-117 inside the SAHP 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 = 35), the other investigator (MS) will recruit students from the other PT cohort via word-of- mouth about the investigation and obtain informed consent until the required number of participants are enrolled. Each participant will be given a random number to ensure patient confidentiality. After enrollment, each participant will sign up with their participant number for a time

to attend an initial data collection session in the rehabilitation faculty clinic and the motion analysis lab 2-217 in the SAHP at LSUHS. Participants will meet in the rehabilitation faculty clinic and age, sex, height, weight, BMI, and dominant lower extremity (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.[7] Participants will take the elevator to the second floor and report to 2-217 for sEMG and FSDT data collection. During this time, sEMG electrodes will be applied to the gluteus maximus and medius of the dominant leg, following the placement criteria from *The ABC of EMG*[21] by EM (for female participants) or DF (for male participants) and an MVIC for each muscle will be performed and recorded, with resistance by CH.[19,22] Participants will be instructed on the procedure for the FSDT by CH prior to completing the test. The FSDT consists of five consecutive repetitions of a forward step down from a 20cm step, with one score given for the whole set of five repetitions.[18] The two student investigators (CH and MS) will both score and average the number between the two scores.[12] sEMG data and FSDT scores will be collected before and after the 8 week HEP. After the initial FSDT is completed, the participant will be educated on the HEP and the compliance chart by MS. The HEP will be a combination of hip musculature activation exercises used by previous researchers that show an increase in hip muscle recruitment.[2,10,19,20] Core activation via a side plank will be added to the clam exercise and the side-lying hip abduction exercise.[9] The HEP consists of five hip activation exercises, clams, clams with trunk activation via side-plank, side-lying hip abduction, side-lying hip abduction with trunk activation via side-plank, and hydrants. The participants will perform isometric contractions of these exercises for up to one minute on the LE used for testing.[10] Once the participant is able to hold all of these exercises for one minute without a break, the participant will advance to the next step, adding a yellow theraband and completing the same exercises. If the participant is able to isometrically hold these five exercises for one minute with a yellow theraband, the participant will progress to a red theraband and repeat the process of working towards one minute holds of each exercise. Each participant will demonstrate the exercises of the HEP to ensure proper form and 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.[11] The participants will take home their HEP, a compliance chart, and a yellow and red theraband. The participants will complete the HEP 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 to the motion analysis lab to turn in their compliance sheet and perform a follow-up sEMG and FSDT 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, weight, BMI)	1
FSDT	2
sEMG	2
HEP education	1
Compliance chart education	1
HEP	16
Compliance chart documentation	16

9.4 To reduce the risk of loss of confidentiality, participants will be assigned numbers. All hardcopy data will be stored in DF office (locked), room 2-234 in the SAHP at LSUHS in a locked drawer. All electronic data will be stored using Sharepoint connected to school email addresses with a password.

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 add a band or progress to a yellow theraband 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 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. An excel sheet 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.

9.5 Data collected will consist of participant age, height, weight, BMI, all at the first visit, in addition to the following pre- and post-intervention: FSDT, sEMG from gluteus medius and maximus, recorded FSDT video. The data from the compliance chart will only be collected post-intervention.

9.6 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 FSDT

Due to the ordinal nature of the FSDT data, a non-parametric repeated-measures analysis will be performed to analyze the data. Therefore, a Wilcoxon signed-rank test will be performed. For the sEMG data, a repeated measures t-test or appropriate nonparametric twin via the Wilcoxon signed-rank test if assumptions are not met for parametric analysis will be used. Descriptive statistics will be provided for the demographic data.

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.

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), 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 29 was calculated to achieve significant results, with beta = .80 and alpha = .05 for a two-tailed hypothesis from a repeated-measures design within groups analysis. We

assumed an attrition rate of 20% given the repeated-measures design of the investigation. Therefore, a final N of 35 will be recruited for the successful completion of this study.

11.3 See 9.4

11.4 The student investigators (CH and MS) will be educated on the proper procedures of the FSDT, sEMG data collection, and the HEP by the primary investigator (DF) and co-investigator (EM). The FSDT will be analyzed and scored by the two student investigators (CH and MS). The student investigators (CH and MS) will record and average their scores following the completion of five repetitions to improve the quality of the data.[12] The sEMG electrodes will be placed on the female participants by EM and on the male participants by DF. CH will provide the pressure for the MVIC and explain the FSDT procedure to every participant. MS will explain the HEP and the compliance chart to the participants. The primary investigator (DF) is a board-certified orthopedic physical therapist with 10 years of experience, who has published research on this test.[12] The co-investigator (EM) is also a board-certified orthopedic physical therapist with 5 years of experience, who also published research on this test with the primary investigator.[12]

11.5 The data that will be collected during the entire study includes: participant number, height, weight, BMI, sex, leg dominance, FSDT pre and post HEP, recorded FSDT video, sEMG from gluteus medius and maximus on the dominant leg during FSDT pre and post HEP, 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 event that the research wants to be continued. The only people to have access to this information will be the primary investigators, student investigators, and the co-investigator (DF, EM, CH, MS). 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 affects ability to complete HEP or FSDT post intervention.

13.2 After the participant has notified any investigator that they wish no longer to continue or no longer meet the inclusion/exclusion criteria, the investigators will notify the participant that they have been

withdrawn from the study and document the nature for withdrawal and date. The participant will return the compliance sheet to the investigators.

13.3 N/A

14.0 Risks to Subjects*

14.1 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.
Participant loss of confidentiality is always a risk; however, this will be minimized via the procedures enumerated in section 9.4.

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 and improved gluteus medius and maximus 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 two cohorts of DPT students. The students are currently attending the SAHP at LSUHS 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 two student investigators (CH and MS) are DPT students in the SAHP at LSUHS. They will be educated on the procedures of the FSDT, described in Park *et al*[18], sEMG electrode placement[21], and data collection and interpretation[19,22] by the primary investigator (DF), who is a board-certified orthopedic physical therapist with 10 years of experience and the co-investigator (EM), who is a board-certified orthopedic physical therapist with 5 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 67. Given the required N=35, there are enough potential participants to successfully complete this investigation. The student investigators (CH and MS) are enrolled in an independent study for the Fall 2022 semester to receive IRB approval. In the spring of 2023, the data collection portion of the study will begin and be concluded by May 2023. 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 2023, the student investigators will begin analyzing the data and disseminating. All data analysis will be concluded by August 2023. 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

22.1 One investigator (CH) will inform one DPT cohort in room 1-117 inside the SAHP 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 = 35), the other investigator (MS) will recruit students from the other 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 one DPT by entering room 1-117 of the SAHP at LSUHS. If not enough participants are enrolled, the remainder will be recruited via word of mouth from the other DPT cohort.

22.4 N/A

22.5 N/A

23.0 Local Number of Subjects

23.1 At least 35 participants will be recruited locally.

23.2 We hope to enroll 35 participants.

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 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 the SAHP at LSUHS in rooms 1-117 and 3-314. There is no waiting period between informing the prospective subject and obtaining the consent. Continued verbal consent will be given during the FSDT/sEMG 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, no device

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