



COVER SHEET
STUDENT INVESTIGATORS
Submit all research documents via SharePoint
(See "Submission Process" at www.gonzaga.edu/IRB)

I. STUDENT INVESTIGATOR (SI)

Student Investigator Name:

(Students must have a "Responsible PI" who is a qualified faculty member or supervisor, and who will monitor and be liable for the conduct of the research.)

Department:		School/College:	Gonzaga University	Email:	
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II. CO-STUDENT INVESTIGATOR(s) (If applicable):

CO-SI Name:

Department:		School/College:	Gonzaga University	Email:	
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CO-SI Name:

Department:		School/College:	Gonzaga University	Email:	
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CO-SI Name:

Department:		School/College:	Gonzaga University	Email:	
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CO-SI Name:

Department:		School/College:		Email:	
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III. RESPONSIBLE PRINCIPAL INVESTIGATOR(s)

Responsible PI (Advisor or Supervisor):

(The "Responsible PI" must monitor and be liable for the conduct of student research.)

Department:		School/College:	Gonzaga University	Email:	
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Responsible PI (Advisor or Supervisor):

(The "Responsible PI" must monitor and be liable for the conduct of student research.)



Department:		School/College	Email:
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IV. PROTOCOL INFORMATION

TITLE OF THE PROJECT: **Effect of a Glute Targeting Warm-Up on Muscle Activation and Knee Kinematics During a Bilateral Squat** *(Please be sure the title and PI name(s) are consistent across all materials submitted.)*

ANTICIPATED START DATE: August 26, 2019 *(The start date should NOT be earlier than the review date for your protocol.)*

ANTICIPATED END DATE: December 16, 2019

THIS PROJECT IS:

Undergraduate Research Master’s Research Doctoral Research

V. ABSTRACT

Provide a brief (about one paragraph) abstract in layman’s terms that includes study goals, background, and methods used for this research:

Weighted squats are a common exercise in weight training and rehabilitation settings. There is a significant patellofemoral joint reaction force produced during a squat and without proper technique, mediolateral movement of the knee throughout a squat may cause excess loading forces leading to increased risk of injury. Weakness in the hip abductors decreases knee stabilization, increasing the occurrence of mediolateral knee movement. Purpose: This study aims to target gluteal muscles prior to weighted squats to increase their activation during squat, therefore increasing knee stability to ultimately provide important implications to injury prevention relating to weightlifting and the patellofemoral joint. **Subjects:** Thirty healthy 18-23-year-old students attending Gonzaga University with no back or lower extremity injury or surgery within the past year will be recruited for this study. Subjects must have experience with weightlifting and participate in weightlifting activity at least three times a week. **Written informed consent** will be obtained from each student prior to testing. **Methods:** Prior to the commencement of data collection, anthropometric data will be collected and each subject will watch a video giving a brief video of the exercises involved in the protocol, including instructions on how to properly perform a squat and the glute-activation warm-up exercises. Subjects will then commence testing where surface electromyography (EMG) and 2-dimensional motion capture data will be collected. Subjects will perform a five-minute jogging warm-up and five barbell squats, rest for five minutes, then perform ten repetitions of four glute-activation warm-ups on each leg, followed by five barbell squats. **Maximum voluntary isometric contractions (MVIC)** will be performed for the gluteus maximus, gluteus medius and vastus lateralis. **Analysis:** Mean muscle activity of the middle three squats will be normalized to subject’s MVIC and compared between trials using a paired t-test. Standard deviation of the mediolateral knee movement from normal, peak medial, and peak lateral knee movement and range will be compared between trials using a paired t-test.

VI. ASSURANCES AND SIGNATURES

- **SIGNATURES:** Signatures can be submitted with Adobe automatic signatures. A typed name can be accepted, too, when accompanied by an email to the IRB stating, “My typed name indicates my signature.” The IRB email is: irb@gonzaga.edu.
- **TRAINING:** All research members must complete ethical training through either CITI or NIH* within 4 years prior to submitting a protocol. Refresher courses are available if needed. **Note that NIH will no longer be accepted after Oct. 1, 2021.*

As Student Investigator, I understand the following (please check):

CHOOSE ONE:

Each student research member has completed NIH* training within 4 years prior to submitting this protocol. (*Good only)



through 10/1/2021.)

Each student research member has completed CITI training within 4 years prior to submitting this protocol.

This research will not begin until a determination is received from the Gonzaga IRB.

I agree to conduct the research in accordance with the three basic principles of the Belmont Report (Respect for Persons, Beneficence, and Justice).

STUDENT INVESTIGATOR(S)

By signing below I certify that I am aware of and agree with the information provided in this application.

Type Name	Student Investigator Signature	Date
Type Name	Co-Student Investigator Signature	Date
Type Name	Co-Student Investigator Signature	Date
Type Name	Co-Student Investigator Signature	Date
Type Name	Co-Student Investigator Signature	Date

RESPONSIBLE PI(s) – Faculty Advisor(s) of Student Investigator (SI)

As the Faculty Advisor for this student investigation, my signature indicates the following:

- I have ***reviewed and concur with this research proposal***, including: purpose, design, methodology, procedures, subjects, and the provided description of risks and benefits.
- I will ***assist the student and Gonzaga*** as requested if any problems develop with the research.
- I will provide ***continued oversight and guidance*** to the student during the course of the research, according to state and federal laws in addition to institutional policies and procedures.
- I have completed the NIH or CITI training.
- I understand that I am the “responsible PI” who is liable for the conduct of the research.

Type Name	Signature of FACULTY ADVISOR	Date
Type Name	Signature of CO-FACULTY ADVISOR	Date

DEPARTMENT CHAIR OR SUPERVISOR

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With my signature, I acknowledge that I have been informed of the research. I also understand it is the responsibility of the IRB to review research protocols as per the criteria in 45 CFR 46.111 (<https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html#46.111>).

