Electromyographic (EMG) Activity of the Gluteus Medius during Various Hip Exercises

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Electromyographic (EMG) Activity of the Gluteus Medius During Various Hip Exercises

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A Scholarly Project Submitted to the Graduate Faculty of the
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This Scholarly Project, submitted by Kalie Maiden, Mitchell Karbo, Taylor Doeden, Analise Richtsmeier, in partial fulfillment of the requirements for the Degree of Doctor of Physical Therapy from the University of North Dakota, has been read by the Advisor and Chairperson of Physical Therapy under whom the work has been done and is hereby approved.

(Graduate School Advisor)

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ABSTRACT

Background and Purpose. The purpose of the study was to record and analyze muscle recruitment patterns of the gluteus medius and gluteus maximus muscles when performing a side lying abduction exercise requiring consistent force to roll a ball up and down the wall using the dominant lower extremity. Comparisons were made between the use of either a small, medium or large ball. The subjects performed a standing abduction exercises with theraband around both ankles as well.

Case Description. Fifteen subjects were recruited from the University of North Dakota Department of Physical Therapy to perform the four different types of exercises. All subjects met the inclusion criteria which required them to be healthy adults over the age of 18. The exclusion criteria included hip or low back pain in the past three months and allergic reactions to adhesives.

Intervention. Exercise order was randomly assigned and all subjects completed each of the exercises. Three repetitions of each exercise were completed, while EMG equipment was used to measure the amount of muscle activity generated in the gluteus medius and maximus muscles in the dominant leg.

Outcomes. There were no statistically significant differences found between the exercises. There were some trends observed in the data which behoove the need for further research to be done.

Discussion. There are multiple factors to take into consideration as to how this study could be changed or expanded upon to yield significant findings. The fact remains that further and more extensive research is needed.
CHAPTER I
INTRODUCTION

Adequate strength of the musculature surrounding the hip joint is an important factor in the prevention of injury and the preservation of function across the lifespan. In the elderly population, lower extremity weakness and balance deficits are well documented risk factors contributing to falls.\(^1\) Falls are a common mechanism of injury in this demographic,\(^2\) with annual incidence estimates ranging from 30% to 40% of community-dwelling adults aged 65 years and older.\(^3,4\) One proposed mechanism for the relationship between weakness and falls relates to the ankle and hip strategies used when one loses balance. If the person is unable to adequately stabilize using an ankle strategy, the hip strategy is employed, resulting in a stepping response to preserve balance and prevent a fall.\(^5\) Weakness around the hip joint can impair the use of this strategy, increasing the risk of a fall. The implications of falls are wide ranging when considering morbidity, mortality, and economic impact. Studies have shown that a fall is an important predictor of difficulty with activities of daily living for up to 2 years following the fall in older adults.\(^6,7\) Mortality rates following emergency department visits due to falls have also been demonstrated to be higher than the annual mortality rates of elderly people up to 10 years following the fall, depending on hospital admission status.\(^6\) A 2010 systematic review by Heinrich et al.\(^2\) found that fall-related costs ranged between 0.85% and 1.5% of the total healthcare expenditures in the 18 countries studied. In the USA, costs per fall-related hospitalization ranged from $10,052 to $42,840.\(^2\)
Because of the central location of the hip joint within the body and its subsequent
dominant role in kinesiology, pathology affecting this joint can lead to numerous
functional limitations. Limitations related to hip joint pathology include difficulty
walking, running, driving, lifting, and negotiating stairs. There are many powerful
muscles in this area that allow for the torque needed to accelerate upward and forward as
well as decelerate. The gluteus medius specifically is one muscle that has been studied
under several different circumstances and has been shown to play a significant role in
proper movement and function of the lower extremities. Sufficient strength in this
particular muscle along with other hip muscles contributes to proper movement of
individuals of all age groups, and has been studied in settings ranging from rehabilitation
of high level athletes to fall prevention programs for the geriatric population. Extensive
study of the muscle can be attributed to the importance of gluteus medius activation in
standing, walking, running and other activities during which the lower extremities move
reciprocally.

The gluteus medius muscle originates between the posterior and anterior gluteal
lines located on the outer surface of the ilium, and inserts on the lateral and superior
surfaces of the greater trochanter of the femur. It is thus in the optimal position to
abduct the femur and stabilize the pelvis and contralateral leg with movements requiring
reciprocal lower extremity motion. When walking, the gluteus medius of the stance leg
works to keep the pelvis level and prevent a dropping of the pelvis on the side of the leg
that is not in contact with the ground. With poor motor control, poor recruitment or
weakness of this muscle, resulting instability can be one of the leading factors
contributing to a plethora of potential injuries in the lower extremities resulting from the biomechanical imbalances that occur.

Because the tensor fascia lata (TFL) shares the actions of flexion, abduction, and internal rotation with gluteus medius, an optimally functioning TFL will augment the gluteus medius and preserve full and pain free range of motion at the joint. The TFL originates on the iliac crest and the anterior superior iliac spine and shares a common insertion with gluteus maximus onto the lateral tibial condyle via the iliotibial tract. The shared insertion enables the two muscles to work together to deliver a pulling action on the iliotibial tract to provide a lateral brace of the knee which is very important in single leg stance and balancing on one foot.\textsuperscript{11} In addition to bracing the knee joint, gluteus maximus also works to extend, abduct, and laterally rotate the hip.\textsuperscript{11} The proximal attachments of the gluteus maximus to the iliac crest, sacrum, coccyx, and thoracolumbar fascia enable it to stabilize the sacroiliac joints and the lumbar region.\textsuperscript{11} During the gait cycle, gluteus maximus is inactive during the swing phase until late swing, at which time its activity is needed to decelerate the flexing hip and initiate extension at the joint.\textsuperscript{8} The function of gluteus maximus during stance phase is to help support the body weight from heel contact to mid stance.\textsuperscript{8} To ensure optimal movement free of any biomechanical imbalances, it is necessary to have a balance between all of these muscles. Recent studies have shown that TFL has been activated in and even has been overactive when trying to recruit gluteus medius and maximus.\textsuperscript{12} Due to the tendency for TFL to become overactive, it is critical to minimize activation of TFL and maximize activation of gluteus medius and minimus during rehabilitation.\textsuperscript{12}
Common musculoskeletal injuries, like anterior cruciate ligament (ACL) tears and ankle sprains, result from muscle imbalances around the hip joint in athletic populations. Unilateral tasks such as cutting and jumping in addition to sprinting and landing activities require a highly active, strong, and efficient gluteus medius muscle to reduce the risk of injury during activities where the foot is in contact with the ground or playing surface. After injury, ensuring appropriate rehabilitation of the gluteus medius strength is critical to achieving full rehabilitation and safe return to sport. Harput et al.\textsuperscript{13} found that in patients post-ACL reconstruction, altered knee muscle function impacted the kinetic chain more proximally at the hip joint, resulting in gluteus medius weakness observed when descending stairs. While the hamstrings and vastus medialis obliquus (VMO) have traditionally been the foci of rehabilitation post-ACL reconstruction, the study by Harput et al.\textsuperscript{13} highlights the equal importance of addressing musculature throughout the entire kinetic chain. Friel et al.\textsuperscript{5} also demonstrated the importance of proximal kinetic chain function with respect to inversion ankle sprains - an injury common to the athletic as well as general populations. Because the stance side hip abductors are the main source of stabilization during single limb support, suboptimally functioning abductors can contribute to malposition of the swing side lower extremity and foot just prior to initial contact. This results in the foot assuming a vulnerable position which increases the likelihood of ankle injury. An ankle injury affects the ability to use an ankle strategy for balance, which normally is implemented as a reactive strategy to keep from losing balance.\textsuperscript{5} If unable to rely on the ankle strategy, one defaults to utilizing the hip strategy; if weakness at the hip is present, the risk of falling is increased in clients with ankle injury and hip weakness.\textsuperscript{5}
Because of the significant health-related and economic ramifications of falls, significant focus has been devoted to optimizing fall prevention strategies. Among other interventions, exercise has been consistently shown to reduce the rate of falls in the elderly population and, in addition to balance training, is a recommended component of fall prevention programs.\textsuperscript{1,14-16} Many of the same hip strengthening strategies are crucial in the prevention of and rehabilitation following various musculoskeletal injuries such as ankle sprains and ACL tears.

