



Department of Kinesiology  
9201 University City Blvd  
Charlotte, NC 28223

## **Informed Consent for Comparative Effectiveness of Massage on Postural Control in those with CAI**

### **Project Title and Purpose**

You are invited to participate in a research study entitled **Comparative Effectiveness of Massage on Postural Control in those with CAI**. This is a study to examine the effects of three different types of single massage treatment sessions on balance. Specifically, the types of massage will include a traditional massage given by an investigator, a massage self-delivered via a massage ball, and a sensory massage given with a sensory brush. We will be measuring your balance before and after each of these 3 independent treatment sessions. These assessments will help us understand how different massage techniques compare to each other with regards to improving balance. If you agree to participate in this investigation, you will be one of 21 participants.

### **Investigator(s)**

This study is being conducted by Dr. Erik Wikstrom, Associate professor in the department of Kinesiology. He can be contacted via phone: 704-687-0871, or [ewikstrom@uncc.edu](mailto:ewikstrom@uncc.edu).

### **Eligibility**

You may participate in this project if you are between the ages of 18 and 45 with self-reported chronic ankle instability (CAI). CAI is defined as self-reported episodes of recurrent ankle sprains and/or the feeling of instability or “giving way” after an initial ankle sprain. You must also have a history of at least two episodes of “giving way” within the past 6 months and meet specific criteria/scores on the Ankle Instability Instrument (AII), the Foot and Ankle Ability Measure (FAAM), and the FAAM Sport. You must meet all of the above criteria to be eligible for the study.

You should not participate in this study if you are younger than 18 or older than 45. Also, you should not participate if you have diabetes, vertigo, or a condition that has affected your ability to balance on one leg other than an ankle sprain. You should not participate in this study if you have ever had surgery on musculoskeletal structures of either leg or a fracture to either leg that required realignment. You should not participate if you sprained your ankle less than 6 weeks ago.

### **Overall Description of Participation**

You have been found to be eligible for this investigation. After reading and signing this form, we will collection general information regarding age, height, leg length, foot measurements, and weight. Next, we will gather further information about your history of ankle sprains and physical activity levels before completing a series of baseline tests (descriptions are below). After the baseline tests, you will receive the first massage treatment (described below). After completing the massage treatment, a series of post-tests will be completed. The post-tests will be identical to the baseline tests except for the ligament tests described below.. All sessions will last about 20-30 minutes.

## Assessments

**Ligament tests:** Because each ankle sprain is slightly different, we will perform two standard assessment tests to quantify the damage to your ankle ligaments (structures that are injured when you sprain your ankle). For both tests, you will be seated on the edge of a table with your knees hanging in a relaxed position. The researcher will firmly grasp your foot in one hand and your lower leg in their other hand. For the first test, the researcher will pull your foot forward (while keeping your leg still) and feel how “loose” your ankle ligaments are. For the second test, the researcher will pull your foot inward (while keeping your leg still) and feel how “loose” your ankle ligaments are. Neither test should hurt or cause pain and are standard tests done to assess ankle injuries.

**Static Postural Control Assessment:** You will stand on one leg on a forceplate with your hands on your hips and your opposite foot held above the forceplate for ten seconds with your eyes open. We will do this test 6 times, 3 times per leg. If, during a trial, you touch down with your opposite limb or have to use your arms to maintain balance, the trial will be stopped and repeated.

**Dynamic Postural Control Assessment:** You will complete a test called the Star Excursion Balance Test (SEBT). Specifically you will reach with one leg while balancing on the other in three directions: front, back-right, and back-left. We will do this 3 times per leg. You will start by standing in the center of a Y-pattern before reaching for and touching the furthest point possible in each of the three directions. You will touch the floor with the most distal part of your reach foot and should keep all of your weight on your stance leg. You will then return to the start position. To normalize reach distances between people of different heights, we will measure the length of your legs with a tape measure (distance from the anterior superior iliac spine [front of pelvic bone] to the medial malleolus [bump on inside of ankle] on the same leg).