Type Name

Signature of DEPARTMENT CHAIR OR SUPERVISOR

Date

NON-EXEMPT PROTOCOL

Allow approximately 3-4 weeks for review of NON-Exempt submissions.

Allow approximately 5-6 weeks for Full Board Review.

Email completed submissions to the IRB at irb@gonzaga.edu.

I. ROLES AND RESPONSIBILITIES

Roles and responsibilities of relevant study team members should be described, and roles and responsibilities of all collaborators and collaborating institutions should be described. Describe responsibilities by role or title (e.g., "Research Assistant will be responsible for note taking and storage.")

- The IRB does not need to know the name of every member of your research team - instead, the IRB wants to know who is fulfilling the specific roles for your research.

RESPONSIBILITIES: During data collection sessions, at least two researchers will be present. At least one researcher will be responsible for explaining the full protocol and ensuring the informed consent and Physical Activity Readiness Questionnaire forms have been completed. At least one researcher will be responsible for collecting anthropometric data for each subject, as well as shoulder width and hip height at 90 degrees knee flexion. One researcher will be responsible for the electromyography (EMG) portion of data collection while another will be responsible for the 2-dimension motion capture portion. At least one researcher will be responsible for setting up the warm-up and squat equipment for each subject and giving vocal cues throughout the experiment. Additionally, one researcher will be responsible for ensuring that the subject is comfortable throughout the entire time that they are in the lab. All four researchers are responsible for understanding and contributing to all aspects of the research protocol from subject consent and data collection, to data analysis and manuscript preparation.

II. STUDY INFORMATION

- Type of Research:** Experimental
(Psychological, Educational, Device, Social/Behavioral, Nursing, Economic, Tissue/Blood/ Specimen, Other).
- Phase of Study (if applicable):** Awaiting IRB Approval
- Version / Date (if applicable):** April 14, 2019

Research Problem and Brief Literature Review:

Weightlifting has become a widespread, popular form of exercise, but just like any other form of physical exercise, there is an associated risk of injury. In many activities, the knee is a commonly injured joint. A previous study examined injury incidences in elite competitive weight lifters and determined that the knee was the second most prevalent site of injury, attributing injury not to traumatic stability issues such as cutting maneuvers, but rather chronic inflammatory problems (1). Additionally, premature patellofemoral osteoarthritis was most common amongst former top-level weightlifters when compared to other former athletes that participated in exercise requiring different loading conditions. Such injuries arise from poor technique and excessive repetitive loading upon the patellofemoral joint (9).

During weight bearing activities, lower extremity muscular weakness at one joint contributes to the entire lower extremity kinetic chain (11). Patellar pain caused by patellar maltracking is associated with an imbalance between vastus medialis oblique and vastus lateralis activation, along with weakened hip abductor muscles, including the gluteus maximus and gluteus medius (14). Additionally, the activation of the gluteus maximus is believed to play an important role of stabilizing the knee and pelvis during a squatting movement (17). A previous study analyzing knee kinematics during narrow stance and wide stance squats determined that both males and females showed changes in knee width regardless of stance and load, suggesting the differences in muscle activation at each phase having an influence on knee width. This mediolateral movement caused by abduction and adduction moments in the lower limb induce either internal or external moments at the knee. Excessive internal moments coupled with a force in the anterior direction at the knee increases strain on the anterior cruciate ligament (13).

It is commonly accepted that warm-up routines prior to dynamic exercise reduced the risk of injury. Previous studies have examined different warm up modalities focusing on both injury prevention and increased muscle activation during activity and it has been determined that stretching is not adequate in increasing an individual's performance or sufficiently reducing the risk of injury (14). Researchers have begun to investigate a warm-up protocol that incorporates exercises that will specifically activate muscles engaged during the activity. While performing a weighted squat, the gluteus maximus and gluteus medius are highly recruited (16). A previous study examined rugby players performing a high hand pull after a glute activation warm up but found no difference in the peak EMG or joint angles when compared to a placebo warmup (16). Our study will focus less on the performance aspect and more on the mechanics of the squat. Other researchers analyzed the gluteus medius after a specific glute activation warm up. They found no increase in glute activation after the warm up (6). While this study examined barbell squats, their warm up consisted of activating the gluteus medius by performing a squat warm up.

Although previous research has shown that glute activation warm-up does not change gluteal activation during dynamic movements, no prior research has been conducted on the effect of a glute activation warm-up on the gluteus medius, gluteus maximus and vastus lateralis activation and mediolateral knee movement during weighted squats. The purpose of this study is to determine if a glute activation warm-up can allow for greater gluteal muscle activation during weighted squats to influence vastus lateralis activation leading to changes in knee stability. It is hypothesized that in performing a glute targeting warm-up prior to a weighted squat in comparison with a non-glute activating dynamic warm-up, activation of the gluteus medius and gluteus maximus will increase, while vastus lateralis activation decreases. The glute targeting activation will additionally decrease mediolateral knee movement during the squat. This study may provide valuable technical information for preventing knee related injury through increases in hip external rotator activation in the gluteus

maximus and gluteus medius while decreasing reliance on the vastus lateralis. Through decreasing reliance on the vastus lateralis and increasing activation of the gluteal muscles, it is believed that there will be decreases in the mediolateral movement of the knee.

III. STUDY DESIGN

Note that as you fill out the sections below, the goal is for another researcher to be able to replicate the research.

