

Official Title: MATCH study: Mindfulness App Training for Cardiovascular Health

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CONSENT TO ACT AS A PARTICIPANT IN A SCREENING PROCEDURE

TITLE: MATCH study: Mindfulness App Training for Cardiovascular Health—Part 1

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QUESTIONS ABOUT THE STUDY:

You can contact the study investigators if you have any questions about the study, concerns, or complaints. Contact Principal Investigators, Dr. Kamarck, at 412-624-4500 or Dr. Lindsay at 412-648-4515.

SOURCE OF SUPPORT:

National Institutes of Health

KEY INFORMATION:

The purpose of the MATCH study is to examine whether a smartphone-based mindfulness training intervention reduces stress and cardiovascular responses to stress during daily life. **This consent form provides information about the screening procedure that allows us to determine whether you are eligible for the MATCH study. This screening procedure should take no more than 45 minutes.** During this screening procedure, we will ask you some questions to confirm that you are eligible for the MATCH study, we will measure your height and weight, and we will measure your resting blood pressure. If all of your measures and responses indicate that you are eligible for the MATCH study, we will give you a second consent form describing the larger study in more detail, we will ask you to decide whether you are still interested in participating, and, if you are, there will be some additional questionnaires and procedures. This second part of the visit should take up to an additional 2 hours (total of 2 hours and 45 minutes). If one or more of your measures or responses during the screening procedure indicate that you are not eligible, you may leave after the first 45 minutes, and you will be unable to participate in the MATCH study at this time. In this case, you will be paid \$15.00 for your time today and your parking or transportation costs for today's visit will be reimbursed.

Why is this research being done?

There is some evidence that chronic stress (for example, work stress or marital conflict) may increase the likelihood of developing high blood pressure or heart disease. There is also some evidence that people who are more biologically reactive to stress may be at higher risk for these conditions. Treatments that focus on mindfulness training have been shown to improve well-being, but not much is known about the effects of these treatments on stress and stress responses during the course of daily living, and what the duration of such effects may be. The purpose of the MATCH study is to examine whether a smartphone-based mindfulness training intervention may reduce chronic stress and blood pressure responses to stress during daily life, and to evaluate whether this intervention is suitable for use in future research studies examining the effects of mindfulness training interventions on early signs of heart disease.

Who is being asked to take part in this screening procedure?

You are being asked to participate in this screening procedure for the MATCH study because you are age 45 or older, because you have some conditions that increase the likelihood of developing heart disease later in life, and because your responses to some of our questions and procedures suggest that you may be a good candidate for stress management training.

What will happen during this screening procedure?

1. We will ask you questions about your consumption and activity patterns this morning, and about your medical history, medication use, and current mental health status to confirm your eligibility for the MATCH study.
2. We will measure your blood pressure at rest using an automated blood pressure device.
3. We will provide you with feedback on your measures and responses, and we will let you know whether you continue to qualify for the MATCH study.

This screening procedure (the first part of this visit) should take no longer than 45 minutes.

Are there any risks to me?

The risk of completing the screening questionnaires in this study is minimal, but the nature of some of the questions is personal (for example, about your emotional well-being) and answering them might be stressful, uncomfortable, or embarrassing to some people. You should know that you are not obligated to answer any questions that make you uncomfortable.

Blood pressure measurement is a standard medical procedure. We will take your blood pressure 3 times over the course of this screening procedure. The cuff inflation can cause some minor discomfort.

As with all studies that involve the collection of personal information, there is a possible risk that your information could become revealed to others. However, this risk is minimized by using a code number rather than your name, birthdate, or other personal identifiers, so that your identity is not directly linked to your responses. In addition, we keep all consent forms, questionnaire data, and other identifying information confidential and maintained in locked files or in password-protected electronic files available only to professional personnel of the research team. All personnel involved in the study will sign a statement agreeing to protect your confidentiality. All data entry will make use of Research Electronic Data Capture (REDCap), which is a secure, password protected, web-based application.

Who will have access to identifiable information related to my participation in this screening procedure?

The principal investigator and research staff will have access to the data files. Your

identity on these records will be indicated by an ID number, rather than by your name; the information linking these numbers with your name will be kept in a separate, secure location until the study is complete, after which this information will be destroyed. Your identity will not be revealed in any description or publications of this research. Only group characteristics will be published.

Authorized representatives of the University of Pittsburgh Office of Research Protections may review your identifiable research information for the purpose of ensuring the appropriate conduct of this research study. In addition, your de-identified information may be used by other researchers for future research studies. If this happens, we will not contact you for additional consent.

