

Informed Consent

Title of Research Project: Efficacy of the Motion Guidance System on correcting medial knee displacement during a single leg squat

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You are invited to participate in a research study. The purpose of this information is to help you to make an informed decision about whether or not you would like to participate. Please read the information in this document carefully. You may ask the researchers [*or contact the researchers to ask (if the study is not in-person)*] questions about the purpose of the research, what you would be asked to do, any possible risks and benefits, your rights if you were to participate, and anything else about the research before deciding whether or not to participate.

Participation in this study is voluntary and confidential. If you do not wish to participate or if you decide to participate and then withdraw or skip any part of the research process, there are no penalties or loss of benefits or services that you are otherwise entitled. Whether or not you choose to participate in this project will have no effect on your relationship with the researchers or Daemen College.

Purpose of the Research Project:

The purpose of this research study is to investigate the efficacy of the Motion Guidance system on correcting medial knee displacement during a single leg squat in healthy, physically active, college students.

Description of the Research Project and Procedures:

Participants will be asked to complete 2 separate questionnaires prior to participation; including a Health History Questionnaire and the International Physical Activity Questionnaire. The health history questionnaire includes questions about physical activity, concussions, color blindness, history of back or lower extremity surgery or injury, driving ability, balance disorders, and a known neuromuscular disorder. Participants will be verbally asked if they have answered all questions honestly and understand that any changes in

their answers may change their ability to participate in the study. The researchers will measure participants' height and weight. Next, a demographic form will ask questions about age, dominant kicking leg, biological sex, use of foot orthotics, and experience with a single leg squat. If participants are eligible for the study, they will then be given the International Physical Activity Questionnaire Short-Form (IPAQ-SF) to quantify your physical activity level.

Once forms have been completed, participants will be asked to change into black spandex and a tank top/sports bra if they have not already come dressed in that attire. If participants do not have black spandex, spandex, in an array of sizes, will be provided for use in the study. Nearby changing areas/bathrooms are located about 20 feet down the hallway. Reflective stickers will be placed on bony landmarks on participants' bodies to help visualize movement patterns in the software used for data collection. These bony landmarks include shoulders, pelvis, hip, knee, ankle and foot.

Participants will be instructed on how to get into the test position which includes taking shoes and socks off, placing the big toe of the dominant kicking foot at the central line of the mat, raising the non-dominant leg to 60 degrees of hip and knee flexion, and extending both arms straight out in front. Participants will be provided with time to practice as many single leg squats on their dominant leg as necessary until they are able to time their squat appropriately to the rhythm of the given metronome as determined by the examiner. After practice, participants will perform a screening examination of 2 sets of 5 consecutive single leg squats in which medial knee displacement will be evaluated. If participants do not display medial knee displacement (MKD) then they will be disqualified. If participants do qualify then the study procedures will continue. If participants qualify, a hypoallergenic strap with a laser will be placed 3-inches above the knee on the dominant kicking leg. Following the placement of the strap/laser, 2 more sets of 5-repetitions of single leg squats will be performed under two different test conditions, one with the laser activated and one without. Participants will have a 5-minute rest in between conditions to reduce the changes of fatigue. During these movements, joint angles at the ankle, knee, hip and trunk will be recorded and examined by video cameras located directly in front and off to the side of the dominant leg exactly 13 feet away. All collected data will be stored in a password protected iPad with no association between participants' name and their data to ensure privacy and protection of the information obtained.

To be included in this study, participants should:

- be 18-24 years old
- be physically active, engaging in moderate-intensity physical activity for a total of 150 minutes per week
- demonstrate medial knee displacement (MKD) during 3 out of 5 single leg squats during the screening trial

Things that would exclude a participant from this study would be:

- being color blind (unable to see green)

- having experienced a back or lower extremity orthopedic injury (i.e., back, hip, knee, ankle, foot) that kept them from physical activity for at least 2-days in the past 6 months
- having a diagnosed concussion in the last 6 months
- having a history of surgery to the back or lower extremity
- having a diagnosed balance disorder
- having visual impairment (defined as not able to drive)
- having a neuromuscular disorder (CP, MS, SCI, TBI, DMD, ALS)

Study Duration:

Participation in this study is expected to take approximately 40 minutes.

Risks:

The researchers do not anticipate any risks beyond what could occur in daily life. This minimal risk includes the chance that a muscle could be strained particularly in the lower extremities during the single leg squat. However, there are protections in place that make this possibility unlikely, such as the physical activity level participants should have to be included in the study and excluding those participants that would be at higher risk (e.g., those with a diagnosed balance or neuromuscular disorder).

Benefits:

Participants will not directly benefit from taking part in this study.

Compensation:

Participants will not receive any compensation for taking part in this study.

Confidentiality:

All data collected from participants will be kept confidential. Only the researchers mentioned above will have access to participant responses, which will be kept in a secure location. All information will be presented or published in group form and will not contain any identifying information or link any individual participant with the data. Any identifying information, such as this consent form, will be stored separately from any other data, and all participants will be given a code to ensure that names will not be associated with any data. This coding sheet will also be stored separately from the consent form and any data.

Reimbursement for Medical Treatment:

Daemen College, its agents, or its employees do not compensate for or provide free medical care for human subjects/participants in the event that any injury or harm results from participation in a human research project. In the unlikely event that you become ill or injured as a direct result of participating in this study, you may receive medical care or treatment, but it will not be free of charge even if the illness or injury is a direct result of your participation. *[Must be included for studies that are greater than minimal risk]*

Contact Information for Questions or Concerns:

You have the right to ask any questions you may have about this research. If you have any question or concerns, please contact Firstname Lastname at FLast@daemen.edu, 716-xxx-xxxx. or Firstname Lastname at first.last@daemen.edu or Firstname Lastname at first.last@daemen.edu. If you would like to report a complaint or have questions regarding your rights as a human subject, you may contact the Daemen College Human Subjects Research Review Committee Chair at hsrrc.chair@daemen.edu, 716-839-8508.

Voluntary Consent:

Please review all the information on this form before deciding whether or not you would like to participate. Taking part in this research study is strictly voluntary. If you choose to take part, you have the right to stop at any time or skip any part of the research that you may wish. If you do not wish to participate, you are free to leave.

If you wish to participate, please sign below. By signing below, you are attesting that you have read the above information, that you understand the tasks and risks associated with the study, and that you have had the chance to ask any questions that you may have and that you are aware that you can contact the researchers now or in the future if concerns arise. By signing below, you are attesting that you understand that your participation is entirely voluntary and that you can choose to discontinue your participation at any time. By signing below, you are attesting that you are at least 18 years of age. Lastly, by signing below, you are providing your consent to participate in this study.

Printed name of participant

Signature of participant

Date

Printed name of researcher

Signature of researcher

Date

Please keep a copy of this document for your records.