Informed Consent Form

TITLE: Shift-and-persist and Cardiometabolic Markers Among Women in Puerto Rico

NCT NUMBER: NCT06250738

IRB APPROVAL DATE: 2/7/2024

You Are Being Asked to Be in a Research Study

Concise presentation of key concepts

You are being asked to be in a research study. A research study is designed to answer a scientific question. If you agree to be in the study you will be one of 30 people who will participate at Emory.

Why is this study being done?

This study aims to find out if a 4-week mindfulness program is practical and suitable for young women in Puerto Rico who have high levels of stress. Mindfulness teaches people to focus on the present moment with an open mind. The research will see if young women in Puerto Rico, dealing with high stress, can complete this program and will identify what parts of it were helpful. The study will also check if mindfulness can improve the emotional well-being and cardiometabolic outcomes (blood pressure, pulse, and weight) of these women. You are invited to participate because you are a woman aged 18 to 29, live in Puerto Rico, feel stressed, are able to answer questions in Spanish, and have access to phone and internet.

Do you have to be in the study?

It is your choice to join this study. You do not have to be in it. Before you choose, take time to learn about the study.

What do you have to do if you choose to join this study?

If you meet the criteria and want to participate, you will be part of a 4-week mindfulness program. This program includes one virtual session per week. The first session lasts 1.5 hours and the remaining three are of 1 hour each. You will also practice mindfulness exercises at home daily, taking between 5 to 15 minutes, depending on your availability. There will be three online assessments in total: one before starting the program, another one at the end of the program, and one a month after doing the program. During the assessments, we will ask you questions about your background, mental well-being, lifestyle, and resilience. We will also ask you to self-report your weight, blood pressure, and pulse, if you know them.

How is this study going to help you?

The main goal of the study is to find out if a 4-week mindfulness program is good for young women with stress who live in Puerto Rico. The study will also see if this program has any benefits. We do not know if you will receive personal benefits from participating in this study. Potential benefits might include learning about mindfulness, feeling less stressed, and having

better emotional well-being. We also hope that the knowledge gained from this study may help others in the future.

What are the risks or discomforts you should know about before deciding?

The mindfulness program may not work and you may not notice any benefits. All studies have some risks. Some risks are small, like being bored. Some are more serious. Risks for this study are:

- the time needed for the weekly sessions and completion of the questionnaires
- feeling uncomfortable when talking about difficult things, such as stressful things
- loss of privacy
- breach of confidentiality

You can find a full list of risks in the section titled "What are the possible risks and discomforts?"

Alternatives to Joining This Study

The alternative to not joining the study is to not participate.

Costs

You won't have to pay anything to do this study. You don't have to pay for any of the research activities.

This study will pay for your time in the study, and you will receive a gift card valued at $25 for completing the first assessment, a $50 gift card for completing the program and a post-intervention assessment, and an additional $25 gift card for completing the online assessment 1-month after the program. Completion of all study activities may add up to $100 in gift cards.

What Should You Do Next?

Read this form, or have it read to you. Make sure the study staff explains the study to you. Ask questions such as how much time you will have to spend on the study, any words you do not understand and details about study. Take time to think about this and talk about it with your family and friends.

Emory University
Consent to be a Research Subject

Title: Shift-and-persist and cardiometabolic markers among women in Puerto Rico: a pilot of a mindfulness-based trial.

IRB #: STUDY00006752

Principal Investigator:
[redacted]
Department of Epidemiology
Emory University

Funding Source:
Emory BIRCWH Program

Introduction
You are being asked to be in a research study. This form will tell you everything you need to think about before you decide to consent (agree) to be or not to be in the study. **It is entirely your choice. If you decide to take part, you can change your mind later and leave the study. You can skip any questions that you do want to answer.**

Before making your decision:
- Please carefully read this form or have it read to you
- Please ask questions about anything that is not clear

You can take a copy of this consent form. Feel free to take your time thinking about whether you want to participate. By signing this form you will not give up any legal rights.

This trial will be registered and may report results on www.ClinicalTrials.gov, a publicly available registry of clinical trials.

What is the purpose of this study?
This study wants to find out if a 4-week mindfulness program is practical and suitable for young women in Puerto Rico who have high levels of stress. Mindfulness teaches people to focus on the present moment with an open mind. The study will explore if young women in Puerto Rico, dealing with high stress, can complete this program and will identify what parts of it were helpful. The study will also check if mindfulness can improve the emotional well-being and cardiometabolic outcomes (blood pressure, pulse and weight) of these women. You are invited to participate because you are a woman between 18-29 years, live in Puerto Rico, feel stressed, are able to answer questions in Spanish, and have access to phone and internet.

