Consent Form

Please complete the survey below.

Thank you!

VUMC Institutional Review Board
Informed Consent Document for Research

Principal Investigator: Martha E. Shepherd, DO, MPH, FAAFP Revision Date: June 22, 2022
Version Number: 2
Study Title: Mindfulness-Based Stress Reduction for Metro Nashville Public School Employees
Institution/Hospital: Vanderbilt University Medical Center

1) Name of Participant: _____

2) Age: _____

The following information is provided to inform you about the research project and your participation in it. Please read this form carefully and feel free to ask any questions you may have about this study and the information given below. You will be given an opportunity to ask questions, and your questions will be answered. Also, you will be given a copy of this consent form.

Key Information:
The first section of this document contains some key points that the research team thought you would find important. The study is described in more detail after this section. If you do not understand something, please ask someone.

Key information about this study:
The purpose of this study is to:
- Assess how a 10-session, virtual, group-based Mindfulness-Based Stress Reduction (MBSR) course delivered over Zoom for public school employees impacts well-being, and
- Learn about participant experiences with the course.

MBSR will offer new ways to manage stress and support your overall well-being. If you decide to take part in this study, your participation will last for approximately 3 months. Before you begin the study, you will be asked to sign this consent form. You will then be asked to complete a baseline assessment survey, a follow-up assessment survey at 8 weeks, and another assessment survey at 12 weeks.

The first 30 employees to enroll in the MBSR course/study who are accepted as participants will participate in the MBSR course as follows: You will attend 10 total sessions virtually via Zoom: one 2.5-hour orientation, eight weekly classes for 2.5 hours each, and one Saturday encompassing a 7.5-hour day-long retreat.

Enrollees beyond the first 30 described above will be allocated to a control group, completing the surveys but not participating in the course. Control group members will receive an advance registration opportunity to a future MBSR course.

The benefits to humankind that might result from this study are that educators, administrators, healthcare providers and mindfulness teachers will learn best approaches for delivering the MBSR curriculum to public school system employees. This study will also help the MBSR instructors discover ways to improve the way the course is offered. The course may also equip you with multiple strategies to manage stress in daily living.

You will be paid for your time as part of this study. You can receive up to $100 for participating. Specifically, you will receive $25 for completing the baseline survey, $35 for completing the 8-week survey, and $40 for completing the 12-week survey. Surveys will occur: (i) prior to the MBSR course, (ii) at 8 weeks (after following the last course class), and (iii) at 12 weeks. We will ask for your Social Security number in order to process your compensation check(s). If you prefer not to provide your SSN, you may still take part in the course and study but waive compensation.

Detailed Information:

The rest of this document includes detailed information about this study (in addition to the information listed above).

You are being asked to take part in this research study because you have expressed interest in the MBSR course for helping with stress, anxiety, or depression. The purpose of this study is to assess how a 10-session virtual, group-based MBSR program delivered over Zoom for public school employees impacts well-being and to learn about participant experiences with the course.

You do not have to be in this research study. You may choose not to be in this study and get other treatments without changing your healthcare, services, or other rights. You can stop being in this study at any time. If we learn something new that may affect the risks or benefits of this study, you will be told so that you can decide whether or not you still want to be in this study.

Procedures to be followed and approximate duration of the study:
If you decide to take part in this study, the time commitment is approximately 3 months following orientation to the MBSR course.

Before you begin the study, you will be asked to sign this consent form. You will then be asked to complete a questionnaire about your mood and well-being. If you are allocated to participating in the course, you will then attend 10 total sessions virtually: a 2.5-hour orientation, 8 weekly classes for 2.5 hours each, plus one Saturday encompassing a 7.5-hour day long retreat.

You will be asked to complete follow-up surveys at 8 weeks and 12 weeks. The surveys will ask you about your mood, well-being, and experiences with the MBSR course, if applicable.

Expected costs:
There is no cost to you for taking part in this study.

Description of the discomforts, inconveniences, and/or risks that can be reasonably expected as a result of participation in this study:
There may be distress related to answering questions and talking about your stressors. Although no personal information shared before or during the course will be made public or shared with MNPS, district staff, or anyone outside Vanderbilt staff coordinating the course, there is the risk that information about you may become known to others. The study staff will try to keep this from happening by using a code instead of your name on information that you give to us.

Compensation in case of study-related injury:
If it is determined by Vanderbilt and the Investigator that an injury occurred as a direct result of the tests or treatments that are done for research, then you and/or your insurance will not have to pay for the cost of immediate medical care provided at Vanderbilt to treat the injury.

