[redacted]

Cover Sheet for EXPEDITED IRB Application

Principal Investigator Name: [redacted]

Project Title: **Is there an association between static and dynamic Q-angle of the knee during a lunge in college aged individuals 18-25 with a history of knee injury?**

Remember that expedited refers to the IRB process requiring fewer reviewers. It does not mean the research does not need a review. [See IRB webpage on Exempt and Expedited Reviews for description and distinction of categories].

1. The nature of the study involves Expedited research categories:
   - ☒ Recording of data on subjects > 18 such as height, weight, EKG, temp, BP
   - ☐ Collection of blood specimens using techniques consistent with routine clinical practice to minimize pain and risk of infection and within the following limits for volume.
   - ☐ Moderate exercise by healthy volunteers
   - ☐ Research on behavior of individuals, no manipulation
   - ☐ Collection of hair, nails, saliva, sweat, amniotic fluid, or dental plaque
   - ☒ Secondary use of materials (data, documents, records, or biological specimens) that have been or will be collected for purposes other than the currently proposed research project.
   - ☐ Other, please describe:

2. The research involves no more than minimal risk to participants, e.g., involving civil or criminal liability, employability, damage to participants' financial standing, or reputation.

   ☒ Yes ☐ No

3. The research involves a protected population, i.e. minors, pregnant women, fetuses, prisoners, mentally handicapped persons. *If YES, this research is not for expedited review*.

   ☐ Yes ☒ No

4. The research involves deception or may intentionally provide misleading information to participants. *If YES, this research is not for expedited review*.

   ☐ Yes ☒ No

INSTITUTIONAL REVIEW BOARD ON HUMAN PARTICIPANTS
Application for IRB Review and Approval Guidelines

General Instructions

Application must be typewritten, completed in its entirety, and saved as:

Lastname_Firstinitial_Keyword_IRB_version#.pdf (e.g., Mai_J_Balance_IRB_v1.pdf).

This Application and supporting documents should be sent as one PDF file to irb@clarke.edu.

Complete applications will include the documents listed below. These documents should be scanned into a single PDF **in the order listed**.

- ☒ Exempt, expedited, or full review cover sheet
- ☒ This form with faculty signature if PI is a student
- ☒ Proposal abstract
- ☒ Appropriate CITI Training Certificate
- ☒ Informed consent forms (if required)
  Note: An IRB number will be assigned when final approval is given. This IRB number must be added to the consent form.
- ☒ Research tool(s) (e.g., questionnaire, survey, interview questions, test questions)
- ☒ Recruitment materials (including but not limited to copies of script for face to face recruitment, a copy of recruitment e-mail, social media post, recruitment flyers/posters)
- ☒ Permission statement from research location(s) if research is to be conducted outside of Clarke University

- All required materials must initially be submitted to irb@clarke.edu.
- Incomplete applications will be returned un-reviewed.
- Revised Applications must be submitted as a complete Application and sent directly to the reviewer who reviewed the first version. When saved and submitted, please do so with a new version number (e.g., Mai_J_Balance_IRB_v2.pdf).
- Exempt and expedited applications may take up to four weeks to review per submission. Full IRB reviews may take longer.

NOTE: When completing this form, the text boxes in which to insert content do not display spell check or grammar check notifications (i.e., no red squiggly lines). Applicants may want to compose some answers in a separate MSWord file before pasting into the Application.

TIP: Tab from text box to text box or from check box to check box instead of using a mouse. Boxes can be checked using the space bar.

IRB Application

I. Project Title: **Is there an association between static and dynamic Q-angle of the knee during a lunge in college aged individuals 18-25 with a history of knee injury?**

Principal Investigator (PI) Information		
(Name) [redacted]	(Department) **Student**	
(E-mail) [redacted]	(Phone) [redacted]	(CITI Certificate #) [redacted]

Faculty Research Advisor Information		
(Name) [redacted]	(Department) **Physical Therapy**	
(E-mail) [redacted]	(Phone) [redacted]	(CITI Certificate #) [redacted]

Additional Investigator(s) Information		
(Name) [redacted]	(Department) **Student**	
(E-mail [redacted]	(Phone) [redacted]	(CITI Certificate #) [redacted]
(Name [redacted]	(Department) **Student**	
(E-mail) [redacted]	(Phone) [redacted]	(CITI Certificate #) [redacted]
(Name) [redacted]	(Department) **Student**	
(E-mail) [redacted]	(Phone) [redacted]	(CITI Certificate #) [redacted]

**If more "Additional Investigators" are required, please include them in the Appendix

II. Is this project funded by an outside agency?

☐ Yes; Sponsor's name is

☒ No

III. If research is being conducted to meet course or graduation requirements, please check all of the following that apply:

☒ A major goal of the project is to practice skills related to conducting research (e.g., administering a previously created tool to learn data collection and analysis procedures).

☐ A major goal of the project is to apply previously researched principles to a specific population (are hand washing procedures being followed by clinic staff and what are the related infection rates at clinic *X* OR does reading skill improve when applying this previously studied technique to my students at school *Y*).

☐ A major goal is to conduct original research, but there may be limitations in the study (e.g., participant pool is too small to make generalizations, the need to use my colleagues as participants means that I will not be able to ask personal questions).

☐ None of these apply. Continue to Question IV

A. Explain any limitations to the research project that might relate to the statements above:

Limitation for this research project is possibly having a small population size to make a true statement.

IV. What are the anticipated start and end dates?

** Recruitment for research cannot start until IRB approval has been obtained. Please allow four weeks for the IRB review process.

Desired date to begin recruitment for the study	[redacted]
Anticipated date for completion of data collection	[redacted]
Anticipated date to submit Completion Form	[redacted]
For Student Researchers only: Final Presentation (estimated date)	[redacted]

** Research is considered complete once data collection is completed. Once completed, researcher(s) must submit a Completion of an Approved Researech Project Form to irb@clarke.edu.

V. IRB must consider the research design in order to assess the risks and benefits of this study. This includes recruitment of participants, data collection, data analysis, and dissemination of the results. Please respond to the questions and statements below so that IRB can complete this evaluation.