What will you be asked to do?
You will complete 3 study assessments and the 4-week mindfulness program
-Before starting the 4-week mindfulness program, you will fill out an online questionnaire, which will ask about socio-demographic characteristics, stress, habits, and well-being. The survey will also ask you to report your weight, height, blood pressure, and pulse if you know them. This questionnaire should take less than 40 minutes.

-During the program, you will participate in four virtual sessions. The first session lasts 1.5 hours, and the remaining three are 1 hour each. You'll also have access to audio files for daily mindfulness exercises at home. These exercises can be short (5-8 minutes) or longer (12-15 minutes) depending on your schedule.

-After completing the program, you will fill out an online questionnaire and tell us what you think about the program. A month after finishing the program, you will complete a final online questionnaire about your stress levels, habits, and well-being.

Who owns your study data and samples?
If you join this study, you will be donating your data. If you leave the study, the data that were already collected may still be used for this study.

What are the possible risks and discomforts?
The mindfulness program might have unknown side effects. Participating in this study could take lot of time for the weekly sessions and filling out questionnaires. It is possible that the mindfulness practices might not be helpful for you, and you might not experience positive effects. Researchers might ask you about stress and stress management, which could make you uncomfortable. The interviewers are trained to be sensitive and will try to minimize any discomfort. We will give you a toll-free number you can call anytime for emotional support. If you need in-person help, we can also provide information about a local clinic. One potential risk is that your confidential information might be accidentally shared. We will do everything we can to keep your information safe, like removing personal details and using passwords and locks. We won't collect any data about your criminal or civil records or any sensitive personal information that could lead to that kind of data.

Researchers may learn something new during the study that may affect your choice to be in the study. If this happens, they will tell you about it. Then you can choose if you want to stay in this study.

Will you benefit from the study?
You may not benefit directly from joining the study. We cannot promise any benefits to others from your participation. However, the potential benefits could include learning about mindfulness, lowering stress, and improving emotional well-being. We also hope that what we learn from this study may help others in the future.

Will you be paid for your time and effort?
You will receive gift cards as compensation for participating in the study. After the first assessment, you will get a $25 gift card. After completing the 4-week program and the second assessment you will get a $50 gift card. After completing the final study assessment, you will get another $25 gift card. So, if you complete all activities, you will get $100 in gift cards. If you do not complete the study, we will compensate you for the activities you did.

What are your other options?
Taking part in this study is your choice. If you decide to participate, you may leave or stop the study at any time. There will be no penalty to you. If you would like to stop participating, you should let us know. We will make sure that you stop the study safely.

How will your private information be protected?
Every effort will be made to make sure that your participation in this study, and all records related to your participation, are confidential. The principal investigator of this study, [redacted], will train and require all study personnel to not quote or identify any participant. Only authorized members of the research team will have access to the data collected and files and will be trained to keep all information confidential.

Electronic files will be kept on password-protected computers or programs. To analyze the data, we will give each participant a unique identification number as part of a coding system to link the information you provide. These data and the link between the research code and the identifiers will be kept in separate files and on a password-protected computer. Your name and other personal identifying information will not be associated with the information you provide. Any results of this research study that become published or presented at meetings will be presented grouped for all participants; your identity will not be revealed.

However, confidentiality cannot be absolutely guaranteed. Data collected, including your identifiable information, may be seen by Emory University's Institutional Review Board (IRB) which oversees the research. We may also share your information related to this study with other parties with the right to review the records from this study, including translators, transcribers, thesis committees, FDA, and/or other federal agencies as applicable. This may occur to ensure that this study is being properly conducted and following all applicable regulations and laws. Your identity will be revealed only as required by law.

Certificate of Confidentiality

There is a Certificate of Confidentiality from the National Institutes of Health for this Study. The Certificate of Confidentiality helps us to keep others from learning that you participated in this study. Emory will rely on the Certificate of Confidentiality to refuse to give out study information that identifies you. For example, if Emory received a subpoena for study records, it would not give out information that identifies you.

The Certificate of Confidentiality does not stop you or someone else, like a member of your family, from giving out information about your participation in this study. For example, if you let your insurance company know that you are in this study, and you agree to give the insurance company research information, then the investigator cannot use the Certificate to withhold this information. This means you and your family also need to protect your own privacy.