All of the previously discussed injuries or issues with movement require extensive and multi-faceted rehabilitation. However, this study focuses primarily on the strengthening of the muscles proximal to the hip joint, specifically gluteus medius and gluteus maximus. Understanding the importance of strength and balance between the hip muscles has led to important research on different methods of activating and strengthening the hip musculature. Selkowitz et al.\textsuperscript{12} investigated the activation of gluteus medius during a variety of open- and closed-chain exercises, however the determination of an exercise shown to effectively recruit multiple hip muscles would be clinically significant. Therefore, our study aims to determine an efficient exercise to recruit gluteus maximus and gluteus medius while minimizing compensations to restore proper biomechanical function.
CHAPTER II

METHODS

This project was reviewed and approved by the University of North Dakota Institutional Review Board (IRB-201804-302) prior to initiation of the study (See Appendix).

Subjects

Subjects were recruited from a sample of convenience in the Department of Physical Therapy at the University of North Dakota. The subjects participating in this study were obtained on a voluntary basis and all subjects completed an informed consent form prior to participation (See Appendix). The inclusion criteria included healthy adults over the age of 18. The exclusion criteria included hip or low back pain in the past three months and allergic reactions to adhesives. Each subject completed a subject questionnaire and data collection form. The subjects attended one session of approximately thirty minutes of testing in the Department of Physical Therapy on the University of North Dakota campus in the School of Medicine and Health Sciences. The testing was completed in a private research room for the confidentiality and privacy of the subjects. Subjects did not receive compensation for participating in this study.

Instrumentation

Instrumentation for this study included electromyography (EMG) hardware and software. The EMG data collection was performed using self-adhesive pre-gelled EMG
surface electrodes. These electrodes were placed over standard electrode sites on the dominant side of each test subject. Muscle activity was collected unilaterally on the gluteus maximus and gluteus medius muscles. The EMG data was collected using the Noraxon EMG software myoMUSCLE module for the myoResearch 3.12 software and the TetoMyo DTS telemetry system. Data analysis for the EMG data was performed on a laptop computer (Dell Technologies, Inc) using Noraxon myoResearch 3.12 software (Noraxon, USA, Scottsdale, AZ).

**Procedure**

Prior to the initiation of the study, the EMG equipment was set up and tested by the researchers to ensure proper signal transmission and reception. The subjects were tested independently in the Department of Physical Therapy located at the University of North Dakota School of Medicine and Health Sciences. The purpose and procedure for the study was explained to the participants prior to each participant signing a statement of informed consent, completing the intake survey, and initiation of data collection.

The dominant lower extremity for each subject was used to perform each exercise, and data was collected only for the muscles on the dominant side. Lower extremity dominance was determined by asking each subject to stand in place and kick a soccer ball rolled toward him or her. Three trials were performed for each subject, and the lower extremity self-selected by the subject to kick the ball two out of the three times was considered the dominant side for the purposes of this study. These methods are similar to those used in other studies.17-21
The collection of EMG data required electrode site preparation, electrode placement, connection of hardware, and testing of the equipment. The electrode site preparation was performed in a standardized fashion including removal of excess hair from the electrode site with an electric razor, gently rubbing the skin surface with 400 grit sandpaper, and cleaning the area with isopropyl alcohol. Electrode placement was determined by using standard electrode placement recommendations. Standard silver/silver chloride electrodes were placed in a bipolar configuration at the appropriate sites using an inter-electrode distance of approximately 1.5 cm. The Noraxon skin impedance analyzer was used to assess electrode placement and ensure low (<50kΩ) impedance (Noraxon, USA, Scottsdale AZ). The electrodes were connected to the TeleMyo DTS transmitter (Figure 1). The EMG signals were transmitted to the TeleMyo DTS receiver and stored on a laptop computer (Dell Technologies, Inc.). The raw EMG data was later analyzed for intensity of activation of the muscles using the myoResearch 3.12 software. (Noraxon, USA, Scottsdale AZ).
Figure 1. EMG Electrode placement for the gluteus maximus and gluteus medius muscles on the subjects dominant lower extremity

Figure 2: Hip abduction exercise positions for hip abduction A. Standing hip abduction with theraband. Hip abduction with three ball sizes (B. small, C. Medium, and D. Large)
Initially the subjects performed a mild muscle contraction to assure accurate electrode placement. The subjects were instructed in performing isometric maximal voluntary contractions (MVCs) for a duration of 5 seconds in standardized positions. For gluteus maximus, the subject laid prone on an examination table with a belt fixed around the distal thigh. The subjects performed an MVC at 10 degrees of hip extension. For the gluteus medius, the subject laid on their non-dominant side. A belt was placed around the distal thigh during 30 degrees of hip abduction for the gluteus medius MVC.

The subjects were randomly assigned a series of four different experimental positions including hip abduction in standing with blue theraband at the ankles, sidelying with a small ball (Thera-Band, USA, Akron OH), sidelying with a medium ball (Valeo), and sidelying with a large ball (Physio Gymnic, Italy) (See Figure 2). The circumferences of the small, medium, and large balls measured approximately 155 cm, 180 cm, and 210 cm, respectively. These sizes reflect the measured circumferences, rather than the diameter listed on the ball, to account for variations in inflation level. In each position, the subject performed three repetitions of hip abduction through an excursion of 12°. The EMG activity was collected during the three repetitions of hip abduction (standing) or hip abduction and extension (sidelying). At least one minute of rest separated each of the trials. Following the completion of data collection in all experimental positions, the electrodes were removed from the subjects followed by cleaning the areas with isopropyl alcohol to remove any remaining gel and adhesive.

DATA ANALYSIS

Raw EMG data was analyzed using the Noraxon MR3.12 Software Program. The EMG data was normalized to the maximal voluntary contractions, rectified, and
smoothed using the root mean square (RMS) option set at 50 millisecond collection frames. Composite data is presented as the average±SD of the three trials for each exercise for all subjects within an experimental condition.