A. Rationale: Using ordinary, non-specialized terms, provide background and rationale for the project.

Knee injuries are very prevalent in populations of patients that physical therapists see daily in the clinic. Severe knee injuries, in particular, can be debilitating to patients who want to return to their prior levels of function. There are many factors that influence knee injuries, which often can result in surgical intervention. A specific factor of interest to our study that has been linked to knee injury is Q-angle. Q-angle is defined as the angle formed between the quadriceps muscles of the thigh and the patellar tendon.[1] The Q-angle is an important factor in assessing knee joint function, as it pertains to forces directed on the knee joint.[2] Larger Q-angles when performing repetitive daily activities, especially those that require large force

outputs, can then exert larger stresses on the ligaments of the knee joint.[2] These forces could ultimately lead to future knee injury as well as possible surgical interventions. During Physical Therapy knee assessments of patients who present with knee complaints, Q-angle can be measured, and proper interventions and therapeutic exercises can be carried out in order to correct the ligamentous stress and force issues that larger Q-angles could pose. In doing so, further injuries and surgical interventions can potentially be prevented.

With respect to our current study, forward lunging activities will be carried out due to their relevance to everyday function. The forward lunge has shown to be more functionally advantageous towards promoting patterns similar to daily living tasks that patients perform each day, specifically gait.[3] Research has been conducted that suggests forward lunging in particular has more functional relevance and muscle activation than squatting activities.[3] Longpre, Acker, and Maly[3] demonstrated that lunging recruits a greater quadriceps activation than squatting, as well as fatigue also playing a role in altering the muscle recruitment in the quadriceps. Therefore, with its relevance to functional activities, the forward lunge will be assessed moving forward in our study in order to more accurately assess the functional relationship between Q-angle and knee injury. Another study compared a biomechanical analysis of an anterior lunge during external-load conditions.[4] This research showed results that a lunge involved greater motion at the knee and is a hip-extensor dominant exercise.[4] These results are relevant to our study, as a lunge will have greater knee motion when measuring Q-angle.

Current research upon literature review related to knee injury and lunging has been conducted on specific populations of subjects. These populations include specific athletics and geriatric populations in relationship to lunging. Further research has been conducted focusing on specific injuries of ligaments, muscle strength of the knee and hip joint, as well as pre versus post op in relation to knee injuries. While these studies have contributed much information to understanding knee injury mechanics and pathology related to these factors, this does not account for functional implications related to Q-angle specifically. Q-angle measurements are advantageous to our study as it can be objectively measured functionally and related back to knee injury history. As stated previously, with an interest in the functional relation of Q-angle to knee injury, our study will look at forward lunging. Research has been done on lunging activities such as comparing side to forward lunge, as well as muscle EMG activity of musculature during those activities.[3] Again, although this is good information in general towards the knee joint and biomechanics, it does not necessarily relate objective measures such as the Q-angle and function to knee injury. Therefore, the purpose of our study is to determine if there is association between static and dynamic Q-angle of the knee during a lunge in college aged individuals 18-25 and history of knee injury.

This study will attempt to discover the Q-angle of the participants who have had a previous knee injury or not. We plan to include a range of knee injuries such as MCL, PCL, LCL, meniscus, and patellar dislocation, we specifically looked at an ACL protocol as it is the most vigorous and time-consuming rehabilitation protocol. Our study is using an ACL protocol for participants to determine if they can participate post operatively in lunging activities. Therefore, according to this protocol, we are not allowing any participants who have had a knee injury within 3 months. In this case, an ACL protocol of University of Wisconsin states

that at 11-12 weeks post-operative where patients will be running normally, begin lunging and squatting.[5]

In addition to Q-angle during a lunge related to kne injury history, we also wanted to discover if there is a relationship between BMI and gender with measurements of Q-angle. Current research has compared Q-angle with multiple different body parameters including gender, height, weight, dominant side, and condylar distance of the femur. Once specific study measured Q-angle using a goniometer in an upright weightbearing position. The results from the study indicate that Q-angle was greater in women than in men.[1] The data also suggested that there were increases in Q-angle of dominant leg, however there was no significant findings for this.[1] Additionally, weight did not show any influence on Q-Angle between genders.[1] This study is comparable with our study where they looked at gender, height and weight between participants.[1] Additionally, the researchers also had similar ways of measuring leg dominance that we will, as in kicking a ball.[1,7] Likewise, they also used the same landmarks when calculating Q-angle such as the ASIS, midpoint of the patella and tibial tuberosity. The difference between our study and the research completed by Khasawneh et al[1], is that we plan on using Dartfish for Q-angle measurements, where they used a goniometer.[1]

Another study that we reveiwed in the literature showed the relationship between alignment characteristics and Q-angle. The study measured Q-angle, tibiofemoral angle, genu recurvatum, femoral anteversion, navicular drop, and internal and external rotation of the hip.[2] The study showed that having greater tibiofemoral angle, femoral anteversion and hip internal rotation were significant predictors of greater Q-angle.[2] The study stated that by knowing these postural changes, this can influence stressors on the knee and increase the risk of potential injury.[2]

Additionally, we will be using BMI between participants where we will be recording their height and weight. Based off of a current research study, an equation can be derived to calculate BMI between different subjects (BMI = $\sqrt[3]{}$kg/(m^2).[6] Based off the equation, the researchers were able to define different classes of BMI ranging from underweight to Class III obesity.[6] This study will give us an equation and classification so we will be able to categorize our participants for data collection and analysis.

In addition to the previous study determining leg dominance, another reserch study showed that kicking a ball can be used as a test to determine dominance. This study determined dominance in the lower extremities that we will find useful in our study. These researchers determined leg dominance by having their participants kick a ball that was placed directly in front of them. The leg that kicked the ball had a 100% agreement between self-reported and observed for both men and women. [1,7] Therefore to detemine dominant leg in our study we will use the same test.

