Clinical Intervention Informed Consent Form

NCT03859076

FULL PROTOCOL TITLE
Mindfulness-Based Blood Pressure Reduction: Stage 2a RCT

Study Chairman or Principal Investigator:
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CONSENT FOR RESEARCH PARTICIPATION

The Mindfulness-Based Blood Pressure Reduction (MB-BP) Study
Version 3.3, April 2, 2019

KEY INFORMATION:
You are invited to take part in a Brown University research study called MB-BP. Your participation is voluntary.

- PURPOSE: In this study, we are looking to see if mindfulness practices improve blood pressure, and if education about hypertension risk factors may also improve blood pressure.
- PROCEDURES: All enrolled participants will be asked to participate in multiple health assessments before and after the mindfulness class. We will also ask you to use a home blood pressure monitor to take your blood pressure at home nine times throughout the study. If eligible and selected to receive the intervention, you will be asked to take part in a 9-week mindfulness course where you will receive free training in meditation, mindful movements, and the roles of things like diet, physical activity and medication in reducing blood pressure. Control group participants will be offered the mindfulness class after their six month follow up assessments are complete.
- TIME INVOLVED: The mindfulness class involves 30 hours of class time and up to 48 hours of at home practice spread out over the course of 9-weeks. The three research assessments are estimated to take around four hours each or around 12.5 hours in total. The assessments will take place at three times throughout the study: at baseline before class begins and then at 10 weeks and 6 months follow up. The total estimated time involved for this study is up to 90.5 hours spread out over 6 months. An abbreviated 1 year follow up assessment will also be administered to individuals randomized to the intervention group to assess long term effects of the mindfulness class.
- COMPENSATION: You will receive $50 USD per follow up (i.e., 10 weeks, 6 month, and 1 year for intervention group; and 10 weeks and 6 month for control group) as compensation for your time (up to $150 USD in total for intervention group and up to $100 USD in total for control group). You will be given a wireless home blood pressure monitor to keep for completing your baseline assessment.
- RISKS: The risks to you in this study are small. They include possible discomfort during research assessments and/or the 9-week intervention as well as possible increases in anxiety, depression, or insomnia or physical injury during the mindfulness intervention. All aspects of the study are voluntary.
- BENEFITS: There are no guaranteed direct benefits to participating in this study. We are investigating whether or not the 9-week intervention actually works to lower blood pressure.
- ALTERNATIVES TO PARTICIPATION: A number of different therapies, including antihypertensive medication, diet changes, physical activity, and reducing excessive alcohol consumption may also be beneficial for reducing blood pressure. Education about these therapies are integrated into this course, but other forms of these alternative therapies are also available in the community.

The remainder of this form will explain in detail the purpose of the study, how the study will be carried out and what you will be expected to do. It will also explain the possible risks and possible benefits of being in the study. If any part of the following description is not clear to you, you are encouraged to contact the researcher to answer any questions before you decide whether to take part in the study. If you decide to participate, please fill out and sign the last page of this form.

1. Researcher(s):

The Principal Investigator on this project is Dr. Eric B. Loucks. He can be reached at 401-863-6283 or by email at eric.loucks@brown.edu. Research staff working on the study can be contacted by phone or email at: 401-400-4768 and mindfulness@brown.edu.

2. What is this study about?

The purpose of the study is to investigate the impact of mindfulness practices and health education on blood pressure. You have been selected for this study because you expressed interest in the project and because you met entrance criteria for having prehypertension or hypertension, or another cardiovascular risk factor that could be influenced by this program. Eligibility for the study is still being assessed. Therefore, it is possible you may not be eligible for the study even after signing this consent form. Your participation in this study is voluntary and can be withdrawn at any point in the project.

In order to assess the effects of the customized mindfulness intervention, you will be asked to complete some questionnaires and laboratory assessments before and after the intervention. Specifically, assessments will be completed at: baseline, 10 weeks, and 6 months. To express our gratitude for participation, you will be given $50 at each of the follow ups ($100 USD total). As part of the study you will also be given a wireless blood pressure monitor (estimated value of $90) to use throughout the study. Members of the intervention group will also be asked to complete an abbreviated 1 year follow up assessment estimated to take 45-60 minutes to complete in order to assess long term effects of the mindfulness intervention.

