**Consent Form**

**IRB Project #:** 2010N8777

**TITLE:** The Influence of Vestibular-Ocular Reflex Training on Static and Dynamic Postural Stability in Subjects with Chronic Ankle Instability

**PRINCIPAL INVESTIGATORS:**

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**PURPOSE:** You have been invited to participate in a research study because you have sprained your ankle on several occasions, and have an orthopedic condition defined “chronic ankle instability.” The purpose of this study is to compare the ability of two rehabilitation protocols to improve functional stability in persons with chronic ankle instability. At the beginning and end of the study, we will use computerized devices to measure your ability to balance and maintain postural stability.

**PROCEDURES:**

You were invited to participate in this research study because you responded to the flier that asked if you have ever had the “feeling of giving way” in one of your ankles, which usually signifies chronic ankle instability. If you decide to participate in this study, you will be expected to participate in 14 experimental sessions (“visits”) over a period of five weeks.

**Visit 1 – Screening and Baseline Testing**

Prior to any procedures, you will be asked to sign a consent form after all your questions about this study have been answered. You will be given a copy of the consent form for your records. To determine your eligibility for participation in this study, you will be asked to complete a screening questionnaire that includes some basic personal and health information questions. These 12 questions will provide the researchers with information about your sex, age, physical activity level, injury history, and current state of health.

You will also be asked to complete a pencil-and-paper questionnaire known as the Foot and Ankle Ability Measure (FAAM). The FAAM consists of 21 questions that ask you to rate your perceived ability at accomplishing the various tasks listed. These forms will help in determining if you are eligible to participate in this study. You are not required to answer any or all of the questions in either the demographic form or the FAAM. In the next paragraph, sample questions from these two evaluative tools are provided.

*Sample Questions*

Screening Questionnaire:

Have you had a feeling of “giving way” in either ankle in the past six months? Yes 🞏 No 🞏

If “yes”, in which ankle have you experienced “giving way”? Right 🞏 Left 🞏 Both 🞏

FAAM Questionnaire:

No Slight Moderate Extreme Unable N/A

Difficulty Difficulty Difficulty Difficulty to do

Walking on even

Ground without shoes 􀀀 􀀀 􀀀 􀀀 􀀀 􀀀

Once it is determined that you are eligible to participate in this study, you will be asked to perform four baseline tests on computerized devices used to measure balance, postural stability and vision accuracy. This research equipment is located in Jowers Center and the Health Professions Building at Texas State University. The baseline testing will last approximately 45 minutes.

**Visits 2 through 13 – Ankle Rehabilitation Program Sessions**

After completion of your baseline testing, you will be randomly assigned to 1 of 2 ankle rehabilitation program groups. Each program is 4 weeks in length. One of the researchers will contact you to arrange a schedule for the days and times of your 12 sessions. You will be expected to come to the End Zone Complex at Bobcat Stadium at Texas State University 3 times a week for 4 weeks (total = 12 visits)and participate in a 20-30 minute ankle rehabilitation protocol. You will be asked to perform three different tasks during the individual sessions. Some of the rehabilitation program tasks are experimental and may require head movement while performing an exercise.

**Visit 14 – Post-testing**

After your 4-week rehabilitation program is over, you will once again be asked to perform the original four baseline tests of balance, postural stability and vision accuracy at Jowers Center and the Health Professions Building. These final tests will take approximately 45 minutes to complete.

At any time during the study, you have the option of not continuing with your participation without any fears of repercussion. Whether you choose to participate or not you will be given a home rehabilitation program and an elastic resistance band (Theraband™) to help assist you in ankle strengthening exercises. If requested, you will be provided with the results of the study upon its completion.

Your total time commitment to this study will be approximately 6 to 8 hours over a 5 week period. To summarize, there are 14 total visits: a screening/baseline testing session (1 hour), 12 20 to 30 minute rehabilitation sessions over a 4-week period (4 to 6 hours total), and one post-testing session (45 minutes).

**POTENTIAL RISKS AND DISCOMFORTS:**

There are a few minor risks or possible discomforts associated with this study. There is a small chance that you may lose balance during the testing or rehabilitation exercises and fall. You may also experience some pain and/or some minor swelling in your ankle. If at any time you feel uncomfortable during the exercises, please do not hesitate to inform the researchers and we will end that session. You may withdraw from the study at any point with no fear of any repercussions from faculty and staff. If you withdraw due to injury we will provide first aid and assist you in contacting the appropriate medical personnel. Any costs of medical treatment that you may need are not covered by the researchers or by any other member of the Texas State University System.

**POSSIBLE BENEFITS:**

By participating in this study you will receive instructions for a home ankle rehabilitation program and an elastic resistance band (Theraband™) to help you improve your level of ankle muscle strength and function. In addition, the exercise program sessions you will be performing are designed to help you improve your daily functional level.

**AVAILABLE TREATMENT ALTERNATIVES:**

There are several physical therapy clinics and related medical facilities in the San Marcos area where you can engage in an ankle rehabilitation program similar to those offered through participation in this study. If you have medical insurance, it is likely that a significant percentage of the costs of this type of program administered by a physical therapist will be reimbursed.

**COMPENSATION/INCENTIVES:**

All participants in this study, including those who withdraw, will be given a home ankle injury rehabilitation program and an elastic resistance band (Theraband™) for use with the home based rehabilitation program.

**CONFIDENTIALITY:**

Your participation in this study is completely confidential. Only the principal investigators will have access to your personal identifiers and to any information that may be linked with your identity. All information that you complete will have an identification number rather than your name to ensure your confidentiality. All data will be stored in a locked cabinet in the Athletic Training Research Laboratory and destroyed after five years. If the results of this study are published, none of your personal identifying information will be disclosed.

**REQUEST FOR FURTHER INFORMATION:**

Please discuss or express any concerns or questions regarding this study with the investigators at any time. You should feel confident and secure about your involvement in this study. You may also contact the IRB chairperson Dr. Jon Lasser at 512-245-3413.

**DISCLOSURE AND FUNDING:**

The researchers have no financial or other potential conflict of interest in performing this project. Summary findings will be provided to the participants upon request.

**AVAILABLE SOURCES OF INFORMATION:**

***For questions about this study call:***

Study Coordinator: Dr. Rod A. Harter Graduate Student Researcher: Jessica Hilgendorf

Phone Number: (512) 245-2972 Phone Number: (512) 618-2141

***For questions you may have about your rights as a research subject call:***

Institutional Review Board Chair: Dr. Jon Lasser Compliance Specialist: Ms. Becky Northcut

Phone Number: (512) 245-3413 Phone Number: (512) 245-2102

**AUTHORIZATION:**

“I have read and understand this consent form, and I agree to participate in this research study. I understand that I will receive a copy of this form. I voluntarily choose to participate, but I understand that my consent does not take away any legal rights in the case of negligence or other legal fault of anyone who is involved in this study. I further understand that nothing in this consent form is intended to replace any applicable Federal, state or local laws. I also understand that I may withdraw from this study at any time without penalty.”

Name of Participant (Printed): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of Participant: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of person obtaining consent: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Study Coordinator (Signature):\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_