In our research study, we are going to be utilizing Dartfish to analyze our data. There has been research conducted that supports Dartfish and confirms that is has reliability and concurrent validity during dynamic functional tasks.[8] One specific study measured sagittal plane movements of the hip and knee during mechanical lifting.[8] They measured the concurrent validity by comparing 2D Dartfish analysis to goniometric measurements of the hip

and knee.[8] Additionally, intrarater and interrater reliability values were measured from the hip and knee flexion angles and were deemed excellent through Dartfish.[8]

Given the literature that exists on Q-angle and its functional relevance to knee injury, we are performing this study to fulfill the need to explore Q-angle related to functionality in a younger population of subjects, while also revealing if there is a correlation history of knee injury in those subjects. Thus, the purpose of this study is to determine if there an association between static and dynamic Q-angle of the knee during a lunge in college aged individuals 18-25 and history of knee injury. We hypothesis that increased Q-angle during a dynamic and static lunge will associate with increased prevalence of knee injury history. As secondary hypotheses, we also predict that there will be a correlation between increased Q-angle in females with a dynamic and static lunge, as well as a correlation between BMI and Q-angle during a static and dynamic lunge.

B. **Research Questions:** List all research questions that will be asked. Questions must be approved by a research advisor if the PI is a student.

We will be asking the subject their name, age, sex, year in school, if they are an athlete, if so what sport, previous knee injury (yes or no), If they answer yes then what specific knee injury, did they have surgery to correct the injury, and how many months post injury / post operative they are.

C. **Participants:**

1. Participants (Please estimate maximum numbers)

Adult volunteers (patients are not to be included in this number)	**80**
Students within a classroom setting	**80**
Minors (under 18)	**0**
Patients as experimental participants	**40**
Patients as controls	**40**
Persons whose first language is not English	**0**
Pregnant women or fetuses	**0**
Adults with cognitive disabilities	**0**
Prisoners, incarcerated	**0**
Other (please specify): **NA**	**0**
Total anticipated participants (maximum)	**80**

2. Will participants be able to participate in a language in which they are fluent? (Check all that apply) It is not acceptable to include participants who are not able to fully understand the consent materials or the tool being used.

☒ Yes, all participants will participate in a language in which they are fluent.

☐ Yes, translations will be offered. Provide evidence that an appropriate translator is being used to create forms and/or to conduct interviews.

☐ No, participants are not used in study.

3. What inclusion and exclusion criteria will be used to determine eligibility to participate?

Inclusion criteria is that they have to be in the age range of 18-25 years old, physically cleared to perform lunge, no other current musculoskeletal conditions affecting lower extremity. Exclusion criteria is if the participants have any recent severe knee / lower extremity injury or surgical intervention within 3 months. Participants will then be classified of having no history of knee injury, history of knee injury within 1 year, history of knee injury within 1-3 years and history of knee injury within the past 5 years.

4. If using a specific sampling method, indicate which sampling method(s) will be used.

☐ Simple Random Sampling
☐ Stratified Sampling
☐ Cluster Sampling
☐ Systematic Sampling
☐ Multistage Sampling
☒ Convenience Sampling
☐ Volunteer Sampling
☐ Network Sampling
☐ Snowball Sampling
☐ Purposive Sampling
☐ Quota Sampling
☐ Other:

D. Recruitment

1. Recruitment Location (Check all that apply)

   ☒ Clarke University

   ☐ Public areas not located at Clarke. Please list specific areas:

   ☐ Social media (e.g., Facebook, Instagram, Twitter, etc.). Please list sites & groups:

   ** Applicant must secure and include documentation of approval to recruit from non-public virtual communities or interest groups (e.g., moderator of a closed Facebook group).

   ☐ Other location(s) (e.g., businesses, other institutions, agencies, etc.). Please list:

   ** Applicant must secure and include documentation of approval to recruit at these location(s). Please include copies of permissions in the Appendix.

2. Will these other locations require this project to be approved by their own IRB?

   ☐ Yes, the following other locations will require this project to be approved by their own IRB:

   ** Note: If Applicant is able, please include the project's IRB approval notification(s) from these other location(s) in this application.

   ☒ No, these other locations will rely on the Clarke University IRB approval process.

3. How will potential participants be contacted in order to recruit them? Please include a copy of the e-mail, script, flyer, or advertisement to be used to recruit potential participants. Refer to IRB website for policy on incentives.

We will email the marketing department to ask the students at Clarke University to participate in our study to gather data for our research project. Here is the script for the email that we will be sending out,

"To whom it may concern,

Our research group is looking for all Clarke University students aged 18-25 to participate in our Physical Therapy Doctoral Project research study. Time of participation will be no more than 15 minutes to attend. The research study will take place this upcoming [redacted], and locations/times will be announced as soon as possible.

Requirements to be included in the study entail being physically able to perform a static and dynamic forward lunge. All Clarke students within the given age range will be accepted, however, participants will be excluded from this study if they have had any severe

knee injuries (MCL, PCL, LCL, ACL, meniscus, or patellar dislocation) or knee surgery within the last 3 months.

We thank you greatly for your participation, and if at all possible spread the word to other students who may be interested!

[redacted]

Clarke Physical Therapy"

4. Is informed consent required? (Research using previously recorded data may not require informed consent.)

   ☒ Yes

   ☐ No

5. How will consent be obtained? Check all that apply. (Include with the application)

   ☒ Informed Consent Form with Cover Letter

   ☐ Parent/Guardian Informed Consent Form with Cover Letter

   ☐ Parental Notification Letter (for Action Research only)

   ☐ Assent Form

   ☐ Verbal Consent (with Script)

   ☐ Participation Consent (for Web and Phone Surveys)

6. If it is not possible to obtain written consent, describe how an understandable explanation will be given to the participants and consent will be acknowledged.

   N/A

E. Data Collection and Analysis

1. Data Collection and Analysis Location (Check all that apply)

   ☒ Clarke University

   ☐ Public areas not located at Clarke. Please list specific areas:

   ☐ Social media (e.g., Facebook, Instagram, Twitter, etc.). Please list:

   ** Applicant must secure and include documentation of approval to collect data from non-public virtual communities or interest groups (e.g., moderator of a closed Facebook group).

   ☐ Other location(s) (e.g., businesses, other institutions, agencies, etc.) Please list:

   ** Applicant must secure and include documentation of approval to collect data at these location(s). Please include copies of permissions in the Appendix.

2. If applicable, will these other locations require their IRB to approve of the project?

   ☐ Yes, the other location's IRB approval is attached.

   ☐ Yes, but the other location has yet to provide notification of IRB approval.

   ☒ No, the other location will be using the Clarke University IRB approval.

