Consent to Participate in a Research Study

Title of the Project: On the Effect of Ankle and Hip Strength on One Leg Balance Capacity in Healthy Young and Older Adults

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Faculty Advisor: James A. Ashton Miller, PhD, Department of Mechanical Engineering, University of Michigan

Research Staff: Grant Kulik, Department of Mechanical Engineering, University of Michigan

Invitation to Participate in a Research Study

We invite you to be part of a research study about "Balancing on One Leg". The study is funded by NIH through the Biomechanics Core of the University of Michigan Claude D. Pepper Geriatric Center.

Description of Your Involvement

This study will be performed in one 3 hour visit to Biomechanics Research Lab on North Campus. A staff member will greet you in the parking lot, hand you a parking pass to hang from your rearview mirror, and escort you to the laboratory. There you will be given time to go over the study consent form, and asked to sign it before any testing can begin (you may choose not to sign the consent form, and decline participation in this study). If you agree to be part of the research study, we will ask you to go through the following tests:

Strength and Cognitive Measurements:

After having had time to stretch and warm up, your ankle strength, hip strength and range of motion, and reaction time will be measured.

To determine your ankle strength, we'll provide you with lab shoes the size of your feet. One shoe and foot will be secured on top of a specially designed pivot board. You will be asked to stand on the board and bring it to the level for 2 seconds. If you don't succeed, we will adjust the pivot to make it a little easier and ask you to try it again. This will be repeated until we find the pivot position that enables you to succeed. This will be repeated for the other foot as well.

To determine the muscle strength at the hip, you will be asked to lie on your back on a special apparatus that supports your body and leg. When requested you will push your foot either out to the side or towards the center as hard as you can for 3 seconds. This will be repeated 3 times

for each leg to find your maximum muscle strength. Similarly we will test the range of motion of your leg out to the side and to the other side.

Your reaction time will be determined in 2 different ways 1) By measuring how quickly you can catch a stick once it starts to fall, and 2) By measuring how quickly you can catch the stick that is attached to a light that will only illuminate on half of the trials. You will have to catch the stick only during trials when the light comes on. There will be up to 20 trials for each part of the test.

You will be given plenty of rest periods to sit and relax.

Test Setup Preparations:

For our one leg balance tests, we need to fit you with a simple elastic brace around your torso which has 2 plastic stiffeners, one on each side. The brace is made from a commercial soft brace that wraps around your lower back and chest. The stiffeners are fitted to your body shape by soaking them in warm water and wrapping them with the elastic brace tightly around your body between the lower ribs and the top of the pelvis. As the plastic cools, they will take the shape of the sides of your torso.

We also use markers to measure your movements during the one leg balance experiments. The markers will be placed on your shoes, legs, arms, top of the pelvis, torso, spine, and head to capture your movement during the experiment.

After you are fitted with the brace and movement markers, we will use a motion capture wand with markers on it to locate points on the tips of your shoulders, the bone in the middle of your rib cage, four points in front and back of the pelvis, your hip bone that is on the outside of your body, your knee, and the sides of your ankle joint, the end of your second toe and your heel bone.

You will be given plenty of rest periods to sit and relax.

One Leg Balance Tests:

Experiment 1: We will ask you to stand on two measuring plates on the floor of the lab. We will first ask you to stand on one leg for as long as possible, do it 2 more times on this and then repeat on the other leg. These will be repeated without the brace as well as not allowing to move your foot sideways. Each test will be performed 3 times with alternate legs.

You will be given rest periods to sit and relax between some of these tests.

Experiment 2: In this test, we'll ask you to stand on your right foot while leaning the right hip bone on the outside of your body lightly against a padded support. You will see the support force on a screen in front of you. We will adjust the support so that it is comfortable. Then we will ask you to try to move very slowly away from the support by only moving your upper body and free leg together so as to balance on that right foot. We will ask you to repeat up to 12 times by lifting your torso, and up to 12 times by allowing your torso to drop. Finally we will repeat these tests with your other foot after a rest period.

At the end of the test, we will ask you to repeat the test of maximum hip strength by asking you to hold half your maximum effort for as many seconds as possible. This will be repeated with the other leg as well.

Video and Photography: Videotapes and photos are helpful for cross-checking the collected data from our sensors, and for scientific reports. If you choose to be videotaped (see end of form), please know that if we use the images in any report, your identity will always be masked by our covering your face in the image using a black rectangle so that you cannot be identified. You may choose to stop the video recording at any time.

Benefits of Participation

Although you may not directly benefit from being in this study, others may benefit as a result of the findings. We're hoping to develop a measure that will help clinicians and physical therapists better aim their treatments for patients with balance problems.

