INFORMED CONSENT FORM

University of Massachusetts Boston
Department of Exercise and Health Sciences
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Boston, MA 02125-3393

Consent Form for "Sex effects on blood pressure regulation to acute isometric handgrip exercise following 4 weeks of isometric handgrip training"

Introduction and Contact Information

You are asked to take part in a research study. **Participation is voluntary.** The researcher is João L. Marôco, a Ph.D. student at the Manning College of Nursing and Health Science. The faculty advisor is Tracy Baynard, Professor at the Manning College of Nursing and Health Science.

Please read this form and feel free to ask questions. If you have questions, João L. Marôco will discuss them with you. His telephone number is 773 893 3897 and his email is joao.maroco001@umb.edu

Description of the Project:

Why is this research study being conducted?

Exercise training just using static handgrip exercise (constant squeezing of the hand) shows promise to lower the risk of high blood pressure among young adults. But we don't know if the blood pressure-lowering effects of static handgrip exercise are influenced by biological sex (e.g., male vs female).

Thus, this research aims to compare the blood pressure response to a single session of static handgrip exercise, and static handgrip exercise training between apparently healthy young men and women.

How much time will you spend on the study?

Your participation in this study will take 2 months and you will be asked to visit the laboratory three times, with each individual visit lasting ~ 2 hours.

What will you do during the study?

If you choose to participate in this study, you will come to the laboratory to do handgrip exercise. In the first visit (baseline), you will fill-out a health and physical activity questionnaire and get your weight, height, fat, and muscle mass measured before the handgrip exercise. We will measure your blood pressure, heart rate, and blood flow of one of your arm's main blood vessels before, during and after handgrip exercise (please see attachment for a study schematic)

After completing the baseline visit, you will be randomized (like flipping a coin) to static handgrip exercise training or to a non-exercising phase, with each phase lasting four weeks. We will ask you to complete the other condition (handgrip or no handgrip), after you complete the first four-week condition.

During the exercise training phase, you will exercise at home 3 days per week over 1 month using a handgrip device (please see picture 1) you will keep at home but will return at the completion of the training period. Each exercise training session will last 12 min. A researcher will monitor each training session through a phone call or via a Zoom meeting to make sure you are doing the exercise at the right intensity.

During the non-exercise phase, we will ask you not to do the handgrip exercise and follow your normal routines over 1 month. After this time period, you will return to the laboratory to repeat the same testing you did in the beginning. The only exception is that we will not ask you to fill out a health questionnaire.

Picture 1. Handgrip device

For more information, please see the section below:

What procedures are involved?

Laboratory visit procedures

1. On the day before each visit, we will call you so that you can answer a health and physical activity questionnaire. This call will last about 10-min

2. You will be asked to report to the Integrative Human Physiology Laboratory at the University of Massachusetts Boston under fasting conditions (not eating for 10-12 hours, and only consuming water) and avoiding coffee and vigorous exercise in the last 24h;

3. A researcher will measure how much you weigh and how tall you are. The information will be used to calculate your body mass index. A researcher will also measure around your waist.

4. We will measure your muscle and fat inside your body using a large egg-shaped chamber where you just sit quietly and breathe into a tube (please see picture 2 below); During this procedure, we will ask you to wear a swim cap and to be on your underwear (men) or on a bathing suit (women).

Picture 2. Chamber that will be used to measure your fat and muscle

5. Afterwards, you will rest for 15-minutes laying down;

6. We will measure how strong your grip is using a specific device shaped like a handle three times. Next after a 2-min rest, you will squeeze tight the handle device at 30% of your maximum strength for as long as possible. You will do this exercise while laying down.

7. We will do cardiovascular measurements before, during and after the handgrip exercise. These will include:
    1. **Blood pressure:** A researcher will place a blood pressure cuff on your non-dominant arm and finger to obtain blood pressure while you are lying down on your back.

    2. **Heart rate and blood pressure control:** A researcher will place 3 stickers on your chest to measure your heart rate. This data will be analyzed later with the blood pressure data (mentioned above) to determine how your body controls your blood pressure response.
    3. **Blood flow measurements:** We will look at the artery in your neck and arm using an ultrasound machine. This machine is like what doctors use to look at babies in the womb. We will place a small amount of gel (consisting of salt and water) on your neck to help us get a clearer picture. The gel washes off very easily. We will place the ultrasound probe on your skin, over the arteries on the inside of your right neck,

base of the neck, and right arm. This probe will allow us to look at the blood flow in the artery, as well as the thickness of your artery.
Flow-mediated dilation: we will ask you to wear a blood pressure cuff on your arm that we will inflate for 5-min to reduce the blood flow to that part of your arm. This is termed occluding blood flow. When the cuff is released, we will measure how the blood vessel reacts to the blood blow being restored and measure the change in the size of the vessel.

4. **Arterial stiffness measurements**: We will also assess how stiff your arteries are and measure your central artery's blood pressure. We will use a very sensitive coin-shaped sensor that will be placed on your neck, arm, forearm and tight. These measurements will tell us how stiff your central and upper limb arterial system (the arteries in the midsection of your body) are, as well as what the blood pressure is in blood vessels that are close to your heart (i.e., the aorta).
5. 24-hour blood pressure monitor—Before you leave the laboratory in each visit, we will place an ambulatory cuff on your arm to wear for the next 24 hours. Ambulatory means that you can walk around and even sleep with this cuff and it will take measurements automatically at various times throughout the day.