3. Indicate which of the collection tools will be used during research and attach all relevant documents. (Check all that apply)

   ☒ Survey, questionnaire(s) created by researcher: Attach tool(s)
   ☐ Survey, questionnaire(s) routinely collected by the site: Attach tool(s)
   ☐ Survey, questionnaire(s) created by other researcher: Attach tool(s) and permission or documentation that the survey is in the public domain
   ☐ Interview: phone/in-person: Attach interview tool(s) or questions being used
   ☐ Focus group: Attach questions being used
   ☐ Analysis of student test scores or routine assignments: Attach sample test(s) and assignment(s)
   ☐ Analysis of existing public records or documents
   ☐ Analysis of medical or other private records
   ☐ Direct observation of people in school, workplace, or other non-public location: Attach tool(s) if relevant
   ☐ Direct observation of people in public places: Attach tool(s) if relevant
   ☐ Collection of physical specimens (e.g., blood, saliva, etc.)
   ☐ Collection of data or physical specimen through non-invasive means (e.g., weight)
   ☒ Other(s) (please specify): **Dartfish 2-D video, SPSS software version 24**

4. How will participants complete the study (e.g., email, phone, mail, face to face)? Include the web address, email, script, survey, or other relevant information.

The participants will complete the study in person on Clarke University campus face to face.

5. How often will participants be expected to meet with researcher(s) and for how long (e.g., two one-hour meetings, two weeks apart; 10-minute survey)?

1 time for 15 minutes

6. Explain <u>in detail</u> the total experience of participants during the research. Be sure to include scripts, forms, surveys, and other documents related to the study.

Script

I. Participants will be waiting in hallway outside of room with social distancing

a. Intake form and Consent

i. Participant will be given an intake form and informed consent to fill out

1. Researchers will document subject # on both intake form and researchers form

II. Height and weight will be measured

a. Recorded on researcher intake form

i. "Thank you for filling out the informed consent for us. Next could you please come over here so that I can get your height and weight."

ii. "Thank you, you can have a seat until they are ready for you in the research room."

III. Participants will then be called into the research room

IV. Measurement of dominant leg

a. "Next, I am going to have you stand facing towards me, with a ball in the middle of your body in front of you. When I count to "3" I want you to kick the ball back to me"

V. "Thank you for your cooperation, I will have you wait in chair until the researchers are ready for you."

VI. Participants will then be asked if it is ok to place skin stickers or marks on ASIS, midline of patella and tibial tuberosity

a. "Is it ok if we place these on your skin to help us take measurements during this experiment? We need to place these on your ASIS, patella and tibial tuberosity, just below you kneecap."

VII. Quiet stance, static and dynamic lunge performance

a. "Next I am going to have you come over to the designated area where we are going to have you stand normally, perform a static lunge, and a dynamic lunge"

b. "Stand here while we get your normal stance, with feet shoulder width apart."

c. "Now we will have you lunge forward on your dominant leg, with your feet 16 inches apart, keeping your feet on the line and then come back to standing.

d. "Next I want you to perform a forward lunge on the opposite leg. With your feet 16 inches apart, keeping your feet on the line and then come back to standing."

e. "Next we will have you lunge forward 4 steps when we say go. Remember to keep your feet 16 inches apart on the designated marks on the floor as you lunge. After the 4th lunge you can come back to a resting position."

VIII. After completion of data collection, participant is free to go

a. "Thank you for your participation in in our study, you are free to go unless you have any questions for us."

7. How will the accuracy of the data collection be ensured (e.g., pilot testing, interrater reliability, single or double blind)? IRB may request raw data in order to assess accuracy.

Subjects are being selected by convience sampling from Clarke University students who show up to perform the test on. The research itself is going to be a double blinded study where the participant has an idea on what they are doing but do not know what we are looking at. The researcher carrying out Dartfish video analysis will blinded also. The 4 researchers will divide tasks, with the one who is handing out the survey and informed consent running Dartfish later. This way the researcher is blinded to participant grouping and is solely measuring Q-angles.

8. Will data be anonymous or confidential? *Anonymous data are data collected with no identifiers available to the researcher. Confidential data include one or more identifiers which is available to the researcher.*

   ☐ Anonymous
   ☒ Confidential

9. How will data be *collected* in order to protect the confidentiality and privacy of participants?

We will use a video camera to gather footage of the participants performing the static and dynamic lung and then utilize Dartfish 2-D video to figure out the participants Q-angle and them inserting that information into SPSS software version 24.

10. How will data be *stored* in order to protect confidentiality and privacy of participants (e.g., locked file in a particular room, password protected file on a specific computer)? Be specific.

Password protected file on SPSS software version 24 on the computer that also has a password requirement to get into the computer.

11. How and when will data be destroyed? The federal government requires data to be retained for at least three years.

The data will be destroyed after 3 years and the files will be deleted on the computer and the trash can will also be emptied on the computer.

12. Describe the specific quantitative or qualitative analysis that will be used to answer the research questions.

MANOVA will be used on SPSS software version 24 for gathering information on quiet stance, static and dynamic lunge with genders being compared as well as BMI. Comparison will be used on SPSS software version 24 to look at the data between previous knee injury vs no injury.

VI. The researcher is responsible for considering any potential risk that a research participant might experience. Risk to participants may be tolerable in research as long as it is necessary to gather the information and as long as the researcher has provided appropriate ways to

minimize the risk. Carefully estimate risk level for participants of this study. Explain plans to minimize the risk to participant(s) and how participant complaints will be handled.

