Consent Form for Participation in The Effect of Prophylactic Devices and Fatigue on Neuromuscular Balance

Department of Health, Physical Education, and Recreation

Texas State University

IRB Approval #:

The principal investigator is Alanna Shay. The researcher can be contacted by email: [as1673@txstate.edu](mailto:as1673@txstate.edu), or phone: 512-245-9282.

INTRODUCTION AND PURPOSE OF THE STUDY

You have been asked to participate in a research study to assess your postural control after fatigue with various prophylactic measures. You will be chosen based on completion of the initial pre-participation questionnaire admitting no previous injuries to the lower extremity in the past year. The investigation will help to determine if prophylactic devices help to maintain balance after lower extremity neuromuscular fatigue.

You will be evaluated in the Athletic Training Research Lab at Texas State University in the Jowers building, room D108. The following form includes more details regarding the research. If you have any questions or concerns about the study, please ask before you decide to participate.

PROCEDURES

Each subject will be instructed to wear athletic clothing, including a t-shirt, gym shorts, tennis shoes, and socks. Workout clothing is necessary for the completion of the fatigue protocol and balance measurement. The following are the procedures for the study which will take approximately 30 minutes to complete:

1. Pre-participation information: Subjects will complete a pre-participation questionnaire with 20 questions as well as a brief orthopedic assessment to get general joint range of motion by a certified athletic trainer.
2. Control/treatment: The subjects will be asked to either remove their shoes for a barefoot assessment or allow a certified athletic trainer to apply ankle tape or ankle braces to their ankles.
3. NeuroCom: The subjects will be fitted for a safety harness and will step onto the NeuroCom force plate in order to complete a baseline balance measurement.
4. Biodex set up: The subjects will then sit in the Biodex chair to allow the principle investigator to set up the lever arms at the appropriate area to allow the patient to plantar flex and dorsiflex their foot.
5. Warm up: Prior to testing for the fatigue protocol, subjects will complete a 5 minute warm up on the Stairclimber and 3 minute warm up with jump rope.
6. Biodex: The subjects will complete the fatigue protocol on the Biodex. Both ankles will be tested for plantar flexion and dorsiflexion. The principle investigator will instruct the subject on how to use the machine to achieve muscle fatigue.
7. NeuroCom: Immediately after the fatigue protocol, the subjects will be asked to step on the NeuroCom force plate in order to test for balance. Once testing is completed, they may remove the safety harness.
8. Cool Down: Once the testing is completed, the subjects will be asked to step on the treadmill for a 5 minute cool down, followed by calf stretching on a slant board.

POTENTIAL RISKS AND DISCOMFORTS

Subjects will be informed about the nature of what is involved as a participant of this study, including a description of anything they might consider to be unpleasant or a risk. The potential risks for this experiment are minimal because the subjects will be supervised by the principal investigator during the duration of the study; however, with any exercise, there are potential risks for injury. Minor discomforts may be experienced due to the fatigue phase of the experiment. Risks will be minimized by warming up prior to the fatigue protocol.

If an emergency occurs during testing, the subjects will be instructed to exit the building immediately. If it is a medical emergency, then emergency services will be contacted. The primary investigator is Professional Rescuer Certified and will assist with all emergency situations until EMS arrives on the scene.

POSSIBLE BENEFITS

The benefits from this investigation will provide information for the athletic and medical community. Also, the results from this investigation may help you learn about:

* Your overall balance
* Your fatigue level of your lower extremity
* Body movement deficits

CONFIDENTIALITY

Each subject in this study will be issued a number to differentiate the results found between subjects and to maintain the confidentiality of the subject’s information and results. Name, social security numbers, telephone numbers, and address are not required for testing; however, name and phone number are required for this form. Results from the study may be shared for future research except for the consent forms. If consent from material is needed for research purposes, then the subjects will be contacted for additional written consent for release of their information. All data from the research will be kept in the primary investigator’s office.

PARTICIPATION

Your participation in this study is voluntary; you may decline to participate without penalty. If you decide to participate, you may withdraw from the study at anytime without penalty and without loss of benefits to which you are otherwise entitled. If you withdraw from the study before data collection is completed, your data will be returned to you or destroyed. If you have any other questions regarding the research, research participants’ rights, and or research-related injuries to participants, please contact the IRB chair, Dr. Jon Lasser, (512)245-3413, [lasser@txstate.edu](mailto:lasser@txstate.edu) or Ms. Becky Northcut, Compliance Specialist, (512)245-2102.

AUTHORIZATION

The Athletic Training Program supports the practice of protection for human subjects participating in this research and related activities. The consent form is provided so that you can decide whether you wish to participate in the present study.

“I have read the above statement and have been fully advised of the procedures to be used in this project. I have been given sufficient opportunity to ask any questions I had concerning the procedures and know that I am free to ask questions as they may arise. I likewise understand that I can withdraw from the study at any time without being subjected to reproach.”

Contact Alanna Shay, Principle Investigator, at (512)245-9282 or email at [as1673@txstate.edu](mailto:as1673@txstate.edu) if you have any questions.

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Participant Name Printed (18 yrs or older) Phone #

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Signature Date

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Principle Investigator Signature