In unusual cases, your research records may be released in response to an order from a court of law. If the investigators learn that you or someone with whom you are involved is in serious danger or potential harm, they will need to inform the appropriate agencies, as required by Pennsylvania law. Per University of Pittsburgh policy, all research records must be maintained for at least 7 years following final reporting or publication of a project. However, the records may be kept indefinitely.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that the researchers cannot release or use information, documents, or samples that may identify you in any action or suit unless you say it is okay. They also cannot provide them as evidence unless you have agreed. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings. An example would be a court subpoena.

The Certificate DOES NOT stop reporting that federal, state or local laws require. Some examples are laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others. The Certificate CANNOT BE USED to stop a sponsoring United States federal or state government agency from checking records or evaluating programs. The Certificate DOES NOT stop disclosures required by the federal Food and Drug Administration (FDA). The Certificate also DOES NOT prevent your information from being used for other research if allowed by federal regulations.

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.

Who will pay if I am injured as a result of taking part in this screening procedure?

If you believe that the research procedures have resulted in an injury to you, immediately contact the Principal Investigator who is listed on the first page of this form. Emergency medical treatment for injuries solely and directly related to your participation in this research study will be provided to you by the hospitals of UPMC. Your insurance provider may be billed for the costs of this emergency treatment, but none of those

costs will be charged directly to you. If your research-related injury requires medical care beyond this emergency treatment, you will be responsible for the costs of this follow-up care. At this time, there is no plan for any additional financial compensation. You do not, however, waive any legal rights by signing this form.

Are there any benefits to me?

You may or may not receive any direct benefit from taking part in this research study. You will receive information about your resting blood pressure. A potential benefit of study participation includes the contribution to knowledge in delivering stress management programs more widely as well.

Will I be paid if I take part in this screening procedure?

If the information you provide to us today indicates that you are eligible for the MATCH study and you decide to enroll, you will not be paid for your participation in this screening visit, but you will be paid up to \$300 for your participation in the MATCH study.

If you are not eligible for or interested in the MATCH study, you will receive \$15 for your participation in this screening procedure.

In any case, parking fees or public transportation costs to the Behavioral Medicine Research Laboratory will be paid for by the research study. There are no additional costs to you for participating in the screening visit.

All compensation is taxable income to the participant regardless of the amount. Because of this, you will be asked for your name, address, and social security number, and this information will be released to the University of Pittsburgh Accounting Office. Individuals who do not provide a social security number may still participate in the research, but the IRS requires that 24 % of the payment be sent by the institution to the IRS for “backup withholding,” thus you would only receive 76 % of the expected payment. If a participant receives \$600 or more in a calendar year from one organization (for example, the University of Pittsburgh), that organization is required by law to file a Form 1099- Miscellaneous with the IRS, and to provide a copy to the taxpayer.

Is my participation in this screening procedure voluntary?

Yes, your participation in this screening procedure is completely voluntary. You can choose to withdraw from this visit at any time. If you decide not to participate or to withdraw from this screening visit, there will be no consequences whatsoever on your current or future relationship with the University of Pittsburgh. If you choose to withdraw, all data collected prior to the date of withdrawal may be continued to be used, unless you request that we destroy it.

If you would like to withdraw from the screening procedure and you are no longer interested in the MATCH study, please inform the research associate who is working with you today.

How can I find out about the results of this research study?

A description of this clinical trial is available on <http://www.clinicaltrials.gov> with identifier [NCT06152185](http://www.clinicaltrials.gov/ct2/show/study?term=NCT06152185), as required by US Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

Is there anything else I should know about this study?

The information you provide to us in this research study may contribute to a new discovery or treatment. In some instances, these discoveries or treatments may be of commercial value and may be sold, patented, or licensed by the investigators and the University of Pittsburgh for use in other research or the development of new products. You will not retain any property rights nor will you share in any money that the investigators, the University of Pittsburgh, or their agents may realize.

Your information collected as a part of this research, after removal of identifiers, could be used for future research studies or distributed to another investigator for future research studies without additional informed consent.

Whom should I contact if I have questions?

You may ask any questions about the research at any time. If you have questions about the research, you should contact the Co- Principal Investigators Thomas Kamarck at

412-624-4500 or Emily Lindsay at 412-648-4515. If you are not satisfied with the response of the research team, have more questions, or want to talk with someone about your rights as a research participant, you should contact the University of Pittsburgh Human Subject Protection Advocate toll-free at 1-866-212-2668.

