School of Biological and Population Health Sciences
Oregon State University
101 Milam Hall, Corvallis Oregon 97331-3302

Human Research Protection Program
Oregon State University
Study # 7967
Current Approval: 07/21/2017
Do not use after: 07/20/2018
Approved

CONSENT FORM

Project Title: The Effects of Kinesio Tape® on Arthrogenic Muscle Inhibition and Rate of Torque Development

Principal Investigator: Marc Norcross, PhD, ATC
Student Researcher: Yu-Lun Huang, MSAT, ATC
Co-Investigator(s): Sam Johnson, PhD, ATC, CSCS; Cathleen Brown Crowell, PhD, ATC
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1. WHAT IS THE PURPOSE OF THIS FORM?

This form contains information you will need to help you decide whether to be in this study or not. Please read the form carefully and ask the study team member(s) questions about anything that is not clear.

2. WHY IS THIS STUDY BEING DONE?

The purpose of the study is to investigate the effects of a prolonged application (> 48hours) of Kinesio Tape®- a medical tape commonly used in physical therapy- incorporated with a therapeutic exercise protocol on lower leg function in individuals with functional ankle instability (FAI). After joint injuries, a decrease in muscle function known as arthrogenic muscle inhibition (AMI) can occur which cannot be reduced by traditional rehabilitation such as strength training alone. Since AMI is associated with longer rehabilitation and greater risk of re-injury, there is a need to identify a treatment that can effectively decrease AMI and improve muscle function.

One common intervention that is used to improve muscle function is Kinesio Tape®. However, previous studies that have researched the effects of Kinesio Tape® have studied participants without AMI. They also did not keep the Kinesio Tape® on for more than 1 day or use it while people performed rehabilitation exercises which is different from the way it used in sports medicine settings. Therefore, we will evaluate the effects of prolonged application (> 48hours) of Kinesio Tape® to an inhibited muscle incorporated with an exercise protocol on muscle function and AMI. Up to 70 participants may be invited to take part in this study.

3. WHY AM I BEING INVITED TO TAKE PART IN THIS STUDY?

You are being invited to take part in this study because:

1. You have a history of at least one significant ankle sprain your involved (injured) limb that:
    i. occurred at least 12 months ago
    ii. was associated with inflammatory symptoms like pain and swelling, and

iii. created at least one interrupted day of desired physical activity.

2. The most recent injury on your involved (injured) ankle occurred more than 3 months ago
3. You have a history of your involved (injured) ankle joint 'giving way', and/or recurrent sprain and/or 'feelings of instability' on your involved (injured) limb
4. You have had at least 2 episodes of 'giving way' in the past 6 months
5. 18-35 years of age
6. You have not had a past allergic reaction to Kinesio Tape®
7. You have no history of previous surgeries to the musculoskeletal structures (i.e., bones, joint structures, nerves, etc.) in either lower extremity.
8. You have no history of a fracture in either lower extremity requiring realignment.
9. You have no history of acute injury to the musculoskeletal structures of other joints of either lower extremity in the past 3 months which impacted joint integrity and function (i.e., sprains, fractures) and interrupted your desired physical activity for at least 1 day.
10. You do not have any current symptoms of an acute sprain including swelling, heat, redness, pain, discoloration and/or loss of range of motion or function
11. You do not have any diagnosed vestibular disorder, Charcot-Marie-Tooth disorder, Ehlers-Danlos, or other hereditary nerve, balance, or connective tissue disorder.
12. You report that there is no chance that you might be pregnant
13. You have not had more than one ankle sprain your uninvolved limb
14. You have not had an ankle sprain your uninvolved limb within the past 12 months
15. You do not have episodes of giving way on the uninvolved ankle besides the single time when you may have sprained this ankle

4. WHAT WILL HAPPEN IF I TAKE PART IN THIS RESEARCH STUDY?

Testing will occur in the Women's Building on the campus of Oregon State University. Your involvement will last for approximately 3 hours and 40 minutes spread out over three different visits: 1 hour for Session 1 (in-depth screening and familiarization session), 2 hours for Session 2 (testing and exercise), and about 40 minutes for Session 3 (testing). The following is a brief description of the study procedures:

Session 1:

You will read, discuss, and sign a written consent form. You will then complete a general eligibility questionnaire, an activity level scale, and three questionnaires that will help us to determine if you have functionally ankle instability. We will also perform two ankle ligament tests on each leg to assess whether your ankle ligaments are "loose". If your answers on these forms and the results of our ankle tests determine that you have functional ankle instability in one- but not both- of your ankles, you will

be eligible to continue participating in the study.