A. Psychological stress greater than daily life (e.g., potential to perceive topic or materials as threatening, offensive, or degrading)	Level of risk ☒ Not Applicable ☐ Minimal risk ☐ Substantial risk
Describe circumstances that could lead to risk if applicable. Explain plans to minimize the risk to participant(s) and how participant complaints will be handled.	**N/A**
B. Social or economic stress greater than daily life (e.g., perception of experience as potentially damaging to financial standing, employability, job retention, or reputation)	Level of risk ☒ Not Applicable ☐ Minimal risk ☐ Substantial risk
Describe circumstances that could lead to risk if applicable. Explain plans to minimize the risk to participant(s) and how participant complaints will be handled.	**N/A**
C. Physical or medical risk greater than daily life (e.g., potential for physical injury or negative impact on health)	Level of risk ☐ Not Applicable ☒ Minimal risk ☐ Substantial risk
Describe circumstances that could lead to risk if applicable. Explain plans to minimize the risk to participant(s) and how participant complaints will be handled.	**Participants who have a current knee injury but following the University of Wisconsin protocol for phase 3 where they are doing lunges for rehab so they have to be in phase 3 to participate anyways.**
D. Unintended disclosure of confidential information (e.g., school or medical records)	Level of risk ☒ Not Applicable ☐ Minimal risk ☐ Substantial risk
Describe circumstances that could lead to risk if applicable. Explain plans to minimize the risk to participant(s) and how participant complaints will be handled.	**N/A**
E. Perceived coercion to participate because of existing or potential relationship between researcher and	Level of risk ☒ Not Applicable ☐ Minimal risk ☐ Substantial risk

participant (e.g., friend-friend, teacher–student, employer–employee)	
Describe circumstances that could lead to risk if applicable. Explain plans to minimize the risk to participant(s) and how participant complaints will be handled.	**N/A**
F. Confusion resulting from experimental deception (e.g., use of placebo)	Level of risk ☒ Not Applicable ☐ Minimal risk ☐ Substantial risk
Describe circumstances that could lead to risk if applicable. Explain plans to minimize the risk to participant(s) and how participant complaints will be handled.	**N/A**
G. List any other risk that may apply: **0**	Level of risk ☒ Not Applicable ☐ Minimal risk ☐ Substantial risk
Describe circumstances that could lead to risk if applicable. Explain plans to minimize the risk to participant(s) and how participant complaints will be handled.	**N/A**

VII. Conflicts of Interest (COI)

A. Financial COI: Do any of the researcher(s) (or their spouse(s), domestic partner(s), significant other(s), and/or dependent children) have financial interests related to this study?

☐ Yes

☒ No

1. If Yes, please disclose this financial COI:

   N/A

2. If Yes, please explain how relevant researcher(s) will manage the influence of this financial COI to avoid any actual or seeming compromised judgement related to the collection, analysis or reporting of this research project. Note: Any COI should be disclosed in publications or presentations.

   N/A

B. Other COI: Do any of the researcher(s) (or their spouse(s), domestic partner(s), significant other(s), and/or dependent children) have any other personal considerations that may compromise—or have the appearance of compromising—an investigator's professional judgment in conducting or reporting research for this project?

☐ Yes

☒ No

1. If Yes, please disclose this other COI:

   N/A

2. If Yes, please explain how relevant researcher(s) will manage the influence of this personal COI to avoid any actual or seeming compromised judgement related to the collection, analysis or reporting of this research project. Note: Any COI should be disclosed in publications or presentations.

   N/A

VIII. Describe the potential benefits of this research to individual participants or to society.

By participating in this study, the participants will be helping researchers determine if there is an association between static and dynamic Q-angle of the knee during a lunge with a history of knee injury. With this information, Physial Therapists can potentially help reduce the amount of knee injuries in the future by recognizing increased Q-angles and performing the appropriate interventions.

IX. Assurance Statements

I understand and agree to follow all of Clarke University's IRB policies and requirements.

[redacted]_____

If the PI is a student, then the Faculty Advisor must agree to the following:

I reviewed this application and approve of the protocols. I worked with this student to ensure that all ethical and procedural concerns have been addressed. I support this research project and attest to the ability of the researcher to conduct this study.

__[redacted]___

Da

If the Student PI is unable to obtain a Faculty signature (e.g., Faculty Advisor is out of town), then student must CC the faculty member when submitting the Application and any revisions. The Faculty Advisor must then "Reply All" confirming approval before the Application or Revision will be considered for review or approval. This alternative signature process is only for exceptional circumstances. Please indicate why this alternative process was necessary.

Is there an association between static and dynamic Q-angle of the knee during a lunge in college aged individuals 18-25 with a history of knee injury?

A Research Project Proposal Presented to

the Faculty of the Physical Therapy Department

of Clarke University

Dubuque, IA

By

In Partial Fulfillment

of the Requirements for the Degree

Doctor of Physical Therapy

Is there an association between static and dynamic Q-angle of the knee during a lunge in college aged individuals 18-25 with a history of knee injury?

Knee injuries are very prevalent in populations of patients that physical therapists see daily in the clinic. Severe knee injuries, in particular, can be debilitating to patients who want to return to their prior levels of function. There are many factors that influence knee injuries, which often can result in surgical intervention. A specific factor of interest to our study that has been linked to knee injury is Q-angle. Q-angle is defined as the angle formed between the quadriceps muscles of the thigh and the patellar tendon.[1] The Q-angle is an important factor in assessing knee joint function, as it pertains to forces directed on the knee joint.[2] Larger Q-angles when performing repetitive daily activities, especially those that require large force outputs, can then exert larger stresses on the ligaments of the knee joint.[2] These forces could ultimately lead to future knee injury as well as possible surgical interventions. During Physical Therapy knee assessments of patients who present with knee complaints, Q-angle can be measured, and proper interventions and therapeutic exercises can be carried out in order to correct the ligamentous stress and force issues that larger Q-angles could pose. In doing so, further injuries and surgical interventions can potentially be prevented.

With respect to our current study, forward lunging activities will be carried out due to their relevance to everyday function. The forward lunge has shown to be more functionally advantageous towards promoting patterns similar to daily living tasks that patients perform each day, specifically gait.[3] Research has been conducted that suggests forward lunging in particular has more functional relevance and muscle activation than squatting activities.[3] Longpre, Acker, and Maly[3] demonstrated that lunging recruits a greater quadriceps activation than squatting, as well as fatigue also playing a

role in altering the muscle recruitment in the quadriceps. Therefore, with its relevance to functional activities, the forward lunge will be assessed moving forward in our study in order to more accurately assess the functional relationship between Q-angle and knee injury. Another study compared a biomechanical analysis of an anterior lunge during 4 external-load conditions.[4] This research showed results that a lunge involved greater motion at the knee and is a hip-extensor dominant exercise.[4] These results are relevant to our study, as a lunge will have greater knee motion when measuring Q-angle.