This is a Randomized Control Trial. Participants enrolled into the study will be randomly assigned to one of two groups: (1) the intervention group or (2) the enhanced usual care wait-list control group. The wait-list control group will be given the opportunity to participate in the intervention after the six month follow up assessments are completed. Both the intervention and the control group will be asked to participate in the research assessments.

3. What will I be asked to do?

If you agree to participate, you will be asked to consent to the following:

a) Participation in a screening interview in which you will be asked questions about past and present mental health, including depression and suicide (previously completed with your verbal consent).

b) Completion of an in-person screening assessment, during which your blood pressure, height, weight and other basic demographic and health data will be collected and assessed in order to determine eligibility for the study.

c) Completion of questionnaires administered in-person and online that ask about a wide range of topics, including your diet, physical activity, smoking, medication use, personality, emotions, attention and past experiences, including stressful or traumatic experiences. These questions will probe sensitive psychological areas, including physical, emotional, and sexual abuse. These questionnaires may take up to 3 hours to complete. By completing the interviews and questionnaires, you are giving the researchers permission to use the information you have provided. You have the right not to answer any of the questions.

d) Directly assessed blood pressure, heart rate, height, weight, physical activity, and antihypertensive (blood pressure) medication use at baseline and after the mindfulness course. If you take antihypertensive medication, we will provide you with an electronic bottle cap that will

automatically record when the pill bottle is opened during the study. This will help us measure how often the medication is used. We will also provide you with a wireless blood pressure monitor and will ask that you take your blood pressure at home systematically during each of the research assessment periods (i.e., baseline, 10 weeks, and 6 months).

e) You will be asked to perform some cognitive tasks. Some of these tasks may involve computer-based tests of attention or decision-making. Together these tests may take as long as 20 minutes.

f) During the in-person assessments you will also be given a battery of stress tests that are designed to induce a stress response so that we can monitor your cardiovascular response and recovery.

g) There will be two follow ups that take place after 10 weeks and 6 months from the start of the intervention. The assessments and questionnaires you will complete for the follow ups will be the same as those completed at baseline. An abbreviated 1 year follow up will also be administered to members of the intervention group.

If randomized into the intervention group…

h) You will be asked to participate in the mindfulness program, which consists of 9 weekly sessions of 2.5 hours each and will include one 7.5 hour weekend retreat. Daily at home practice assignments may take as long as one hour and consist of practicing mindfulness exercises with the aid of guided meditations and completing worksheets related to stress, thoughts, and common reactions to various types of events. Individuals randomized into the enhanced usual care wait-list control group will be invited to take part in the mindfulness class after the completion of the 6 month follow up assessments.

i) Class sessions may be video and/or audio recorded for training purposes and in order to analyze the quality of the treatment you receive. Class videotapes may be made available to MB-BP supervisors, teacher trainers, teacher trainees and researchers through the Mindfulness Center at Brown University. It may be used by them for professional education and training purposes via various secured outlets, including a password-protected and private YouTube channel, a password-protected and private DropBox account, and electronic academic learning software tools. The video monitor will focus on the face of the course instructor, and not on the faces of study participants. However, there is a possibility that your voice and face may be recorded. The study staff will have you review and sign a separate media permission form regarding this study requirement.

j) You may be asked to complete a few short questionnaires each week during the 9 week intervention.

k) Additionally, if you are randomly selected to the waitlist control group, we will be asking you to refrain from initiating and engaging in mindfulness practices and formal meditation during the six-month period of your participation in this research study. As part of this research study we are evaluating the impact of the mindfulness course on the health of its participants. If the control group members engage in mindfulness during the intervention period, it may misguide the study results.

Table Summarizing Activities and Time Commitment for this Study.

