INSTRUCTIONS

Before completing this form, researchers and the faculty supervisor (if student researchers are involved) must complete the checklist below to determine if the protocol can be considered for Expedited Review or if it must be sent for Full Review. If either are unsure of the criteria, please see a description of each type of review on Daemen’s Institutional Review Board - Human Subjects Research (IRB) website. If your project meets the criteria for Expedited Review, it will be reviewed as such. If not, it will be sent to the committee for Full Review. However, Full Review protocols must be received at least 10 business days in advance of the meeting date, so it’s best to plan accordingly in case you categorize into the wrong review type.

As you complete the form, please be sure to read the directions for each section thoroughly, and provide relevant and detailed responses where applicable. In addition, be sure to append all relevant study materials to the end of this document in the order in which they are referred to within the document, and in the manner in which they will appear to participants. Lastly, when the form is complete, be sure that all researchers sign the form (use electronic signatures or type names), and submit an electronic version with all supporting materials/appendices in a Single MSWord file to the IRB Chair at irb@daemen.edu. Please copy (cc) all associate investigators and use Daemen University e-mail addresses (where applicable). For student projects, faculty supervisors must submit on behalf of the student researcher(s).

I. Complete All Items Below:

Type of Proposal (Please check one):

☐ New
☐ Resubmission with Requested Revisions

\* If a resubmission with requested revisions, please either use track changes or highlight in yellow all new changes from the original submission (or the most recent resubmitted version) and indicate date of current submission below.

Review Requested (Use checklist below):

☐ FULL
☑ EXPEDITED

Date Submitted to IRB: 07-20-22

Principal Investigator: Firstname Lastname

Title of above: ☐ Dr. ☑ Mr. ☐ Mrs. ☐ Miss ☐ Ms. ☐ Other: __________

Daemen e-mail address: firstname.lastname@daemen.edu

Phone: (716) XXX-XXXX

Associate Investigator(s): Firstname Lastname

Daemen e-mail addresses (where applicable): firstname.lastname@daemen.edu

Course: ATH XXX

Faculty Supervisor: Dr. Firstname Lastname

Campus Address: XXX Hall, Room XXX, Mailbox XX

Daemen e-mail address: flast@daemen.edu

Phone: (716) XXX-XXXX

Title of Project: Efficacy of the Motion Guidance Visual Feedback System on Correcting Medial Knee Displacement During a Single Leg Squat
If any of the following are true, your proposal constitutes greater than minimal risk and requires Full Review:

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II. Funding:

1. Please identify all sources of the funding for the present study:
   - X Unfunded
   - Governmental Agency/ies: ____________________________
   - Foundation(s): ____________________________
   - Corporation(s): ____________________________
   - Organization(s): ____________________________
   - Daemen University Administrative Office: ____________________________
   - Daemen University Department: ____________________________
   - Individual(s): ____________________________
   - Other: ____________________________

2. Is this proposal part of a grant?  
   - X No
   - Yes

   If YES, please answer the following questions:
   a. Name of grant: ____________________________
   b. Name of institute or agency that awarded the grant: ____________________________
III. Coordination with other Institutions:

1. Will this proposal involve the coordination with any other institution (e.g., recruitment, location, participants)?
   
   Note: If coordination is required, a signed letter of agreement must be appended to this application. Letters of agreement must be submitted on official letterhead and contain an original signature, and it must be explained how the individual granting permission has the authority to do so. The letter should be written so that IRB has a record that the institution acknowledges an understanding of general protocol/recruitment procedures (these should be briefly included in the letter) and must specifically indicate approval to recruit and/or conduct the study at the location.

   [ ] Yes
   [X] No

   If yes, please discuss the nature of this coordination and indicate the name of the institution(s):

2. Has this proposal been or will it be submitted to other Human Subjects Review Boards (IRB Committees), departmental committees, or community agencies for review and approval?

   Note: according to 45 CFR §1.114, cooperative research must rely on a Single IRB unless it is indicated that the research is not subject to the provision. Typically, if Daemen participants are involved, Daemen should be the lead IRB.

   [ ] Yes
   [X] No

IV. Location of Research:

1. Where will research be physically conducted?
   
   (If online, indicate relevant platforms/websites)

   Daemen University Academic and Wellness Center (AWC), Room 201

V. Participants:

1. Types of participants and controls:
   a. Please check if you are planning to study any of the following vulnerable populations:

   [X] Minors       [ ] Prisoners       [ ] Economically Disadvantaged Individuals       [ ] Educationally Disadvantaged Individuals
   [ ] Individuals with Impaired Decision-Making Ability       [ ] Other: ________________________

   b. Age range of participants:
   [ ] 18-24 years of age

   c. Estimated sample size:
   [ ] 50 participants

   d. Population from which participants will be derived:

   Daemen University Students

   • 18-24 years old
   • Physically active, defined as 150 minutes of moderate-intensity exercise per week.
   • Demonstrate medial knee displacement (MKD) during 3 out of 5 single leg squats during screening trial

   • Color blind so that seeing a green laser would be difficult
   • In the past 6-months, 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
   • Diagnosed concussion in the last 6 months
   • History of surgery to the back or lower extremity
   • Diagnosed balance disorder
   • Visual impairment (defined as not able to drive)
   • Neuromuscular disorder (i.e., Cerebral Palsy, Stroke, Parkinson's, Multiple Sclerosis, ALS, Muscular Dystrophy)

   e. Inclusion criteria for participants and controls:

   (This refers to inclusion criteria for participation in the study, not criteria for inclusion in data analysis)

   f. Exclusion criteria for participants and controls:

   (Include any restrictions in addition to inclusion criteria (i.e., those specifically excluded from participation, not the opposite of inclusion criteria)
a. Describe the specific steps to be used to identify and recruit prospective participants. Recruitment telephone and/or e-mail scripts and advertisements must be appended to the end of this application.

