Informed Consent Form – Michigan Technological University

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NCT03626363

Mindfulness and Neural Cardiovascular Control in Humans

July 24, 2018 (original study approval date at Michigan Technological University)

Consent form
Mindfulness and Neural Cardiovascular Control in Humans

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Introduction

Dr. Durocher, Dr. Carter, and Michigan Tech undergraduate/graduate students will be conducting the research surrounding the effects of Mindfulness Based Stress Reduction (MBSR). Dr. Durocher is an assistant professor in the Department of Biological Sciences, and Dr. Carter is a professor and chair of the Department of Kinesiology and Integrative Physiology.

The primary purpose for this research is to examine the effects of 8-week MBSR and how these programs can affect 24-hour blood pressure, the sympathetic nervous system, and arterial stiffness.

You will be excluded from this study if:

- You are not between the ages of 18 and 45 years
- You are a smoker
- You have a history of diabetes
- You are pregnant
- You have a seated clinical blood pressure < 120/80 or > 180/120 mmHg
- You have a wake-time ambulatory systolic blood pressure < 130 mmHg
- You have a history of autonomic dysfunction
- You are taking cardiovascular medication
- You have a body mass index ≥ 30 kg/m^2

Study Design and Risks

Orientation:

1. The orientation meeting will take place at the Integrative Physiology Research Laboratory (SDC 235) to explain the research study, the data collection methods, research protocols, and allow participants to examine the equipment and laboratory.
2. Baseline vitals will be taken to ensure the participants meet the inclusion criteria, and the participants can sign the IRB approved consent form if the criteria are met.

3. Two and four days after baseline vitals are taken, participants will report back to the Integrative Physiology Lab to have baseline vitals re-assessed to ensure they are still within the inclusion criteria.
4. Once the baseline vitals have been completed, then the rest of the experiment can proceed with 24-hour ambulatory blood pressure and accelerometer measurements.

Study Design and Testing:

1. If all of the inclusion criteria from above are met, then you will be randomly assigned into the 8-week MBSR group or the 8-week active control group. Each group will meet their program leader.
2. Prior to the start of the 8-week program, a 24-hour blood pressure reading will be taken. The device is compact and easily attached to a belt. You will also be fitted with a wrist accelerometer (similar to a Fitbit) that will track your sleep-wake cycle for five consecutive nights.
3. Following the accelerometer recordings, nervous system functions will be tested with microneurography (small electrode needle that can measure electrical activity in nerves) in a baseline setting along with a mental stress test (doing mental math calculations). Nerve activity will be continuously measured during the baseline and mental stress test. In addition to the nerve recordings, heart rate will be recorded with 3-lead electrocardiography, continuous blood pressure with a small cuff on your finger, and forearm blood flow with two cuffs and a gauge on your arm during the math protocol. We will also estimate arterial stiffness with a small probe that will be placed at the radial (wrist), carotid (neck), and femoral (groin) pulse sites.
4. With the programs outlined, you will then proceed with the 8-week program to which you were randomly assigned. It is requested that you do not change your normal exercise schedule or eating habits. Both the MBSR and active stress management control programs will require a once weekly group meeting and at home exercises.
5. Once the 8-week program is completed, you will once more complete the 24- hour blood pressure readings, accelerometry, microneurography, heart rate, blood pressure, and arterial stiffness.

Benefits

There are numerous potential benefits to participating in this study, but nothing is guaranteed. You could learn how to better manage the stress in your life, your cardiovascular risk could be lowered, and findings could benefit the scientific community.

Compensation

This study does compensate the participants. You will receive the following: 1) $50 for each microneurography session completed; and 2) $200 for the completion of the 8- week MBSR or stress management education course.

Consent Form

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Cost of Participation
There is no cost for you to participate in this research.

Research Related Injury
In the event of physical and/or mental injury resulting from participation in this research project, Michigan Technological University does not provide any medical, hospitalization or other insurance for participants in this research study, nor will Michigan Technological University provide any medical treatment or compensation for any injury sustained as a result of participation in this research study, except as required by law. If you are taking medications, it is your responsibility to consult with your physician regarding your participation in this research study. Do not volunteer for this study if you have been instructed to abstain from this research study by a physician. Any problems you experience should be discussed immediately with your physician.

Confidentiality of Records
We will treat your identity with professional standards of confidentiality. The information obtained in this study may be published, but your identity will not be revealed. Subject information and corresponding six digit alphanumeric codes will be stored in a secured file cabinet in Dr. Durocher's laboratory (Dow 731). Michigan Technological University reserves the right to inspect both the research data collected and your experimental records. Summary (but not individual) results will be registered and published at ClinicalTrials.gov in accordance with requirements from the National Institutes of Health.

Withdrawal
Participation in this study is strictly voluntary. Dr. Durocher will answer any questions you may have about the study. Any significant new findings which develop during the course of the research study which in my opinion may affect your willingness to continue to participate will be provided to you as soon as possible. **You are free to withdraw your consent and discontinue participation at any time and for any reason**. This includes the right to withdraw during the actual test.

Subject's Rights Information
The MTU Institutional Review Board has reviewed my request to conduct this project. If you have any concerns about your rights in this study, please contact the MTU-IRB at 906-487-2902 or email irb@mtu.edu.

I,_____, have read through this consent form. I have been provided detailed information about all of the procedures that I will be volunteering to do in an orientation session, I have been given and have read the detailed information about procedures being done, and I have had an opportunity to ask questions. **I confirm that I am at least 18 years old.** I agree to participate in this study.

_____ _____
Signature of Participant Date

_____ _____
Signature of Investigator Date

Initial Here _____