



Department of Kinesiology
9201 University City Blvd
Charlotte, NC 28223

Informed Assent / Consent for Charlotte Ankle Sprain Tracking Study (CASTS)

Project Title and Purpose

You are invited to participate in a research study entitled **Charlotte Ankle Sprain Tracking Study (CASTS)**. This is a study to examine the healing process in people who have an ankle sprain. Specifically, we want to better understand how long it takes for the ligaments and neuromuscular control to be restored after an acute ankle sprain. To do this, we will measure the amount of movement in the ankles and how well the nervous and musculoskeletal systems work together in a group of healthy individuals and compare that information to individuals who have sprained their ankle. If you have sprained your ankle, we would repeat the same measurements over time (12 months) to learn more about the healing process. Studying how these systems recover after an ankle sprain will help us develop better treatment programs. You will be one of 72 participating in this study.

Investigator(s)

This study is being conducted by two investigators from the Department of Kinesiology. Dr. Erik Wikstrom is an assistant professor and can be contacted via phone: 704-687-0871, or ewikstrom@uncc.edu. Dr. Tricia Hubbard-Turner is an associate professor and can be contacted via phone: 704-687-0868 or thubbar1@uncc.edu.

Eligibility

To be included in the proposed investigation as an ankle sprain participant the following criteria must be met: 1) be between the ages of 16 and 50, 2) have a first time ankle sprain or first repetition of an ankle sprain more than 1 year after the last sprain, and 3) have the ankle sprain occur within the past 72-hours. You cannot participate as an ankle sprain participants if you have chronic ankle instability in the involved ankle, a previous history of ankle surgery, fractures of the foot or ankle suffered at the same time as the ankle sprain, or a condition known to affect pain and/or balance.

To be included as a healthy control, you must be between 16 and 50 years of age, free from acute lower extremity injuries and concussions for the past 3 months and must not have had any major lower extremity surgeries or any conditions know to effect balance. Additionally, you must be within $\pm 10\%$ of an ankle sprain participant's age, height, weight, physical activity level, and be of the same sex. You cannot participate as a healthy control if you have suffered an acute lower extremity and/or head injury within the past 3 months, suffer from a condition known to affect pain and/or balance, have a chronic musculoskeletal condition (e.g. you have torn your ACL), or have a history of a lateral ankle sprain at any point in their life. You will also be excluded if they are outside of $\pm 10\%$ of an acute LAS participant's age, height, and weight, physical activity level and are not of the same sex of an acute LAS subject.

Overall Description of Participation

At this point, you have been deemed eligible to participate in this investigation. The rest of the study will take place in this location (UNC Charlotte BioDynamics Laboratory). After signing this document, you will complete the first post-injury session where you will have your height, weight, and leg length measured. Measurements of height and leg length will be taken with a tape measure. Your body weight will be measured with a scale. Next you will complete the testing protocol described below.

TESTING PROTOCOL

1. Questionnaires: You will first fill out 6 questionnaires; 2 about your previous history of ankle injuries, 2 about how your ankle feels doing certain activities (walking, running, going up and down stairs) in different ways, and 2 about your physical activity levels. Finally, we will give you a sheet with a list of treatments. You will simply check which treatments you completed to care for your ankle sprain. Completing these questionnaires will only take about 30 minutes. All questionnaires will be repeated.

2. Clinical Assessment: We will perform a clinical exam on your ankle (like what a physician would do) to examine your ankle's range of motion, the amount of swelling you have in your ankle, and determine if you have pain in specific areas of your ankle. To measure range of motion, you will complete a weight bearing lunge test. This test measures the distance that your big toe can be from a wall when your heel is flat on the ground and the knee on the same leg is touching the wall. You will be able to support yourself with your hands (on the wall) and the researchers will demonstrate this procedure before you start. To measure swelling we will use a tape measure. We will do this 3 times. Specifically, we will wrap the tape measure around your ankle in a figure-8 pattern. We will also touch specific areas of your ankle and simply ask if touching that area causes pain. We will also perform 5 special tests to determine how severe your ankle sprain is. To do these tests, you will sit on a table and the researchers will hold your ankle in one hand and your lower leg in the other hand. Then your ankle will be moved in different directions (pulled forward, rotated inward, rotated outward, pushed towards the inside of your foot, and pulled up). During these tests, we are looking for the looseness of your ankle and to determine if any of these tests cause pain. The results will let us know what structures are damaged. This will take 10 minutes or less.

4. Mechanical assessment: These tests are similar to the special tests that were performed above. First, we will objectively measure the amount of movement you have in your ankle (laxity) with an ankle measurement system. This system will pull your ankle forward/backward and then turn it inward/outward. During testing your leg and foot will be strapped into this device by the examiner. This will keep your foot still while we pull forward/backward and inward/outward. After your ankle is pulled, the system will give a read out of the amount of looseness in your ankle. Measurements will be taken on just the injured ankle (matched ankle is you are a healthy control). The arthrometer, ankle measurement system, will be shown and further explained after the informed consent form has been signed. The second test will allow the examiner to look at your ankle ligaments using a technology called ultrasound. For this test, we will apply a gel to your ankle before placing a sound head (looks like a giant marker) over your ankle ligaments. The sound head will be moved around to get a picture of your ankle ligament. A picture of your ligament will then be taken and used to measure the thickness of your ankle ligament. This will take about 20 minutes.

