Informed Consent Form - Purdue University

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Mindfulness and Neural Cardiovascular Control in Humans

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RESEARCH PARTICIPANT CONSENT FORM

Mindfulness and Neural Cardiovascular Control in Humans (IRB-2020-1547)

John J. Durocher, Ph.D.[1]
[1]Department of Biological Sciences
Purdue University Northwest

Key Information

Please take time to review this information carefully. This is a research study. Your participation in this study is voluntary which means that you may choose not to participate at any time without penalty or loss of benefits to which you are otherwise entitled. You may ask questions to the researchers about the study whenever you would like. If you decide to take part in the study, you will be asked to sign this form, be sure you understand what you will do and any possible risks or benefits.

Dr. Durocher and Purdue University Northwest undergraduate/graduate students will be conducting research surrounding the effects of Mindfulness Based Stress Reduction (MBSR). MBSR involves learning ways to manage stress through gentle breathing, yoga, and more. We are examining its possible effects on lowering blood pressure, preventing nervous system overactivity, and reducing arterial stiffness. This study will run for 8 weeks with approximately 45 minutes of commitment required each day and one 90-minute commitment each week. Your participation in this study is entirely voluntary. Please read the information below and ask questions about anything you do not understand before deciding whether or not to participate.

You will be excluded from this study if:

- You are not between the ages of 18 and 55 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 history of autonomic dysfunction
- You are taking cardiovascular medication
- You have a body mass index ≥ 30 kg/m^2
- You have a pacemaker
- You have a history of MRSA infections
- You have a history of neuropathy
- You have a history of illicit substance abuse

What is the purpose of this study?

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. We would like to enroll approximately 24-30 participants (both men and women) between the ages of 18 and 55 years old in this study.

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What will I do if I choose to be in the study?

You will be asked to refrain from caffeine, alcohol and exercise 12 hours prior, and eating 3 hours prior to the study screening and testing measurements.

1. If all of the inclusion criteria 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 (schedule to be provided).
2. Prior to the start of the 8-week program, a 24-hour blood pressure reading (ABPM) will be taken. The device is compact and easily attached to a belt. You will also be fitted with a wristwatch device (similar to a Fitbit) that will track your sleep-wake cycle for one weeknight.
3. When reporting to the autonomic nervous system testing session, we will first ask you to complete questionnaires including exercise habits, decentering (ability to disconnect from emotions), the 5 facets of mindfulness, state/trait anxiety, and resilience. Following 5-minutes of quiet seated rest after completing the questionnaires, we will complete three resting blood pressure assessments on your right arm.
4. Following the blood pressure 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. The microneurography electrode would remain inserted for approximately 1 hour, and does not typically cause any discomfort after the initial insertion. We use a tungsten microelectrode behind the right knee as the recording electrode and a small acupuncture electrode about 3 cm away as the ground. In addition to the nerve recordings, heart rate will be recorded with 3-lead electrocardiography (ECG), continuous blood pressure with a small finger cuff, and your breathing rate with an elastic belt placed over your clothing at chest level. 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.
5. 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.
6. Once the 8-week program is completed, you will once more complete the 24- hour blood pressure readings, accelerometry, questionnaires, microneurography, heart rate, blood pressure, and arterial stiffness.

How long will I be in the study?

If you choose to volunteer, you will be asked to participate in three initial screening visits to the laboratory to accurately assess your resting blood pressure to confirm you meet the blood pressure eligibility. Each of the screening visits will take approximately 15 minutes to complete. Eligible volunteers that choose to participate in the research study will use a take-home ambulatory blood pressure monitor and wristwatch device for 24-hours once before and once after the 8-week study intervention. Participants would also

report to the Clinical and Applied Human Physiology Research Lab (Gyte 6) for an autonomic testing session (~3 hours) before and after the 8-week intervention. Participants in this study would report once per week for 2-2.5 hours to either the MBSR or Stress Management Education class, and perform about 45 minutes of at-home practice each day. Finally, the 8-week classes require attendance of a single 8-hour Saturday class at the end of the 6th week.

What are the possible risks or discomforts?

Measurement of Blood Pressure: *Blood pressure will be measured similar to a similar doctor's office visit. There are no known risks with this procedure. If discomfort is experienced the cuff can be deflated.*

24-Hour Blood Pressure Recording (ABPM): *It is possible for 24-hour blood pressure recordings to interfere with normal activity and sleep habits. We will try to minimize disruption to normal habits by gaining snapshots of 24-hour blood pressures once before, and once after, the 8-week intervention. We will record on a work or school day according to previous recommendations. To enhance user comfort, our ABPM devices are very compact, lightweight, and can be easily attached to a belt. We will collect only two readings per hour at night to help reduce the chance of sleep interference.*

Questionnaires: *We do not anticipate risk or discomfort in regard to questionnaires, but if you feel uncomfortable with any question, or any questionnaire, you can leave it blank.*

Microneurography: *There is a risk of infection after insertion of the leg electrode. Sterile techniques will be used to help prevent infection. We have never had any participants report infection after the procedure. Also, about 7% of subjects experience some aching or "pins and needles" sensations for a few days after the procedure. There is no specific treatment for these sensations, which are believed to be the result of tissue inflammation. Study volunteers who have experienced these sensations report they have disappeared spontaneously and completely without treatment within a few days. Dr. Durocher has safely performed over 200 successful sessions.*

