THE INFLUENCE OF VESTIBULAR-OCULAR REFLEX TRAINING ON STATIC AND DYNAMIC POSTURAL STABILITY IN SUBJECTS WITH CHRONIC ANKLE INSTABILITY

1. **Identify the sources of the potential subjects, derived materials or data. Describe the characteristics of the subject population, such as their anticipated number, age, sex, ethnic background, and state of health. Identify the criteria for inclusion or exclusion. Explain the rationale for the use of special classes of subjects, such as fetuses, pregnant women, children, institutionalized mentally disabled, prisoners, or others, especially those whose ability to give voluntary informed consent may be in question.**

Participants will be 24 physically active adult volunteers between the ages of 18 to35 years of age. These volunteers will be Texas State University- San Marcos collegiate athletes, intramural athletes, students enrolled in personal fitness and wellness course, or students who use the student recreational center.

**Inclusion Criteria:**

Participants will be: physically active as defined by the American Heart Association guidelines (performing exercise at moderate and/or vigorous intensity for at least 30 minutes per day, 4-5 days per week, and the bouts of exercise must last at least 10 minutes at a time). Subjects will be 18 to 35 years old and have a history of chronic ankle instability which consists of self reports of giving way and having at least 2 lateral ankle sprains in the past.

Participants will have had no other lower extremity injury in the past six months and be symptom free from any previous injury for at least six months. Participants must also be free from any head injury in the past year and sign an informed consent form.

**Exclusion Criteria:**

Potential participants will be excluded if they do not have a contralateral normal limb to use as a control or if they have had an ankle sprain in the past two weeks.

**2. Describe the procedures for recruitment of subjects and the consent procedures to be followed. Include the circumstances under which consent will be solicited and obtained, who will seek it, the nature of information to be provided to prospective subjects, and the methods of documenting consent. (Include applicable consent form(s) for review.) If written consent is not to be obtained, this should be clearly stated and justified.**

Subject recruitment will take place on the Texas State University-San Marcos campus. Participants will be intercollegiate athletes, intramural athletes, recreation sports athletes, or physical activity course students. Recruitment will be completed by the principal investigator via pre-approved flyers and announcements (see attached), and word of mouth. No coercion tactics will be used by the principal investigator during the recruitment of potential participants. All potential participants interested in participating in the study will be required to contact the principal investigator to set up a time to meet at the EndZone Athletic Training Room to complete the IRB approved consent form. The potential participants will be given time to read through all of the material, ask questions if needed, and consent to participation in the study. Two copies of the consent form will be signed; one will be given to the participant; while the other will be kept in the principal investigator’s locked office for a seven year period. The potential participants will be asked to answer a brief questionnaire to ensure that they meet all inclusion and exclusion criteria (see attached).

**3. Describe the project’s methodology in detail. If applicable, detail the data collection procedures, the testing instruments, the intervention (s), etc. If using a survey, questionnaire, or interview, please provide a copy of the items or questions.**

After consent has been obtained participants will be given an ID number to ensure confidentiality. Participants will complete a self-report demographic form to ensure each participant will meet the inclusion criteria. The self-reported demographic survey will consist of questions regarding history of injury and other general health questions. Potential participants will also be required to fill out the Foot and Ankle Ability Measure (FAAM) questionnaire to help determine the functional limitations of a subject’s ankle. Participants must also self-report no neurological symptoms, no vestibular problems, no ear infections, and no lower extremity injury.

Once inclusion criteria has been met the participant will be randomly allocated to one of two groups: Typical Balance Protocol Group and vestibular-ocular reflex (VOR) Protocol Group and will be asked to schedule times where they can be tested on the NeuroCom, Biodex, and inVision systems. Each participant’s order of tests will be randomly assigned. They will be asked to perform the Motor Control Test on the NeuroCom SmartEquiTest, the Unilateral Stance test on the NeuroCom’s Long Force Plate, the Athlete Single Leg Stability Test on the Biodex, and the Dynamic Visual Acuity Test on the inVision system.

After baseline data is collected from the above four tests the participant can start their four week, three sessions per week protocol of exercises that include: single limb stance, single limb hop to stabilization, and unanticipated hop to stabilization. Each group will utilize the same set of exercises, but the VOR protocol group will also incorporate side-to-side rotational head movement at the paces of 60 bpm in Week 1, 80 bpm in Week 2, 100 bpm in Week 3, and 120 bpm in Week 4. After the four week intervention is over, participants will be asked to take the four original tests again to gather comparative data.

**What follows is a description of all the tests used in this research project:**

**Foot and Ankle Ability Measure (FAAM)**

The FAAM is a valid and reliable self-report measure that can give feedback on a person’s lower leg functionality. The questionnaire is based on a Likert scale and asks about activities of daily living and sports related activities.

**General Demographic and Health Questionnaire**

This questionnaire will help determine who will meet inclusion criteria into the study. Questions will ask basic demographic questions and questions about past injury, chronic ankle instability, and history of any vestibular issues.

**Single Limb Stance**

Subjects will be asked to focus on a specific point on the wall while balancing on a single limb. Three repetitions will be performed with eyes open on both limbs. Each limb will be progressed individually and will only be progressed if the subject can perform two sets of three repetitions on a single limb error free to be progressed to the next level. The VOR protocol group will include the head movement while performing the task.

**Single Limb Hop to Stabilization**

Subjects will be asked to hop one-legged from the starting position to the target position. Once the subject is stabilized they must hop back to the beginning the same way they came from. Subjects will perform five repetitions for each limb in the following directions: anterior/posterior, medial/lateral, anteromedial/posterolateral, and posteriormedial/anterolateral. Subjects must perform two sets of five repetitions in each direction error free before advancing to the next level for that limb. The VOR protocol group will include the right and left rotational head movement while performing the task.