5. Balance assessments: To examine your balance, you will be asked to complete 5 different tests. You will be barefoot for all of the tests. The first test will require you to stand on one leg on the force plate for 10 seconds. You will do this three times with your eyes open. If you touch the ground with your other foot while balancing, the trial will be stopped and repeated. The second test requires you to stand on one leg with your eyes closed for as long as you can (max of 60 seconds). As soon as you make an "error" the examiner will record the time and have you stop. The third test also requires you to stand on a single leg with your eyes closed. This test will be 30 seconds long and the examiner will count the number of "errors" you make in a 30-second time frame. The fourth test will require you to stand on a single leg with your eyes open. For this test, you will keep your balance while reaching as far as you can in 3 directions with your other leg. Finally, we will have you walk 15 feet while we record how fast you walk and the distance of your steps. We will also have video cameras recording how you walk during this test. Each of the above mentioned tests will be performed 3 times. You will only complete the balance activities if you can bear your full weight.

If you indicate that you are in too much pain or discomfort to participate in these activities, then you have 2 options. You can 1) withdraw from the study immediately with no consequences or repercussions, or 2) continue in the study by completing tests that you do feel comfortable with (on the day in question) and then reporting to the next scheduled test session where the study would continue as planned. If your pain levels remain high, an identical protocol would be followed for the next test session. These tests should take no more than 20 minutes to complete. If you sprain your ankle again, while completing this investigation, you will be withdrawn from the study.

Length of Participation

The basic duration of the study is outlined below. The test sessions and data collection procedures are listed below. Each test session is thought to take about 80 minutes.

<u>Time</u>	<u>Data Collection Procedures</u>
w/in 72 hours of injury	Clinical, mechanical, and sensorimotor outcomes*
1-week after injury#	Questionnaires, clinical, mechanical, and sensorimotor outcomes*
2-weeks after injury#	Questionnaires, clinical, mechanical, and sensorimotor outcomes*
1-month after injury#	Questionnaires, clinical, mechanical, and sensorimotor outcomes*
6-weeks after injury^	Questionnaires, clinical, mechanical, and sensorimotor outcomes*
2-months after injury^	Questionnaires, clinical, mechanical, and sensorimotor outcomes
3-months after injury^	Questionnaires, clinical, mechanical, and sensorimotor outcomes
4-months after injury^	Questionnaires, clinical, mechanical, and sensorimotor outcomes
6-months after injury%	Questionnaires, clinical, mechanical, and sensorimotor outcomes
9-months after injury%	Questionnaires, clinical, mechanical, and sensorimotor outcomes
12-months after injury%	Questionnaires, clinical, mechanical, and sensorimotor outcomes

*Balance will only be tested in the subject has returned to full weight bearing.

Indicates that a 24 hour flexibility window will be allowed to accommodate subject schedules.

^ Indicates that a 48 hour flexibility window will be allowed to accommodate subject schedules.

% Indicates that a 72 hour flexibility window will be allowed to accommodate subject schedules.

If you are a healthy control, you will come in twice and complete the questionnaires, clinical, mechanical, and sensorimotor outcomes. Each session will take about 80 minutes and be separated by at least 1-week.

Risks and Benefits of Participation

There is no risk of injury or other known risks to participation in this study greater than those of daily activity after an ankle sprain. However, there may be risks which are currently unforeseeable. There are no direct benefits to participating in this study. Additionally, medical supplies are available to treat minor musculoskeletal injuries if they were to occur. We are able to compensate you for your time.

If you have an acute ankle sprain, you will be compensated a total of \$195 in Best Buy gift cards.

Distribution of the \$195 will be made in the following sums and at the following times:

- \$10 after the 1-week post injury test session
- \$10 after the 2-week post injury test session
- \$30 after the 4-week post injury test session
- \$10 after the 6-week post injury test session
- \$20 after the 8-week post injury test session
- \$10 after the 12-week post injury test session
- \$30 after the 16-week post injury test session
- \$75 after the 1- year post injury test session

If you are a healthy control, you will be paid \$10 in Best Buy gift cards after your second test session.

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

Confidentiality Statement

Any information about your participation, including your identity, is completely confidential. The following steps will be taken to ensure this confidentiality: All subjects will be coded upon entry into the investigation. The master sheet (listing names with code numbers) will be stored on a password protected computer in the primary investigator's personal office. Coded data sheets will be kept in a locked filing cabinet in the office of the primary investigator. As data sheets are transferred to electronic files for data analysis, the electronic records associated with the investigation will also be coded and de-identified, and kept on the password protected computer in a separate folder/location. All data sheets and individual electronic participant files will be destroyed (hard copies will be shredded, electronic copies deleted) at the conclusion of the investigation. Upon completion of data collection, only completely de-identified summary sheets necessary to calculate group means and conduct subsequent statistical analysis will be maintained.

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 (704-687-1871) 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 Assent / 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 16 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