Activity	Estimated Time Commitment
In-person screening assessment	0.75 hours
Baseline In-person assessment Online questionnaire At home health monitoring (i.e., blood pressure)	 2.5 hours 0.75 hours 0.25 hours
Intervention* Mindfulness course Home practice assigned during course **Intervention group only; control group will be invited to take part in a class post 6 month follow up but it will not be required as part of the study.*	Nine 2.5 hour sessions 7.5 hour all day retreat Up to 1hr daily home practice assignments *Total course time: 30.0 hours* *Max. practice time: 48 hours*
Follow Ups – 10 week ($50) and 6 month ($50) In-person assessments Online questionnaires At home health monitoring (i.e., blood pressure) 1 year follow up (*intervention group only*) ($50)	Total follow up time: 5.0 hours 1.75 hours 0.5 hours Up to 1.0 hours
TOTAL ESTIMATED TIME COMMITMENT	11.5 hours – CONTROL 90.5 hours - INTERVENTION

Your participation in this study may last up to 6 months in duration (1 year for intervention group members) and is estimated to take up to 11.5 or 90.5 hours in total depending on which group you are assigned to.

Feedback: At the end of the study, you will receive individual feedback about the changes that occurred since the first assessment. Specifically, you will receive an individualized handout listing % change (increase or decrease) on scales of attention, stress, mood, health behaviors, weight, and blood pressure across the study.

Uncontrolled Hypertension: If during the in-person assessments it appears that you have stage 2 uncontrolled hypertension (your average systolic blood pressure reading is 140 mmHg or greater and/or your average diastolic blood pressure is 90 mmHg or greater) AND you indicate to us that you are not currently being treated for hypertension, then we will be requesting your permission to contact your health care provider to notify him/her of the blood pressure results. If you do not have a health care provider and/or do not have health insurance, our staff will provide you with resources to help you search for one; although we cannot guarantee that we will be able to find you one nor that it will be free. It is your choice on whether or not you would like us to follow up with your health care provider. Your participation in the study is not contingent on this communication; however, it is our recommendation that all individuals with uncontrolled hypertension be under the care of a health care professional.

4. Will I be paid?

You will be given $50 at each of the follow up assessments ($100 USD total for control group members and up to $150 USD for intervention group members).

5. What are the risks?

The risks to you in this study are small. The questionnaires used in the study are routine, standardized forms for epidemiologic research. Certain questions may be upsetting as they may probe sensitive psychological areas and inquire about upsetting or traumatic events, including physical, sexual or emotional abuse and/or current psychiatric symptoms. The cognitive tests and stress battery may also invoke a stress response that may be uncomfortable. All aspects of the study are voluntary; you have the right to skip anything during the study that makes you uncomfortable.

Meditation-based interventions may result in discomfort with attention to unpleasant thoughts, feelings or body sensations. Some individuals may experience re-experiencing of traumatic memories, increased anxiety, depression or insomnia.

It is possible that injuries could be sustained during the study either from the gentle mindful movements (i.e., yoga), or from physical activities that participants engage in as a way to reduce blood pressure. To help limit this, you will receive a handout showing the yoga poses that will be offered during the course that you can show your health care provider so that they can advise on which poses to do, and which to avoid. Modifications of poses will be available as needed. None of the poses (or the yoga as a whole) are mandatory to be done. You will also be encouraged to explore physical activities that promote strength and conditioning as a way to reduce blood pressure. You will be encouraged to not go beyond any physical limits of your body, and will be encouraged to ask your healthcare provider about advised physical activities and mindful movements if you have any physical limitations.

While physical and mental injury is always a possibility the potential for harm is limited. Note that a research injury is any physical or mental injury or illness caused by your participation in the study. If you are injured by a medical treatment or procedure that you would have received even if you were not in the study, that is not a research injury. To help avoid research injury and potential added medical expenses, it is important to follow all study directions carefully. If you are covered by insurance and suffer a research injury, it is possible that some or all of the costs of treating your condition could appropriately be billed to your insurance company. If such costs are not covered by your health insurance company, it is possible you would have to pay for these costs out of pocket. Brown University's policies do not cover payment for such things as lost wages, medical care expenses, or pain and suffering.

Precautions should be taken to avoid injuries. If you do become injured during the study, you should call your doctor immediately. You should also alert the study staff that you have been injured. Heart attack and sudden death related to heart problems have been known to occur in people while they are exercising. This is very rare, however. Estimates of sudden cardiac death range from 0 to 2 per 100,000 hours. However, the researchers cannot guarantee that no complications will happen to you.

The mindfulness classes may be video and/or audio recorded for training and educational purposes. The video monitor will focus on the face of the course instructor, and not on the faces of study participants. However, there is a possibility that your voice and face may be recorded.