- 1. A. PROCEDURES:** The purpose of this study is to examine if a glute activation warm up is an effective way to increase glute activation, subsequently stabilizing mediolateral movement of the knee throughout the squat. If subjects perform a glute activation warm up before performing a weighted squat, it will increase gluteus maximus and gluteus medius activation and decrease vastus lateralis activation, compared to completing a submaximal running warm up.

Subjects will be asked to come into the laboratory for a single day for familiarization and data collection. Immediately upon arrival, subjects will be asked to read and sign an informed consent document (Appendix A) as well as fill out a physical activity readiness questionnaire (PAR-Q) (Appendix B). Researchers will screen PAR-Q forms for each subject for any outstanding health risks that would exclude them from participating in this study. Health risks can include any trunk, shoulder, arm or leg injuries that required medical attention within the last year. The biological sex of each subject will be recorded. The subject will record their dominant leg, this will be determined by which leg can kick a ball the furthest. Subject height, age, weight, shoulder width, and gluteus maximus height at 90 degrees knee flexion will be measured. Prior to the beginning of data collection, subjects will watch a brief overview video in which the full protocol as well as the exercises asked to be performed are explained. The video includes specific instructions for the correct way to perform the glute activating warmups, squats, and the maximum voluntary isometric contractions (MVIC) for each muscle of interest. Each subject will be assigned a unique subject code which will identify the subject for the duration of the study, as described in Sections XI and XV.

During the time subjects are watching the video, researchers set the subject testing area to subject's specific measurements including a squat height indicator set to gluteus maximus height at 90-degrees of knee flexion, foot placement indicators taped shoulder width apart, and weight added to barbell so that the total mass of the barbell is equivalent to 15% of body mass. Using 15% of body weight will generate a greater muscle activation than an unweighted bilateral squat without the risk of participants experiencing fatigue (11). Additionally, the motion capture apparatus will be preset, including a camera set to 210 frames per second four meters away from subject testing area (Casio EXILIM EX-FH20), two external lights set one meter away from subject testing area (SP-AD35 SpectroLED-9 Light (100-240 VAC/12 VDC), Genaray, Garadus Group Brand, LLC), and two tripods one meter apart in plane with the subject testing area for points of reference. Subjects are asked to wear black compressive shorts and a shirt that can be tucked in and athletic shoes. The subjects will be prepped for electrode placement. Previous studies examining patellofemoral pain found that the gluteus maximus, gluteus medius, and vastus lateralis muscles were dominant contributors, we will use these muscles in the electromyography signal collection (11). Participants will self-shave the areas where electrodes and reflective markers contacting the skin will be placed (gluteus muscles, above and on knee, and the anterior ankle) using a disposable razor available in the lab. Participants will complete this in the privacy of their gender appropriate bathroom. The researcher will palpate each of the muscles one at a time to ensure proper electrode placement (Appendix D). Once the muscle body is palpated, a marker will be used to note this location. The researcher will then clean the area with an alcohol swab to ensure a clean surface. An EMG electrode (Trigno, Delsys, 3.1.1, Natick, MA,

USA) will then be placed on the surface of the skin along the direction of the muscle fibers. LabChart (LabChart Pro 8.1.11, AD Instruments, Sydney, AU) will be used for collection and analysis of the EMG data. Each subject's EMG signals collected throughout the duration of the study will be normalized to a maximum contraction.

Following electrode placement, individuals will perform a submaximal running warm up on the treadmill. Submaximal is characterized by previous studies as below 80% of their maximum heart rate. Maximum heart rate will be determined by the equation: $(220 - \text{age}) \times 0.8$. Heart rate will be determined by a heart rate monitor strapped onto the chest (Polar Electro CE 0537, A Bethpage, NY, USA). Previous studies saw that a five a minute submaximal run is an ideal warm up, we will perform six minutes of running which includes a one minute period to get to a self-selected pace (6). Afterwards, reflective markers will be placed on the anterior superior iliac spine (hip), center of patella (knee), and midline of the medial and lateral malleolus axis (ankle). The subject will then perform five weighted squats. The subject will squat at a rate of 60 bpm. They will be given vocal cues of "down, up, hold..." The subject will have five minutes of recovery after performing the trial of five squats, designated by previously published studies (5). The subject will then perform four glute activation exercises: single leg deadlift, single leg hip abduction, a glute bridge, and lateral squat steps with resistance band. Single leg deadlift will have the subject stand on one leg with their knee and hip flexed at 30 degrees and with their same hand on their hip and their opposite hand out in front of them. They will flex their hip and trunk to touch the middle finger of the opposite hand of their standing leg to the toe of the standing leg. They will then return to the starting position. The single leg abduction will have subjects lay on their side on a mattress pad with their leg in full knee extension and their hip in a neutral position. The subject will abduct their leg to 30 degrees, while keeping their leg in full extension. A glute bridge will consist of a subject lying in a supine position (on back) on a cushioned pad with their knees bent. Feet will be shoulder width apart with toes facing away from the subject. The subject will contract their glutes to press their hips upwards off the floor and then lower them back down to the cushioned pad. Lateral squat steps with a resistance band will have subjects use one universal band that will be around the ankles. They will stand upright with their feet together and their knees and hip at 30 degrees of flexion. They will side step laterally. Each exercise will be performed 10 times on each leg. The subject will then perform five more weighted squats with the same previous protocol. They will have five minutes of recovery after the trial of five continuous squats.