Current research upon literature review related to knee injury and lunging has been conducted on specific populations of subjects. These populations include specific athletics and geriatric populations in relationship to lunging.[5,6] Further research has been conducted focusing on specific injuries of ligaments, muscle strength of the knee and hip joint, as well as pre versus post op in relation to knee injuries.[3,4] While these studies have contributed much information to understanding knee injury mechanics and pathology related to these factors, this does not account for functional implications related to Q-angle specifically. Q-angle measurements are advantageous to our study as it can be objectively measured functionally and related back to knee injury history. As stated previously, with an interest in the functional relation of Q-angle to knee injury, our study will look at forward lunging. Research has been done on lunging activities such as comparing side to forward lunge, as well as muscle EMG activity of musculature during those activities.[3] Again, although this is good information in general towards the knee joint and biomechanics, it does not necessarily relate objective measures such as the Q-angle and function to knee injury. Therefore, the purpose of our study is to determine if there is

association between static and dynamic Q-angle of the knee during a lunge in college aged individuals 18-25 and history of knee injury.

This study will attempt to discover the Q-angle of the participants who have had a previous knee injury or not. We plan to include a range of knee injuries such as MCL, PCL, LCL, meniscus, and patellar dislocation, we specifically looked at an ACL protocol as it is the most vigorous and time-consuming rehabilitation protocol. Our study is using an ACL protocol for participants to determine if they can participate post operatively in lunging activities. Therefore, according to this protocol, we are not allowing any participants who have had a knee injury within 3 months. In this case, an ACL protocol of University of Wisconsin states that at 11-12 weeks post-operative where patients will be running normally, begin lunging and squatting.[7]

In addition to Q-angle during a lunge related to knee injury history, we also wanted to discover if there is a relationship between BMI and gender with measurements of Q-angle. Current research has compared Q-angle with multiple different body parameters including gender, height, weight, dominant side, and condylar distance of the femur. Once specific study measured Q-angle using a goniometer in an upright weightbearing position. The results from the study indicate that Q-angle was greater in women than in men.[1] The data also suggested that there were increases in Q-angle of dominant leg, however there was no significant findings for this.[1] Additionally, weight did not show any influence on Q-Angle between genders.[1] This study is comparable with our study where they looked at gender, height and weight between participants.[1] Additionally, the researchers also had similar ways of measuring leg dominance that we will, as in kicking a ball.[1,9] Likewise, they also used the same landmarks when calculating Q-angle such as the ASIS, midpoint of the patella and tibial tuberosity. The difference between

our study and theirs is that we plan on using Dartfish for Q-angle measurements, where they used a goniometer.[1]

Another study that we reviewed in the literature showed the relationship between alignment characteristics and Q-angle. The study measured Q-angle, tibiofemoral angle, genu recurvatum, femoral anteversion, navicular drop, and internal and external rotation of the hip.[2] The study showed that having greater tibiofemoral angle, femoral anteversion and hip internal rotation were significant predictors of greater Q-angle.[2] The study stated that by knowing these postural changes, this can influence stressors on the knee and increase the risk of potential injury.[2]

Additionally, we will be using BMI between participants where we will be recording their height and weight. Based off of a current research study, an equation can be derived to calculate BMI between different subjects (BMI = $\sqrt[3]{}$kg/(m^2).[8] Based off the equation, the researchers were able to define different classes of BMI ranging from underweight to Class III obesity.[8] This study will give us an equation and classification so we will be able to categorize our participants for data collection and analysis.

In addition to the previous study determining leg dominance, another research study showed that kicking a ball can be used as a test to determine dominance. This study determined dominance in the lower extremities that we will find useful in our study. These researchers determined leg dominance by having their participants kick a ball that was placed directly in front of them. The leg that kicked the ball had a 100% agreement between self-reported and observed for both men and women.[1,9]

In our research study, we are going to be utilizing Dartfish to analyze our data. There has been research conducted that supports Dartfish and confirms that is has reliability and

concurrent validity during dynamic functional tasks.[10] One specific study measured sagittal plane movements of the hip and knee during mechanical lifting.[10] They measured the concurrent validity by comparing 2D Dartfish analysis to goniometric measurements of the hip and knee.[10] Additionally, intrarater and interrater reliability values were measured from the hip and knee flexion angles and were deemed excellent through Dartfish.[10]

Given the literature that exists on Q-angle and its functional relevance to knee injury, we are performing this study to fulfill the need to explore Q-angle related to functionality in a younger population of subjects, while also revealing if there is a correlation history of knee injury in those subjects. Thus, the purpose of this study is to determine if there an association between static and dynamic Q-angle of the knee during a lunge in college aged individuals 18-25 and history of knee injury. We hypothesis that increased Q-angle during a dynamic and static lunge will associate with increased prevalence of knee injury history. As secondary hypotheses, we also predict that there will be a correlation between increased Q-angle in females with a dynamic and static lunge, as well as a correlation between BMI and Q-angle during a static and dynamic lunge.

Methods

Participants

For this study we will aim for at least 30 human participants aged 18-25 selected from Clarke University via convenience sampling. Participants will volunteer for this study and will not be reimbursed in any way. It is our goal to obtain at least 15 subjects with a previous knee injury and 15 without previous knee injury history. At the beginning of the study participant consent will be obtained through an informed consent statement, with identity remaining confidential. Participants will then fill out a subjective questionnaire to

differentiate participants into groups based upon gender, previous knee injury history, how recent the injury was, what type of surgical interventions were performed if any, and if they are an athlete. Participants height and weight will also be recorded using a standard tape measure and scale, which will then be converted to meters and kilograms respectively for body mass index (BMI) calculations. Inclusion criteria for this study is that each participant must be within 18-25 years old, physically cleared to perform a lunge following UW Madison return to activity following ACL reconstruction[7], as well as no current musculoskeletal conditions affecting the lower extremity. Exclusion criteria includes recent severe knee or lower extremity injury or surgical intervention within 3 months.

Instrumentation

For this study there will be several different types of equipment utilized for data collection and analysis. First, we will need a standard scale and tape measure to measure weight and height. Next, we will need skin markers or stickers to identify important landmarks required for analysis (ASIS, midline of the patella, and tibial tuberosity). These markers will be important because it is how we will mark each bony prominence for analysis through Dartfish 2-D video analysis software. Dartfish 2-D video software is based in Fribourg, Switzerland. Dartfish will be used to analyze videos taken from video cameras supplied by the PT department. Once data is taken it will be analyzed in SPSS version 24 put into commission by SPSS Inc out of Chicago, IL.

