

Brain and Meditation (BAM) Study

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University of Wisconsin-Madison Consent to Participate in Research

Study Title: Brain and Meditation (BAM) Study

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Institution: University of Wisconsin-Madison

Key Information

The information in this section will help you decide whether or not to be part of this study. You can find more detailed information later in this form.

Why are researchers doing this study?

The purpose of this study is to understand the impact of the Healthy Minds Program, a meditation-based well-being app, on measurements of brain health, stress, and well-being. This program involves integrating mental exercises into daily life, similar to how physical exercise is a part of healthy living. You will be asked to complete memory tasks and provide daily movement data because this information has been linked to the function of specific brain regions that influence overall health.

We invite you to take part in this research study because you are 25 to 65 years old and have no significant experience with mindfulness or other forms of meditation.

What will I need to do in this study?

If you decide to participate, you will complete surveys and a memory task on your smartphone at the beginning of the study, each week for 4 weeks, and again 3 months later. You may be asked to complete a 4-week well-being program through an app on your phone. Additionally, you will be asked to install an app on your phone that will passively monitor your movements.

You will be randomly assigned to a study group. If you are assigned to Group A, you will use the Healthy Minds Program app on your phone and complete surveys and tasks. If you are assigned to Group B, you will only complete surveys and tasks. You will not use the Healthy Minds Program during the study.

We expect that your participation will take about 8 hours spread over 4 to 5 months.

You can find detailed information about the study procedures in the section called **If I take part in the study, what will I do?**

What are reasons I might – or might not – want to be in this study?

You may want to participate if you are:	You may NOT want to participate if:
<ul style="list-style-type: none">● Comfortable answering questions about your physical and mental health.● Willing to participate in the study for about 4-5 months.● Interested in contributing to scientific knowledge even though you won't benefit directly from the study.	<ul style="list-style-type: none">● You may not have time to complete all study procedures, including the Healthy Minds Program and study surveys.

Do I have to be in the study?

No, you do not have to be in this study. Taking part in research is voluntary. If you decide not to be in this study, your choice will not affect your healthcare or any services you receive. There will be no penalty to you. You will not lose medical care or any legal rights. You can ask all the questions you want before you decide.

Detailed Information

The following is more detailed information about this study in addition to the information listed above.

How is research different from health care?

When you take part in a research study, you are helping answer a research question. Study tests and procedures are not for your health care.

Who can I talk to about this study?

If you have questions, concerns, or complaints, or think that participating in the research has hurt you, please contact the Lead Researcher, Daniel Grupe, at (608) 263-7572.

If you have any questions about your rights as a research participant or have complaints about the research study or study team, contact UW Health Patient Relations at (608) 263-8009. The Patient Relations Representatives work with research subjects to address concerns about research participation and assist in resolving problems.

If I take part in the study, what will I do?

Screening: We determined that you were eligible for the study when you completed the online eligibility survey.

Zoom Consent Call (30 to 45 minutes): Study staff will speak with you over Zoom to complete the consent process and study enrollment.

Daily Movement: We will ask you to install an app on your phone that runs in the background and allows us to passively monitor your movements throughout the study, which requires no responding from you. The app will collect information about your phone, such as device type, device ID, date, time, GPS location (latitude and longitude coordinates), direction, altitude, and speed of travel. We ask that you keep your phone with you and powered on as much as possible throughout the study, while allowing the app to run in the background.

We're collecting daily movement information because research has shown that psychological well-being may be related to how people move around their environment. We're interested in learning how daily movements are related to well-being and other study measures. We will use the GPS data to create summary measures for each day, such as how far you travel and how many locations you visit. To protect your privacy, we will not look at the specific places you visit.

Initial Activities (30 to 45 minutes): Two days after your Zoom Consent Call, we will send you an email with surveys and a memory task for you to complete on your phone. The surveys will ask about your demographic information (e.g., age, marital status), physical and mental health, feelings and mood, and stressful life events. The memory

task will involve looking at pictures and indicating whether you remember seeing them previously. You need to complete these activities within 1 week of receiving the email, or you may be unenrolled from the study, so we recommend completing them as soon as you can after you receive them.

Group Assignment: The week after you complete the Initial Activities, you will be randomly assigned to a study group. The group that you are assigned to will be chosen by chance, like flipping a coin. Neither you nor the study team will choose your group.

Group A (1.5 to 2 hours each week for 4 weeks): If you are assigned to Group A, you will receive an email asking you to install the Healthy Minds Program app on your phone. Then you will start a 4-week well-being program. The program will involve listening to short podcast-style lessons to learn about meditation from scientists and experts in well-being, along with completing seated and/or active meditation practices. The lessons and practices will take between 5 and 30 minutes each day for 4 weeks, depending upon how much time you choose to spend meditating. The app may also ask questions about your demographic characteristics, meditation experience, current level of well-being, and emotions. Throughout the study we will collect information from the app, including when and how much you use it, which lessons you complete, and how you feel about the meditation practices, to learn more about how the program affects well-being over time. The app will also collect information about your device type and GPS location if you allow it.