Next the subjects will perform a MVIC test. This test has the subject perform a muscle contraction exercise at their maximum strength against resistance. MVIC is left to the end of this study to ensure that subjects do not activate their glutes prior to the non-activation warm up. Also, this will allow for fatigue from a maximum contraction to not have an effect on either squat trial. The MVIC will allow us to normalize the subject's results which will allow us to compare their results with other subjects. To measure the MVIC for the gluteus maximus the subject will lay on their stomach and extend their right hip. They will maximally push up against a researcher's two hand resistance on their hamstring for five seconds. The subject will do this three times with three seconds of rest in between each lift. The MVIC for the gluteus medius will be measured with the subject laying on their left side. They will maximally abduct their right leg against a researcher's manual two hand resistance on their quadriceps for five seconds. The subject will do this three times with three seconds of rest in between each lift. EMG sensors on the gluteus maximus and medius will be removed prior to vastus lateralis MVIC to prevent damage to them. To measure the MVIC for the vastus lateralis, the subject will sit in a chair and extend their right knee while keeping their thigh on the chair. They will maximally push up against a researcher's two hand manual resistance on their shin for five seconds. The subject will do this three times with three seconds of rest in between each lift. The electrodes will then be removed and they will be excused.

Provide the purpose of the study and list the research objectives (e.g., hypotheses). For each of the research objectives, provide a chronologically ordered, step-by-step description of the corresponding study procedures.

****Attach ALL research instruments used in your study.**

1. B. INCLUSION / EXCLUSION CRITERIA:

1. Subjects must meet all of the following criteria to participate in the study:
 - a. Are between the ages of 18-23 years old
 - b. Have completed the informed consent and PAR-Q forms
 - c. Are currently enrolled as an undergraduate at Gonzaga University
 - d. Have no current illness or any injuries requiring medical attention in the last year.
 - e. Perform weight lifting activities at least three times a week

Subject candidates identified as having any health risks according to the PAR-Q (appendix B), candidates that are not actively weight lifting at least three times a week, or candidates that have had any injuries requiring medical attention in the last year will be excluded from this study.

Subject candidates will be informed of inclusion and exclusion criteria and self-report eligibility for this experiment via a PAR-Q (Appendix B). The exclusion criteria are necessary for the safety of the subject and to control for uncontrolled variables. Residual effects of injury could cause the subject to perform a squat with a different form or make it more likely for the subject to become re injured during the course of the experiment. Subjects should be consistent weightlifters to ensure a similar fitness levels of subjects and so that they are familiar with squat technique before the experiment.

Justify the exclusion criteria. Explain how subjects will be screened to determine whether they meet the Inclusion criteria and exclusion criteria.

C. SUBJECT RECRUITMENT:

Subjects recruited by the research team will be healthy male and female undergraduate students at Gonzaga University between 18 and 23 years of age. Approximately 30 subjects will volunteer to participate in this study.

Subject candidates meeting the inclusion criteria will be approached by a research team member or recruited via a flyer sent by email (Appendix C) and asked to voluntarily participate in the experiment. Email recruitment will be exclusively to students enrolled at Gonzaga University. Interested candidates will be informed of exclusion criteria and protocol of the study and given the opportunity to consider participation. Subjects who are willing to participate will read and sign an informed consent form (Appendix A) and PAR-Q form (Appendix B). The research team will review each PAR-Q form before participation. The subjects will be given an opportunity to ask questions about voluntary participation before consenting. The dates and times the subject will need to be in the lab will be given. Email addresses will be obtained during recruitment for communication between the research team and subject candidates. These email addresses will be stored on a password protected computer and deleted permanently after completion of the study.

The informed consent will make clear any potential risks or discomforts. Subjects will be allowed to ask questions from the research team or research advisor regarding potential risks. Subjects will be reminded that their participation is completely voluntary, and they have the right to withdraw at any time.

Include a detailed description of the recruitment process and method (who, when, where). Provide recruitment material(s) such as newspaper/email advertisements, telephone interview scripts, radio scripts, etc.

Add any additional information, if needed (e.g., how email addresses will be obtained and how these email addresses will be stored securely then destroyed, how materials will be translated for non-English speakers).

D. PARTICIPANTS:

If applicable, explain how subjects will be randomized or placed into groups: Subjects will not be randomized or placed into groups due to the fact that each subject will act as their own control. The order subjects will participate in will be based on subject availability. Each subject will perform the protocol in the same order because trial 1 is aiming to determine gluteal muscle activation in a squat following a non-gluteal muscle activation warm up. Trial 1 therefore needs to be performed before trial 2 so that any residual gluteal muscle activation that occurs during the squat does not influence the data acquired.

In the table below, list Number of Subjects (and potential attritions rate), Target Study population, Subject Age Range, and number of those who will serve as “controls” (when applicable).

PARTICIPANT	NUMBER	AGE RANGE
*Normal	30	18-23
**Vulnerable (45 CFR 46 subparts B-D)	n/a	n/a
Control (if applicable)	Each subject is own control	n/a
TOTAL	30	18-23

* A “normal” subject would be 18 years of age or older and not in a vulnerable group.

** A “vulnerable” subject includes but is not limited to the following groups: children, prisoners, pregnant women, veterans, economically disadvantaged persons, individual with diminished mental capacity, illiterate persons or persons for whom English is a second language, or individuals who are being questioned about a traumatic event (e.g., sexual assault).

IV. DATA ANALYSIS

Describe how the data collected in the Procedures will be analyzed

Statistical analyses will be completed using version 25 of the IBM SPSS Statistics Software (Amaorak, NY, USA). An $\alpha = .05$ level of statistical significance will be used. Muscle activation for the gluteus maximus, gluteus medius, and vastus lateralis from each trial will be normalized to a percent of their MVIC in order to compare results between subjects. Squat one and squat five in each trial will be excluded from data analysis to account for variability due to learning in the first squat and fatigue in the last squat. The values for each muscle will be compared between trials one and two using a paired samples t-test to determine if a relationship exists between muscle activation and warm-up protocol. Motion analysis data will first be analyzed with Kinovea software. Mediolateral knee movement will be analyzed and normalized

to the distance between the left and right ASISs. Standard deviation of the mediolateral knee movement from normal, peak medial, and peak lateral knee movement and range will be compared between trials using a paired t-test.