The Certificate does not stop Emory from making the following disclosures about you:

- Giving state public health officials information about certain infectious diseases,
- Giving law officials information about abuse of a child, elderly person or disabled person.
- Giving out information to prevent harm to you or others.

Giving the study sponsor or funders information about the study, including information for an audit or evaluation.

Storing and Sharing your Information

We will store all the data that you provide using a code. We need this code so that we can keep track of your data over time. This code will not include information that can identify you. Specifically, it will not include your name, initials, date of birth, or medical record number. We will keep a file that links this code to your personal identifying-information in a secure location separate from the data.

We will not allow your name and any other fact that might point to you to appear when we present or publish the results of this study.

Your data may be useful for other research being done by investigators at Emory or elsewhere. We may share the data, linked by the study code, with other researchers at Emory, or with researchers at other institutions that maintain at least the same level of data security that we maintain at Emory. We will not share the link between the study code and your identity.

Costs
There will be no costs to you for participating in this study.

Withdrawal from the Study
You have the right to leave a study at any time without penalty.

The person in charge of the research study, [redacted], or any of the study representatives designated by her, can remove you from the research study without your approval for any reason. Possible reasons to remove you are lack of commitment to the study, hostility or aggressive behavior towards study staff, study discontinuation, or changes in study protocols. We will tell you about any new information that may affect your choice to stay in the research.

Confidentiality
Certain offices and people other than the researchers may look at study records. Government agencies and Emory employees overseeing proper study conduct may look at your study records. These offices include the Office for Human Research Protections, the Emory Institutional Review Board, the Emory Office of Compliance. Study funders may also look at your study records. Emory will keep any research records we create private to the extent we are required to do so by law. A study number rather than your name will be used on study records wherever possible. Your name and other facts that might point to you will not appear when we present or publish this study.

People Who will Use/Disclose Your Information:
The following people and groups will use and disclose your information in connection with the research study:

- The Principal Investigator and the research staff will use and disclose your information to do the study.
- The Principal Investigator and research staff may share your information with other people and groups to help with the study.
- The NIH BIRCWH Program is the Supporter of the study. The Supporter may use and disclose your information to make sure the research is done correctly and to collect and analyze the results of the research. The Sponsor may disclose your information to other people and groups like study monitors to help conduct the study or to provide oversight for the study.
- The following people and groups will use your information to make sure the research is done correctly and safely:
    - Emory offices that are part of the Human Research Participant Protection Program and those that are involved in study administration and billing. These include the Emory IRB, the Emory Research and Healthcare Compliance Offices, and the Emory Office for Clinical Research.
    - Government agencies that regulate the research including: Office for Human Research Protections
    - Public health agencies.
    - Research monitors and reviewer.
    - Accreditation agencies.
- Sometimes a Principal Investigator or other researcher moves to a different institution. If this happens, your information may be shared with that new institution and their oversight offices. Information will be shared securely and under a legal agreement to ensure it continues to be used under the terms of this consent.

Contact Information

If you have questions about the study, appointments, research-related injuries, or other questions or concerns about the research or your part in it, contact [redacted] You can also contact the study email: estudio.mindfulnesspr@gmail.com

This study has been reviewed by an ethics committee to ensure the protection of research participants. If you have questions about your **rights as a participant**, or if you have **complaints** about the research or an issue you would rather discuss with someone outside the research team, contact the Emory Institutional Review Board at 404-712-0720 or 877-503-9797 or irb@emory.edu.

To tell the IRB about your experience as a participant, fill out the Research Participant Survey at https://tinyurl.com/ycewgkke.

Consent

I have read the information in this consent form including risks and possible benefits. All my questions about the research have been answered. I understand that I am free to withdraw at any time without penalty or loss of benefits to which I am otherwise entitled.

I consent to participate in the study.

☐Yes ☐No

If you consent to participate in the study:

1. **Do you agree to have a study representative from Emory University contact you regarding possible participation in a future study if you qualify?**

☐Yes ☐No

TO BE FILLED OUT BY SUBJECT ONLY

Print your name, **sign**, and **date** below if you choose to be in this research study. You will not give up any of your legal rights by signing this form. We will give you a copy of the signed form to keep.

_____

Name of Subject

_____ _____

Signature of Subject (18 or older and able to consent) **Date** **Time**

TO BE FILLED OUT BY STUDY TEAM ONLY

_____

Name of Person Conducting Informed Consent Discussion

_____ _____

Signature of Person Conducting Informed Consent Discussion **Date** **Time**