STATISTICAL ANALYSIS

Data are presented as mean±standard deviation. A one-way, repeated measures analysis of variance was utilized to determine differences between the experimental trials for each individual muscle (alpha≤0.05). Mauchley's Test of Sphericity was performed followed by the ANOVA. When the data did not meet the assumption of sphericity, a Lower Bound correction was utilized to determine the critical F-value for the ANOVA. Pairwise comparisons were reviewed where the critical F-value was found to be statistically significant (p<0.05). If the data was not normally distributed, non-parametric tests were used to identify differences in EMG activity between conditions. The Friedman Test, an alternative to the Repeated-Measures ANOVA, was used to identify differences between conditions. When significance was found, the Wilcoxon Test with Bonferroni correction addressed pairwise comparisons.
CHAPTER III

RESULTS

Fifteen subjects participated in the study including 11 females and four males. The data and analysis of the genders are combined for reporting purposes. The average age of the subjects was 23±2 years old.

The average height was 68±3 inches while the average weight was 150±25 lbs. (See Figure 3) EMG means and standard deviations are reported for the gluteus medius and gluteus maximus for all conditions. (See Figure 4 and 5.) The small sample size and within- and between-subject variability resulted in kurtosis and/or skewness in most distributions.

Figure 3. Average demographics of the 15 subjects (11 females and 4 males) for age in years, height in inches, and weight in pounds.
As data was not normally distributed, non-parametric tests were used to identify differences in EMG activity between conditions. The Friedman Test, an alternative to the Repeated-Measures ANOVA, was used to identify differences between conditions. When significance was found, the Wilcoxon Test with Bonferroni correction addressed pairwise comparisons.

For 15 subjects, the Friedman Test identified a significant difference between conditions for gluteus medius EMG activity ($=8.2 (3, n=15), p=.042$). The apparent difference occurred between the medium and large ball activity with the larger ball resulting in a higher level of activity ($41.07\pm12.82$ versus $36.64\pm9.36$). At the same time, the level of significance ($p=0.011$) between the medium and large ball activity did not survive the application of a Bonferroni correction ($a=.0083$).

The Friedman Test for EMG activity of the gluteus maximus did not find a significant difference between the four conditions ($=6.44 (3, n=15), p=.092$).
Ten of the original subjects in the study were instructed in a fifth activity, specifically anti-gravity hip abduction in side-lying without the resistance of a ball. Friedman’s test for EMG activity of the gluteus medius did not find a significant difference between the five conditions ($=8.80 (4, n=10), p=.066$).

The Friedman Test did demonstrate a significant difference in EMG activity of the gluteus maximus when five conditions were compared ($=18.16 (4, n=10), p=.001$). The Wilcoxon Test identified significant differences between the antigravity side-lying hip abduction and the small, medium and large ball conditions ($p=0.005, p=0.022, p=0.013$, respectively). However, only the difference between hip abduction without a ball and hip abduction with a small ball retained significance when the Bonferroni correction factor ($\alpha=.005$) was applied. EMG values were $9.27\pm6.41$ and $18.96\pm10.27$, respectively. Gluteus maximus EMG activity was increased with the use of the small ball.
The purpose of the study was to compare muscle recruitment patterns when using a small, medium or large therapeutic ball as a method of measured overload during a hip abduction exercise. Fifteen subjects performed four different types of exercises to determine the level of gluteus medius and gluteus maximus muscle activity. We observed increased gluteus medius EMG activity as ball size was increased during the performance of the sidelying exercise. However, the gluteus medius activity in all sidelying exercises was less than standing hip abduction against a blue theraband and only approached statistical significance between the medium and large ball conditions. Activation of the gluteus maximus was lowest in the standing position and highest when the smallest ball was used during sidelying hip abduction. Surprisingly, the difference in gluteus maximus activity was significantly different between anti-gravity hip abduction without and with a small ball behind the heel while no significant difference was observed with increasing ball size.

The original hypothesis of the study expected an increase in EMG activity with increasing ball size. Intuitively, a larger ball was hypothesized to require greater force and control thereby resulting in higher levels of EMG activation from the gluteus medius and gluteus maximus muscles. For the gluteus medius, the hypothesis of increasing activity associated with the larger ball size appears to hold true although EMG activity
only approached significance between the medium and largest sized balls. Alternatively, the gluteus maximus activity was significantly higher in the small ball condition compared to anti-gravity hip abduction alone. During the study, it was noted that several subjects required a greater level of concentration and hip extension force when performing the exercise with the smallest ball. At the same time, the size of the larger ball provided greater contact between the wall and the subjects’ heel so that less concentration may have been required to stabilize the ball against the wall when moving through the hip abduction range of motion. In this sense, the greater amount of force noted could be due to either an actual increased demand on the musculature needed to control a smaller object or simply a perceived need for greater mental concentration to complete the activity.

Mental concentration on a muscle during activity can result in increased EMG activity. In a study of subjects completing an elbow flexion exercise against resistance, Marchant et al.\(^{23}\) observed increased EMG activity when the subjects concentrated on the arm musculature rather than on the weight in their hand. In the study, twenty five participants of mean age 23 years were instructed to complete ten repetitions of elbow flexion on one arm using an isokinetic dynamometer while EMG equipment was used to measure both activity in the biceps brachii musculature and net joint elbow flexor torque. They completed this activity once with no instruction in order to serve as a control trial, and then completed the activity two more times, once with internally focused conditions and once with externally focused conditions. Adequate rest of an allotted five minutes was allowed between trials to prevent fatigue. For the internally focused condition, subjects were instructed “focus upon the movement of your arm and muscles during the
lift,” while for the externally focused condition, subjects were instructed, “focus upon the movement of the crank hand bar during the lift.” Analysis of the results found that there was a significantly greater amount of EMG activity during the internally focused trials. In regard to the application of the concepts from this study to the ball exercises, the idea is that the use of different cues such as control the motion of the ball and focus on contracting the muscle in your buttock may increase EMG activity during the wall exercises.

Another study investigated the effects of altered task demands on motor control by having subjects alter their point of visual focus on a stick as they balanced it in their hands. Muscle activity in the forearm and back muscles was monitored with surface EMG electrodes during the task. When the point of focus was directed lower on the stick, there was greater movement of the stick and greater forearm and trunk muscle activation was required to perform the task of keeping the stick in an upright position. Although visual focus was a main variable in this study, the results do indicate that greater uncertainty in the position of the stick made the task more challenging and correlated with an increase of muscle activity. This finding supports our hypothesis that maintaining the small ball against the wall was more challenging and required greater motor control and thus increased muscle activity than the medium and large balls.