Risks and Discomforts of Participation

There may be some risk or discomfort from your participation in this research. The known or expected risk areas follows. The measures that will adopt to try to prevent them are shown in *italics* after each risk:

a) A bruise, laceration, fracture or concussion on the way into or out of the laboratories, caused by a trip or a slip.
   We will personally escort you from your car to the laboratory and back.
b) Fainting during a test
   Sometimes this can happen even to a healthy person if they forgot to eat. We will have snacks and water on hand to keep you going. In addition a staff member will stand by you during the tests to catch you if you lose your balance. In addition you will wear a special belt that (s)he can grab if (s)he thinks you are in danger of falling.

c) Straining a muscle or increasing joint pain during a maximum strength test or balance test.
We will ask you to warm your muscles up by stretching and doing exercises before the strength tests. During strength testing we will ask you frequently about any pain you experience beyond discomfort associated with muscle exertion. If you experience such pain we will ask that you to rest and choose whether to continue in the study.

d) A laceration from hitting your body against a sharp edge in the laboratory space
We use padding to reduce this risk, and the spotter should catch you if you do fall near something that might cause injury.

e) Becoming overly tired due to having to repeat each test several times.
You'll be offered frequent rest periods.

f) Feeling discomfort while fitting the brace
We will adjust or pad the brace to reduce this risk.

As with any research study, there may be additional risks that are unknown or unexpected.

Compensation for Participation

For your participation in this research project, you will receive $10/hour (maximum of $30).

Confidentiality

We plan to publish the results of this study. We will not include any information that would identify you. Your privacy will be protected and your research records will be confidential.

It is possible that other people may need to see the information you give us as part of the study, such as organizations responsible for making sure the research is done safely and properly like the University of Michigan, government offices.

Storage and Future Use of Data

We will store your data to use for future research studies. Your name and any other identifying information will be secured and stored separately from your research data at separate computers in Biomechanics Research Lab. Only Professor Ashton-Miller, the faculty advisor, and Payam Mirshams Shahshahani, the Principal Investigator, will have access to your research files and data. Research data may be shared with other investigators but will never contain any information that could identify you.

Voluntary Nature of the Study

Participating in this study is completely voluntary. Even if you decide to participate now, you may change your mind and stop at any time. If you decide to withdraw before this study is completed, all the data recorded from your experiment will be deleted, and you will be compensated for the time that you have spent in the laboratory**.**

Contact Information for the Study Team

If you have questions about this research, including questions about scheduling or your compensation for participating, you may contact

Faculty Advisor: James A. Ashton-Miller, Ph.D.
Mailing Address: 3443 GGB (George G. Brown Laboratory) 2350 Hayward Ann Arbor, MI 48109-2125, Telephone: 734.763.2320

Principal Investigator: Payam Mirshams Shahshahani, PhD Candidate
Mailing Address: GGB 3449 GG Brown, Department of Mechanical Engineering, University of Michigan, 2350 Hayward St, Ann Arbor, MI 48109-2125
Telephone: 734.936.0367

Contact Information for Questions about Your Rights as a Research Participant

If you have questions about your rights as a research participant, or wish to obtain information, ask questions or discuss any concerns about this study with someone other than the researcher(s), please contact the:

University of Michigan Health Sciences and Behavioral Sciences Institutional Review Board
2800 Plymouth Road
Building 520, Room 1169
Ann Arbor, MI 48109-2800
Phone: (734) 936-0933 or toll free, (866) 936-0933
Email: irbhsbs@umich.edu

Consent

By signing this document, you are agreeing to be in the study. We will give you a copy of this document for your records. We will keep one copy with the study records. Be sure that we have answered any questions you have about the study and that you understand what you are being asked to do. You may contact the researcher if you think of a question later.

I agree to participate in the study.

_____
Printed Name

_____
Signature Date

Consent/Assent to be videotaped and/or photographed

I agree to be videotaped/ photographed as a subject in this research study. I also agree that the recording/photograph may be used for the purpose of this research. I understand that I can stop the recording at any time and not continue as a participant in this research study.

_____
Printed Name

_____
Signature Date

Consent/Assent for future use of the collected data

I agree that after this study ends, the recorded research data from this experiment (video recordings NOT included) may be used for future research use.

_____
Printed Name

_____
Signature Date

Principal Investigator or Designee

I have provided this participant and/or his/her legally authorized representative(s) with information about this study that I believe to be accurate and complete. The participant and/or his/her legally authorized representative(s) indicated that he or she understands the nature of the study, including risks and benefits of participating.

_____
Printed Name

_____
Signature Date