The student researchers will place recruitment flyers (Appendix A) around the Daemen University campus. Locations included are: the Academic and Wellness Center (AWC), Wick Student Center, Lumsden Gymnasium, Duns Scotus Hall and Schenck Hall. The faculty supervisor will use the Daemen University student designated list serve to recruit participants via email (Appendix B), which will be sent out once per month over the course of three months (September-November).

b. Describe how you have permission to access to potential participants or explain why permission is not needed:

All potential participants are affiliated with Daemen University. The student researchers are currently graduate students at Daemen University, and the faculty advisor is a member of Daemen faculty. Further permission is not needed as all researchers are affiliated with the institution.

3. Will this project utilize post-consent screening procedures (e.g., for inclusion or exclusion purposes)?

Note: Screening cannot take place prior to the consent process.

[ ] Yes  [ ] No

If yes, describe any screening procedures you will use and how the results of your screening procedures will identify those who are eligible to continue participating (e.g., those who meet inclusion criteria), and identify persons who are ineligible and whose participation will be discontinued (e.g., those who meet exclusion criteria).

Participant informed consent (Appendix C) will be obtained prior to the screening and data collection. A Health History Questionnaire (Appendix D) will be used after informed consent to determine if anyone is ineligible due to the aforementioned exclusion criteria. Participants will be verbally asked if they answered all questions honestly and that they understand any changes in their answers may change their ability to participate in the study. They will also be told that any questions which they answer “yes” to, except for number 1, will exclude them from participation.

The screening session will be performed after consent and confirmation of all inclusion and exclusion criteria. All single leg squat trials will be performed on the dominant leg, defined as the leg chosen to kick a soccer ball for maximum distance. A verbal instructions script (Appendix H) will be utilized for all conditions of the single leg squat during the study. Participant instructions will state “you should stand on your right/leg (dominant) leg with your arms held straight out in front of you so that they are parallel to the floor. Hold your right/left (non-weight bearing) leg in front of you so that your hip and knee are flexed to 60 degrees. You are going to squat down as far as you are comfortable but must reach at least 60 degrees of knee flexion. You will squat down for two beats of the metronome and then return to the start position for two beats of the metronome. You will perform 5 consecutive squats following this cadence. You can start any time after I say, ‘get set… go ahead.’ Participants will be allowed as many practice squats as they need prior to the screening to perform the task successfully. The number of practice squats will be recorded.

A trial is deemed successful if participants 1) maintain proper test position, 2) squat to at least 60 degrees (determined visually by investigator), 3) complete the movement assessment at the appropriate rate, 4) do not touch down with the non-dominant foot or touch the legs together, and 5) maintain the heel of the test leg in contact with the ground. Participants will not receive coaching or feedback concerning technique, other than what constituted a successful trial. Participants will be given as many practice trials as needed to perform the movement successfully. Video will be recorded during the test trials and investigators will observe in real time for the occurrence of medial knee displacement (MKD) during at least 3 out of the 5 test trials of the screening session. MKD is defined as the mid-point of the patella moving medially (inward) in relation to the great toe.

If participants demonstrate MKD during at least 3 of the 5 baseline screening trials, they have qualified to move forward to the intervention phase of the study. If they do not demonstrate MKD during at least 3 of the 5 baseline screening trials, they will be thanked, and their participation will conclude at this time.

4. Will participants be compensated in any way (e.g., for time or travel) for their participation?

[ ] Yes  [x] No

If yes, please explain below how and when the participants will be compensated.

VI. Study Duration:

1. Expected duration of study (e.g., March 2020 – May 2020): September 2022 - November 2022
VII. Description of the Research Plan:

1. **Project Background:** Please include (1) a brief background summary of the literature, (2) the importance of or need for the study, (3) the study purpose, and (4) study hypotheses. Include a reference list and cite work where appropriate.

Movement patterns during athletic tasks can contribute to the risk of sport related injury. Improper joint alignment when performing athletic movements could affect knee and hip mechanics negatively during the activity. (1) One known joint alignment pattern that may contribute to injury is knee valgus. Knee valgus is characterized by hip adduction and hip internal rotation causing the knee to collapse medially (inward) when the hip moves into a flexed position. The only way to truly measure knee valgus is through high tech 3D motion analysis. This equipment is very expensive and requires extensive training to use. Fortunately, tablet based (iPad) motion analysis apps are making motion analysis more available to the clinician through 2D video analysis techniques. Medial knee displacement (MKD) is the clinical presentation of knee valgus that can be picked up by the naked eye or 2D motion analysis. MKD is defined as the mid-point of the patella (kneecap) moving inward relative to the great toe. Clinicians often look to observe MKD during functional movements to identify patients or athletes at greater risk of sustaining injury.

One movement assessment task often utilized to identify faulty movement patterns is the single leg squat, which addresses lower leg function. (1) Previous studies have demonstrated that individuals with increased knee valgus during the single leg squat test are more likely to result in injury (2). Clinicians can successfully identify MKD and other faulty movement patterns during functional movement, however the most effective means to retrain these movement patterns is an ongoing investigation.