CHECKLIST TO BE COMPLETED BY INVESTIGATOR	Yes	No
A. Will materials with potential radiation risk be used, e.g., x-rays, radio isotopes? If yes, please indicate: <ul style="list-style-type: none"> Status of annual review by Radiation Safety Officer (RSO). If approved, attach one copy of approval (Attachment F). Date the Title of Application was submitted to Radiation Safety Committee (RSC). 	—	—
B. Will any other hazardous materials come in contact with research subjects? -- If yes, indicate nature of hazard and steps taken to mitigate risk to subjects. Subjects will come into contact with disposable razors which will be used to prepare the site for EMG electrode placements. This hazard is minimal, and steps will be taken to mitigate risk to subjects. Each subject will be provided a new razor to prevent contamination, and if in the unlikely circumstance the subject receives a small cut from the razor, a first aid kit will be available.	—	—
C. Will an investigational new drug (IND) be used? If yes, <ul style="list-style-type: none"> Give name, proposed dosage, how administered, status with FDA, and IND number. Enclose one copy of: (1) available toxicity data; (2) reports of animal studies; (3) description of human studies done in other countries; (4) a concise review of the literature prepared by the investigator. 	—	—
D. Will other drugs be used (including over the counter drugs)? If yes, give names, dosages, how administered, and side effects:	—	—
E. Will medical, academic or other records be used?	—	—
F. Will audio-visual or tape recordings, or photographs be made?	—	—
G. Should this activity be covered by adverse effects insurance? If yes, provide name of insurance company and explain why it is needed:	—	—

Note: Video recordings (F) will be made for performing motion analysis for kinematic data collection. However, the camera will be positioned such that faces will not be captured, therefore the recordings will have no identifying information.

V. INFORMED CONSENT / ASSENT PROCESS

A. Subject Recruitment:

The four members of the research team will approach and inform potential subject candidates about the study by word of mouth. Additionally, a flyer will be sent via email to recruit subjects (Appendix C). Email recruitment will be exclusively to students enrolled at Gonzaga University.

B. Describe the informed consent / assent process in detail. Include, but do not necessarily restrict yourself to, the following information:

If someone expresses interest in volunteering as a subject in this study, they will be contacted by one of the researchers to come into the lab where they will be given an informed consent form (Appendix A) to read, acknowledge and sign in the presence of one of the researchers. This will inform subjects of the risks involved in participating in this study and will make the subject fully aware that their involvement in the study is completely voluntary and that they can withdraw at any moment. In addition, the informed consent will provide the contact information of the principal investigator, Gonzaga IRB, and

research advisor involved in this study. Potential subjects will be allowed to ask questions after the study is explained to them through an informative video. Additionally, subjects will fill out a PAR-Q to confirm their eligibility to participate in the study.

Is this medical research? YES NO

C. INFORMED CONSENT / ASSENT DOCUMENT STORAGE

- 1) Where will consent/assent forms, research records and data be stored? Consent/assent forms, research records, and data will be stored in a locked cabinet in the locked office of research advisor (Ryan McCulloch, Ph. D).
- 2) How long will consent/assent forms, research records and data be stored? Consent/assent forms, research records, and data will be stored for 3 years.
- 3) How will consent/assent forms, research records and data be destroyed/disposed of? Consent/assent forms, research records, and data will be destroyed after seven years. Hard copies of written forms will be shredded, and digital data will be permanently deleted.

D. Concealment and/or Deception

If any concealment or deception (withholding of complete information) is required for the validity of this study, explain why this is necessary, and describe a debriefing plan and attach a debriefing statement.

- 1) Is Concealment necessary? YES NO
If yes, why?
If yes, is a debriefing statement attached? YES NO
What is the debriefing plan?
- 2) Is Deception necessary? YES NO
If yes, why?
If yes, is a debriefing statement attached? YES NO
What is the debriefing plan?

VI. SUBJECT & DATA CONFIDENTIALITY / ANONYMITY

“CONFIDENTIAL” is used if the PI has access to identifiable information.

- Confidentiality has to do with keeping data secure once they are collected – e.g., by storing data in a locked file, etc.
- Confidentiality for data is **required** unless subjects give express written permission that their data may be identified.

“ANONYMOUS” is used if the PI has no ability to link data to individual subjects.

- You can “anonymize” subjects or a research setting by giving them pseudonyms.

DATA STORAGE: Per federal guidelines, raw study data must be held for **three years** in a secure place. Paper documents should then be shredded, tapes erased and destroyed, etc.

A. **ANONYMITY:** Will participation be **ANONYMOUS**? YES NO

Participants' identities will be known by the researchers because this study requires face to face interactions. 2D motion capture includes the use of video, however the face of the subject will be kept out of frame. However, each subject will be given a number in place of their name before data collection has occurred so that the investigator will have no way to identify subjects by appearance, name, or data. The subject information and codes will be kept on one password protected excel file, separately from any data collected to ensure anonymity from the PI.

- B. CONFIDENTIALITY:** Will participation be **CONFIDENTIAL**? YES NO
- a. If yes, describe the methods that will be used to ensure the confidentiality of data obtained: Subjects will be assigned a number for all of their data files. The file linking their names to their data will be password protected.
- C. DATA ACCESS:** Who will have access to some, or all, of the data? All four researchers and the research advisor will have access to all of the data.
- a. What provisions are there for control over access to documents and data? The documents and data will be kept on one excel file stored on the password protected personal computers of all four researchers. No data will be shared to other persons or devices. Only one Excel file will contain information that links data and names of subjects, and this will be stored on the password protected computer of one researcher.
- D. DATA STORAGE:**
1. How long will data be held? (Be advised that federal guidelines state that research data are to be held for 3 years. The data will be held for a minimum of three years and a maximum of seven.
 2. How will data be ultimately disposed of? Hard copies of any forms will be shredded while electronic data files will be permanently deleted.
 3. Who will dispose of data? The research advisor will dispose of all data after seven years.