**Unanticipated Hop to Stabilization**

A nine number grid with each number 45.7 cm apart will be placed on the floor. Each square will be 20.3 x20.3 cm. The grid will be constructed with tape, and measured out using a tape measure. Each session the participant will have to complete two sequences of hops on each leg. Each sequence includes nine numbers to which the subject will be required to hop. The order of the numbers will be randomly selected for each session. Subjects will hop one-legged from the starting position to the target position. Once they subject is stabilized they must hop to the next number in the sequence. The subject can use any sequence of hops to reach the next number. The subject must perform two sets of two sequences of numbers error free and in the time allowed to progress to the next level. Each limb is progressed independently of the other. The VOR protocol group will incorporate the head movement while performing the exercises.

**5. Describe the procedures for protecting against or minimizing any potential risks and include an assessment of the likely effectiveness of those procedures. Include a discussion of confidentiality safeguards, where relevant, and arrangements for providing mental health or medical treatment, if needed.**

The inclusion and exclusion criteria for this study will help to minimize the potential risks in this study. Participants that are physically active, free from concussion or vestibular problems, and free from any other lower extremity injury are unlikely to fall during the Single Limb Stance, Single Limb Hop to Stabilization, and Unanticipated Hop to Stabilization exercises. In addition, participants who pass the screening process, but feel uncomfortable at any point during the testing are free to withdraw from the study. The safety of the participants is more important than the completion of the tests. All steps have been taken in the creation of the inclusion and exclusion criteria to help minimize the potential for injury to the participants.

Participant confidentiality will be ensured by having all consent and screening forms kept in a locked filing cabinet in the Athletic Training Research Laboratory in Jowers Center.. Data collected will be identified by participant ID rather than participant names and kept in a password-protected file on the data collection computer housed in the Athletic Training Research Laboratory. Following data analysis, the information will be removed from the computer and placed with the previously collected information.

In the event that a participant is injured during the activities associated with this study, medical treatment will be limited to first aid and ice. Participants will also be instructed on the RICE (rest, ice, compression and elevation) principle and given contact information for the Texas State University Student Health Center in the case that further medical attention is needed.

**6. Describe and assess the potential benefits to be gained by the subjects, as well as the benefits that may accrue to society in general as a result of the proposed study.**

Volunteers who qualify for the study and choose to participate will be provided with exercises that will help with strengthening their ankle muscles. All subjects will be given an elastic resistance band (Theraband ™) at the end of the study, so that they can use it to aid them in the continuation of a program to strengthening the ankle muscles.

The benefits to society will be mostly to clinicians in athletic training and related fields. From this study, a better idea of whether head movement needs to be incorporated in a standard lower extremity rehabilitation protocol will be shown. This information will directly impact the effectiveness of lower extremity rehabilitation protocols.

**7. Clearly describe any compensation to be offered/provided to the participants. If extra credit is provided as an incentive, include the percentage of extra credit in relation to the total points offered in the class. Also, if extra credit is provided, describe alternatives to participation in your research for earning extra credit.**

Compensation for participation in the study will include home rehabilitation exercises and an elastic resistance band (Theraband™) for the use in the home rehabilitation program.

**8. Discuss the risks in relation to the anticipated benefits to the subjects and society.**

The risks are minimal to participants in this study. The exercises used in the protocol should not be risky for the physically active participants that are required for this study. People with chronic ankle instability will have similar chances of hurting themselves walking around normally as they would participate in the study. The potential benefit is to see if incorporating head movement within a regular balance protocol is more effective than the traditional balance protocol, and in turn would help patients get better faster.

**9. Identify the specific sites/agencies to be used as well as approval status. Include copies of approval letters from agencies to be used (note: these are required for final approval). If they are not available at the time of IRB review, approval of the proposal will be contingent upon their receipt.**

All data collection will take place at the EndZone complex, Jowers Center, and the Health Professionals building. No agencies or sites outside of Texas State University will be used for subject recruitment and data collection.

**10.** **If you are a student, indicate the relationship of the proposal to your program of work and identify your supervising/sponsor faculty member.**

My thesis advisor, Dr. Rod Harter, is a Professor of Athletic Training at Texas State University, where I am a current graduate student in the Master of Science degree program in Athletic Training.

**11.** **In the case of student projects, pilot studies, theses, or dissertations, evidence of approval of Supervising Professor or Faculty Sponsor should be included. Thesis and dissertation proposals must be approved by the student’s committee before proceeding to the IRB for review.**

Please see attached approval form.

**12. If the proposed study has been approved by another IRB, attach a copy of the letter verifying approval/disapproval and any related correspondence. If the proposed study has not been reviewed/approved by another IRB, please state this explicitly.**

The proposed study has not been reviewed or approved by another IRB.

**13. Identify all individuals who will have access, during or after completion, to the results of this study, whether they will be published or unpublished.**

All interested individuals or groups may contact the principal investigators for results of the study. No persons, except the principal investigators, will have access to the raw data or personal indentifying information.

**In addition to this synopsis, you are required to submit all relevant documentation for review. This may include, but is not necessarily limited to: 1) recruiting documents (e.g., flyers, letter, e-mails, brochures, etc.), 2) a consent form, 3) an assent form, 4) letters of approval from relevant organization(s), 5) surveys/instruments/questionnaires, esp. those created by the researcher, 6) a list of questions that the researcher may ask (e.g., focus groups questions, questions for qualitative studies, etc.), and 7) all documents in translated versions.**