There are no plans for Vanderbilt to pay for any injury caused by the usual care you would normally receive for treating your illness or the costs of any additional care. There are no plans for Vanderbilt to give you money for the injury.

Good effects that might result from this study:

a) The benefits to science and humankind that might result from this study are that educators, administrators, healthcare providers and mindfulness teachers will learn best approaches for delivering the MBSR curriculum virtually to public school system personnel. This study will also help the MBSR instructors in determining ways to improve adherence and satisfaction with the MBSR curriculum by determining barriers and facilitators to participation in this course.
b) The benefits you might get from being in this study are to learn more about stress and ways to actively cope with and manage stress personally and inter-personally.

Study Results:
Study results will not be directly communicated or shared with study participants.

Alternative treatments available:
This is not a study designed to determine effectiveness of a new treatment for stress, anxiety, or depression. Mindfulness interventions like those used in the study are available through many psychologists and other healthcare providers.

Compensation for participation:
You will be paid for your time as part of this study. You can receive up to $100 for participating. Specifically, you will receive $25 for completing the baseline survey, $35 for completing the 8-week survey, and $40 for completing the 12-week survey. Surveys will occur: (i) prior to the MBSR course, (ii) at 8 weeks (at or following the last course class), and (iii) at 12 weeks. We will ask for your Social Security number in order to provide you compensation check(s). If you prefer not to provide your SSN, you may still take part in the course and study but waive compensation.

Circumstances under which the Principal Investigator may withdraw you from study participation:

The entire study could be stopped at any time if the safety of research participants is found to be at significant risk. If the study is stopped for any reason, you will be told that the study is being stopped. If you are taken out of the study, you will be told the reason why.

What happens if you choose to withdraw from study participation?
If you decide to stop being part of the study, you should tell the Principal Investigator. Deciding to not be part of the study will not affect your regular medical care in any way.

Contact Information. If you should have any questions about this research study or possible injury, please feel free to contact Martha E. Shepherd, DO, MPH, FAAFP at 615-259-8755.

For additional information about giving consent or your rights as a participant in this study, to discuss problems, concerns, and questions, or to offer input, please feel free to contact the Institutional Review Board Office at (615) 322-2918 or toll free at (866) 224-8273.

Confidentiality:
All efforts, within reason, will be made to keep your personal information in your research record confidential, but total confidentiality cannot be guaranteed. The results of this research study may be presented at scientific or medical meetings or published in scientific journals. However, your identity will not be disclosed.

All information will be collected using electronic Case Report Forms (CRFs). Martha E. Shepherd, DO, MPH, FAAFP will ensure that adequate clinical investigation records, including CRFs, signed patient informed consent forms, Adverse Event reports and any source documents are maintained. These documents will be kept in REDCap, a secure platform for research. The primary investigator and study personnel will be the only people who have access to these records.

Any information you provide to us will also be stored in a password-protected database and will only be accessed by the study staff. Any information that could link you to the study will be removed from this database and destroyed.

This study may have some support from the National Institutes of Health (NIH). If so, your study information is protected by a Certificate of Confidentiality. This Certificate allows us, in some cases, to refuse to give out your information even if requested using legal means.

It does not protect information that we have to report by law, such as child abuse or some infectious diseases. The Certificate does not prevent us from disclosing your information if we learn of possible harm to yourself or others, or if you need medical help.

Disclosures that you consent to in this document are not protected. This includes putting research data in the medical record or sharing research data for this study or future research. Disclosures that you make yourself are also not protected.

Vanderbilt may share your information, without identifiers, to others or use it for other research projects not listed in this form. Vanderbilt, Martha E. Shepherd, DO, MPH, FAAFP, and staff will comply with any and all laws regarding the privacy of such information. There are no plans to pay you for the use or transfer of this de-identified information.

Privacy:
Any samples and information about you may be made available to others to use for research. To protect your privacy, we will not release your name. You will not receive any benefit as a result of the tests done on your samples. These tests may help us, or other researchers learn more about the causes, risks, treatments, or how to prevent this and other health problems.

STATEMENT BY PERSON AGREEING TO PARTICIPATE IN THIS STUDY

I have read this informed consent document and the material contained in it has been explained to me verbally. All my questions have been answered, and I freely and voluntarily choose to participate.

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3) Date: _____

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4) Signature of patient/volunteer: _____

Consent obtained by:

5) Date: _____

6) Signature _____

7) Printed Name and Title _____

Date of IRB Approval: 07/15/2022

Institutional Review Board