VII. BENEFITS

Explain the benefits as stated in the consent form: The subjects will have the opportunity to practice their squat technique from participating in this project. If the results support our hypothesis, the subjects will learn the benefit of a glute-activation warm-up prior to squatting. This information could be used in the future to improve their squat performance and decrease their risk of knee injury. The glute muscles are an extremely powerful group, which host a wide variety of functions in both athletic and every-day activities. Developing the strength and coordination of these muscles could provide new knowledge that may be implemented in a broad range of activities.

Consider potential psychological, social, material and physical benefits.

- Payment of any kind for participation in the study **IS NOT** a benefit (Instead, go to Section VIII).

VIII. PAYMENT / COMPENSATION

INDUCEMENTS should never be so great that it might be considered coercion.

- It is okay to give study subjects a small token of appreciation (e.g., a Power Bar after they participate in a physical fitness test, refreshments during a focus group interview).
- It is okay to reimburse subjects for expenses they incur as a result of study participation – e.g., parking fees, babysitting, etc.
- If students will get **EXTRA CREDIT** for being in a study, then those students who do not want to be in the study should be given an alternative way of earning the same extra credit.

A. Will subjects receive an inducement (e.g. payment, services without charge, extra course credit?) YES NO

A. *Be sure the informed consent communicates these details to potential subjects so participants understand your plan and know about any alternatives or options.*

IX. RISK & INJURY MITIGATION / ADVERSE EVENTS

- Consider IMMEDIATE as well as DELAYED physical/psycho/social/emotional risks.
- Consider risks that could be incurred by losing privacy.

A. RISK MITIGATION:

There is minimal to no risk associated with squatting and electromyography (EMG) use. There is potential for there to be slight residual soreness in the lower extremity following the light exercise routine due to the nature of the activity. These potential effects would be expected to dissipate within a few days.

There is the possibility that the barbell will cause irritation to the subjects' upper back and/or neck. This potential effect would be expected to dissipate within a few days. In the event that the barbell is too heavy for the subject, at least one researcher will be available to take the barbell from the subject to alleviate the pain. However, this is unlikely due to the protocol's use of minimal weight, and it is expected that the weightlifting subject population will be able to readily perform the protocol.

The subject will be equipped with EMG electrodes to measure muscular signaling. There is the possibility of skin irritation from the placement of the electrodes or the alcohol swab used to clean the skin. If irritation or redness occurs it is expected to dissipate within 24 hours. Subjects will be instructed to remove hair from the sites where the electrode will be placed. A disposable razor available in the lab will be used to remove body hair. In the unlikely event the subject receives a small cut from the disposable razor, a first aid kit will be in the lab to be used to properly dress the wound, and the disposable razor will be disposed of in the lab's sharps container. The subject reserves the right to cease participating in the project at any time for any reason. In case of any emergency, all researchers have been instructed to cease the trial, call 911 and contact the supervising instructor. This information will also be provided in the informed consent document (Appendix A).

1. Is any follow-up planned as part of risk mitigation procedures?: YES NO

B. ADVERSE EVENTS:

All researchers have been informed on how to contact 911 in the event of an emergency. In addition, all researchers are informed on how to contact Gonzaga University campus security at (509)313-2222. An emergency action plan for the Human Physiology building has been created and is posted in the lab. Phones are in each office, as well as at the front desk approximately 30 feet down the hall from the lab. A faculty or staff member of the Human Physiology Department will be available within the building to assist with any emergency. Any expenses acquired as a result of voluntary participation in this study will be the responsibility of the subject. Any adverse events will be reported to the IRB as soon as possible.

a. Has this been clearly stated in your INFORMED CONSENT form? YES NO

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SUBMISSION CHECKLIST:

- COVER SHEET—Faculty or Student version as appropriate (with all signatures/approvals)
- THIS FORM—With detailed answers that are cohesive throughout
- Letter(s) of permission, if applicable
- ALL INSTRUMENTS used in the project:
 - Informed Consent (and/or Assent) documents
 - Recruitment script and/or materials
 - If deception is involved, provide the debriefing statement
 - Additional information about the intervention, if an intervention is involved

Please be sure the information in the attached materials is aligned to the answers in this protocol form.

Appendix A: Informed Consent

Title of Project:

Effect of a Glute Targeting Warm-Up on Muscle Activation and Knee Kinematics During a Bilateral Squat

Principal Investigator: Kathryn Delaney, BS Human Physiology, kdelaney2@zagmail.gonzaga.edu, (206)920-4053, Gonzaga University; Class of 2020

Other Investigators: Martina Hunt, Grace Garza, Lauren Bourgeois, BS Human Physiology, Gonzaga University; Class of 2020

Advisor or Sponsor Information: Ryan McCulloch, Ph.D., Assistant Professor, Department of Human Physiology, Gonzaga University, Spokane WA, 99258-004, mcculloch@gonzaga.edu, (509) 313-3440

PURPOSE OF THE RESEARCH

We invite you to take part in the research study “Effect of a Glute Targeting Warm-Up on Muscle Activation We invite you to take part in the research study “Effect of a Glute Targeting Warm-Up on Muscle Activation and Knee Kinematics During a Bilateral Squat” at the Human Physiology Building at Gonzaga University. The purpose of this study is to explore how warming up muscles used in a squat affects the activation of muscles and knee stability during a squat. Weightlifting is a common physical activity amongst college-aged individuals, but without proper technique, injuries may occur. During a weighted squat activity, inward and outward movement of the knee is used as a strategy in the descent and ascent phases to compensate for weakness in the muscles of the hip. However, this movement causes increased strain at the knee joint that increases the risk of injury. In this research, we want to determine if activating these hip muscles prior to squatting will decrease knee movement and increase the use of other muscles contributing to knee stabilization. Furthermore, as the hip muscles are a powerful group that contribute to a wide variety of movement, we hope to provide a new warm up technique that may be implemented in a broad range of activities to support knee stability. Please discuss any questions you have about this study with the research team or research advisor. If you decide to participate, you must sign this form showing you agree to take part. About 30 people will take part in this research.