Procedure

The variables we are looking at in this study include the static and dynamic lunge for our independent variables. Dependent variables include Q-angle and the prevalence of knee injuries. This will be a double-blind study where the participants are blinded to what we are

investigating. The analyzer of the data will also be blinded, this will be accomplished by having the researcher in a different room as to where the subjective questionnaire is handed out so that the researcher does not know the history of the participant. The researcher in the hall handling the questionnaires will be the only individual that knows the patient's previous history. Participant dominant foot will be determined with a dominance test by placing a ball at midline, whichever foot the participant kicks the ball with will be the dominant. Participants Q-angle will be recorded in static stance for a baseline with feet at shoulder width apart, patients will then perform a static and dynamic lunge with right and left foot leading. For both the static and dynamic lunge, participants will be instructed to perform a forward inline lunge with toes pointed anteriorly and feet spaced out 16" apart. The patients will be instructed to take a series of four steps and perform a lunge between each step with the second and third lunges being recorded so that we can analyze a dynamic lunge one each leg. Participants will be classified into four different groups: no history of knee injury, history within one year, history within 1-3 years, and a history past 5 years.

Data Processing and Analysis

Data will be processed at a later date after data collection. BMI calculations will be made with the following formula BMI = $\sqrt[3]{}$kg/(m^2) shortly after subject intake.[8] Data will be analyzed through Dartfish with the q-angle measured with each criterion (quiet stance, static lunge, and dynamic lunge). Once data is collected it will be placed into SPSS where a MANOVA will be performed to compare the q-angle during quiet stance, static and dynamic lunge with genders, as well as BMI. A comparison will be completed for the q-angle of previous knee injury vs no injury.

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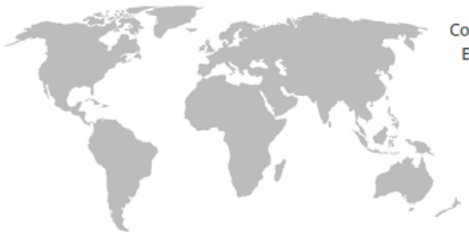

Completion Date [redacted]
Expiration Date [redacted]
Record ID [redacted]

This is to certify that:

[redacted]

Has completed the following CITI Program course:

Not valid for renewal of certification through CME. Do not use for TransCelerate mutual recognition (see Completion Report).

Biomedical Research - Basic/Refresher (Curriculum Group)
Biomedical Research (Course Learner Group)
1 - Basic Course (Stage)

Under requirements set by:

Clarke University

CITI
Collaborative Institutional Training Initiative

Verify at www.citiprogram.org/verify/[redacted]

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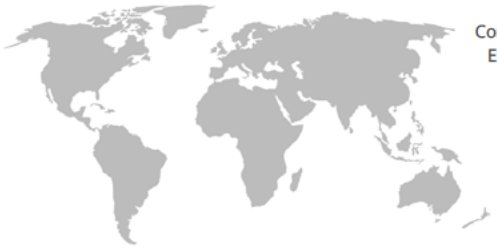

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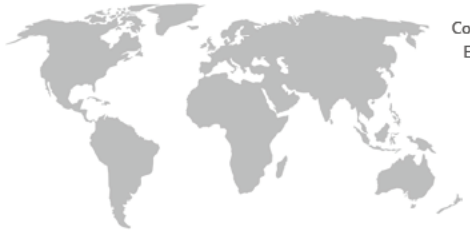

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(Curriculum Group)
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(Course Learner Group)
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(Stage)

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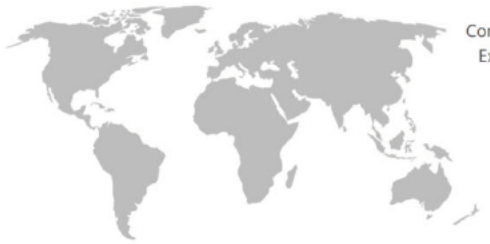
CITI PROGRAM



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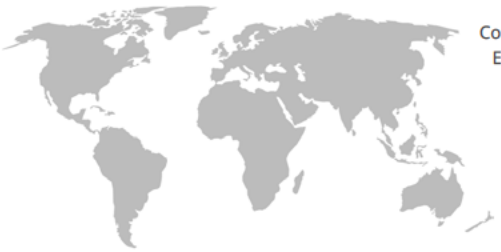
CITI PROGRAM



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Biomedical Research (Course Learner Group)
1 - Basic Course (Stage)

Under requirements set by:

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Is there an association between static and dynamic Q-angle of the knee during a lunge in college aged individuals 18-25 with a history of knee injury?

Informed Consent Form

KEY INFORMATION
You are being asked to consent to participate in a research study. The purpose of our study is to predict the relationship between Q-angle of the knee and previous knee injuries. Participation is voluntary. There is no penalty if you decide not to participate or withdraw from the study, and your relationship with [redacted], the Research in Physical Therapy, the department of Physical Therapy at Clarke University, and Clarke University will not be affected by this decision. The estimated time of participation is 15 minutes. You will be videotaped and expected to perform a series of static and dynamic inline lunges. Potential benefits for participating include helping the researchers understand the correlation between static and dynamic q-angle of the knee during a lunge with a history of knee injury to help reduce the amount of knee injuries in the future. Potential risks of participating include the possibility of falling over when performing the lunge should you lose your balance. Other risks include minimal potential muscle strains.

QUALIFICATIONS TO PARTICIPATE
You are being asked to participate because you are in the age range of 18-25 years old, physically cleared to perform lung, and have no other current musculoskeletal conditions affecting lower extremity. Unfortunately, there are some reasons why you may not be able to participate. You will be excluded from participating if you have had any recent sever knee / lower extremity injury or surgical intervention within 3 months.