Motor learning literature demonstrates that the type of feedback (intrinsic, extrinsic) or focus of attention (internal, external) provided to a learner is a key factor in their ability to learn a new movement pattern. Intrinsic feedback is the physical feel of a movement that the performer uses to alter the movement going forward. Extrinsic feedback is any source of information or feedback on their movement pattern provided by an external source during or after the performance. Previous studies have examined the effectiveness of extrinsic feedback compared to intrinsic feedback. Extrinsic feedback was determined to be more effective at maintaining proper alignment while performing a single leg squat compared to intrinsic feedback (3, 4). One type of extrinsic feedback is the verbal instruction provided to a performer that induces an internal or external focus of attention. An internal focus of attention draws the attention to the body part in question, such as “keep your knee in line with your hip.” An external focus of attention draws the attention to an outside goal, such as “try to bring your knees as close to the outside walls as possible.” An external focus of attention affects motor learning by directing the attention to the outcomes of the movements instead of the movements themselves. The more complex or challenging the task, the greater the advantages of adopting an external focus of attention (4). The challenge in the rehabilitation setting is finding a way to utilize an external focus of attention in commonly used exercises or techniques.

Previous research has not investigated the effectiveness of a novel laser visual guidance system (Motion Guidance), as an external focus of attention, on improving single leg squat kinematics. The developers of the product claim the laser guidance system provides instant extrinsic feedback and an external focus of attention for participants. Therefore, the purpose of this research study is to investigate the effects of an internal versus external focus of attention, using laser guidance, on performance of the single-leg squat in physically active adults. We hypothesize that the external focus of attention using the laser will reduce medial knee displacement in participants that demonstrate this movement pattern during a single leg squat.

References:
2. Please describe your study design (e.g., experimental and control conditions, etc.) and identify your variables (e.g., independent/predictor variables and dependent/outcome variables, etc.) if applicable:

The study design is a within-subjects repeated measures design with dependent variables of medial knee displacement (MKD), peak knee flexion angle, pelvis angle relative to horizontal, ankle dorsiflexion angle, and trunk forward flexion angle.

3. Informed Consent/Assent

The consent form must be written in appropriate-language (i.e., 8th grade level for adult participants) and use wording that is easily understandable to those outside your area of expertise. In the case of vulnerable participants, consent must be obtained from appropriate legally authorized representative(s). Please be sure the consent form contains the minimal necessary information as required by the Daemen University IRB (see IRB website).

Please note that all procedures must be included in the consent form unless deception is planned. If deception is planned, whenever possible, participants should prospectively agree to being unaware of or misled regarding the nature and the purpose of the research.

Assent is also required for minors and individuals with impaired decision-making ability (in addition to consent of the appropriate legally authorized representative). Assent language must also be age-appropriate, which varies depending on the age of the minor (e.g., an assent for a 15-year old participant will use older language than an assent for 7 year-old participants). As a general rule, written documentation of assent should be obtained for minors 7 years of age or older.

In the box below, list the individual name(s) of each researcher who will obtain consent (signed or otherwise) from study participants:

XXX XXX, Ph.D., ATC, PES; XXX XXX, B.S., SPT; XXX XXX B.S., SPT

b. Are you requesting a waiver of signed (written or electronic) informed consent?

If you answered "YES" (to 3b), please justify this request:

Note: Waiver of signed consent is justifiable if (1) the only record linking the subject and the research would be the informed consent form, and the principal risk would be potential harm resulting from a breach of confidentiality; (2) the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context; (3) if the subjects or legally authorized representatives are members of a distinct culture group or community in which signing forms is not the norm, that the research presents no more than minimal risk of harm to the subjects, and provided there is an appropriate alternative mechanism for documenting that informed consent was obtained.

Informed consent will be obtained and documented prior to any data collection via the understanding and signature of a consent form (Appendix C). Once the informed consent document is read, the subject will be asked if they have any questions, and if they do then they will be appropriately answered. If they do not have any questions and are willing to participate in the study, then both themselves and the researcher will sign and date two copies of the consent form. It is important that the participant understands that they are not required to be a part of the study, and if they so choose, they can withdraw from the study at any point with no penalties. One copy of the informed consent document will be kept by the researcher, while the other will be given to the participant.

If you answered "YES" (to 3b), please explain the process of how and when you will obtain and otherwise document informed consent in the absence of signed informed consent (e.g., providing an online consent sheet or oral consent procedures) and how you will ensure that participants fully understand the study:

c. If you answered “NO” (to 3b; i.e., you are NOT requesting a waiver of signed consent), please explain the process of how and when you will obtain signed informed consent and how you will ensure that participants fully understand the study:

4. Procedures and Materials

   a. Please describe your full methodology, step by step, specifically referencing each of the materials that participants are exposed to throughout the study (e.g., surveys, tests, questionnaires, stimuli, and/or instruments).

   **Study Design:** Study Design: The study design is a within-subjects repeated measures design with dependent variables of medial knee displacement (MKD), peak knee flexion angle, pelvis angle relative to horizontal, ankle dorsiflexion angle, and trunk forward flexion angle.

   **Informed Consent:** Informed consent will be obtained by having the potential participant read the informed consent document (Appendix C). Once the informed consent document is read, the subject will be asked if they have any questions, and if they do then they will be appropriately answered. If they do not have any questions and are willing to participate in the study, then both themselves and the researcher will sign and date two copies of the consent form. It is important that the participant understands that they are not required to be a part of the study, and if they so choose, they can withdraw from the study at any point with no penalties. One copy of the informed consent document will be kept...
kept by the researcher, while the other will be given to the participant. After the participants sign the informed consent
document, the participant will complete the health history questionnaire (Appendix D). Participants will be verbally
asked if they answered all questions honestly and that they understand any changes in their answers may change
their ability to participate in the study. They will also be told that any questions, which they answer “yes” to, except #1,
will exclude them from participation. If the participant is eligible for the study, the participant will then complete the
International Physical Activity Questionnaire Short-Form (Appendix E) to quantify participants’ physical activity level
into either moderate-intensity or vigorous-intensity. This questionnaire will help confirm adequate physical activity
level. Participant demographics will then be assessed and recorded on the Demographic & Data Collection Form
(Appendix F). Information recorded includes, age, sex, height (cm), mass (kg), dominant kicking leg, use of foot
orthotic, and experience with single leg squat. This form will also be used for data collection during the single-leg squat
trials.