PROCEDURES

You will be asked to attend a single day data collection session. Prior to participation in this study, you will be asked to sign this informed consent form as well as fill out a Physical Activity Readiness Questionnaire (PAR-Q) to identify possible risk factors or exclusion criteria that would disqualify you from participation. The questions will include general medical history and current medical conditions. In the beginning of the laboratory session, we will record your sex, weight, and height as well as record your hip height at the bottom of the squat and your foot placement at shoulder-width distance. Additionally, we will have you watch a brief overview video describing the procedures you will follow during data collection. This includes information on how to properly perform a squat with a back barbell set at 15% of your body weight and following our vocal cues. For example, a person who weighs 160 pounds will be asked to lift 24 pounds. The video also contains instructions on how to perform the 4 glute-activation exercises. Following the video, you will be able to ask any questions you may have and then you will begin the protocol. We will be measuring the activity of 3 muscles on your right leg (using surface electromyography (EMG)). We will place the EMG recorders on your glute and thigh muscles on your right leg as well as reflective markers on both hips, knees, and ankles. Trial #1: You will perform a five-minute jog on a treadmill at your own desired pace. Immediately following that, you will perform five continuous squats with minimal weight. You will then rest for five minutes. Trial #2: You will perform four glute-specific exercises immediately followed by five more continuous squats. You will then rest for five minutes. Following these two trials, you will perform maximum contractions of the three muscles we observed. You will push as hard as possible against our hand for short bursts. After performing all trials, the EMG markers will be removed from your skin and you will be dismissed.

TIME TO PARTICIPATE

If you agree to participate in this study, you will be asked to attend one lab period lasting about an hour.

DISCOMFORTS AND RISKS

There is minimal to no risk associated with low-weight squats, warm-up activities, or electromyography (EMG) used in this study. There is a potential for you to get slight residual soreness in your lower extremity from the squat or warm-up activities. These potential side effects are expected to dissipate within a couple days. Your gluteal muscles and thigh will be equipped with EMG electrodes to measure muscular signaling. There is a small possibility of skin irritation from the placement of these electrodes. Additionally, there is a potential for skin irritation from the alcohol swab used to clean the skin. If irritation or redness results, it is expected to dissipate within 24 hours. You will be instructed to remove hair from sites where electrodes will be placed. A disposable razor will be provided in Gonzaga University lab to do so. In the unlikely event you get cut, a first aid kit will be in the lab to properly dress the wound, and the disposable razor will be disposed of in the lab's sharps container. You reserve the right to cease participation in the study at any time and for any reason. In the case of an emergency, all researchers have been instructed to cease the trial and contact with campus security or 911 as well as inform the supervising instructor.

POTENTIAL BENEFITS

Your participation could help further the knowledge and understanding of the effect of performing glute-specific exercises before a squat and its association with improved squat technique and decreased risk of knee related injury. The glute muscles are powerful group of muscles in the human body and therefore the development of these muscles could provide new knowledge that may be implemented in not only athletics but everyday activities.

COSTS FOR PARTICIPATION

Costs: There is no cost for you to participate in this study.

Treatment and compensation for injury: In the event of an injury, proper medical staff will be called: either campus security and/or 911, depending on the severity of the injury. There will be no compensation for treatment of any injuries incurred by participating in this study. Any expenses acquired as a result of voluntary participation in this study will be the responsibility of the subject. You will not lose any legal rights by signing this form.

COMPENSATION FOR PARTICIPATION

You will not be paid for being in this research study.

STATEMENT OF CONFIDENTIALITY

Your research records that are reviewed, stored, and analyzed at Gonzaga University will be kept in a secured area and will be stored in a locked filing cabinet in the Human Physiology department. All electronic files, including video captured for 2-dimensional motion analysis, will be stored by the Principle Investigator(s) and Advisor's and secured with password protection. Access to these files will be password protected. All data will be retained for a minimum of three years and a maximum of seven years at which time all paper records will be destroyed and computer files permanently deleted. In the event of any publication or presentation resulting from the research, no personally identifiable information will be shared. We will keep your participation in this research study confidential to the extent we are able. However, it is possible that the Gonzaga Institutional Review Board (a committee that reviews and approves research studies) may inspect and copy research records.

STUDY WITHDRAWAL

If you choose to participate, you are free to withdraw your permission for the use and sharing of your information at any time. You must do this in writing. Write to Kathryn Delaney and let her know that you are withdrawing from the research study. Her email is kdelaney2@zagmail.gonzaga.edu. You may also contact the study advisor, Ryan McCulloch at mcculloch@gonzaga.edu

VOLUNTARY PARTICIPATION

Appendix B: PAR-Q

NAME: _____ AGE: _____ GENDER: _____ For most people, physical activity should not pose any problem or hazard. This questionnaire has been designed to identify the small number of adults for whom physical activity might be inappropriate, or those individuals who should have medical advice concerning the type of activity most suitable. Please take a minute to answer the following questions as part of your evaluation.