PROCEDURES
If you agree to participate in this study, you will be asked to fill out a subjective questionnaire. This questionnaire will help the researchers to place each participant into certain criterion and to determine if each subject is able to partake in this study. After the subjective questionnaire is filled out participants will enter the testing room where they will be recorded for the duration of the study, this video will then be utilized at a later date for data analysis. When the participant enters the room, dominant foot will be assessed with a foot dominance test. Each participant will then be asked to standing quiet stance with feet at shoulder width apart. Patients will then be asked to perform a forward inline lunge with feet 16 inches apart which will be recorded. Patients will then be asked to perform a set of 4 of dynamic lunges.

PARTICIPANT CONFIDENTIALITY
In order to maintain confidentiality, your name will not be connected to any publication or presentation that uses the information and data collected about you or with the research findings from this study. The researcher will refer to subjects as numbers and the data will then be kept in a computer and file requiring a password to identify participants rather than your name. Your identifiable information will only be shared if required by law or you give written permission.

DISCLAIMER
The risk of participating is minimal. Researchers and participants will follow University approved procedures for safety related to COVID-19 including screening temperature and current health status prior to participation. Social distancing will be maintained as safety allows for activity, otherwise researchers will wear additional Personal Protective Equipment. If you have health concerns that impact your ability to participate, however, you may want to consult a health care professional before agreeing to participate in this study. If you need medical or mental health attention during the course of the study, Clarke University emergency procedures will be followed. The researchers and Clarke University are not responsible for any medical or mental health expenses.

REFUSAL TO SIGN CONSENT AND AUTHORIZATION
You are not required to participate in this study and have the right to refuse signing this form. Refusal to participate in this study or to sign the form will not affect your rights to services you currently are receiving or may receive from Research in Physical Therapy, Physical Therapy at Clarke University, or Clarke University. If you refuse to sign this form, you cannot participate in the study.

CANCELLING THIS CONSENT:
At any time during the study, you have the right to withdraw your consent to participate in this study. To withdraw from the study, we ask you to contact the researcher in writing. If you withdraw from the study, the researcher will stop collecting additional information and data about you. You can contact the researcher at the contact information listed in the next section.

PARTICIPANT CERTIFICATION:
I have read this Informed Consent form. I have been given the opportunity to ask questions regarding the study, and I have received answers to any questions I had regarding the study. I understand that if I have any additional questions about the study or my rights as a research participant, I may contact [redacted]

I agree to be a participant in this study. I acknowledge that I am aware of what this study involves, that I am at least 18 years old, and that I have received a copy of this Informed Consent form.

_____

Participant's Signature Date

_____

Participant's Name (print legibly)

To whom it may concern,

Our research group is looking for all Clarke University students aged 18-25 to participate in our Physical Therapy Doctoral Project research study. Time of participation will be no more than 15 minutes to attend. The research study will take place this upcoming [redacted], and locations/times will be announced as soon as possible.

Requirements to be included in the study entail being physically able to perform a static and dynamic forward lunge. All Clarke students within the given age range will be accepted, however, participants will be excluded from this study if they have had any severe knee injuries (MCL, PCL, LCL, ACL, meniscus, or patellar dislocation) or knee surgery within the last 3 months. We thank you greatly for your participation, and if at all possible spread the word to other students who may be interested!

[redacted]
Clarke Physical Therapy

Clarke UNIVERSITY

Physical Therapy Department

Clarke University Students!

Please help us by participating in our research study!

Who? Students aged 18-25 with a previous history of knee injury or no history at all.

Where? TBD

When? TBD

What? You have to be able to perform a lunge!

For more information contact [redacted]

Subject# _____

Physical Therapy Department

TO BE COMPLETED BY THE PARTICIPANT

1. Name: _____
2. Age: _____
3. Sex: _____
3. Year in school: _____
4. Are you a collegiate athlete? _____ If so, what sport? _____
5. Previous injury to the knee? (Y/N) _____
6. If applicable, what was the specific knee injury? _____
7. If applicable, did you have surgery to correct the injury to your knee? _____
8. If applicable, how many months post-injury/post-operative are you? _____

Subject #:_____

Physical Therapy Department

TO BE COMPLETED BY THE RESEARCHERS

1. Height: _____
2. Weight: _____
    a. BMI calculation: _____
    b. Class BMI: _____
3. Leg dominance: _____
4. Group classification: no history:_____, within 1 year:_____, within 1-3 years:____ within 5 years:_____
5. Q-angle calculation:

	L Leg	R Leg
Quite Stance		
Static lunge		
Dynamic lunge		

Script

I. Participants will be waiting in hallway outside of room with social distancing
    a. Intake form and Consent
        i. Participant will be given an intake form and informed consent to fill out
            1. Researchers will document subject # on both intake form and researchers form

II. Height and weight will be measured
    a. Recorded on researcher intake form
        i. "Thank you for filling out the informed consent for us. Next could you please come over here so that I can get your height and weight."
        ii. "Thank you, you can have a seat until they are ready for you in the research room."

III. Participants will then be called into the research room

IV. Measurement of dominant leg
    a. "Next, I am going to have you stand facing towards me, with a ball in the middle of your body in front of you. When I count to "3" I want you to kick the ball back to me"

V. "Thank you for your cooperation, I will have you wait in chair until the researchers are ready for you."

VI. Participants will then be asked if it is ok to place skin stickers or marks on ASIS, midline of patella and tibial tuberosity
    a. "Is it ok if we place these on your skin to help us take measurements during this experiment? We need to place these on your ASIS, patella and tibial tuberosity, just below you kneecap."

VII. Quiet stance, static and dynamic lunge performance
    a. "Next I am going to have you come over to the designated area where we are going to have you stand normally, perform a static lunge, and a dynamic lunge"
    b. "Stand here while we get your normal stance, with feet shoulder width apart."
    c. "Now we will have you lunge forward on your dominant leg, with your feet 16 inches apart, keeping your feet on the line and then come back to standing.
    d. "Next I want you to perform a forward lunge on the opposite leg. With your feet 16 inches apart, keeping your feet on the line and then come back to standing."
    e. "Next we will have you lunge forward 4 steps when we say go. Remember to keep your feet 16 inches apart on the designated marks on the floor as you lunge. After the 4th lunge you can come back to a resting position."

VIII. After completion of data collection, participant is free to go
    a. "Thank you for your participation in in our study, you are free to go unless you have any questions for us."