Another factor for the outcomes received in this study could be the placement of the dominant leg. In our study we placed the dominant leg as the top limb because we assumed the dominant leg would utilize greater muscle activity when completing the exercise. In another study by Boren et. al., they placed the dominant leg as the bottom limb. Boren et. al. chose to put the dominant leg on the bottom for some exercises to
assess whether the stabilizing limb was working harder to stabilize the entire body throughout the exercise and therefore required more activation as well as to see the difference between the two limbs. They utilized 24 healthy patients, with electrodes placed on the gluteus medius and maximus, who completed 18 different exercises. Of these 18 exercises, side plank with the abduction dominant leg on bottom, side plank abduction with dominant leg on top, single limb squat, clam shell, and front plank with hip extension were identified to elicit the most force from the gluteus medius respectively. For gluteus maximus the exercises that produced the most force included front plank with hip extension, glute squeeze, side plank abduction with dominant leg on top, side plank abduction with dominant leg on bottom, and single limb squat respectively. An additional study performed by Widler et al.\textsuperscript{26} studied the activation of gluteus medius in three different positions that were side lying, supine, and standing. This study included sixteen subjects with eight being female and eight male. They placed electrodes to measure the muscle activation in all three positions. Their electromyographic results demonstrated the best testing/muscle activation position for both the dominant and non-dominant lower extremity was sidelying. This study reinforces that our method of testing in the side lying position was the best option. In future studies, investigating differences between the stabilizing limb and the limb performing the activity may allow for a better understanding of how the gluteus medius is best activated. With that being said it could very possibly vary from person to person in regards to their thought process and motor planning. Because we were not extremely strict on exactly how to perform the exercise, subtle compensatory strategies that may be unnoticeable to the human eye could have been used or the gluteus medius on the bottom
limb as in the study mentioned above could have exerted more force to complete the activity. Depending on the way the subjects are told to complete the exercise or how they are told to concentrate on a certain action could change the activation as well.

Lastly, a factor that is potentially contributing to the outcomes observed during this study includes the involvement of the tensor fascia lata muscle. Because the TFL is a strong hip abductor, its contribution to the production of abduction force may affect that of the gluteus medius muscle. Berry et al. demonstrated that the activity of the TFL was reduced when the hips were flexed as compared to a neutral position required during a standing abduction exercise with a resistance band. Due to the reduced activity of the TFL in a flexed position, greater activity in the gluteus medius is required to produce the abduction force at the hip during this activity. Our findings that the EMG activity of the gluteus medius was greatest during the standing hip abduction exercise with the hips flexed are in agreement with the findings in their study. It is possible that the TFL was more active in the sidelying position than in the standing position, requiring less force production from the gluteus medius and therefore contributing to the relatively lower EMG recordings noted for the gluteus medius during the sidelying exercises. However, because EMG activity was not recorded for the TFL in the present study, conclusions cannot be drawn. Future research may benefit from including the TFL in the EMG analyses in order to obtain a more comprehensive picture of the muscular activity involved in producing these motions.

This research was done to find the best exercise to activate gluteus medius and gluteus maximus. There are multiple benefits to strengthening these specific muscles. Benefits include decreased fall risk, injury prevention, rehabilitation, and the
enhancement of activities such as walking, running, driving, lifting and negotiating stairs. Strengthening of these muscles is therefore something that can be of use not only to elderly individuals, but all individuals throughout the lifespan. Although the results did not find significance that would indicate the effectiveness or ineffectiveness of one specific exercise, it is clear that further research is needed possibly with more subjects, more specific inclusion criteria, and more detailed instructions as per the performance of the exercises. The fact remains that strengthening of gluteus medius and gluteus maximus is beneficial. Ideally, sufficient research will be conducted in the future to illuminate the optimal exercises and positions for achieving the goal of efficiently strengthening the gluteus medius and gluteus maximus muscles.
APPENDIX
University of North Dakota Human Subjects Review Form  
January 2015 Version

All research with human participants conducted by faculty, staff, and students associated with the University of North Dakota, must be reviewed and approved as prescribed by the University's policies and procedures governing the use of human subjects. It is the intent of the University of North Dakota (UND), through the Institutional Review Board (IRB) and Research Development and Compliance (RD&C), to assist investigators engaged in human subject research to conduct their research along ethical guidelines reflecting professional as well as community standards. The University has an obligation to ensure that all research involving human subjects meets regulations established by the United States Code of Federal Regulations (CFR). When completing the Human Subjects Review Form, use the “IRB Checklist” for additional guidance.

Please provide the information requested below. Handwritten forms are not accepted – responses must be typed on the form.

**Principal Investigator:** David Relling, PT, PhD  
Telephone: 701 777-4091 E-mail Address: david.relling@med.und.edu

Complete Mailing Address: UND School of Medicine & Health Sciences Rm 3321 Dept of Physical Therapy Stop 9037 1301 N Columbia Rd Grand Forks ND 58202-9037

School/College: School of Medicine & Health Sciences  
Department: Physical Therapy

**Student Advisor (if applicable):**

Telephone:  
E-mail Address:  
Address or Box #:  
School/College:  
Department:  

***All IRB applications must include a Key Personnel Listing.***

**Project Title:** Electromyography (EMG) activity of the Gluteus Medius during various hip exercises.

**Proposed Project Dates:**  
Beginning Date: May 15, 2018  
Completion Date: May 1, 2019  
(Including data analysis)

**Funding agencies supporting this research:** N/A

Did the grant proposal with the funding entity go through UND Grants & Contracts Admin.?  
☐ YES or ☑ NO

Attach a copy of the grant proposal. Do not include any budgetary information. The IRB will not be able to review the study without a copy of the grant proposal submitted to the funding agency.

- Does any researcher associated with this project have an economic interest in the research, or act as an officer or a director of any outside entity whose financial interests would reasonably appear to be affected by the research? If yes, submit on a separate piece of paper an additional explanation of the financial interest. The Principal Investigator and any researcher associated with this project should have a Financial Interests Disclosure Document on file with their department.

- ☐ YES or ☑ NO

- Will any research participants be obtained from another organization outside the University of North Dakota (e.g., hospitals, schools, public agencies, American Indian tribes/reservations)?

- ☐ YES or ☑ NO

- Will any data be collected at or obtained from another organization outside the University of North Dakota?

- ☐ YES or ☑ NO

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If yes to either of the previous two questions, list all organizations:

Letters from each organization must accompany this proposal. Each letter must illustrate that the organization understands its involvement and agrees to participate in the study. Letters must include the name and title of the individual signing the letter and should be printed on organizational letterhead.

Does any external site where the research will be conducted have its own IRB?  □ YES □ NO □ N/A

If yes, does the external site plan to rely on UND’s IRB for approval of this study?  □ YES □ NO □ N/A

(If yes, contact the UND IRB at 701 777-4279 for additional requirements)

If your project has been or will be submitted to other IRBs, list those Boards below, along with the status of each proposal.

<table>
<thead>
<tr>
<th>Date submitted</th>
<th>Status</th>
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(include the name and address of the IRB, contact person at the IRB, and a phone number for that person)

**Type of Project:** Check “Yes” or “No” for each of the following.

☑ YES or ☐ NO New Project

☐ YES or ☐ NO Continuation/Renewal

☐ YES or ☐ NO Dissertation/Thesis/Independent Study

☐ YES or ☐ NO Student Research Project

☐ YES or ☐ NO Is this a Protocol Change for previously approved project? If yes, submit a signed Protocol Change Form, along with a signed copy of this form with the changes bolded or highlighted.

