Post-exercise Hot Water Immersion to Improve Overnight Blood Pressure

Consent Form

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NCT: FY24-10

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PROVIDENCE
COLLEGE

THE IMPACT OF POST-EXERCISE HOT WATER IMMERSION ON BLOOD PRESSURE CONTROL

The present study is being conducted by Brett Romano Ely, PhD from the *Department of Health Sciences* at Providence College. The purpose of the study is to investigate whether using a hot tub, cold tub, or no treatment after running exercise changes your recovery from exercise.

If you agree to participate, you will be asked to visit the lab up to seven different times:

1. A brief visit (<1hr) where you can see the equipment, ask questions, and fill out a brief questionnaire to see if you qualify for the study
2. Three study visits (1.5-2 hrs each) where you will either:
    a. walk on a treadmill for 30 minutes then place your legs in a lukewarm bath for 45 minutes
    b. place your legs in a hot bath for 45 minutes
    c. Walk on a treadmill for 30 minutes then place your legs in a hot bath for 45 minutes
    d. Rest for 30 minutes

After each treatment, you will be asked to lay on a padded table while we measure your heart rhythm using foam stickers, measure your blood pressure using a cuff on your arm and finger, and use ultrasound to look at the blood vessels in your arm. During the ultrasound test, we will inflate a cuff on your forearm for five minutes to look at changes in blood flow. This is a measure of how healthy your blood vessels are.

At the end of each visit, we will place a blood pressure cuff on your arm that you will wear for 24 hours while it measures your blood pressure once per hour. The entire study will take place over about 3 weeks and your total time commitment should be no more than 10-12 hours.

There are some minor risks associated with participation in this study. These risks include a chance of muscle soreness from exercise (treadmill walking), feeling slightly warm or uncomfortable during heating, and a chance of skin irritation from the foam stickers. There is also a chance you will feel mild discomfort when the blood pressure cuff is inflated on your arm.

There are no direct benefits from participating in this study. The interventions in this study (moderate exercise, heat exposure) have been shown to improve blood pressure and cardiovascular health with repeated use, but it is unlikely that a meaningful long-term change in fitness or health will occur with this brief study. You will have the option to review your results after you finish the study, and may share these results with your physician to discuss lifestyle interventions to manage your blood pressure.

You will earn $200 for your participation at the conclusion of the study, as compensation for your time and inconvenience.

Your responses during the study are anonymous. Each participant is assigned a number and the names are in no way associated to the numbers. We do not collect any information about your personal identity. All responses are confidential and are stored on a password-protected computer. Finally, we are only interested in participants' responses in aggregate and therefore do not analyze individual responses.

Your decision to participate is entirely voluntary. You are free to end your participation (i.e., stop the experiment) at any time without penalty (i.e., you will still be paid a pro-rated amount). The experimenter also reserves the right to end your participation in the study at any time. Finally, you have the right to request that your data not be used.

You are free to ask questions at any time during the study. If you have concerns about your experiences in the study and/or your rights as a participant, please contact the Providence College IRB via e-mail at irb@providence.edu or you may contact the Principle Investigator (Brett Romano Ely, Phd; bely@providence.edu*)* or phone *(cell: 978-697-1145)*.

Your signature on this form indicates that you have read and understand the form, the general procedures of the study, and agree to participate in the study. You will be given a copy of this form to keep for your records.

Participant's Name: _____

_____I confirm I am 18 years of age or older and can consent to participation in this study.

Participant's Signature: _____ Date: _____