We will next have you complete a familiarization session to orient you to the study procedures. During the familiarization, we will position your foot on a machine called a Biodex that measures muscle strength. We will then teach you how to push out with your foot against the footplate when performing fast muscle contractions and slower, gradually increasing muscle contractions. You will practice several times with both legs until you are familiar with the procedures and can perform them correctly. The second part of the familiarization session is that we will play a video to teach you how to perform several different ankle exercises. You will then practice the exercises until you can perform them correctly.

Finally, we will schedule you for the two study testing sessions.

Total time Session 1 = ~60 minutes

Session 2:

We will measure your height and weight without shoes and use a plastic tool similar to a protractor to measure the range of motion of both your ankles. We will then position you on the Biodex and place small electrodes on the lower part of your leg after shaving (if necessary) cleaning your leg. To find the proper position for one of the electrodes, we will apply an electrical stimulus to the nerve on the outside of your lower leg that will feel like a small shock and cause a muscle contraction. We will give you about 5-10 of these small shocks so that we can find the electrode location that causes the strongest contraction. Then, we will mark the location with a permanent marker and tape the electrode in place.

You will then be asked to perform the same fast muscle contractions and slow, gradually increasing muscle contractions on the Biodex that you practiced in Session 1. You will complete 3 good trials for each type of contraction with 60 seconds of rest between trials. Next, we will have you perform some more slow, gradually incresing muscle contractions during which the electrical stimulus will be applied to the nerve on the outside of your lower leg to induce a larger muscle contraction than you can do voluntarily. You will be asked to complete 3 good trials with 60 seconds of rest between trials. Finally, we will repeat the all of the muscle function tests on the opposite leg.

After the measurements are completed, you will be assigned to either a treatment group that will receive Kinesio Tape® or a control group that will not. You will then complete the ankle exercise protocol that you practiced. If you are assigned to the Kinesio Tape® group, you will be instructed to keep the tape on until after the final testing session (Session 3) is completed. However, it is okay for the tape to get wet so that you may shower or swim.

Total time Session 2 = ~120 minute

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Session 3.

You will be asked to return to the testing site two days after Session 2. We will position you on the Biodex and place the small electrodes back on the lower part of your leg in the same way as we did in Session 2. We will then ask you to complete the same three tests: 1) fast muscle contractions, 2) slow, ramped contractions, and 3) ramped contractions during which you will be given the small shocks. You will complete 3 good trials of each test with 60 seconds of rest between trials with only the leg with functional ankle instability.

Total time Session 3 = ~40 minutes

Storage and Future Use

It is not possible for us to know what studies we may do in the future. We ask that you give permission now for us to use your personal information without being contacted about each future study. Future use of your information will be limited to studies about muscle function in individuals with functional ankle instability, the methodology of the AMI measurements, and/or the effects of Kinesio Tape®. If you decide later that you do not want your information stored for future use, you may contact the principal investigator, Marc Norcross, PhD, ATC at marc.norcross@oregonstate.edu or 541-737-6788.

_____You may store my information for use in future studies.
Initials

_____ You may not store my information for use in future studies.
Initials

Future contact:

We may contact you in the future for another similar study. You may ask us to stop contacting you at any time.

5. WHAT ARE THE RISKS AND POSSIBLE DISCOMFORTS OF THIS STUDY?

As with any physical activity, participation in this study carries a risk of bodily injury such as muscle strain, ligament sprain, or (in rare instances) a potentially disabling injury. The motions that you will be asked to perform are ones that repeatedly occur during physical activity and performance testing. Following testing and completion of the exercise protocol, you may experience muscle soreness and/or fatigue. To minimize these risks, you will be instructed to warm up to prepare for testing and exercises and you will be provided with 60 seconds of rest between testing trials.