**Data Collection:** Data will be collected in AWC 201. Participants will be asked to wear dark colored spandex shorts
and a dark colored fitted tank top, sports bra (women) or shirtless (men). The purpose of the dark colored clothing is to
be able to view the reflective stickers in the motion analysis software for data reduction. The purpose of the tight-fitting
clothing is to prevent movement of the reflective stickers placed on landmarks during data collection. This improves
reliability and validity of data collected. If a participant does not have their own spandex shorts they will be provided a
pair by the lab. These spandex shorts will be laundered in between use. After the consent process, the performance of
the single-leg squat conditions will be in the same order for all participants (screening, internal focus, external focus).
Participants will not perform the external focus (laser) prior to the internal focus to eliminate the potential carryover
effects from having the external focus first. The screening trials will take place after consent and confirmation of all
inclusion and exclusion criteria. All single leg squat trials will be performed barefoot on the dominant leg, defined as
the leg chosen to kick a soccer ball for maximum distance. A verbal instructions script (Appendix H) will be utilized for all
conditions of the single leg squat during the study. Participant screening instructions will state “align the big toe of
your right/left (dominant) leg on the center line of the mat and keep both arms straight out in front of you so that they
are parallel to the floor. Lift your non-dominant (right/left) leg in front of you at least 6 inches off the ground. You are
going to squat down as far as you are comfortable, but you must reach at least 60 degrees of knee flexion. You will
squat down for two beats of the metronome and then return to the start position for two beats of the metronome. You
will pause for one beat at the top and repeat the same single-leg squat cadence. You will perform a total of 5
consecutive squats to the beat of the metronome. If you touch down with the non-dominant foot, lift your heel off the
ground or touch your legs together, we will discontinue that trial and repeat another in its’ place. You can start any time
after I say, ‘get set… go ahead.’”

A single-leg squat trial is deemed successful if participants 1) maintain proper test position, 2) squat to at least 60
degrees (determined visually by investigator), 3) complete the movement assessment at the appropriate rate, 4) do
not touch down with the non-dominant foot or touch the legs together, and 5) maintain the heel of the test leg in
contact with the ground. Participants will not receive coaching or feedback concerning technique, other than what
constituted a successful trial. Participants will be given as many practice trials prior to the screening as needed to
perform the movement successfully. Video will be recorded during the test trials and investigators will observe in real
time for the occurrence of medial knee displacement (MKD) during at least 3 out of the 5 test trials of the screening
session. MKD is defined as the mid-point of the patella moving medially (inward) in relation to the great toe. If
participants demonstrate MKD during at least 3 of the 5 baseline screening trials, they have qualified to move forward
to the intervention phase of the study. If they do not demonstrate MKD during at least 3 of the 5 baseline screening
trials, they will be thanked for their participation.

Participants will be allowed a 5-minute rest in between the screening session and the first intervention condition while
data collection markers and the motion guidance laser are placed. During this rest period the participants will be asked to
indicate how fatigued they are on the Visual Analogue Fatigue scale (Appendix G). Participants will be donned with
round reflective stickers on bony landmarks that will allow the researchers to identify key landmarks to quantify 2D
Kinematics. The landmarks include bilateral anterior superior iliac spine (ASIS) and acromion processes of the scapula
(shoulders) as well as unilateral placement (dominant side) on the greater trochanter (hip), lateral femoral condyle
(knee), midpoint of the patella (kneecap), lateral malleolus (ankle), and the 5th metatarsal head on the outside of the foot.

Two iPad Air 2 with Retina display tablets will be positioned on tripods placed 13-feet in front of (frontal plane view)
and to the side of (sagittal plane view) the participant. The side (right/left) chosen for camera placement will match the
side of the dominant kicking leg. The tripods will be positioned to ensure that the camera height is 32 inches (80
centimeters) from the ground surface. Coach’s Eye (TechSmith Corp., Okemos, Michigan) tablet-based motion
analysis software will be used to record 2D videos of the single-leg squat conditions and to calculate all relevant joint
angles.

To measure the effect of different focus of attention instructions on single-leg squat performance, all participants will
perform both conditions in a standard order. One instruction set has an internal focus, while the other instructions will
have an external focus. The Motion Guidance laser feedback system will be worn for both conditions, however the laser will only be turned on for the external focus instructions.

The Motion Guidance Laser (Appendix I) will be attached, via a hygienic non-slip strap, to the participants’ thigh at a standard location of 3 inches above the superior pole of the patella (top of the kneecap) measured from the inferior (bottom) edge of the strap. The motion guidance 3’ x 5’ tracking grid is a target placed on the floor that will be used by the participant to view the location and trajectory of the green laser during the external focus condition. The grid is placed on the floor in a standardized location. Participants will be instructed to stand with the tip of their great toe touching the edge of the grid directly in line with the black center line. After proper placement the green laser will be attached to the mounting piece on the strap. The laser will remain off for the internal focus of attention instructions and will be turned on for the external focus of attention instructions. Wearing the motion guidance laser for both conditions allows the tactile cueing provided by wearing the laser to be the same in both conditions.

**Internal Focus of Attention:**
Participants will be lined up with the great toe in line with the black center line. The laser beam will remain in the OFF position. The verbal instructions for this condition include, “In this condition, you will perform the single-leg squat the same as you did in the screening. In this condition, focus on your knee staying in line with your foot as you perform the squat.” Participants will be given an opportunity to practice one set of 5 repetitions, the attentional focus instructions will be read again, and 5 consecutive squats will be performed for data collection. Three minutes of rest will be afforded between the practice and data collection trials.