VOLUNTARY CONSENT TO PARTICIPATE

The above information has been explained to me and all of my current questions have been answered. I understand that I am encouraged to ask questions about any aspect of this research study during the course of this study, and that such future questions will be answered by a qualified individual or by the investigator(s) listed on the first page of this consent document at the telephone number(s) given. I understand that I may always request that my questions, concerns, or complaints be addressed by a listed investigator.

I understand that I may contact the Human Subjects Protection Advocate of the IRB Office, University of Pittsburgh (1-866-212-2668) to discuss problems, concerns, and questions; obtain information; offer input; or discuss situations in the event that the research team is unavailable.

By signing this form, I agree to participate in this screening procedure. A copy of this consent form will be given to me.

Printed Name of Participant

Signature of Participant

Date

CERTIFICATION of INFORMED CONSENT

I certify that I have explained the nature and purpose of this screening procedure to the above-named individual, and I have discussed the potential benefits and possible risks of study participation.

Any questions the individual(s) have about this study have been answered, and we will always be available to address future questions as they arise. I further certify that no research component of this protocol was begun until after this consent form was signed.

Printed Name of Person Obtaining Consent

Role in Research Study

Signature of Person Obtaining Consent

Date



University of Pittsburgh

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Department of Psychology

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CONSENT TO ACT AS A PARTICIPANT IN A RESEARCH STUDY

TITLE: MATCH study: Mindfulness App Training for Cardiovascular Health—Part 2

CO-PRINCIPAL INVESTIGATORS:

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Brittany Alberts
Study Coordinator
University of Pittsburgh

William Eckerle
Graduate Student
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Eli Rice
Graduate Student
University of Pittsburgh

QUESTIONS ABOUT THE STUDY:

You can contact the study investigators if you have any questions about the study, concerns, or complaints. Contact Principal Investigators, Dr. Kamarck, at 412-624-4500 or Dr. Lindsay at 412-648-4515.

SOURCE OF SUPPORT:

National Institutes of Health

KEY INFORMATION:

The purpose of the MATCH study is to examine whether a smartphone-based mindfulness training program reduces stress and cardiovascular responses to stress during daily life. This consent form provides information about the MATCH study to help you decide if you would like

to enroll. For scientific reasons, this consent form does not include all of the information about the research question being tested, but the researchers will give you more information when your participation in the study is over. The study involves a 5-month commitment.

There are two conditions in this study: mindfulness training and life as usual. Some participants will be assigned to receive mindfulness training, and other participants will be assigned to life as usual. Participants in the mindfulness training condition will listen to a 20-minute lesson each day over the course of a one-month period, and they will be asked to practice some mental exercises to apply mindfulness skills in daily life. Participants in the life as usual condition will not receive the mindfulness training program, but they are free to pursue other treatments for stress management if they wish. At the end of the 5-month period, participants in the life as usual condition will be given access to the mindfulness training program, if they choose to use it.

Participants in both conditions will attend 7 visits over the course of 5 months (20 weeks), and they will participate in 3 one-week periods of daily life monitoring. Participants will be asked to monitor their blood pressure during 3 days of each week. The purpose of the visits and the daily life monitoring is to help us determine if there are any changes in daily life stress or responses to stress over the course of the study.

Table 1. Study Visits

Week 1-2	Visit 1	Informed Consent and Screening
	Visit 2	First Daily Monitoring Training → 3 days of monitoring during 7-day period
	Visit 3	Post-Monitoring and Treatment Assignment Visit
Week 3-6		Four-week Training Period
Week 7	Visit 4	Second Daily Monitoring Training → 3 days of monitoring during 7-day period
	Visit 5	Second Post-Monitoring Visit
Week 18-20	Visit 6	Third Daily Monitoring Training → 3 days of monitoring during 7-day period
	Visit 7	Third Post-Monitoring Visit

Why is this research being done?

There is some evidence that chronic stress (for example, work stress or marital conflict) may increase the likelihood of developing high blood pressure or heart disease. There is also some evidence that people who are more biologically reactive to stress may be at higher risk for these conditions. Treatments that focus on mindfulness training have been shown to improve well-being, but not much is known about the effects of these treatments on stress and stress responses during the course of daily living, and what the duration of such effects may be. The purpose of this study is to examine whether a smartphone-based mindfulness training program may reduce chronic stress and blood pressure responses to stress during daily life, and to evaluate whether this program is suitable for use in future research studies examining the effects of mindfulness training programs on early signs of heart disease.

Who is being asked to take part in this study?

You are being asked to participate in this study because you are age 45 or older, because you have some conditions that increase the likelihood of developing heart disease later in life, and

because your responses to some of our questions and procedures suggest that you may be a good candidate for stress management training.