ECG: *There is a risk of skin irritation from the electrodes used for ECG. This is unusual, but we can stop the experiment if this irritation occurs. To date, we have never had a problem with our electrodes.*

Finger Cuff*: Rarely, some people experience mild discomfort in the fingers from the blood pressure cuff. If this occurs, we will stop the finger cuff.*

Arterial Stiffness: *This is a non-invasive procedure that is comparable to someone checking your radial (wrist) or carotid (neck) pulse via finger. A buildup of fats on artery walls are known as plaques. The use of a tonometry device could cause hardened plaques to dislodge. For that reason, there is still a possibility of stroke, or even death, for any person if plaques were to be dislodged during the use of this device. These risks are lower for a person with an aortic pulse pressure < 50 mmHg. Therefore, to mitigate risk of plaques dislodging, if aortic pulse pressure is 50 mmHg or greater, as estimated from the radial (wrist) pulse site with the tonometer, then we will not proceed with carotid (neck) or femoral (groin) pulse recordings.*

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Breach of confidentiality: *This is always a risk with data, but we will take precautions to minimize this risk as described in the confidentiality section.*
Under Indiana law, Purdue researchers must report any suspected child abuse or neglect to law enforcement or to the Department of Child Services hotline. Under federal law, Purdue researchers must report all incidents of discrimination, harassment, and/or retaliation in the Purdue workplace and/or educational environment to the Title IX Coordinator or Equal Opportunity/Affirmative Action Officer. "Harassment" includes sexual harassment, sexual violence, rape, and any non-consensual sexual act. If you tell us something that makes us believe that you or others have been or may be physically harmed, we may report that information to the appropriate agencies.

Are there any potential benefits?

There are no guaranteed benefits with this study. Some potential benefits may include learning how to better manage the stress in your life, your blood pressure values could be lowered, and findings could benefit the scientific community.

Will I receive payment or other incentive?

This study does compensate participants. You will receive the following: 1) $50 for each microneurography (autonomic) session completed; and 2) $200 for the completion of the 8-week MBSR or stress management education course (or $25 for each week that you have completed if you decide to discontinue the study at any time). The maximum payment that you can receive from this study is $300. According to the rules of the Internal Revenue Service (IRS), payments that are made to you as a result of your participation in a study may be considered taxable income. Professor Durocher will keep a human subject invoice log that will include your name and address so that payments can be processed. This information will only be kept on a password protected computer on a secure research drive.

Are there costs to me for participation?

There are no anticipated costs to participate in this research.

This section provides more information about the study

What happens if I become injured or ill because I took part in this study?

If you feel you have been injured due to participation in this study, please contact:
Dr. John Durocher
jjduroch@pnw.edu
(219) 216-2836
Purdue University will not provide medical treatment or financial compensation if you are injured or become ill as a result of participating in this research project. This does not waive any of your legal rights nor release any claim you might have based on negligence.

Will information about me and my participation be kept confidential?

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 (Gyte 6) only accessible by Dr. John Durocher and limited graduate/undergraduate students under supervision of Dr. John Durocher. This study is funded by the National Institutes of Health. The project's research records may be

reviewed by the National Institutes of Health, Food and Drug Administration (if FDA regulated), US DHHS Office for Human Research Protections, and by departments at Purdue University responsible for regulatory and research oversight. Summary (but not individual) results will be registered and published at ClinicalTrials.gov in accordance with requirements from the National Institutes of Health.

Certificate of Confidentiality

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects. For additional information about CoCs see http://grants.nih.gov/grants/policy/coc/faqs.htm.

Researchers may release information about you when you say it is okay. For example, you may give them permission to release information to insurers, medical providers or any other persons not connected with the research. The Certificate of Confidentiality does not stop you from willingly releasing information about your involvement in this research. It also does not prevent you from having access to your own information.

Study data will be kept strictly confidential to researchers and affiliated organizations, however, we cannot guarantee that other study participants will not breach information regarding group class participation. Beginning all classes instructors will encourage others to preserve confidentiality of all participants in the study.

What are my rights if I take part in this study?

Participation in this study is strictly voluntary and you may withdraw your participation at any time without penalty. Researchers are permitted to terminate the study if a participant becomes pregnant during the study or in the event of hypertensive crisis. 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.

Who can I contact if I have questions about the study?

If you have questions, comments or concerns about this research project, you can talk to one of the researchers. Please contact:

Dr. John Durocher
jjduroch@pnw.edu; (219) 989-2625

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To report anonymously via Purdue's Hotline, see www.purdue.edu/hotline
If you have questions about your rights while taking part in the study or have concerns about the treatment of research participants, please call the Human Research Protection Program at (765) 494-5942, email (irb@purdue.edu) or write to:
Human Research Protection Program - Purdue University
Ernest C. Young Hall, Room 1032
155 S. Grant St.
West Lafayette, IN 47907-2114

Documentation of Informed Consent

I have had the opportunity to read this consent form and have the research study explained. I have had the opportunity to ask questions about the research study, and my questions have been answered. I am prepared to participate in the research study described above. I will be offered a copy of this consent form after I sign it.

_____ _____

Participant's Signature Date

_____

Participant's Name

_____ _____

Researcher's Signature Date