☐ YES or ☐ NO Does your project involve abstracting medical record information? If yes, complete the HIPAA Compliance Application and submit it with this form.

☐ YES or ☐ NO Does your project include Genetic Research?

**Subject Classification:** This study will involve subjects who are in the following special populations: Check all that apply.

☐ Children (< 18 years) ☐ UND Students

☐ Prisoners ☐ Pregnant Women/Fetuses

☐ Cognitively impaired persons or persons unable to consent

☐ Other

Please use appropriate checklist when children, prisoners, pregnant women, or people who are unable to consent will be involved in the research.

**This study will involve:** Check all that apply.

☐ Deception (Attach Waiver or Alteration of Informed Consent Requirements) ☐ Stem Cells

☐ Radiation ☐ Discarded Tissue

☐ New Drugs (IND) IND # ______ Attach Approval ☐ Fetal Tissue

☐ Investigational Device Exemption (IDE) # ______ Attach Approval ☐ Human Blood or Fluids

☐ Non-approved Use of Drug(s) ☐ Other _____

☐ None of the above will be involved in this study

**I. Project Overview**

Please provide a brief explanation (limit to 200 words or less) of the rationale and purpose of the study, introduction of any sponsor(s) of the study, and justification for use of human subjects and/or special populations (e.g., vulnerable populations such as children, prisoners, pregnant women/fetuses).

Falls in older individuals result in substantial direct medical costs, morbidity and mortality. Reduced strength and size of the gluteal muscles is a risk factor for falls in older people. Exercises to increase gluteal muscle strength can be effective in reducing the risk for falls. There are many different types of hip exercises. Surface electromyography (EMG) has been used to determine the effectiveness of some exercises.
to recruit the gluteal muscles. The purpose of this study is to use surface EMG to assess an exercise that uses a therapeutic ball to purportedly activate the muscles of hip abduction and hip extension at the same time. This study will provide important information about the effectiveness of the exercise on activation of critical hip muscles for preventing falls.

II. Protocol Description

Please provide a thorough description of the procedures to be used by addressing the instructions under each of the following categories.

1. Subject Selection.

   a) Describe recruitment procedures (i.e., how subjects will be recruited, who will recruit them, where and when they will be recruited and for how long) and include copies of any advertisements, fliers, etc., that will be used to recruit subjects. Subjects will be recruited from the UND professional physical and occupational therapy classes. A flier (see attached) will be displayed in multiple rooms on the third floor of the SMHS building during the summer 2018 session. The principle investigator will announce the posting of the flier to students enrolled in the professional programs.

   b) Describe your subject selection procedures and criteria, paying special attention to the rationale for including subjects from any of the categories listed in the “Subject Classification” section above. Subjects must be apparently healthy, 18 years of age or older, free of hip pathology, and no recent injuries or conditions affecting the ability to move the hips and exercise. The use of UND students in the professional physical therapy and occupational therapy program reflects a sample of convenience.

   c) Describe your exclusionary criteria and provide a rationale for excluding subject categories. Under the age of 18 due to the inability to provide their own consent (minor). Subjects with hip or back injuries or pathology, disease or recent injuries or conditions affecting the hips or back due to difficulty or inability to perform the exercises or assume the research positions. The EMG electrodes utilize a tape-like adhesive for adherence to the skin and therefore individuals with tape allergies will be excluded. Only apparently healthy individuals over the age of 18 will be utilized for the study.

   d) Describe the estimated number of subjects that will participate and the rationale for using that number of subjects. It is estimated that 30 subjects will be recruited into the study. Each subject will serve as their own control in the different exercise positions. The 30 subjects are expected to provide a normative distribution of EMG activity for healthy individuals. At the same time, this number of subjects should provide the statistical power needed to identify significant differences in EMG activity due to the different exercise positions.

   e) Specify the potential for valid results. If you have used a power analysis to determine the number of subjects, describe your method. A statistical power analysis was not performed. However, in previous studies with EMG we have observed 20-30 subjects provides adequate data to determine effectiveness of position or movement changes on the muscles being studied.

2. Description of Methodology.

   a) Describe the procedures used to obtain informed consent. The principle investigator will announce the availability of the study to students in the professional programs. A flyer will be used to provide additional information. Potential participants will be provided with an overview of the purpose, study design, risks and results/outcomes of the study. Each subject will be informed of the potential for adverse effects. Subjects will be provided with the opportunity to retain a copy of the written consent form. Time will be allowed for any potential questions or concerns. Prior to the initiation of subject participation, each subject must provide verbal and written consent.
b) Describe where the research will be conducted. Document the resources and facilities to be used to carry out the proposed research. Please note staffing, funding, and space available to conduct this research.

The research will be conducted in the Department of Physical Therapy in the School of Medicine & Health Sciences at the University of North Dakota. The department has both electromyography (EMG) software and hardware available for this project. The Noraxon Telemyo DTS EMG system is used to collect and analyze EMG data. The principle investigator has experience in utilizing the equipment and software. The UND PT department will provide the EMG electrodes for the study.

c) Indicate who will carry out the research procedures.

The principle investigator, Dr. David Reiling, will oversee all aspects of the study. Students in the professional physical therapy program (Taylor Doeden, Mitchell Karbo, Kalie Maiden, and Analise Richtsmeier) will assist with subject recruitment, intervention (data collection) and data analysis. Taylor Doeden, Mitchell Karbo, Kalie Maiden and Analise Richtsmeier have undergone training on the EMG system and will obtain proficiency prior to initiation of the study.

d) Briefly describe the procedures and techniques to be used and the amount of time that is required by the subjects to complete them.

Subjects will initially be fit with pre-gelled, self-adhesive electrodes placed over the motor points of the relevant muscles. The electrodes collect underlying electrical activity within the muscles but do not provide any electrical shock or current to the subject. The muscles to be monitored include the gluteus medius and gluteus maximus. The subjects will be asked to wear shorts and a t-shirt to facilitate access to the muscles and protect modesty. Prior to electrode placement, the skin will be prepared in a standardized fashion and skin impedance will be measured to ensure adequate electrical conduction at each site. Preparation of the skin includes removing excess hair from the electrode site with an electric clipper and wiping the skin surface lightly with 400 grit sandpaper followed by wiping the area with isopropyl alcohol wipes. The electrodes will be connected to individual transmitters which are attached to the skin with double sided tape. The EMG signals will be transmitted to a receiver and then to a computer. Raw EMG data will be obtained for analysis. An electrogoniometer will be applied with double sided tape over the hip joint. The electrogoniometer provides joint motion data through a process similar to the EMG electrodes. Each subject will perform hip abduction exercises in standing with elastic theraband around the legs and sidelying hip abduction while pushing the heel of one leg into a ball. The sidelying exercise will be repeated with a total of three different sized balls. The sequence of exercises will be randomized.

e) Describe audio/visual procedures and proper disposal of tapes.