What procedures will be performed for research purposes?

You will attend 7 visits, and 3 daily monitoring periods over the course of 5 months. In addition, if you are assigned to the mindfulness training condition, you will be asked to complete a 20-minute lesson each day over the course of a one-month period. Each of these procedures is described below.

Pre-Visit Reminder Phone Calls (5 - 10 minutes each): Before each of your visits, we will contact you to remind you about your appointment and provide you with pre-visit instructions. These pre-visit instructions include specific times when you will need to avoid meals or exercise (3 hours before the visit), caffeine (2 hours before the visit), smoking (1 hour before the visit), alcohol (no alcohol after 9 pm the night before), and non-caffeinated beverages (30 minutes before the visit). We ask that you follow these instructions because we want the measurements of resting blood pressure collected during the visit to be as accurate as possible.

Visit 1, Informed Consent and Screening (Sennott Square, 2 hours). You have already participated in the first part of Visit 1, which involved answering some screening questions, measuring your height and weight, and measuring your blood pressure at rest. At this point, you will learn about the details of the study, and decide whether to participate (informed consent). If you do decide to participate, the remainder of the Visit will take approximately 2 hours, and will involve completing some questionnaires and participating in two challenging laboratory tasks meant to simulate some of the stressors you face during your daily life, one involving rapid decisions, and one involving a public speaking task. You may be videotaped during the public speaking task. We will measure your blood pressure about 20 times before and during the tasks, and this procedure will take about 30 minutes.

Visit 2, First Daily Monitoring Training (Sennott Square, 2-1/2 hours). At your next visit, Visit 2, we will take your blood pressure at rest again, then we will train you in the procedures that will be used for daily monitoring. You will learn how to use an automated portable blood pressure device for measuring your blood pressure each hour during the day, and you will learn how to use a Fitbit wristband activity monitor, for measuring physical activity and heart rate. We will install two applications on your smartphone, one that will administer hourly questionnaires (questionnaire application), and one that will collect sensor data during the monitoring period (sensor application). These are all safe devices and procedures used to assess a person's activity habits and daily behaviors. You will be provided with detailed instructions regarding the devices, and we will assist in helping you remove the devices or the applications if any of these become a problem.

Following the training session, you will be asked to practice using these devices for the rest of the day, and for the first part of the following day. During late morning the day after Visit 2, you will receive a "practice day" phone call (15 minutes). A research associate will phone you to

assist with any problems that may have occurred, and to answer any questions you may have before the first daily life monitoring period.

First Daily Life Monitoring Period (7-day period, 3 days of full monitoring):

We will ask you to begin your first daily life monitoring period (7 days) the day after your practice phone call. The Fitbit activity monitor will be worn on your wrist at all times (day and night) during the 7-day monitoring period. The Fitbit will be used to assess activity levels as well as heart rate, breathing rate, skin temperature, oxygen level, and sleep. We will install the Fitbit application on your phone to permit wireless syncing of your data, and we will ask you to charge your Fitbit as needed (approximately once every 5-10 days). We will ask you to carry your smartphone with you at all times during the daily life monitoring period. The blood pressure device will be worn during 3 “full monitoring” days during the daytime only.

On the 3 “full monitoring” days, your blood pressure will be taken every 60 minutes throughout the day (approximately 16 hours). Immediately following each blood pressure reading, you will be prompted to complete a 2-3 minute questionnaire about your current mood and activities on the smartphone questionnaire app. If you smoke cigarettes, you will also be asked to respond on the smartphone each time you smoke a cigarette.

Right before bedtime, you will be prompted on the smartphone to turn off the portable blood pressure equipment. You will set a wake-up alarm on the smartphone for the time of your choosing for next morning. If the next day is a full monitoring day, you will be asked to put on the blood pressure equipment (allowing time for grooming, showering, etc.). Once again, the Fitbit activity monitor will be worn at all times (day and night) during the 7-day monitoring period.

The sensor application that we will install on your smartphone will collect sensor data during the monitoring period as you go about your daily life. You will need to carry your smartphone with you at all times in order for this application to work correctly. This software will collect information several times per hour, including movement, approximate location of the phone, time zone, screen status (on/off), Wifi, battery level, and call metadata. We are collecting this information in order to help us measure indicators of stress in people’s daily lives. The application will store this information on the device, and will transmit this information to one of our secure servers at least once a week.