At the end of each week, you will receive an email with a set of surveys for you to complete on your phone, including a memory task the fourth week. Please complete the surveys and task within 1 week of receiving the email regardless of how much time you've spent doing the Healthy Minds Program each week.

After you complete the 4-week program, you will have the option to continue using the Healthy Minds Program app until the 3-Month Follow-Up. We will continue to use data collected through the app until you complete the study so that we can see how the program affects well-being over time.

Group B (10 to 45 minutes each week for 4 weeks): If you are assigned to Group B, you will receive an email with a set of surveys to complete on your phone each week for 4 weeks, including a memory task the fourth week. Please complete the surveys and task within 1 week of receiving the email. You will not complete the Healthy Minds Program during the study. If you want to use the Healthy Minds Program, you can use it for free after you finish the 3-Month Follow-Up, or you may leave the study at any time so that you can use it.

3-Month Follow-Up (30 to 45 minutes): Three months after completing the fourth week of surveys and tasks, you will receive an email with a final set of surveys and tasks to complete on your phone.

What happens if I say yes, but I change my mind later?

You can leave the research at any time. If you choose to leave the study, your choice will not affect your healthcare or any services you receive. No matter what decision you make, and even if your decision changes, there will be no penalty to you. You will not lose medical care or any legal rights.

If you decide to leave the research, please contact the study staff. We will give you the opportunity to tell us your reason for leaving, ask questions, and provide comments about the study. We will discuss your payment, which will be adjusted based on the portions of the study that you completed (see “Will I receive anything for participating?” below for payment information). We will keep any data collected while you were in the study.

Will being in this study help me in any way?

This study is not intended to help you directly. Your participation may benefit other people in the future by helping us learn more about the ability of the Healthy Minds Program to improve well-being.

What are the study risks?

Emotional Responses: Some of the study activities may be tedious or difficult, and you may experience emotions, such as frustration or guilt, while participating in the study. It is completely normal to have these feelings and we understand that you may not be able to complete all activities. We just ask that you do your best. Also, some of the surveys include questions about your mental health that could affect your mood or make you feel embarrassed. You may skip any questions that you do not feel comfortable answering, except for certain required items. Responses to the surveys will not be reviewed immediately, and if you have concerns about your mental health, you should contact your healthcare provider.

Daily Movement: There is a slight risk that GPS data collected from your phone could be used to see specific locations you have visited and whether you may have done activities or visited places that are potentially stigmatizing or embarrassing.

To reduce this risk, the location tracking app will not collect any identifying information, such as your name or email address. GPS data will only be associated with a non-identifiable device ID and participant ID. Data will be encrypted during download and stored on secure password-protected servers. We will not view real-time GPS locations or minute-by-minute data, other than to confirm that the app is functioning correctly and check the data for quality control. When reviewing these data, we will view lists of GPS coordinates and will not link them to specific places. We will only use the GPS data to create summary measures for each day, such as how far you travel and how many locations you visit.

Confidentiality Breach: There is a slight risk that your information could become known to someone not involved in this study. If this happens, it could affect your relationships with family and friends, affect your employment, or make it harder to get insurance or a job.

What happens to the information collected for the research?

We have strict rules to protect your personal information. We will limit the use and disclosure of your personal information, including research study records, to people who have a need to review this information. To minimize the risk of confidentiality breach, your information will be protected by a coding system. All data will be stripped of identifying information and coded with a unique identification number. All identifiable information will be stored in locked filing cabinets or on our password-protected secure server that is only accessible to authorized study staff. Additionally, this study has a Certificate of Confidentiality from the National Institutes of Health. A Certificate of Confidentiality prohibits researchers from disclosing information that may identify you in a legal proceeding or in response to a legal request without your consent.

However, we cannot promise complete confidentiality. Federal or state laws may permit or require us to show information to university or government officials and to study sponsors responsible for monitoring this study. This includes the University of Wisconsin and its representatives and affiliates, including those responsible for monitoring or ensuring compliance, such as the Human Research Protection Program, the National Institutes of Health, and the FDA.

We may also have to tell appropriate authorities, such as child protective services or health care providers, if we learn during the study that you or others are at risk of harm (for example, due to child or elder abuse, or suicidal thoughts).

A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, as required by U.S. 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.

Will information from this study go in my medical record?

None of the information we collect for this study will go in your medical record.

Will I receive the results of research tests?

Most assessments done as part of a research study are only for research and have no clear meaning for health care. In this study, you will not be informed of your individual survey or task results.