**External Focus of Attention Instructions:**
Participants will be lined up with the great toe in line with the black center line. The laser beam will be turned ON and positioned to shine on the first yellow circle on the black center line. “In this condition, you will perform the single-leg squat the same as you did in the screening. In this condition, focus on not letting the laser cross over the black center line.” Participants will be given an opportunity to practice one set of 5 repetitions, the attentional focus instructions will be read again, and 5 consecutive single-leg squats will be performed for data collection. Three minutes of rest will be afforded between the practice and data collection trials.

In between conditions (internal, external) participants will be given a 5-minute rest. Following each condition, participants subjective fatigue levels will be assessed using the Visual Analogue Fatigue Scale (Appendix G). This scale will be used to monitor subjective fatigue levels across the repetitive trials. If a participant records fatigue level of 7 or greater, additional rest time will be afforded. Participants will also complete a Condition Check following each intervention condition, which asks 1) What were you focusing on during the last trials and 2) Did the instructions make the task seem easier or more challenging? Participants will be instructed to be honest, even if they do not focus on the instructions that were provided.

The average joint angle of the middle 3 squats (reps 2-4) will be used for data analysis.

b. Please describe each of the materials that participants are exposed to throughout the study. Append these materials along with the instructions that will be given to participants, in the manner that they will be presented to participants and in the order in which they will appear. If a measure that is used that is not retrievable in the public domain, please also append appropriate permission.

**Appendix A. Recruitment Flyer:** This flyer will be hung up by the student researcher around the Daemen University campus to recruit potential participants.

**Appendix B. Email via listserv.** This recruitment text will be used to recruit participants via the student listserv.

**Appendix C. Informed Consent.** This form will include all of the necessary information in order for the potential participants to be fully aware of the content of the study, risks involved, other studies and risks of those studies, and the opportunity to ask questions prior to the study starting.

**Appendix D. Health History Questionnaire.** This questionnaire will be used to screen for inclusion and exclusion criteria of the patient.

**Appendix E. International Physical Activity Questionnaire:** This questionnaire will be used to gather subjective information about patient’s activity levels and uses that information to quantify participants as either having a high or a moderate physical activity level. (1)

**Appendix F. Demographic & Data Collection Form:** This form will be used to obtain data such as height (cm), weight (kg), race, hand dominance, caffeine consumption, and education level
Appendix G. Visual Analogue Fatigue Scale: This scale will be used to measure the participants subjective level of fatigue throughout data collection following each condition of the single-leg squat.

Appendix H. Verbal Instructions: These instructions will be given to each participant for each condition.

Appendix I. Motion Guidance Laser Feedback System Images: Two figures are included in this application to demonstrate visually what the motion guidance laser feedback system consists of.

Appendix J. Condition Check: Internal / External
1) What were you focusing on during the last trials?
2) Did the instructions make the task seem easier or more challenging?

c. Please list below each appendix that relates to the materials described above, including the title of each, following the examples below.

Appendix B. Recruitment Email Script for Student Listserv.
Appendix C. Informed Consent
Appendix D. Health History Questionnaire
Appendix E. International Physical Activity Questionnaire
Appendix F. Demographic & Data Collection Form.
Appendix G. Visual Analogue Fatigue Scale
Appendix H. Verbal instructions
Appendix I. Motion Guidance Laser Feedback System Images
Appendix J. Condition Check: Internal / External

5. Deception
a. Does the protocol involve any deception? [ ] Yes [x] No
b. If YES (to 5a), please fully describe the debriefing process and append a copy of the debriefing script:

c. If YES (to 5a), will participants have prospectively agreed to the deception during the consent process? [ ] Yes [ ] No
d. If NO (to 5c; i.e., participants have not prospectively agreed to the deception), please justify why the deception is necessary:

6. Risks and Benefits: Please note that expedited proposals, by definition, should not carry more than minimal risk.
a. Please list and describe any real or perceived risk (e.g., physical, psychological, economic and/or social) to participants. Each of these risks needs to also be presented during the consent process. If this is an Expedited Protocol, please justify why these risks are no greater than minimal:

There is a chance that the participant could become fatigued or a muscle could be strained particularly in the lower extremities during the single leg squat. This type of injury can occur during normal daily activity and/or exercise, so it should not constitute more than minimal risk.

b. Describe the procedures and precautions that will be taken to minimize or avoid each of these risks (to the extent it is possible):

The risks are minimized by using physically active participants and allowing adequate rest time. Participants will have 3-minutes of rest in between all practice trials and data collection trials. They will also have a full 5-minutes of rest in between the screening trials, internal focus trials and external focus trials. We will also use a visual analogue fatigue scale that will help us determine if anyone needs a longer rest period. This will not be cause for exclusion.

c. Please list and describe any real benefits to the participants:

d. If appropriate, describe any withholding of normal treatment and/or alternative treatments:

e. Explain the conditions under which you would discontinue the participation of any or all participants:
VIII. Privacy, Confidentiality, & Data Management:

a. **Participant Privacy:** When gathering data, what measures will you take to protect your participants’ privacy during the study? Examples include interviewing subjects individually in a closed room, interviewing over the phone, surveying participants using dividers or empty seats between them, or using online data collection platforms such as SurveyMonkey or Google Forms, etc.

Each participant is run individually in a private room. Only the researchers will be present along with the participant.

b. **Participant Confidentiality:** Will any identifying information (name, email, date of birth, voice/video recordings, company working for, etc.) or protected academic or health information (for example, anything protected by FERPA or HIPPA, such GPA, transcripts, disease diagnoses, medical information) be collected from participants or their records?