All sensor data captured for this research will be linked only to your participant ID, and will not include any personally identifiable information about you. We are only collecting general data patterns, such as the timestamp of phone events. We do not collect the names or phone numbers of individuals who you are calling. Each person with whom you communicate with via smartphone will be assigned a unique ID number so that we know frequency of contact with each person, but not the identity of anyone with whom you communicate. We will not be recording any audio data or collecting any data about anything you speak on your phone. The data plan requirements of the application are not significantly different from what most smartphone users require if they use their device to access the Internet for web searching. At

the end of each monitoring period, we will assist you in uninstalling the sensor application from your smartphone.

We will not collect any data that gives us information about life-threatening medical conditions, and we will not fully process your data until after the end of the study. We encourage you to report any medical concerns/conditions to your doctor.

Additional Contacts (15 minutes): A phone call will be scheduled for the first or second day of your daily monitoring period to answer any questions you may have and to address any difficulties you may be having.

Visit 3, Post-Monitoring and Treatment Assignment Visit (Sennott Square, 2 hours). At the end of the first daily monitoring period, you will return to the lab so that we can check in your equipment and download your data. We will take your blood pressure at rest once again. We will check the number of blood pressure readings and hourly questionnaires that you completed during the daily monitoring period. If you did not complete the expected number of blood pressure readings or hourly questionnaires, we may ask you to complete additional day(s) of monitoring. If any technical problems arise in the use of the devices that cannot be resolved over the phone, you may be asked to return to the office in order to exchange equipment.

If the quality and quantity of daily monitoring data are sufficient to merit continuation in the study, you will be assigned to one of two conditions, the mindfulness training condition, or the life as usual condition. The decision about which condition you are assigned to will be based upon chance (like a roll of the dice), using a computer program. If you are assigned to the mindfulness training condition, you will watch a brief video, you will be given a questionnaire asking about the training program, we show you how to access the training program on your smartphone, and we will schedule an appointment 4 weeks later for your second daily monitoring training. If you are assigned to the life as usual condition, you will be given an information pamphlet with self-help and treatment resources, and we will schedule an appointment 4 weeks later for Visit 4.

Mindfulness Training Condition. If you are assigned to the mindfulness training condition, we will ask you to complete a 20-minute audio recording lesson and 3 brief (2-3 minute) practice assignments at home each day over the course of a one-month (28 day) period between Visit 3 and Visit 4. During this one-month period, you will also answer several questions at the beginning and end of each day about daily stressors and the helpfulness of the training program. On four occasions during this one month period (Days 3, 9, 14, and 21), the researchers will contact you briefly by phone to answer any questions and address any concerns you may have about the program. After this one-month period, you will return for Visit 4.

Life As Usual Condition. If you are assigned to the life as usual condition, you will be given a list of stress management resources, but there will be no structured training program, and no required questions to respond to over the one month period. You will return at the end of the month for Visit 4.

Visit 4, Second Daily Monitoring Training (Sennott Square, 1.5 hours). At Visit 4, you will complete a number of questionnaires asking about your experiences during the month and about your current psychological state, and we will measure your blood pressure at rest once again. We will review with you the procedures for daily life monitoring (wearing the Fitbit activity monitor, wearing the portable blood pressure device, and carrying the smart phone), we will re-install the sensor application on your smartphone, and we will ask you to undergo a second 7-day monitoring period.

Second Daily Life Monitoring Period (7-day period, 3 days of full monitoring). The procedures for the second daily monitoring period will be identical to those used during the first daily monitoring period. Once again, you will wear the Fitbit activity monitor during day and night throughout the 7-day period, and you will wear the blood pressure device during 3 of the 7 days, during daytime only (3 “full monitoring days”). During the full monitoring days, we will collect a blood pressure reading each hour during the waking day, and you will be prompted to complete a 2-3 minute questionnaire after each blood pressure reading. The sensor application on your smartphone will collect sensor data during the monitoring period as you go about your daily life, as before. A phone call with the research staff will be scheduled for the first or second day of your daily monitoring period to answer any questions you may have and to address any difficulties you may be having.

Visit 5, Second Post-Monitoring Visit (Sennott Square, 1.5 hours). After the second daily monitoring period is over, you will return to the lab so that we can check in your equipment and download your data. We will take your resting blood pressure once again. We will check the number of blood pressure readings and hourly questionnaires that you completed during the daily monitoring period. We will administer the two challenging laboratory tasks once again and we will measure your blood pressure responses to these tasks. Then we will schedule you for Visit 6, 3 months later.

Monthly Follow-up Questionnaires (2-3 minutes each): Between Visit 5 and Visit 6, you will receive monthly questionnaires about the use of stress management techniques in the past month.