**Cutaneous Sensation Measurement:** You will lie on a table and we will use a set of Semmes-Weinstein monofilaments (thin pieces of plastic) to determine how sensitive 3 parts of your foot are (head of the first metatarsal [just below your big toe], base of the fifth metatarsal [outside of the middle portion of your foot], and the heel). During the test, you will be asked to keep your eyes closed while we apply the monofilament tip to your skin. You will then be asked whether or not you can feel the monofilament. We start with the smallest monofilament and continue until you can feel one. This process will be repeated for each of the above mentioned points on your foot.

## Treatments

The traditional plantar foot massage treatment will consist of 1, 5 minute plantar foot massage. This massage will consist of kneading and gentle stroking of the skin and muscles on the bottom of your foot from the ball of the foot to the heel. During this treatment, the investigator will massage with their thumbs and grasp your foot with their fingers to maintain contact while you lie on your back.

The ball massage will consist of 1, 5 minute plantar foot massage that is self-delivered. You will place your foot on top of a massage ball (ball with small rubber bumps all over it) and move your foot around so that you get a massage over the entire bottom surface of your foot. You will be seated comfortably during this treatment.

The sensory massage will consist of 1, 5 minute massage using a sensory brush. You will lie on your back, we will gently stroke the brush over the bottom of the foot (imagine a motion similar to painting or brushing hair). This technique will feel “light” and may tickle.

After each treatment, you will complete another set of assessments as described above.

**Length of Participation**

You will complete 3 test sessions. Each test session takes about 20-30 minutes for a total time commitment of 60-90 minutes. Each session will be completed at least a week apart.

**Risks and Benefits of Participation**

There are no known risks to participating in this study. However, there may be risks which are currently unforeseeable. In an effort to minimize any possible risk, all members of the investigative team are current in CPR and first aid. Additionally, medical supplies are available to treat minor musculoskeletal injuries if they were to occur and the evaluation and treatment of such injuries is within the scope of practice for first aiders.

The benefits of participation in this study are unknown. There is the possibility that undergoing one of the massage treatments may improve your balance but it is unknown how long these benefits will last.

**Possible Injury Statement**

If you are hurt during this study, we will make sure you get the medical treatment you need for your injuries. However, the university will not pay for the medical treatment or repay you for those expenses.

**Volunteer Statement**

You are a volunteer. The decision to participate in this study is completely up to you. If you decide to be in the study, you may stop at any time. You will not be treated any differently if you decide not to participate in the study or if you stop once you have started.

**Confidentiality Statement**

Any information about your participation, including your identity, is completely confidential. The following steps will be taken to ensure this confidentiality: You will be coded upon entry into the investigation and the master sheet (connecting your name and code number) will be stored on a password protected computer in the primary investigator's office. Coded data sheets will be kept in a locked filing cabinet in the same office. All electronic files will only use coded data and will also be kept on the password protected computer in a separate folder. All documents and data collected from participants in this study will be retained for three years in a secure location.

**Statement of Fair Treatment and Respect**

UNC Charlotte wants to make sure that you are treated in a fair and respectful manner. Contact the university's Research Compliance Office (704-687-3309) if you have questions about how you are treated as a study participant. If you have any questions about the actual project or study, please contact Dr. Erik Wikstrom (704-687-0871, ewikstrom@uncc.edu)"

**Approval Date**

This form was approved for use on 8-20-2014 for use for one year.

**Participant Consent**

I have read the information in this consent form. I have had the chance to ask questions about this study, and those questions have been answered to my satisfaction. I am at least 18 years of age, and I agree to participate in this research project. I understand that I will receive a copy of this form after it has been signed by me and the principal investigator of this research study.

\_\_\_\_\_  
Participant Name (PRINT) \_\_\_\_\_  
DATE

\_\_\_\_\_  
Participant Signature

\_\_\_\_\_  
Investigator Signature \_\_\_\_\_  
DATE