No audio data will be collected. Video images of the clients waist and legs will be collected at the same time as the EMG activity. The images are digital and are retained with the EMG data in the Noraxon system software. Images will be deleted three years after the completion of the study.

f) Describe the qualifications of the individuals conducting all procedures used in the study.

David Reiling is a faculty member in the department of physical therapy. He is a licensed physical therapist and has performed research projects with EMG in the past. All key personnel have received training on the EMG equipment and completed IRB training.

g) Describe compensation procedures (payment or class credit for the subjects, etc.).

No compensation will be provided for subjects participating in the study.

Attachments Necessary: Copies of all instruments (such as survey/interview questions, data collection forms completed by subjects, etc.) must be attached to this proposal.


a) Clearly describe the anticipated risks to the subject/others including any physical, emotional, and financial risks that might result from this study.
The potential physical risks associated with this study are minimal. The EMG electrode placement and analysis is a non-invasive procedure utilized in clinical practice. Minor skin irritation from the skin preparation and EMG electrodes is possible.

b) Indicate whether there will be a way to link subject responses and/or data sheets to consent forms, and if so, what the justification is for having that link.
Subject's names will not be used in any reports of the results of this study. Each participant will complete a written consent form. There will be no association between the written consent form and the subjects data. At the completion of the study, the research data and the consent forms will be stored in separate, locked locations in the Department of Physical Therapy for three years at which point the forms and data will be destroyed. Data will only be reported in aggregate form to protect the confidentiality of all subjects.

c) Provide a description of the data monitoring plan for all research that involves greater than minimal risk.
N/A

d) If the PI will be the lead-investigator for a multi-center study, or if the PI's organization will be the lead site in a multi-center study, include information about the management of information obtained in multi-site research that might be relevant to the protection of research participants, such as unanticipated problems involving risks to participants or others, interim results, or protocol modifications.
N/A

4. Subject Protection.

a) Describe precautions you will take to minimize potential risks to the subjects (e.g., sterile conditions, informing subjects that some individuals may have strong emotional reactions to the procedures, debriefing, etc.).
The possibility of skin irritation will be minimized by proper skin preparation and subject screening prior to participation. New, clean materials will be used for preparation and application of electrodes for each subject. Subjects will be informed of the placement of electrodes to prevent emotional reactions to concerns about impeding on the subjects personal space. Investigators will use appropriate draping of the subject during preparation and placement of EMG electrodes. The investigator(s) or participant may stop the experiment at any time if the participant is experiencing discomfort, pain, fatigue, or any other symptoms that may be detrimental to their health. All subjects will be allowed to terminate their participation in this study at any time without prejudice.

b) Describe procedures you will implement to protect confidentiality and privacy of participants (such as coding subject data, removing identifying information, reporting data in aggregate form, not violating a participants space, not intruding where one is not welcome or trusted, not observing or recording what people expect not to be public, etc.). If participants who are likely to be vulnerable to coercion and undue influence are to be included in the research, define provisions to protect the privacy and interests of these participants and additional safeguards implemented to protect the rights and welfare of these participants.

Subject data will not be linked to the consent form in order to protect the confidentiality of the subjects. Data collection forms and electronic data collection EMG files will be linked together using an alphanumeric code. Data will only be reported in aggregate form to assure privacy of the subjects. Participants will wear appropriate clothing to allow access to the EMG electrode sites. However, researchers will utilize appropriate draping with sheets and towels during placement of electrodes to assure subject comfort and modesty.

c) Indicate that the subject will be provided with a copy of the consent form and how this will be done.
Prior to participation in this study, each subject will read and sign a consent form. Participants in this study will all be capable of independent decision making and will sign a consent form stating their understanding and willingness to participate in this study. Participants will be encouraged to ask any questions regarding the consent form to ensure their understanding of the document. Each participant will be provided the opportunity to receive a copy of the consent form for their records.

d) Describe the protocol regarding record retention. Please indicate that research data from this study and consent forms will

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both be retained in separate locked locations for a minimum of three years following the completion of the study. Describe: 1) the storage location of the research data (separate from consent forms and subject personal data) 2) who will have access to the data 3) how the data will be destroyed 4) the storage location of consent forms and personal data (separate from research data) 5) how the consent forms will be destroyed

Participant consent forms and data (collection sheets and electronic files) will be stored separately and secured in separate locked locations in the Department of Physical Therapy. Only the principal investigator will have access to both the consent forms and data. Subject data and consent forms will be retained in room E336 in separate, locked file cabinets. After a period of three years from the completion of the study, the consent forms and data collection sheets will be shredded. Electronic data will be deleted or destroyed from all disks/drives.

e) Describe procedures to deal with adverse reactions (referrals to helping agencies, procedures for dealing with trauma, etc.). The investigators or participant may stop the experiment at any time if the participant is experiencing discomfort, pain, abnormal fatigue, or any other symptoms that may be detrimental to their health. If subjects consent to participate, they will be allowed to terminate their participation in this study at any time without prejudice or jeopardizing any future relationships with the UND Department of Physical Therapy. Medical treatment will be provided to each subject as needed, including first aid, CPR, and follow-up care as that provided to a member of the general public in a similar circumstance.

f) Include an explanation of medical treatment available if injury or adverse reaction occurs and responsibility for costs involved.

In the event an adverse event occurs during participation in this study, the subject will be prompted to seek immediate medical attention. All incurred medical expenses will be the responsibility of the subject or the subject's third-party payer.

III. Benefits of the Study
Clearly describe the benefits to the subject and to society resulting from this study (such as learning experiences, services received, etc.). Please note: extra credit and/or payment are not benefits and should be listed in the Protocol Description section under Methodology.

Possible benefits of this study include but are not limited to: 1) furthering the knowledge concerning the muscle activity used in different exercise positions; 2) identifying optimal exercises for activating and strengthening muscles that play an important role in fall prevention; 3) further research may be stimulated. Subjects participating in the study will not receive any compensation nor will they incur any cost associated with this study.

IV. Consent Form
Clearly describe the consent process below and be sure to include the following information in your description (Note: Simply stating ‘see attached consent form’ is not sufficient. The items listed below must be addressed on this form.): 1) The person who will conduct the consent interview 2) The person who will provide consent or permission 3) Any waiting period between informing the prospective participant and obtaining consent 4) Steps taken to minimize the possibility of coercion or undue influence 5) The language (English, French, German, etc.) to be used by those obtaining consent 6) The language (English, French, German, etc.) understood by the prospective participant or the legally authorized representative 7) The information to be communicated to the prospective participant or the legally authorized representative

The person to conduct the consent interview will be Dr. David Relling. Consent will be provided by the subject. Since the study is a one time event with minimal risk, there will be no waiting time between informing the subject and consent. The investigator will announce the opportunity to participate and post the appropriate sign while key personnel recruit subjects. Removing the PI from recruitment should decrease undue influence from the faculty led study. English will be used for obtaining consent and all subjects must be able to understand and utilize English. Information communicated to the prospective participant will include a reading of the study purpose and what will happen from the informed consent
A copy of the consent form must be attached to this proposal. If no consent form is to be used, document the procedures to be used to protect human subjects, and complete the Application for Waiver or Alteration of Informed Consent Requirements. Refer to form IC 701-A, Informed Consent Checklist, and make sure that all the required elements are included. Please note: All records attained must be retained for a period of time sufficient to meet federal, state, and local regulations; sponsor requirements; and organizational policies. The consent form must be written in language that can easily be read by the subject population and any use of jargon or technical language should be avoided. The consent form should be written at no higher than an 8th grade reading level and must be written in the second person (please see the example on the RD&C website). A two inch by two inch blank space must be left on the bottom of each page of the consent form for the IRB approval stamp.