Visit 6, Third Daily Monitoring Training, 3-month follow-up (Sennott Square, 1.5 hours). We will review with you the procedures for daily life monitoring (wearing the Fitbit activity monitor, wearing the portable blood pressure device, and carrying the smartphone with the questionnaire app), we will re-install the sensor application on your smartphone, we will take your resting blood pressure once again, and then we will ask you to undergo a third 7-day monitoring period.

Third Daily Life Monitoring Period (7-day period, 3 days of full monitoring). The procedures for the third daily monitoring period will be identical to those used during the first and second daily monitoring periods. Once again, you will wear the Fitbit activity monitor on your wrist during day and night throughout the 7-day period, and you will wear the blood pressure device during 3 of the 7 days, during daytime only (3 “full monitoring days”). During the full monitoring days, we will collect a blood pressure reading each hour during the waking day, and you will be prompted to complete a 2-3 minute questionnaire after each blood

pressure reading. The sensor application on your smartphone will collect sensor data during the monitoring period as you go about your daily life, as before. A phone call will be scheduled for the first or second day of your daily monitoring period to answer any questions and to address any difficulties you may be having.

Visit 7, Third Post-Monitoring Visit (Sennott Square, 1 hour). After the third daily monitoring period is over, you will return to the lab so that we can check in your equipment and download your data. We will take your resting blood pressure once again. We will check the number of blood pressure readings and hourly questionnaires that you completed during the daily monitoring period. We will measure your resting blood pressure, and we will ask you to complete several additional questionnaires measuring your psychological state and your reactions to the study. We will have a chance to discuss the study and any final questions you have, and you will be given access to the mindfulness training program.

Are there any risks to me?

Some participants may feel uncomfortable, bored, or aggravated while completing the mindfulness training program. We will monitor your progress and reactions to the program, and we will provide suggestions for resolving any problems you may experience. You should know that you are not obligated to continue the study if the mindfulness program makes you uncomfortable.

The risk of completing the questionnaires in this study is minimal, but the nature of some of the questions is personal (for example, about your psychiatric or emotional well-being) and answering them might be stressful, uncomfortable, or embarrassing to some people. You should know that you are not obligated to answer any questions that make you uncomfortable.

The two laboratory challenges that we will ask you to complete at Visit 1 and Visit 5 may be difficult for some people, but these tasks are not associated with any risks that exceed those encountered during daily life.

Although ambulatory blood pressure monitoring is a standard medical procedure, the repeated inflation of the arm cuff during the daily monitoring periods can commonly cause some minor discomfort (approximately 10-25 out of 100 people) and can infrequently cause some temporary bruising (approximately 1-10 out of 100 people). We minimize discomfort by using hourly inflation intervals (rather than more frequent intervals), by implementing thorough training procedures to ensure that you learn correct cuff placement procedures, and by monitoring you carefully during the data collection procedure (through follow-up telephone contact) to assess the presence of any problems with the devices.

You will be wearing a Fitbit activity monitor for measuring physical activity, heart rate, and other physiological activity during the daily monitoring periods. Most participants are able to tolerate this, however, you may experience mild chafing or skin irritation. All participants will undergo thorough training to ensure that they understand how to use the Fitbit activity monitor, and that they understand the rationale for this data collection procedure. You may discontinue to use of the activity monitoring device if you are unable to wear it comfortably on either wrist.

During the daily monitoring periods, the smartphone will interrupt your normal activities every 60 minutes reminding you to complete a brief questionnaire, a process that may be bothersome or irritating to some people. All participants will undergo thorough training to ensure that they understand how to use the questionnaire procedures, and that they understand the rationale for this data collection procedure. They will be provided with strategies for reducing the burden to be used when the questionnaire prompt interrupts an important activity.

You will not detect any effects of the sensor application that we install on your smartphone during the monitoring periods in this study. There is a risk that the sensors could drain the battery of your smartphone more quickly than usual. While the phone uploads data, it might reduce the performance of the local Wi-Fi network. You are encouraged to call the study team if you notice problems thought to be related to the sensor data collection, so that steps can be taken to address the issue.

As with all studies that involve the collection of personal information, there is a possible risk that your information could become revealed to others. However, this risk is minimized by using a code number rather than your name, birthdate, or other personal identifiers, so that your identity is not directly linked to your responses. In addition, we keep all consent forms, questionnaire data, and other identifying information confidential and maintained in locked files or in password-protected electronic files available only to professional personnel of the research team. All data will be stored in secure locations, including locked file cabinets and password-protected computers and databases, and identified only by study ID numbers. All personnel involved in the study will sign a statement agreeing to protect your confidentiality. Only research associates, who have signed a confidentiality statement, will have access to your research information for coding purposes. No research findings will be provided to your family members, insurance companies, employers, or any third party without your authorization. All data entry will make use of Research Electronic Data Capture (REDCap), which is a secure, password protected, web-based application.