Training sessions procedures
We will give you a handgrip device so that you can exercise at home. In each training session, we will measure how strong your grip is over three repetitions. Then, you will squeeze tight the handle device at 30% of your maximum strength without letting go for 2 minutes. You will repeat this three times with 1-minute of rest in between each handgrip squeeze. We will ask you to do the same type of exercise 3 days per week during 4-weeks. A study team member will be with you during the training session via phone and/or Zoom to monitor your training session and answer any questions you might have

Risks or Discomforts

Cardiovascular measurements in this study are non-invasive which means they do not involve breaking the skin or entering body cavities. Still:

1. There are no known risks with the use of ultrasound or with the devices used to measure your central artery stiffness or central blood pressure. During ultrasound measurements, the gel used may feel cool and sticky, but it is unlikely that you will get an allergic reaction. We will make every effort to maintain your modesty. Additionally, you may feel some pressure in your neck, legs, and arms during the ultrasound and vessel measurements. To make you comfortable, there will be a pillow to rest your arm and measurements will be done by a trained researcher;

2. Blood pressure will be measured using a cuff around your arm or your finger, so you may feel some discomfort or tingling when the cuff is inflated;

3. We will measure how the blood vessel in your upper arm changes in size after 5-min of restricted blood flow to the arm (e.g., occlusion). You may feel hand discomfort and numbness during the cuff occlusion, which is quickly restored after the cuff is released

4. We will use stickers placed on your chest to measure your heart rate. These may feel sticky and sometimes may cause your skin to turn red.

Exercise: with any exercise type there are minor health risks that go along with the chance of fatigue, cardiovascular events, and hand or arm soreness. These risks are small for people with no prior history of cardiovascular and musculoskeletal disease. Serious events (heart attacks) during exercise happen very rarely (< 1%).

Body fat measurement: You will seat quietly inside an egg-shaped chamber for 5-min, and we will ask you to breathe into a tube for 20 seconds. You may feel dizzy and confined in the chamber when the door is closed. If you do not like closed spaces this measurement may be stressful but there is an emergency button you can use to open it at any time. We will be closely observing you, should you want to end the test early.

Questionnaires: You may feel uncomfortable when completing the health questionnaires. You may skip any questions or stop participating at any time.

There is also a potential risk of loss of privacy (revealing to others that you are taking part in this study) or confidentiality (revealing information about you to others to whom you have not given permission to see this information). To minimize this risk, all data will be stored coded (without your name).

Benefits:

There may not be any direct benefit to you from participating in this study. Your participation will help us understand how blood pressure and the cardiovascular system respond to a single session of handgrip exercise and training.

Confidentiality:

Your part in this research is **confidential**. That is, the information gathered for this project will not be published or presented in a way that would allow anyone to identify you. Information gathered for this project will be password protected or stored in a locked file cabinet or computer, and only the research team will have access to the data.

The University of Massachusetts Boston Institutional Review Board (IRB) that oversees human research and other representatives of this organization may inspect and copy your information.

All identifiable information that could directly identify you (e.g., your name) will be removed from the information collected in this study. After we remove all identifiers, the information may also be used for future research or shared with other researchers without additional consent.

Voluntary Participation:

The decision whether or not to take part in this research study is voluntary. If you do decide to take part in this study, you may end your participation at any time without consequence. If you wish to end your participation, you should directly tell or call the researcher João L. Marôco or his supervisor Tracy Baynard. Whatever you decide will in no way penalize you or involve a loss of benefits to which you are

otherwise entitled, and it will not affect your grades or status as a student, and it will also not affect your relationship with the organization.

Will you receive compensation?

You will receive monetary compensation, a total of $150 for taking part in this study. You will get a $30 gift card for each completed data collection visit (3 visits), which would equal to $90 in gift cards. If you finish the study, you will receive an additional gift card of $60.

Is there any cost to take part in this study?

You are expected to commute to campus using your own means. If you choose to drive, the parking option includes On Campus at West Garage ($9 for 2 hours) and Campus Center ($15), or Off Campus at Bayside ($9).

Questions

You have the right to ask questions about this research before you agree to be in this study and at any time during the study. If you have further questions about this research or if you have a research-related problem, you can reach out to João L. Marôco (773 893 3897, joao.maroco001@umb.edu) or his faculty advisor Tracy Baynard (tracy.baynard@umb.edu).

If you have any questions or concerns about your rights as a research participant, please contact a representative of the Institutional Review Board (IRB), at the University of Massachusetts, Boston, which oversees research involving human participants. The Institutional Review Board may be reached by telephone or e-mail at (617) 287-5374 or at human.subjects@umb.edu.

Signatures:

I HAVE READ THE CONSENT FORM. MY QUESTIONS HAVE BEEN ANSWERED. MY SIGNATURE ON THIS FORM MEANS THAT I CONSENT TO PARTICIPATE IN THIS STUDY.

Signature of Participant	Date	Signature of Participant

Printed Name of Person Obtaining Consent	Date	Signature of Person Obtaining Consent

Attachment – Study schematic