Necessary attachments:
- Signed Student Consent to Release of Educational Record Form (students and medical residents only);
- Investigator Letter of Assurance of Compliance; (all researchers)
- Consent form, or Waiver or Alteration of Informed Consent Requirements (Form IC 702-B)
- Key Personnel Listing
- Surveys, interview questions, etc. (if applicable);
- Printed web screens (if survey is over the Internet); and
- Advertisements (flyer, social media postings, email/letters, etc.).

By signing below, you are verifying that the information provided in the Human Subjects Review Form and attached information is accurate and that the project will be completed as indicated.

Signatures:

[Signature]

4/10/2018

[Signature]

4/10/2018

(Principal Investigator)

(Student Advisor)

**All students and medical residents must list a faculty member as a student advisor on the first page of the application and must have that person sign the application.**

Requirements for submitting proposals:
Additional information can be found on the IRB website at: http://und.edu/research/resources/human-subjects/index.cfm

Original, signed proposals and all attachments, along with the necessary number of copies (see below), should be submitted to: Institutional Review Board, 264 Centennial Drive Stop 7134, Grand Forks, ND 58202-7134, or brought to Room 106, Tumley Hall.

Required Number of Copies:
- Expedited Review: Submit the signed original and 1 copy of the entire proposal.
- Full Board Review: Submit the signed original and 22 copies of the entire proposal by the deadline listed on the IRB website: http://und.edu/research/resources/human-subjects/meeting-schedule.cfm
- Clinical Medical Subcommittee and Full Board Review: Submit the signed original and 24 copies of the entire proposal by the deadline listed on the IRB website: http://und.edu/research/resources/human-subjects/meeting-schedule.cfm

Prior to receiving IRB approval, researchers must complete the required IRB human subjects’ education. Please go to: http://und.edu/research/resources/human-subjects/human-subject-education.cfm

The criteria for determining what category your proposal will be reviewed under is listed on page 3 of the IRB Checklist. Your reviewer will assign a review category to your proposal. Should your protocol require full Board review, you will need to provide additional copies. Further information can be found on the IRB website regarding required copies and IRB review categories, or you may call the IRB office at 701 777-4279.

In cases where the proposed work is part of a proposal to a potential funding source, one copy of the completed proposal to the funding agency (agreement/contract if there is no proposal) must be attached to the completed Human Subjects Review Form.
the proposal is non-clinical; 5 copies if the proposal is clinical-medical. If the proposed work is being conducted for a pharmaceutical company, 5 copies of the company’s protocol must be provided.
INVESTIGATOR LETTER OF ASSURANCE OF COMPLIANCE
WITH ALL APPLICABLE FEDERAL REGULATIONS FOR THE
PROTECTION OF THE RIGHTS OF HUMAN SUBJECTS

I, David Relling, PT, PhD
(Name of Investigator)

agree that, in conducting research under the approval of the University of North Dakota Institutional Review Board, I will fully comply and assume responsibility for the enforcement of compliance with all applicable federal regulations and University policies for the protection of the rights of human subjects engaged in research. Specific regulations include the Federal Common Rule for Protection of the Rights of Human Subjects 45 CFR 46. I will also assure compliance to the ethical principles set forth in the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research document, The Belmont Report.

I understand the University's policies concerning research involving human subjects and agree to the following:

1. Should I wish to make changes in the approved protocol for this project, I will submit them for review PRIOR to initiating the changes. (A proposal may be changed without prior IRB approval where necessary to eliminate apparent immediate hazards to the subjects or others. However, the IRB must be notified in writing within 72 hours of any change, and IRB review is required at the next regularly scheduled meeting of the full IRB.)

2. If any problems involving human subjects occur, I will immediately notify the Chair of the IRB, or the IRB Coordinator.

3. I will cooperate with the UND IRB by submitting Research Project Review and Progress Reports in a timely manner.

I understand the failure to do so may result in the suspension or termination of proposed research and possible reporting to federal agencies.

Investigator Signature ________________________ Date 4/10/18

Revised 1/9/15
UNIVERSITY OF NORTH DAKOTA  
INSTITUTIONAL REVIEW BOARD  
KEY PERSONNEL LISTING

<table>
<thead>
<tr>
<th>Name of Research Personnel</th>
<th>Position</th>
<th>Highest Academic Degree</th>
<th>Consent Subjects</th>
<th>Recruit Subjects</th>
<th>Research Design</th>
<th>Intervention</th>
<th>Data Analysis</th>
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<tbody>
<tr>
<td>1  David Reiling</td>
<td>Faculty</td>
<td>Ph.D.</td>
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<td>2  Taylor Doeden</td>
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<td>3  Mitchell Karbo</td>
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<td>5  Analise Richtsmeyer</td>
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* Attach proof of education in human subjects research for all non-UND personnel

Revised 03/15/2017
ID #: 2018---

TITLE: Electromyography (EMG) Activity of the Gluteus Medius during various hip exercises

Subject Questionnaire and Data Collection

DOB: _______________ Height (in) _______________
Gender: M / F Weight (lbs) _______________
Hand Dominance: R / L

1) Have you had any injuries to your legs? YES/NO
   If YES, please explain: __________________________________________

2) Have you had any injuries to your pelvis or back? YES/NO
   If YES, please explain: __________________________________________

3) Have you experienced itching, rash or irritation from bandages or adhesives on tape? YES/NO
   If YES, please explain: __________________________________________

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<tr>
<th>POSITION</th>
<th>Sequence of Testing (1-4)</th>
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<tr>
<td>Standing hip abduction</td>
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<tr>
<td>Sidelying hip abduction, small ball</td>
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<tr>
<td>Sidelying hip abduction, medium ball</td>
<td></td>
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<tr>
<td>Sidelying hip abduction, large ball</td>
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RESEARCH STUDY PARTICIPANTS NEEDED
TO STUDY HIP MUSCLE ACTIVITY DURING HIP EXERCISES

The PURPOSE of this study is to better understand the effect of hip exercises on the activation and use of hip muscles. You can participate if you are over the age of 18, do not have any recent hip injuries or diseases and do not have any allergies to adhesives like tape.

Participation in the study will last for 1 session of approximately 1 hour. You will need to visit the physical therapy department (1301 N Columbia Rd, Room E312, and its research lab) where the study will take place.

