

Healthy Minds Program (HMP) App Dosage Study

NCT05229406

Informed Consent Form approved 2/3/2022

UNIVERSITY OF WISCONSIN MADISON
Research Participant Information and Consent Form
Title of the Study: HMP App Dosage Study

- Principal Investigator: Simon Goldberg, PhD: phone: (608) 265-8986, email: sbgoldberg@wisc.edu
- Research coordinator: [insert name]: phone: [insert phone], email: [insert email]

DESCRIPTION OF THE RESEARCH

The Healthy Minds Program is an app-based well-being program that involves mental exercises integrated into daily life, with an approach that parallels the way physical exercise becomes a part of healthy living.

The purpose of the study is to understand whether this approach to well-being is feasible as well as to identify the impact of the intervention for individuals experiencing symptoms of depression and anxiety. We are seeking 90 people willing to take part in this research. You have been asked to participate because you are 18 years old or older, are experiencing symptoms of depression and/or anxiety, and have no significant experience with mindfulness or other forms of meditation.

WHAT WILL MY PARTICIPATION INVOLVE?

If you decide to participate in this research, you will be asked to complete about 10 to 30 minutes of surveys online two times over the course of 5 weeks. You will also be asked to complete 4 very brief (1-2 minutes) surveys daily throughout the study. To enroll in the study, you will be asked to meet with a study staff person over the phone or Zoom for approximately 30 minutes. You will learn more about the study, ask questions and download the Healthy Minds Program during this call.

You will be assigned to use the Healthy Minds Program smartphone app for either 5 or 15 minutes per day for four weeks. This program consists of mental exercises that are integrated into daily life, with an approach that parallels the way physical exercise becomes a part of healthy living. The Healthy Minds program delivers core content with instruction administered through a curriculum of high-quality guided audio practices.

The program will be delivered through a phone application that uses about 40MB of memory space and uses battery at levels similar to music or podcast programs. The app will only collect usage data. For example, the type of practice you select and the amount of time you spend practicing. You will be provided with instructions on how to install and uninstall the app.

At the end of using the Healthy Minds Program for four weeks, you may be invited to take part in an exit interview with study staff over the phone or Zoom for approximately 20-30 minutes. The purpose of this optional interview is to give feedback about the study. These interviews may be recorded and transcribed. Quotes from these interviews may be used in scientific publications,

presentations, and other outlets (e.g., on the Center for Healthy Minds website). Your identifying information (e.g., name) will not appear with any quotes from these interviews.

ARE THERE ANY RISKS TO ME?

We believe there is minimal risk associated with participation in this study.

Some of the survey questions will ask for information about personal or sensitive topics (e.g., psychological health). Answers will not be monitored in real time. However, mental health resources will be provided at the end of the survey. You also may skip any questions you are uncomfortable answering.

ARE THERE ANY BENEFITS TO ME?

There are no direct benefits to participating, but your participation in the study may benefit other people in the future by helping use learn more about stress and well-being.

WILL I BE COMPENSATED FOR MY PARTICIPATION?

Yes. You will receive a check for up to \$170 at the end of the study:

- \$100 for completing the longer surveys at the beginning and at the end of the study.
- \$50 bonus for completing an average of 3 out of 4 of the brief daily surveys throughout the duration of the study (completion of the longer surveys at the beginning and at the end of the study is necessary to earn bonus).
- \$20 for participating in an optional exit interview.

If you are not a US citizen or resident or do not have an F-1 or J-1 visa you can still participate in the study. However, we will not be able to provide monetary compensation.

HOW WILL THE RESEARCHERS KEEP MY RESEARCH INFORMATION CONFIDENTIAL?

We have strict rules to protect your personal information. We limit who has access to your name, address, phone number, and other information that can identify you. We will also store this information securely. Your information will be assigned a code number. The key connecting your name to this code will be kept in a password protected computer file separate from your data. Only study team members will have access to the code. Your name will not be used in any report. We will not share identifiable data from this study with any outside parties.

IP addresses are collected for network management purposes and will not be linked with the data they are providing through the surveys or through the phone app.

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.

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.

WHAT WILL HAPPEN TO MY DATA AFTER MY PARTICIPATION ENDS?

Data collected for this research may be published in journals or magazines. When the data are shared with publishers it will not be shared in any way that can identify you personally. Data shared with publishers may be used by other researchers outside of the University of Wisconsin-Madison, but only data that cannot identify you personally will be used. There are no limits on who might use these data or how the data may be used in the future.

We will keep your data for an indefinite period of time, meaning we have no plans of ever destroying your data. Keeping data for future research is called “banking.” The banked data will be kept in a secure location by researchers.

This is what will happen with your banked data:

- We will use the data in future research projects.
- The data may be shared with other researchers at the University of Wisconsin-Madison and outside the University. Outside researchers may be at other universities, private companies, or other kinds of organizations.
- The banked data will be labeled with a code instead of your name.
- When we give your data to other investigators for research projects, they will not be able to use the code to figure out which data are yours.
- The research team will maintain a link between your data and your identifiable information.
- You can request to have your data removed from the bank by contacting the research team at any time.

This is what will NOT happen with your banked data:

- Banked data will not be shared with your health care providers or used in your treatment outside this study.

Data may be sent to researchers outside of the UW-Madison or shared publicly in service or research transparency. Any data that is shared in this way will have all personal information that could identify you removed before the data are shared.

The HMP app privacy policy can be found here: <https://hminnovations.org/hmi/privacy-policy>

CONFLICT OF INTEREST

A member of this research team has a personal interest in or might profit financially from the

results of this study. There may be a financial benefit to the non-profit organization Healthy Minds Innovations, Inc. (HMI) from what is learned from this study. Dr. Richard J. Davidson is the Founder and President of HMI. Dr. Davidson is an investigator on this study. This is called a “conflict of interest.” The University of Wisconsin-Madison manages conflicts of interest so that they do not affect study participants or the quality of data collected. Researchers with a conflict are not allowed to obtain informed consent or recruit potential subjects. We are telling you about the conflict of interest in case it affects whether you want to take part in the study.

WHAT IF I HAVE QUESTIONS?

You may ask any questions about the research at any time. If you have questions about the research after you leave today you should contact the study coordinator, [insert name] at [insert phone] or via email at [insert email]. You may also call the Principal Investigator Simon Goldberg, PhD by phone: (608) 265-8986, or email: sbgoldberg@wisc.edu.

If you are not satisfied with the response of research team, have more questions, or want to talk with someone about your rights as a research participant, you should contact the Education and Social/Behavioral Sciences IRB for UW Madison at: (608) 263-2320.

Your participation is completely voluntary. If you begin participation and change your mind you may end your participation at any time without penalty. Your signature (i.e., typing your name) indicates that you have read this consent form and voluntarily consent to participate. Please print this page for your records or you can request a copy at any time.

Name (type first and last name): _____

By checking this box and typing my name below, I am electronically signing this consent form.
☐

Email address: _____

Signature (Please type your name again)

Date