YES NO

- Has your doctor ever said you have heart trouble?
- Do you frequently have pain in your heart and chest?
- Do you have a history of back pain/injury?
- Do you have a history of knee pain/injury?
- Have you undergone any knee surgery in the past year?
- Do you often feel faint or have spells of severe dizziness?
- Has a doctor ever said your blood pressure was too high?
- Has your doctor ever told you that you have a bone or joint problem such as arthritis, which may be aggravated by exercise, or might be made worse with exercise?
- Is there a good physical reason not mentioned here why you should not follow an activity program even if you wanted to?
- Do you perform weight lifting activities at least three days a week?
- Are you over age 40 and not accustomed to vigorous exercise?

BRIEF MEDICAL HISTORY

1. Considering your age, how would you describe yourself with regard to your physical fitness? ___
excellent ___ good ___ fair ___ poor
2. Considering your age, how would you describe yourself with regard to your health status? ___
excellent ___ good ___ fair ___ poor
3. When did you have your last medical exam?
___ within a year ___ 1-2 years ago ___ 3 or more years ago
4. Please check any of the following medications you are currently taking:
 heart medicine
 blood pressure medicine
 hormones
 medicine for breathing/lungs (asthma)
 insulin
 arthritis medicine
 other

If other, please specify name and purpose.

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Have you ever had or currently have any of the following?

- heart problems
- high blood pressure
- lung/breathing problems
- stroke
- diabetes
- varicose veins
- anemia
- orthopedic problems
- arthritis
- back pain / chronic / frequent

Recent illness / hospitalization or surgeries:

Have you previously undergone surgery on your legs, back, or shoulders? (circle one)

YES

NO

Do you currently have any injury or problem of your legs, back, or shoulders? (circle one)

YES

NO

Signature _____

Date _____

Appendix C: Email Flyer

EXPERIENCED WITH WEIGHTLIFTING?



WE NEED YOUR HELP

PARTICIPATE IN OUR HUMAN PHYSIOLOGY RESEARCH PROJECT.
GROUND BREAKING RESEARCH WILL BE CONDUCTED IN TWO
SESSIONS. MAXIMUM TIME COMMITMENT IS ONLY 2 HOURS!

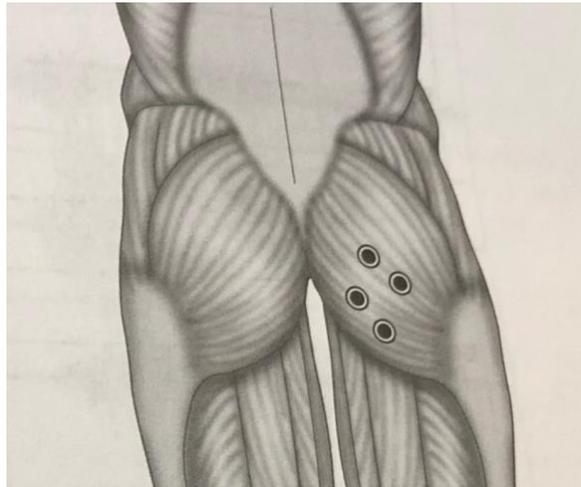
INTERESTED?

CONTACT _____

AT _____ FOR MORE INFORMATION

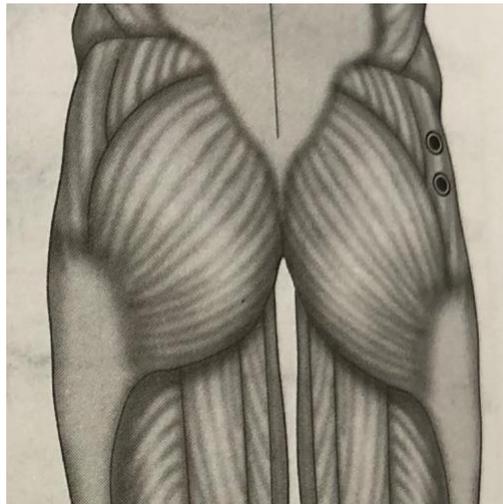
Appendix D: Electrode Placement Options

Gluteus Maximus:



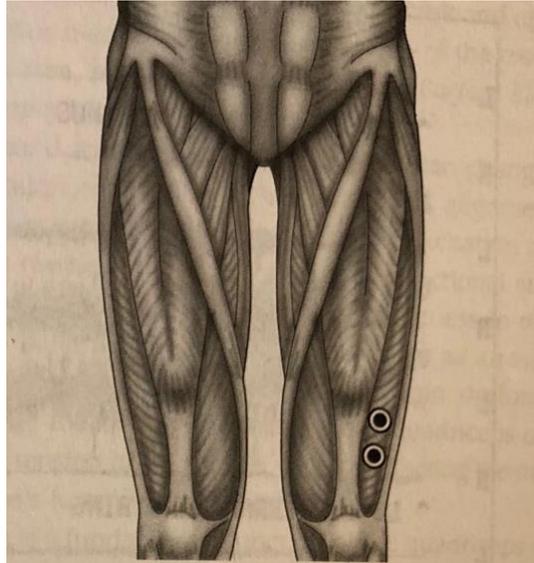
The Gluteus Maximus will be palpated while the subject performs hip extension in a prone position. The marker will be placed below the trochanter and 2 inches above the gluteal fold.

Gluteus Medius:



The Gluteus Medius will be palpated by having the subject perform a hip abduction while in a standing position. The marker will be placed between the greater trochanter and the iliac crest.

Vastus Lateralis:



The Vastus Lateralis will be palpated while the subject performs a single leg squat. The marker will be placed lateral to the patella and 2 inches superior to the patella.