PROCESS: You will complete a form that asks about your age, height, weight, gender, hip injuries and allergies to tape. Following completion of the form, the researchers will collect information regarding your muscles' activity using electromyography (EMG) while you perform four different exercises for the hip. The exercises include standing hip movements with resistive band at your ankles followed by laying on your side and lifting your leg into the air while moving one of three different sized balls. You will be asked to perform the sidelying exercise with all three balls.

RISKS from this study are minimal but do include mild skin irritation at the site of the electrode that reads the muscle activity, a common short-lasting occurrence in studies using EMG.

HOW TO PARTICIPATE:
If you are interested in participating or would like more information please contact Doctor of Physical Therapy students Taylor Doeden, Mitchell Karbo, Kalie Maiden, or Analise Richtsmeier at 777-2831.
**EMG Electrode Placement**

<table>
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<tr>
<th>Muscle</th>
<th>Description</th>
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<tr>
<td>Gluteus Medius</td>
<td>Proximal 1/3 of the distance between the iliac crest and the great trochanter.</td>
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<tr>
<td>Gluteus Maximus</td>
<td>½ the distance between the greater trochanter and sacral vertebrae.</td>
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INFORMED CONSENT

TITLE:
Electromyography (EMG) activity of the Gluteus Medius during various hip exercises

PROJECT DIRECTOR:
David Reiling, PT, Ph.D.

PHONE #
(701)777-4091

DEPARTMENT:
Physical Therapy

STATEMENT OF RESEARCH

A person who is to participate in the research must give his or her informed consent to such participation. This consent must be based on an understanding of the nature and risks of the research. This document provides information that is important for this understanding. Research projects include only subjects who choose to take part. Please take your time in making your decision as to whether to participate. If you have questions at any time, please ask.

WHAT IS THE PURPOSE OF THIS STUDY?

You are invited to take part in a research study conducted by David Reiling, a faculty member of the Department of Physical Therapy at the University of North Dakota. The purpose of this study is to better understand the effect of hip exercises on the activation and use of hip muscles. You were selected because you are over the age of 18, do not have any recent hip injuries or diseases and do not have any allergies to adhesives like tape.

HOW MANY PEOPLE WILL PARTICIPATE?

Approximately 30 people will take part in this study at the University of North Dakota.

HOW LONG WILL I BE IN THIS STUDY?

Your participation in the study will last for 1 session of approximately 1 hour. You will need to visit the physical therapy department (1301 N Columbia Rd, Room E312, and its research lab) where the study will take place.

WHAT WILL HAPPEN DURING THIS STUDY?

You will complete a form that asks about your age, height, weight, gender, hip injuries and allergies to tape. The information is needed to determine eligibility to participate in the study. Following completion of the form, the researchers will prepare to collect information regarding your muscles’ activity using electromyography (EMG). EMG uses small, adhesive-backed electrodes attached to the skin and a device that can detect the electrical activity present in
muscles at rest and in action. The device does not give off an electrical current or shock to your body—it only detects electrical activity present in muscles over which electrodes are attached. The researchers will clip any hair present over areas of muscle on which electrodes are to be placed. This will be followed by rubbing the skin lightly with sandpaper and an alcohol wipe in order to improve the ability to detect electrical activity. The electrodes will convey electrical information to the device for actual measurement. Once electrodes are in place, you will be asked to perform four different exercises. Standing hip movements with resistive band at your ankles followed by laying on your side and lifting your leg into the air while moving one of three different sized balls. You will be asked to perform the sidelying exercise with all three balls.

**WHAT ARE THE RISKS OF THE STUDY?**

There may be some risk from being in this study, such as the small risk of mild skin irritation at the site of the electrode that reads the muscle activity, a common short-lasting occurrence in studies using EMG. Steps will be taken to ensure your modesty and comfort by covering areas where electrode application may approach more personal body areas.

If you are pregnant or become pregnant during the study, we foresee no additional risks to you or the baby during the course of the research.

**WHAT ARE THE BENEFITS OF THIS STUDY?**

You may not benefit personally from being in this study. However, we hope that, in the future, other people might benefit from this study because results from this research may help the understanding of the best exercises to activate and strengthen muscles that minimize the risk of falling.

**WILL IT COST ME ANYTHING TO BE IN THIS STUDY? WILL I BE PAID?**

You will not have any costs for being in this research study other than perhaps traveling or parking costs. You will not be paid for being in this research study.

**WHO IS FUNDING THE STUDY?**

The University of North Dakota and the research team are receiving no payments from other agencies, organizations, or companies to conduct this research study.
CONFIDENTIALITY

The records of this study will be kept private to the extent permitted by law. In any report about this study that might be published, you will not be identified. Your study record may be reviewed by Government agencies, the UND Research Development and Compliance office, and the University of North Dakota Institutional Review Board.

Any information that is obtained in this study and that can be identified with you will remain confidential and will be disclosed only with your permission or as required by law. Confidentiality will be maintained by means of coding data and computer files with an independent number for each subject. You should know, however, that there are some circumstances in which we may have to show your information to other people. For example the law may require us to show your information to a court or to tell authorities if we believe you have abused a child, or you pose a danger to yourself or someone else. Confidentiality will be maintained by means of storing of all records and research information in separate locked file cabinets in Room E336 of the Physical Therapy Department. All collected research information and records will be destroyed by shredding after 3 years.

If we write a report or article about this study, we will describe the study results in a summarized manner so that you cannot be identified.

COMPENSATION FOR INJURY

In the event that this research activity results in an injury, treatment will be available including first aid, emergency treatment and follow-up care as needed. Payment for any such treatment is to be provided by you (you will be billed) or your third-party payer, if any (such as health insurance, Medicare, etc.) No funds have been set aside to compensate you in the event of injury. Also, the study staff cannot be responsible if you knowingly and willingly disregard the directions they give you.

IS THIS STUDY VOLUNTARY?

Your participation is voluntary. You may choose not to participate or you may discontinue your participation at any time without penalty or loss of benefits to which you are otherwise entitled. Your decision whether or not to participate will not affect your current or future relations with the University of North Dakota.
CONTACTS AND QUESTIONS

The researcher conducting this study is David Relling. You may ask any questions you have now or anytime during your participation in the study. If you later have questions, concerns, or complaints about the research please contact David Relling in the Physical Therapy Department at 777-2831 during the day and at (701)741-3481 after hours. If you have questions regarding your rights as a research subject, or if you have any concerns or complaints about the research, you may contact the University of North Dakota Institutional Review Board at (701) 777-4279.

- You may also call this number about any problems, complaints, or concerns you have about this research study.
- You may also call this number if you cannot reach research staff, or you wish to talk with someone who is independent of the research team.
- General information about being a research subject can be found by clicking “Information for Research Participants” on the web site: http://und.edu/research/resources/human-subjects/research-participants.cfm

Your signature indicates that this research study has been explained to you, that your questions have been answered, and that you agree to take part in this study. You may receive a copy of this form by requesting one.

Subjects Name: ____________________________________________

Signature of Subject ____________________________ Date __________

I have discussed the above points with the subject or, where appropriate, with the subject’s legally authorized representative.

Signature of Person Who Obtained Consent ____________________________ Date __________
REFERENCES