The electrical stimulation may cause some discomfort. In rare situations, the electrical stimulation could cause a participant to feel dizziness, nausea, and/ or faint. The researchers will closely monitor you throughout the testing, and you will be able to tell us if you are not willing to continue the testing session. In addition, although Kinesio Tape® is latex-free and rarely irritates an individual's skin, some people may have an allergy to Kinesio Tape®. If you experience any allergic reaction, the tape should be removed immediately and you should immediately seek medical attention. You have right to stop participation anytime or all study procedures with no negative consequences.

All activities included in this study are similar to those performed in clinical settings or in many other studies, and we believe that we have taken the necessary steps to protect you. However, you may experience side effects from the study procedures that are not known to us. To the best of our knowledge, we have identified any potential risks and/or discomforts that you may experience because of being in this study. This information will help you decide whether to be in this study or not. We have procedures in place to protect your privacy. However, there is a small risk that we could accidentally disclose information that identifies you. Please see the section "WHO WILL SEE THE INFORMATION I GIVE?" for our procedures to minimize your risk.

6. WHAT HAPPENS IF I AM INJURED?

Oregon State University has no program to pay for research-related injuries. If you think that you have been injured from being in this study, please contact your doctor and any member of the study team immediately.

7. WHAT ARE THE BENEFITS OF THIS STUDY?

This study is not designed to benefit you directly.

8. WILL I BE PAID FOR BEING IN THIS STUDY?

You will not be paid for participating in this study.

9. WILL IT COST ME ANYTHING TO BE IN THIS STUDY?

You will be responsible for your own transportation to and from the testing site.

10. WHO IS PAYING FOR THIS STUDY?

This project is unfunded.

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11. WHO WILL SEE THE INFORMATION I GIVE?

The information you provide during this research study will be kept confidential to the extent permitted by law. Research records will be stored securely and only researchers will have access to the records. Federal regulatory agencies and the Oregon State University Institutional Review Board (a committee that reviews and approves research studies) may inspect and copy records pertaining to this research. Some of these records could contain information that personally identifies you.

To help protect your privacy, your name and contact information will be stored on one "master" document. All other information that we collect about you will not be directly associated with your name. Instead, we will use a unique identification code. Your information will be safely stored on-campus, either on a researcher's password-protected computer, on a computer that is in the researcher's locked laboratory, or in a locked file cabinet available only to the research staff. The results of this study will be submitted in the form of research manuscripts to Oregon State University's Scholars' archive and for peer-reviewed publication in academic journals. In these cases, your identity will not be disclosed and the results will be reported in a summarized manner such that participants cannot be identified.

12. WHAT OTHER CHOICES DO I HAVE IF I DO NOT TAKE PART IN THIS STUDY?

Participation in this study is voluntary. If you decide to participate, you are free to withdraw at any time without penalty. You will not be treated differently if you decide to stop taking part in the study. If you choose to withdraw from this project before it ends, the researchers may keep information collected about you and this information may be included in study reports.

Participation terminated by investigator: Your participation may be terminated by the investigator with regard to your consent, if you do not follow instructions for study activities or meet study eligibility criteria.

Students: Your decision to take part or not take part in this study will not affect your grades, your relationship with your professors, or standing in the University.

Employees: Your decision to take part or not take part in this study will not affect your job

13. WHO DO I CONTACT IF I HAVE QUESTIONS?

If you have any questions about this research project, Marc Norcross at (541) 737-6788 or by email at marc.norcross@oregonstate.edu.

If you have questions about your rights or welfare as a participant, please contact the Oregon State University Institutional Review Board (IRB) Office, at (541) 737-8008 or by email at IRB@oregonstate.edu

14. WHAT DOES MY SIGNATURE ON THIS CONSENT FORM MEAN?

Your signature indicates that this study has been explained to you, that your questions have been answered, and that you agree to take part in this study. You will receive a copy of this form.

Do not sign after the expiration date: 07/20/2018

Participant's Name (printed): _____

_____ _____
(Signature of Participant) (Date)

_____ _____
(Signature of Person Obtaining Consent) (Date)