

Healthy Minds Comparison Study

NCT06282523

5/3/2024

University of Wisconsin-Madison

Consent to Participate in Research

Study Title: Healthy Minds Comparison 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 difference between two versions of the Healthy Minds application, a digital well-being program. This program involves mental exercises integrated into daily life, with an approach similar to the way physical exercise becomes a part of healthy living. We are doing this research because we believe it will help us understand the differences between versions of the Healthy Minds application and their effects on well-being.

We invite you to take part in this research study because you are ≥ 18 years old, are experiencing symptoms of depression and/or anxiety, 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 join the study, you will be asked to complete a four-week well-being program online. You will complete online surveys one time each week for one month and again three months later.

You will be put into a study group that will receive a version of the Healthy Minds application. The group that you are put in will be chosen by chance, like flipping a coin. Neither you nor the study team will choose your group. One group will be asked to install the Healthy Minds application on their smartphone, the other group will be able to access the Healthy Minds

application on any device (smartphone, tablet, or computer).. We expect that you will be in this research study for about four months.

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

What are the 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 you:
<ul style="list-style-type: none">• comfortable answering questions about your mental health and other potentially sensitive topics.• willing to participate in the study for about 4 months.• interested in contributing to scientific knowledge even though you may not benefit directly from the study.	<ul style="list-style-type: none">• do not have time to complete the study.• are not interested in using a well-being app.

Do I have to join 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.

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.

This study does not provide psychotherapy or mental health treatment or replace any professional treatment or support you may be receiving. You are free to continue any treatment you are receiving or to begin any treatment at any point and continue with the study.

Who can I talk to about this study?

If you have questions, concerns, or complaints, or think that being part of the study has hurt you, please contact the Lead Researcher, Simon Goldberg, at (608) 265-8986.

If you have any questions about your rights as a research participant or have complaints about the research study or study team, call the confidential research compliance line at 1-833-652-

2506. Staff will work with you to address concerns about research participation and assist in resolving problems.

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

You will do most of the things for this study online. You will not need to come to the lab for any part of the study.

Initial Surveys: You will complete the first set of surveys online, which will take about 15-30 minutes.

Healthy Minds Application: We will send you an email with instructions on how to download and log in to the study version of the app. You will spend four weeks using the app to do mental exercises for a few minutes every day. After the study, you can keep using the app if you want. We will track when and how much you use the app during and after the study, so we can learn more about how it can change well-being.

Weekly Surveys: You will answer questions about yourself one time each week for four weeks. You will have about one week to complete each set of surveys, which will take approximately 10-20 minutes to complete each week, except the fourth week of surveys which will take 15-30 minutes to complete.

3-Month Follow-Up: Three months after the last weekly surveys, you will complete a final set of surveys online. You will have about 2 weeks to complete the surveys, which will take about 15-30 minutes to complete.

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 stop being in the research, data you have provided, including the data you have provided during the screening process, will be retained indefinitely.

If you decide to leave the research, please contact the study staff. If you want, you can tell us why you are leaving the study, ask questions, and tell us what it was like for you to be in 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?” for payment information). We will keep any data collected prior to you leaving the study.

Will being in this study help me in any way?

Being in this study will not help you directly. Your participation in the study may benefit other people in the future by helping us learn more about the ability of the Healthy Minds application to improve well-being.

What are the study risks?

There is a 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.

The surveys include questions about your mental health and other potentially sensitive topics that could affect your mood or make you feel embarrassed. Participation in this study involves the risk of revealing sensitive information through your responses to the survey questions. You may skip any questions that you do not feel comfortable answering. However, there are a few surveys at each timepoint that ask about symptoms of depression, anxiety, or stress that will require answers. Responses to the surveys will not be reviewed immediately, and if you have concerns about your mental health, you should contact your healthcare provider.

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. All your data is coded with your participant ID, not your name.

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.

A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>. 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?

In this study, you will not be informed of your individual results for the survey data.

The surveys you will complete in this study ask about symptoms of emotional distress, such as depression, suicidal thoughts, and anxiety. We will provide you with a list of resources where you can obtain help if needed.

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.

Conflict of Interest

Members of this research team have 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, investigators on this study team are also part of HMI. 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 the data collected. We are telling you about the conflict of interest in case it affects whether you want to take part in this study.

Will I receive anything for participating?

If you agree to take part in this research study, we will pay you up to \$100 for your time and effort. Due to UW-Madison limitations on payments, we are only able to provide payment for this study to individuals who are United States citizens or permanent residents (green card holders). Payment will be provided via a check at the end of the study. Below is the payment schedule for this study:

- \$0 for initial survey
- \$10 for each weekly survey (weeks 1-3)
- \$30 for week 4 survey
- \$40 for follow-up survey

If you leave the study early, you will receive payment for the portions of the study you completed.

Researchers may develop products from the information you provide for this study. Some of these products may have commercial value. If the research team or others use your information

to develop products of commercial value, you will not receive any profits from products created from your information.

Permission to communicate about the study by email

We are requesting your email address so we can send you information about the study, such as reminders about study tasks. Email is generally not a secure way to communicate about your health as there are many ways for unauthorized users to access email. You should avoid sending sensitive, detailed personal information by email. Email should also not be used to convey information of an urgent nature. If you need to talk to someone regarding the study, please contact study staff at 608-263-0303 .

How many people will be in this study?

We expect about 500 people will be in this research study.

Who is funding this study?

This research is being funded by the Center for Healthy Minds and UW-Madison.

Therapeutic Resources

If you or somebody you know is in need of help with mental health concerns, visit <https://www.mentalhealth.gov/> for a list of resources.

If you are in a crisis situation and need help now, you can call 988 or visit <https://988lifeline.org/talk-to-someone-now/> for confidential support 24 hours a day.

If you have concerns around substance abuse, you can call 1-800-662-HELP (4357). This is a free, confidential, 24/7, 365-day-a-year treatment referral and information service offered in English and Spanish.

What will happen to my data after I'm done with the study?

We plan to use your data in future research, and do not ever plan to delete it. Keeping data for future research is called “banking.” The banked data will be kept in a secure location for use by researchers.

We may share your data with other researchers or publish your data on the internet for anyone to use. We will not share any data with your health care providers. If we publish your data on the internet, we will remove any information that could be used to identify you.

Future Contact: Are you interested in being contacted about future opportunities (e.g., research studies, focus groups, media requests)? If yes, only your name and contact information (e.g.,

phone number and address) will be maintained in our contact list, which can only be used by Center for Healthy Minds researchers. You do not need to join our contact list to be in this study.

Yes, I would like to be contacted in the future.

No, I DO NOT want to be contacted about future opportunities.

Agreement to participate in the research study

Please print or save a copy of this form for your records. You may also request a copy from us at any time. If you have any questions before proceeding, please reach out to study staff at comparisonstudy@chm.wisc.edu or 608-263-0303. Your signature (i.e., typing your name) indicates that you have read this consent form and voluntarily consent to participate.

Name (type first and last name): _____

Email address: _____

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

Signature (Please type first and last name): _____

Date: _____

Next, you will proceed to the initial surveys.