6. What are the benefits?

We cannot and do not guarantee or promise that you will receive any direct benefits from this study. However, participation in the study creates the potential benefit of a) identifying effective treatments for elevated blood pressure, b) gaining knowledge of the effects of mindfulness practices, c) receiving information about your psychological and physical functioning. As part of the study, you will receive a wireless blood pressure monitor that will be yours to keep. This monitor may provide additional

opportunity to monitor your blood pressure at home, which may benefit your health by providing additional biofeedback.

7. How will my information be protected?

Your responses for this study will be kept confidential. All data that we collect will be linked to a study ID# instead of your name. All questionnaires in this study will be filled out through an online survey or a paper version of the survey if you prefer. All of these questionnaires will be linked solely to your study ID#, so that your identity is protected and your answers are confidential. All paper forms and data collection tools will be kept in a locked filing cabinet in a secure location. Study consent forms, including this one, will be kept in a locked filing cabinet separate from the research data. All electronic data files containing identifying information will be encrypted with a cloud-based software. Note that although these measures have been taken to protect your personal information, complete confidentiality cannot be guaranteed when transmitting information over the internet.

While your confidentiality is protected to the extent of the law, there are limitations to confidentiality. If your questionnaire responses indicate that you pose a serious danger to yourself or to another person, then a collaborator (Dr. Ellen Flynn) who is a licensed psychiatrist, may contact you to discuss your responses and possible referral to a treatment provider. Questionnaire items that may warrant follow-up include endorsements of statements about hurting yourself, any high scores in depression, anxiety, or other clinically significant problems. You should also know that there are times when the law might require the release of your responses without your permission. For example, State law requires researchers to report abuse or neglect of children to the Department of Children, Youth and Families (DCYF). State law also requires researchers to report abuse or neglect of people age 60 and older to the Division of Elderly Affairs.

The findings of the study may be used for medical publication. Your name will not be used in any published reports about this study. Results will be reported in a summarized manner in such a way that you cannot be identified. All personally identifiable information will be "de-identified" and only a unique code number will be used. Study records will be identified with a unique code number and initials. All study records and specimens will be stored in a secure storage area.

Keeping study records: The Principal Investigator for this study will keep your research records indefinitely for research purposes.

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.

The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by the National Center for Complementary and Integrative Health, which is funding this project. You should understand that a Certificate of Confidentiality does not prevent you from

voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it. The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law of situations of child abuse and neglect, or harm to self or others.

Finally, Brown University staff sometimes review studies like this one to make sure they are being done safely and correctly. If a review of this study takes place, your records may be examined. The reviewers will protect your confidentiality.

8. Are there any alternatives to this study?

A number of different therapies, including antihypertensive medication, diet changes, physical activity, and reducing excessive alcohol consumption may also be beneficial for reducing blood pressure. Education about these therapies are integrated into this course, but other forms of these alternative therapies are also available in the community.

9. What if I want to stop?

You do not have to be in this study if you do not want to be. Even if you decide to be in this study, you can change your mind and stop at any time. If you refuse to participate in or leave the study, your current or future relationship with Brown University as well as with your physician will not be affected. If you decide not to participate, or if you quit the study, we will provide you with referrals for alternative treatments, if desired.

10. Who can I talk to if I have questions about this study?

If you have any questions about your participation in this study, you can call the Senior Project Coordinator, Frances Saadeh, at 401-400-4768 or email at mindfulness@brown.edu. You may also contact the Principal Investigator at any time: Dr. Eric B. Loucks, email: eric.loucks@brown.edu, telephone (401) 863-6283.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This will not include information that can identify you. At most, the website will include a summary of the results. You can search this Web site at any time.

11. Who can I talk to if I have questions about my rights as a participant?

If you have questions about your rights as a research participant, you can contact Brown University's Human Research Protection Program at 401-863-3050 or email them at IRB@Brown.edu.

12. Consent to Participate

Your signature below shows that you have read and understood the information in this document, and that you agree to volunteer as a research participant for this study.

You will be offered a copy of this form.

Participant's Signature and PRINTED NAME	Date
Research Staff Signature and PRINTED NAME	Date