You are encouraged to use a password for your smartphone. Text messages used for study reminders, for practice prompting as part of the mindfulness training, or for communicating with staff are not encrypted or secure during their transmission, and could be intercepted. If you need to contact the study during your participation, you are encouraged to use voice rather than text.

Who will have access to identifiable information related to my participation in this research study?

The principal investigator and research staff will have access to the data files. Your identity on these records will be indicated by an ID number, rather than by your name. In order to contact you during the study, we will collect identifying information about you, including your name, address, phone number, and email address. This identifying information and its link with your ID will be stored in a secure location (password protected) separately from the research records. Your Social security number may also be collected in order to facilitate payment (see paragraph below), but this information will be destroyed on our end as soon as it is transmitted

to the University of Pittsburgh Accounting Office. Your identity will not be revealed in any description or publications of this research. Only group characteristics will be published.

Authorized representatives of the University of Pittsburgh Office of Research Protections may review your identifiable research information for the purpose of ensuring the appropriate conduct of this research study. In addition, your de-identified research records may be used by other researchers for future research studies. If this happens, we will not contact you for additional consent.

In unusual cases, your research records may be released in response to an order from a court of law. If the investigators learn that you or someone with whom you are involved is in serious danger or potential harm, they will need to inform the appropriate agencies, as required by Pennsylvania law. Per University of Pittsburgh policy, all research records must be maintained for at least 7 years following final reporting or publication of a project. However, the records may be kept indefinitely.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that the researchers cannot release or use information, documents, or samples that may identify you in any action or suit unless you say it is okay. They also cannot provide them as evidence unless you have agreed. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings. An example would be a court subpoena.

The Certificate of Confidentiality DOES NOT stop reporting that federal, state or local laws require. Some examples are laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others. The Certificate CANNOT BE USED to stop a sponsoring United States federal or state government agency from checking records or evaluating programs. The Certificate DOES NOT stop disclosures required by the federal Food and Drug Administration (FDA). The Certificate also DOES NOT prevent your information from being used for other research if allowed by federal regulations.

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.

Who will pay if I am injured as a result of taking part in this research study?

If you believe that the research procedures have resulted in an injury to you, immediately contact the Principal Investigator who is listed on the first page of this form. Emergency medical treatment for injuries solely and directly related to your participation in this research study will be provided to you by the hospitals of UPMC. Your insurance provider may be billed for the costs of this emergency treatment, but none of those costs will be charged directly to you. If your research-related injury requires medical care beyond this emergency treatment, you will be responsible for the costs of this follow-up care. At this time, there is no plan for any

additional financial compensation. You do not, however, waive any legal rights by signing this form.

Are there alternative treatments?

There are a number of alternative treatments for individuals who are experiencing stress or who are reactive to stress, including psychotherapy, exercise, and medication. In addition, some individuals may benefit from self-help methods that do not require formal treatment. The investigators are available to discuss alternatives to research study participation and to answer any additional questions.

Are there any benefits to me?

You may or may not receive any direct benefit from taking part in this research study. You will receive information about your resting blood pressure as well as your blood pressure during acute stress and during daily life. You may find the mindfulness application useful and decide to continue practicing upon completion of the study. We will provide you with the audio-guided mindfulness training program upon completion of the study if you do wish to continue practicing. In addition, you may learn about your blood pressure and other factors that may affect your risk for chronic disease. A potential benefit of study participation includes the contribution to knowledge in delivering stress management programs more widely as well.

Will I be paid if I take part in this research study?

You will be paid up to \$300 for your participation in this study.

At Visit 1, if you are deemed ineligible to participate in the study (due to meeting exclusionary criteria, etc.) or if you decline participation, you receive \$15, plus reimbursement for parking or public transportation.

If you are eligible for the study and you are assigned to the mindfulness training condition,

- You will receive \$40 at Visit 3 if you complete the study up to this point, plus an additional \$10 bonus **(total of \$50)** for completing 80 % or more of the hourly interviews during the first monitoring period.
- You will receive an additional \$70 at Visit 5 if you complete the study up to this point, plus an additional \$20 bonus for completing 80 % or more of the hourly interviews during the second monitoring period, plus an additional \$30 bonus for completing at least 90 % of the mindfulness lessons and at least 65 % of the mindfulness prompts during the training period **(total of \$120)**.
- You will receive an additional \$100 at Visit 7 if you complete the study up to this point, plus an additional \$30 bonus **(total of \$130)** for completing 80 % or more of the hourly interviews during the third monitoring period.