Note: if you are obtaining signed consent or collecting email addresses, you will have to check "YES" for identifying information. If you are collecting any information protected by FERPA or HIPPA, you will have to check "YES" for protected information.

Identifying Information:  
- [ ] YES  
- [ ] NO

Protected Information:  
- [ ] YES  
- [ ] NO

c. Please describe the methods of protecting confidentiality (i.e., protecting the identity and responses of participants) prior to, during, and after data are collected. Describe in detail how all data will be handled so that participants’ identities and data remain confidential. For example, how will any coding systems be protected so others can’t like participants’ data with their identities, how will any video and audio recordings be handled (e.g., how/when will recordings be transcribed and the original recordings deleted, etc.), and how will any written or electronic responses be handled (e.g., written responses are placed in a sealed envelope/lock box, electronic responses are password protected and do not collect IP or email addresses, and are downloaded to a secure device and deleted from the online platform, etc.)

Note: Presentations/publications (including theses/dissertations) must not contain any information that would reveal the identities of participants.

Any and all participant data that is collected will be de-identified. The researchers will assign each participant a specific number that can only be accessed by the researchers using a coding document. Documents with personal information (consent forms, health history questionnaire) will be stored under lock and key in Dr. XXX office (AWC, XXX) in a different file cabinet than any data, separate from each other. There will be one electronic coding document that links the names and participant identification numbers, which will be password protected and stored on the researchers’ computers. This will be deleted as soon as data is linked.

Video recording will be performed to calculate kinematic joint angles during the single-leg squat. Videos can only be viewed by the researchers and will be stored on password protected computers for processing. The videos will be stored for a maximum of three years. After which time the videos will be destroyed. The procedures that are video recorded contain no sensitive information.

d. **Data Storage:**

1. How long will you store your data?

   Note: Raw data and consent documents (if applicable) must be stored for a minimum of 3 years per federal regulations. However, data should be deidentified whenever possible.

2. Where (physically) will you store your data during and after data collection? Please be specific (e.g., video/audio recordings will be stored on a computer during data collection and in a locked cabinet after transcription, or electronic responses will be stored in the online platform during data collection but on a password protected computer after data collection, etc.)
Note: After the project is complete, all data from student research studies should be stored only with the faculty supervisor for the remainder of the storage period.

Hard copies of data collection instruments will be kept in separate, locked filing cabinets in the faculty supervisor’s office in AWC XXX.

3. Other than the investigators listed on this application, please explain who will have access to the raw data and under what circumstances, and how you will protect the data from unauthorized access.

4. Describe specifically how you will dispose of/destroy your data at the end of the 3-year (minimum) storage period.

Hard copies of data collection instruments will be shredded, and all identifiable electronic documents and emails will be permanently deleted. Data that is de-identified will be stored indefinitely.

**Compliance with HIPAA and FERPA Privacy Regulations**

It is expected that all studies approved by the Daemen University IRB comply with federal regulations including HIPAA and FERPA.

In accordance with the provisions of the Health Insurance Portability and Accountability Act of 1996 (HIPAA), investigators shall respect the confidential nature of all information that they may have access to, including but not limited to the subjects’ personal health information provided to them orally or contained in medical records in written or electronic form. If your study involves information derived from electronic medical records, a HIPAA authorization is required in addition to an informed consent document.

Additionally, in accordance with the provisions of the Family Educational Rights and Privacy Act (FERPA), investigators shall respect the confidential nature of any student education records and may not disclose this information or access it without consent unless they have a legitimate educational interest.

IX. CERTIFICATION:

This form must be signed (either by typing in your name or inserting an electronic signature) and submitted to the IRB Chair (irb@daemen.edu) with a copy (cc) to all investigators on the protocol using daemen.edu addresses (where applicable).

The signatures below indicate that both the researcher(s) and the faculty supervisor (if student researchers are involved) will operate in accordance with the details in this protocol and all professional, federal, and Daemen University regulations governing research involving human subjects as stated in the IRB guidelines for the protection of human subjects.

I (we) certify that the information in the project identified above is true to the best of my (our) knowledge.

I (we) certify that this research project will NOT commence without first receiving a letter of IRB approval from the Chairperson of the Daemen University IRB.

I (we) certify that, when approved, the project identified above will not be changed without filing a Study Modification Form and receiving IRB approval.

I (we) certify that I (we) completed the CITI training and have read a description of each type of review on the IRB website and that this protocol meets the appropriate requirements for the level of review stated on the website.

I (we) certify that I (we) will follow all of the details outlined in the study protocol and the method of obtaining informed consent as approved by the IRB during the period of the research project.

I (we) certify that I (we) will maintain all records of this research as required by the Daemen University IRB, submit a Study Closure Form at the conclusion of this study, and will report any adverse reactions or subject complaints within 48 hours to the Chair of the IRB.

Principal Investigator’s Signature: ___________________________ Date: ___________________________

In addition, the faculty supervisor’s signature indicates he or she has reviewed the entire protocol and endorses it.
Faculty Supervisor’s Signature: __________________________ Date:

Associate Investigator’s Signature: __________________________ Date:

Associate Investigator’s Signature: __________________________ Date:

Associate Investigator’s Signature: __________________________ Date:

Associate Investigator’s Signature: __________________________ Date:

Associate Investigator’s Signature: __________________________ Date:
APPENDIX A. Flyer Requesting Participation

Volunteer Research Participants Wanted

Study Title: Efficacy of the Motion Guidance Visual Feedback System on Correcting Medial Knee Displacement during a Single Leg Squat

Daemen University Department of Athletic Training

Purpose: Investigate the effects of internal versus external focus of attention, using laser guidance, on performance of the single leg squat in physically active adults.