Some surveys you complete in this study ask about symptoms of emotional distress, such as depression and anxiety. We are using the surveys only for research, not to diagnose mental health issues. We will not tell you the results, but we will provide you

with a list of resources where you can obtain help. If you are experiencing emotional distress, you should contact your physician or other health care provider, such as a mental health professional. If your responses reveal suicidal ideation or intent to harm others, clinical research personnel will assess intent. If you indicate that self-harm or harm to others is imminent, we will call local authorities in your area for immediate help.

Can I be removed from the research without my agreement?

The researchers or study sponsor can remove you from the study without your approval. Possible reasons for removal include:

- your health changes and the study is no longer in your best interest
- you do not follow the study rules or no longer meet the study requirements
- the study is stopped by the sponsor or researchers

What else do I need to know?

What happens if I am injured or get sick because of this study?

If you are injured or get sick because of this study, medical care is available to you through UW Health, your local provider, or emergency services, as it is to all sick or injured people.

- If it is an emergency, call 911 right away or go to the emergency room.
- For non-emergency medical problems, contact your regular health care provider.
- Call the Lead Researcher, Daniel Grupe, at (608) 263-7572 to report your sickness or injury.

Here are some things you need to know if you get sick or are injured because of this research:

- If the sickness or injury requires medical care, the costs for the care will be billed to you or your insurance, just like any other medical costs.
- Your health insurance company may or may not pay for this care.
- No other compensation (such as lost wages or damages) is usually available.
- UW-Madison and UW Health do not have a program to pay you if you get sick or are injured because of this study.
- By signing this consent form and taking part in this study, you are not giving up any legal rights you may have. You keep your legal rights to seek payment for care required because of a sickness or injury resulting from this study.

Will I receive anything for participating?

We will pay you \$150 if you complete all study activities. For payment purposes, you must either be a U.S. citizen or a permanent U.S. resident (Green Card holder). If you are a permanent U.S. resident, you will need to provide a copy of your Green Card.

Payment Schedule:

1. Payment 1 (\$65) includes compensation for the Initial Activities and the Weeks 1 to 4 Activities. It will be mailed to you as either a check or a reloadable prepaid debit card after you complete the Week 4 Activities.
2. Payment 2 (\$55) includes compensation for the Daily Movement and the 3-Month Follow-Up. It will be mailed to you as a check or added to your reloadable debit card after you complete the 3-Month Follow-Up. To receive payment for Daily Movement, you must provide at least 60 valid days of data.
3. Bonus Payment (\$30) – To receive the Bonus, you must complete all study activities, including all surveys and tasks. If you qualify for the Bonus, we will add it to your second check or to your reloadable debit card along with Payment 2.

If you leave the study early or do not complete all study activities, you will receive payment for the portions of the study you completed as follows:

- Initial Activities = \$10
- Week 1 Activities = \$10

- Week 2 Activities = \$10
- Week 3 Activities = \$10
- Week 4 Activities = \$25
- Daily Movement (must provide at least 60 valid days of data) = \$10
- 3-Month Follow-Up = \$45

Your information may be used to create products, including some that may be sold and/or make money for others. If this happens, there are no plans to tell you, pay you, or give any compensation to you or your family.

How many people will be in this study?

We expect about 150 people to be in this research study.

Who is funding this study?

This research is being funded by the National Institutes of Health.

What will happen to my data after my participation ends?

We may keep your data indefinitely, meaning we have no plans of ever destroying them. Keeping data for future research is called “banking.” The banked data will be kept in a secure location for use by researchers only. With appropriate confidentiality protections, we may use banked data in future research projects about the Healthy Minds Program or for other research. We may also share banked data with other researchers or organizations within or outside the University without additional consent from you. Banked data will not be shared with your health care providers or used in your treatment outside this study.

Permission to communicate by email and text message

We are requesting your email address so we can schedule study activities and send you information about the study, such as reminders about study tasks. We may also communicate with you by sending text messages. Email and text messaging are generally not secure ways to communicate about your health as there are many ways for unauthorized users to access email and text messages. You should avoid sending sensitive, detailed personal information by email or text message. Email and text messages should also not be used to convey information of an urgent nature. If you need to talk to someone immediately, please contact study staff at (608) 571-2575.

During the oral consent process, we will ask if you give permission to the study team to contact you by sending text messages. If you agree, we will ask you to provide your cell phone number and cell phone service provider.

Future contact

During the oral consent process, we will ask if you would like to be contacted about future opportunities, such as research studies or focus groups. If so, only your name and contact information (e.g., phone number and email address) will be maintained in

our contact database, which can only be used by Center for Healthy Minds researchers. You do not need to join our contact list to participate in future opportunities.

Agreement to participate in the research study

During the oral consent process, we will ask if you consent to participate in the study. By providing your verbal consent, you certify that:

- You have read this consent form.
- You have had a chance to ask questions about the research study, and the researchers have answered your questions.
- You want to be in this study.