If you are eligible for the study and you are assigned to the life as usual condition,

- You will receive \$40 at Visit 3 if you complete the study up to this point, plus an additional \$10 bonus **(total of \$50)** for completing 80 % or more of the hourly interviews during the first monitoring period.
- You will receive an additional \$70 at Visit 5 if you complete the study up to this point, plus up to an additional \$50 bonus **(total of \$120)** for completing 80 % or more of the hourly interviews during the second monitoring period.
- You will receive an additional \$100 at Visit 7 if you complete the study up to this point, plus an additional \$30 bonus **(total of \$130)** for completing 80 % or more of the hourly interviews during the third monitoring period.

If you do not choose to complete the entire study, you will be compensated for your partial participation using the schedules described above.

For all appointments, parking fees or public transportation costs to the Behavioral Medicine Research Laboratory will be paid for by the research study. Phone costs incurred are not reimbursed. There are no additional costs to you for participating in the study.

All compensation is taxable income to the participant regardless of the amount. Because of this, you will be asked for your name, address, and Social Security number, and this information will be released to the University of Pittsburgh Accounting Office. Individuals who do not provide a Social Security number may still participate in the research, but the IRS requires that 24 % of the payment be sent by the institution to the IRS for “backup withholding,” thus you would only receive 76 % of the expected payment. If a participant receives \$600 or more in a calendar year from one organization (for example, the University of Pittsburgh), that organization is required by law to file a Form 1099- Miscellaneous with the IRS, and to provide a copy to the taxpayer.

Is my participation in this research study voluntary?

Yes, your participation in this research study is completely voluntary. You can choose to withdraw from the study at any time. If you decide not to participate or to withdraw from the study, there will be no consequences whatsoever on your current or future relationship with the University of Pittsburgh. If you choose to withdraw from this study, all data collected prior to the date of withdrawal will be continued to be used, unless you request that we destroy it.

If you would like to withdraw from the study, contact the co-Principal Investigators.

If I agree to participate in this research study, can I be removed from the study without my consent?

It is possible that you may be withdrawn from the study by the researchers, for example, due to not following the instructions provided to you by the investigators and staff.

How can I find out about the results of this research study?

A description of this clinical trial is available on http://www.clinicaltrials.gov_with_identifier_NCT06152185, as required by US Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

Is there anything else I should know about this study?

The information you provide to us in this research study may contribute to a new discovery or treatment. In some instances, these discoveries or treatments may be of commercial value and may be sold, patented, or licensed by the investigators and the University of Pittsburgh for use in other research or the development of new products. You will not retain any property rights, nor will you share in any money that the investigators, the University of Pittsburgh, or their agents may realize.

Your information collected as a part of this research, after removal of identifiers, could be used for future research studies or distributed to another investigator for future research studies without additional informed consent.

Whom should I contact if I have questions?

You may ask any questions about the research at any time. If you have questions about the research, you should contact the Co-Principal Investigators Thomas Kamarck at 412-624-4500 or Emily Lindsay at 412-648-4515. If you are not satisfied with the response of the research team, have more questions, or want to talk with someone about your rights as a research participant, you should contact the University of Pittsburgh Human Subject Protection Advocate toll-free at 1-866-212-2668.

VOLUNTARY CONSENT TO PARTICIPATE

The above information has been explained to me and all of my current questions have been answered. I understand that I am encouraged to ask questions about any aspect of this research study during the course of this study, and that such future questions will be answered by a qualified individual or by the investigator(s) listed on the first page of this consent document at the telephone number(s) given. I understand that I may always request that my questions, concerns or complaints be addressed by a listed investigator.

I understand that I may contact the Human Subjects Protection Advocate of the IRB Office, University of Pittsburgh (1-866-212-2668) to discuss problems, concerns, and questions; obtain information; offer input; or discuss situations in the event that the research team is unavailable.

By signing this form, I agree to participate in this research study. A copy of this consent form will be given to me.

Printed Name of Participant

Signature of Participant

Date

CERTIFICATION of INFORMED CONSENT

I certify that I have explained the nature and purpose of this research study to the above-named individual, and I have discussed the potential benefits and possible risks of study participation.

Any questions the individual(s) have about this study have been answered, and we will always be available to address future questions as they arise. I further certify that no research component of this protocol was begun until after this consent form was signed.

Printed Name of Person Obtaining Consent

Role in Research Study

Signature of Person Obtaining Consent

Date