- **Recruitment:** College students, ages 18-24, who participate in at least 150 minutes/week of moderate-intensity exercise.
  - Demonstrate medial knee displacement (MKD) during a single-leg squat
- **Exclusion Criteria:** Participants must NOT HAVE
  - Color blindness (unable to see green)
  - In the past 6-months, 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
  - Diagnosed concussion in the past 6-months
  - History of surgery to the back or lower extremity
  - Diagnosed balance disorder
  - Visual impairment (defined as not able to drive)
  - Neuromuscular disorder (CP, MS, SCI, TBI, DMD, ALS)

Research will take place in the Academic & Wellness Center (AWC) 201
4433 Main Street (across the street from the main Daemen University campus)

Participants would be asked to wear dark colored spandex shorts and a dark colored fitted tank top, sports bra (women), or shirtless (men) during the study.

There are no expected risks, benefits, or compensation related to participation in the study.

**Time Duration:** One single testing session lasting 40 minutes

If you are interested in volunteering please contact
XXXX at XXX@daemen.edu

This project has been approved by the IRB at Daemen University
APPENDIX B. Email Recruitment

Subject: Invitation for Voluntary Participants for Research

The Athletic Training Department is seeking voluntary participants for our study entitled:

**Efficacy of the Motion Guidance Visual Feedback System on Correcting Medial Knee Displacement during a Single Leg Squat**

The purpose of this research project is to investigate the effects of an Internal versus External Focus of Attention, using laser guidance, on performance of the single leg squat in physically active adults.

We are looking for healthy participants who are physically active and able to perform a single leg squat. Rest periods will be provided, and subjective fatigue level will be recorded to ensure that adequate rest is given. The time duration would be one single session lasting 40 minutes. Participants would be asked to wear dark colored spandex shorts and a dark colored fitted tank top, sports bra (women), or shirtless (men) during the study.

There are no expected risks, benefits, or compensation related to participation in the study.

Data collection will be conducted on Daemen University’s campus in the Academic and Wellness Center (AWC), Room 201.

To be included in this study you should be:
- 18-24 years old
- 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 screening trials

Things that would exclude you from this study would be:
- Color blind (unable to see green)
- In the past 6-months, 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
- Diagnosed concussion in the last 6-months
- History of surgery to the back or lower extremity
- Diagnosed balance disorder
- Visual impairment (defined as not able to drive)
- Neuromuscular disorder (CP, MS, SCI, TBI, DMD, ALS)

If you are interested in participating, please email XXX at XXX@daemen.edu
Appendix C: Informed Consent Document

Informed Consent

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

Faculty Research Advisor:

Dr. XXX XXX
Daemen University
Athletic Training Department
XXX@damen.edu
716 XXX-XXXX

Student Researchers:

XXX XXXX     XXX XXXX     XXX XXXX
XXX@damen.edu XXX@damen.edu XXX@damen.edu

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 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 University.

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 height and weight and ask a few questions to complete a participant demographic form. The demographic form includes 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 complete the International Physical Activity Questionnaire Short-Form (IPAQ-SF) to measure physical activity level. All forms will be used for data collection during the single-leg squat trials.
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 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 the body 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 the dominant leg as necessary until they are able to time your 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 they study will continue. 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’ names and their data to ensure privacy and protection of the information obtained.

To be included in this study you should be:
- 18-24 years old
- 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 you from this study would be:
- Color blind (unable to see green)
- In the past 6-months, 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
- Diagnosed concussion in the last 6 months
- History of surgery to the back or lower extremity
- Diagnosed balance disorder
- Visual impairment (defined as not able to drive)
- 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. However, There is a chance that a muscle could be strained particularly in the lower extremities during the single leg squat. The risk is minimized due to participants’ physical activity levels.
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:
Participants will be given a code number, so that no identifying information will be linked to the data collection sheets (aside from the health history form). Any identifying information, such as this consent form, coding document, and the health history form will be stored separately in a secure location so that they cannot be linked to participant data. 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 data will be stored for 3 years and then shredded. Electronic, de-identified data will be stored indefinitely.

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 Dr. XXX or XXX, XXX, or XXX. If you would like to report a complaint or have questions regarding your rights as a human subject, you may contact the Daemen University Institutional Review Board Chair at irb@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.
Appendix D: Health History Questionnaire

Health History Questionnaire

Please read the questions carefully and answer each one honestly:

<table>
<thead>
<tr>
<th>YES</th>
<th>NO</th>
</tr>
</thead>
</table>
| ☐   | ☐  | 1. Are you physically active for at least 150 minutes per week?  
   If you answered yes, please list the types of physical activity you participate in:  
   ____________________________________________ |
| ☐   | ☐  | 2. Are you color blind to the color green? |
| ☐   | ☐  | 3. Have you been diagnosed with a concussion in the last 6 months?  
   If you answered yes, please detail how many concussions you have had:  
   ____________________________________________ |
| ☐   | ☐  | 3. Have you ever had surgery on your back or lower extremity? |
| ☐   | ☐  | 4. Are you able to drive? If not, why? ________________________________ |
| ☐   | ☐  | 5. Do you have a diagnosed balance disorder? |
| ☐   | ☐  | 6. Do you have a known NM disorder (i.e. CP, stroke, MS, muscular dystrophy, ALS) |
| ☐   | ☐  | 7. In the past 6 months have you experienced an injury to the back or lower extremity  
   i.e. back, hip, knee, ankle, foot that kept you from physical activity in the last 2 days |

I certify that all of the above questions were answered honestly. I understand that any changes in my answers should immediately be reported to the researcher and that this may change my participation in the study.

Printed Name ___________________________ Date ________________________

Signature ________________________________
Appendix E: International Physical Activity Questionnaire – Short Form

INTERNATIONAL PHYSICAL ACTIVITY QUESTIONNAIRE – Short Form
(August 2002)

We are interested in finding out about the kinds of physical activities that people do as part of their everyday lives. The questions will ask you about the time you spent being physically active in the last 7 days. Please answer each question even if you do not consider yourself to be an active person. Please think about the activities you do at work, as part of your house and yard work, to get from place to place, and in your spare time for recreation, exercise or sport.

Think about all the vigorous activities that you did in the last 7 days. Vigorous physical activities refer to activities that take hard physical effort and make you breathe much harder than normal. Think only about those physical activities that you did for at least 10 minutes at a time.

1. During the last 7 days, on how many days did you do vigorous physical activities like heavy lifting, digging, aerobics, or fast bicycling?

____ Days per week

☐ No vigorous physical activities → Skip to question 3

2. How much time did you usually spend doing vigorous physical activities on one of those days?

____ Hours per day

____ Minutes per day

☐ Don’t know/Not sure

3. During the last 7 days, on how many days did you do moderate physical activities like carrying light loads, bicycling at a regular pace, or doubles tennis? Do not include walking.

____ Days per week

☐ No moderate physical activities → Skip to question 5
4. How much time did you usually spend doing moderate physical activities on one of those days?

____ Hours per day
____ Minutes per day

☐ Don't know/Not sure

Think about the time you spent walking in the last 7 days. This includes at work and at home, walking to travel from place to place, and any other walking that you have done solely for recreation, sport, exercise, or leisure.

5. During the last 7 days, on how many days did you walk for at least 10 minutes at a time?

____ Days per week

☐ No walking → Skip to question 7

6. How much time did you usually spend walking on one of those days?

____ Hours per day
____ Minutes per day

☐ Don't know/Not sure

The last question is about the time you spent sitting on weekdays during the last 7 days. Include time spent at work, at home, while doing course work and during leisure time. This may include time spent sitting at a desk, visiting friends, reading, or sitting or lying down to watch television.

7. During the last 7 days, how much time did you spend sitting on a week day?

____ Hours per day
____ Minutes per day

☐ Don't know/Not sure

This is the end of the questionnaire, thank you for participating.
Appendix F: Demographic & Data Collection Form

<table>
<thead>
<tr>
<th>Subject ID:</th>
<th>Date:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age:</td>
<td>Biological Sex:</td>
</tr>
<tr>
<td>Height (cm):</td>
<td>Body Mass (kg):</td>
</tr>
<tr>
<td>Dominant Kick Leg:</td>
<td>(Right / Left)</td>
</tr>
<tr>
<td>Use of foot orthotics:</td>
<td>(Yes / No)</td>
</tr>
<tr>
<td>-Type of foot orthotic:</td>
<td></td>
</tr>
</tbody>
</table>

*For use by investigators only

**Baseline Screening:**
- No Motion Guidance, Barefoot, Verbal Script Instructions
  - No demonstration or comments aside from what constitutes a successful trial
- 1 Trial = 5 Consecutive Single-Leg Squat repetitions

Practice Trials: _________ (# of Practice Repetitions / Trials)
Data Trials: _________ 5 Consecutive SLS
MKD Present in 3/5: (YES / NO)
Fatigue: _________

**Internal Focus of Attention:**
- Motion Guidance, Laser Off, Barefoot, Verbal Script for Instructions
Fatigue: _________

**External Focus of Attention:**
- Motion Guidance, Laser On, Barefoot, Verbal Script for Instructions
Fatigue: _________
Appendix G: Fatigue Visual Analogue Scale

Subject ID: __________

Condition 1 (Internal Focus): _____

Condition 2 (External Focus): _____
Appendix H: Verbal Instructions Scripts

Once you have completed the initial paperwork, you will be given verbal instructions on what to expect for the remaining tasks included in study. These instructions include:

**Screening Procedures:**

“Align the big toe of your right/left (dominant) leg on the center line of the mat and keep both arms straight out in front of you so that they are parallel to the floor. Lift your right/left (non-dominant) leg in front of you at least 6 inches off the ground. You are going to squat down as far as you are comfortable, but you must reach at least 60
degrees of knee flexion. You will squat down for two beats of the metronome and then return to the start position for two beats of the metronome. You will pause for one beat at the top and repeat the same single-leg squat cadence. You will perform a total of 5 consecutive squats to the beat of the metronome. If you touch down with the non-dominant foot, lift your heel off the ground or touch your legs together, we will discontinue that trial and repeat another in its' place. You can start any time after I say 'get set… go ahead.'

**Internal Focus of Attention Instructions: (condition A)**
- Read prior to practice trials and data collection trials
- 3 minutes of rest in between each of the practice and data collection trials

"I want you perform the squat the same way you did in the first trial but this time focus on keeping your knee in line with your foot."

**External Focus of Attention Instructions: (condition B)**
- Read prior to practice trials and data collection trials
- 3 minutes of rest in between each the practice and data collection trials

"I want you to perform the squat the same way that you did in the first trial but this time I want you to focus on keeping the laser on the line."
Appendix I: Motion Guidance Laser Feedback System Images

Figure 1. Motion Guidance Clinician Kit, including the green laser, mount, and hygienic strap to secure the laser to the participant

Figure 2. Motion Guidance 3’ x 5’ Tracking Grid
Appendix J: Condition Check

Subject ID: __________

Internal Focus of Attention (Laser Off):

1) What were you focusing on during the last trials?

2) Did the instructions make the task seem easier or more challenging?

Reminders: Participants receive 5-minutes rest in between conditions. Perform Visual Analogue Fatigue Scale.

External Focus of Attention (Laser On):

1) What were you focusing on during the last trials?

2) Did the instructions make the task seem easier or more challenging?