

**Study Title: Behavior, Biology, and Well-Being (BeWell) Study**

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## **University of Wisconsin-Madison Consent to Participate in Research**

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**Study Title:** Behavior, Biology, and Well-Being (BeWell) Study

**Lead Researcher:** Dr. Simon Goldberg; (608) 265-8986; Center for Healthy Minds, 625 W. Washington Ave., Madison, WI 53703

**Institution:** University of Wisconsin-Madison

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### **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, an app-based well-being program, on measurements of well-being. 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 connections between our mind, body, and well-being.

We invite you to take part in this research study because you are 18 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 join the study, you will be asked to take part in an interview over a phone or video call. You may also be asked to complete a four-week well-being program via an app on your phone. You will complete surveys and simple games on your phone one time each week for one month and again three months later.

You will be put into a study group. 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. Depending on which group you are in, we may ask you to install and use the Healthy Minds Program app on your phone.

We expect that you will be in this research study for about four months.

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?**

<b>You may want to participate if you are:</b>	<b>You may NOT want to participate if you:</b>
<ul style="list-style-type: none"><li>• comfortable having researchers ask questions about your mental health.</li><li>• comfortable with providing biological specimens at the beginning and at the end of the study.</li><li>• willing to participate in the study for about 4 months.</li><li>• interested in contributing to scientific knowledge even though you may not benefit directly from the study.</li></ul>	<ul style="list-style-type: none"><li>• do not have time to complete the study.</li><li>• are not interested in using a well-being app or waiting to use a well-being app if you are assigned to the waitlist group.</li></ul>

### **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 on your phone. You will not need to come to the lab for any part of the study.

**Initial Surveys, Games, and Biological Samples:** You will complete the first set of surveys and games on your phone, which will take about 60-90 minutes. You will answer some of the questions by recording a video on your phone. With this video, you will provide the study team with a video recording of your face and your voice while you answer a question about your day and/or will provide a video recording of your face while you watch short video clips and pictures. The study team will provide instructions on how to do the surveys, games, and video recording on your phone. We will mail you a kit to collect samples of your blood and stool at home, which will take 15-25 minutes. These samples measure things happening inside of the body which can relate to how we feel, mentally and physically. We are interested in whether the mental exercises taught in the Healthy Minds Program can impact things happening inside of the body. Here are the materials that will be sent to you:

- The stool sample collection kit contains a disposable collection material to sit over your toilet bowl where you will deposit your stool sample. We are including a mailing box with pre-paid mailing labels. Immediately after collecting your sample, you will mail the sample back to our lab. We will measure the presence of various kinds of bacteria in your stool which may relate to your mental health.
- The dried blood spot collection kit includes an alcohol wipe, a disposable lancet, and filter paper. You will use the lancet to prick your finger and put five spots of blood on the filter paper. Once the blood has dried, you will mail the filter paper to our lab in the same box as the stool sample. We will measure inflammation as well as other signs of your body's immune response.

**Interview:** You will complete an interview over a phone or video call with a clinical interviewer. The interviewer will ask you about your mental health, including questions about past and current depression, suicidality, and other mental health problems. The interview will last approximately 30-90 minutes.

**Group Assignment:** You will be randomly put you into one of three groups. Depending on which group you are in, we may ask you to install the Healthy Minds Program app on your phone. If so, 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 over a long time.

If you are in the group that does not use the Healthy Minds Program app, you will be able to download and use it after the study is over, free of charge, if you want.

**Weekly Surveys and Games:** You will answer questions about yourself and play simple games on your phone one time each week for four weeks. You will record your voice and a video of your face during one of these surveys. You will have about one week to complete each set of surveys and games, which will take approximately 30 minutes to complete each week, except the fourth week of surveys which will take 60-90 minutes to complete.

**3-Month Follow-Up:** Three months after the last weekly surveys, you will complete a final set of surveys and games on your phone. Just as before, you will record your voice and a video of your face during some of these surveys. You will have about two weeks to complete the surveys and games, which will take about 60-90 minutes to complete. We will mail you another kit to collect samples of your stool and blood at home, which will take 15-25 minutes.

### **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, already collected data may not be removed from the study database.

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 Program 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 interview and 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. 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.

During the video recording task, you may experience some embarrassment answering the question about your day. You choose the content of your response.

For the dried blood spot collection, you may experience some tenderness at the site of the finger prick. Occasional bruising at the site can occur and is not permanent. In very rare cases, infection at the site can occur.

For the stool sample collection, you may experience embarrassment about collecting this sample. You will be provided with detailed instructions and information regarding how to hygienically collect your stool sample.

### **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. The recordings of your voice and your face will be encrypted (such that they will no longer be identifiable). Only those who are part of this research team or researchers who sign a data use agreement limiting use of the video recording will have access to the decryption key. If we share the decryption key, those researchers will be able to see your face.

This study has a Certificate of Confidentiality which 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 FDA, the Hope for Depression Research Foundation, the National Institutes of Health, or Joy Ventures.

We may also have to tell appropriate authorities, such as law enforcement or child protective services, 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).

Also, with appropriate confidentiality protections, we might use information and biospecimens that we collect during this study for other research or share it with other researchers without additional consent from you.

We will share information and samples collected for this study with researchers or organizations within and outside of UW-Madison, including MIT and Northwestern University. MIT will analyze the video task data. MIT will only have access to unencrypted video recordings after signing a data use agreement. Northwestern University will process the dried blood spot samples. These samples will be coded with your participant ID; no identifiable information will be shared with Northwestern University. Another laboratory at UW-Madison will process the stool samples. These samples will also be labeled with your participant ID and no identifiable information will be shared with that laboratory.

A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, as required by U.S. Law. This Web site 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 data collected 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 results for the dried blood spot samples, stool samples, video task data, survey data, or interview data.

The surveys and interview 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. If your responses during the clinical interview reveal suicidal ideation or intent to harm others, the clinical research personnel will assess intent and discuss safety with you. If you indicate that self-harm or harm to others is imminent, we will call local authorities in your area for immediate help. We are only using the information collected for research, not to diagnose your mental health. We will not tell you the results. If you are experiencing emotional distress, you should contact your physician or other health care provider, such as a mental health professional.

### **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**

A member of this research team has a personal interest in or might profit financially from the results of 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 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 \$265 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 either via a check at the end of the study or via a debit card. If paid via a debit card, you will receive the debit card in the box with the stool and dried blood spot collection kits or soon thereafter; additional funds will be loaded onto the debit card as you complete each assessment. Below is the payment schedule for this study:

- Initial Surveys and Interview = \$0
- Week 1 Assessments = \$10
- Week 2 Assessments = \$10
- Week 3 Assessments = \$10
- Week 4 Assessments = \$40
- 3-Month Follow-Up Assessments = \$45
- Stool sample collection = \$60 (\$30 for initial assessment completion and \$30 for follow-up assessment completion)
- Dried blood spot collection = \$40 (\$20 for initial assessment completion and \$20 for follow-up assessment completion)
- Bonus for completing everything in the study = \$50

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

If you are determined to be ineligible for the study during the interview, you will receive \$15 for your time and effort.

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) 890-3073.

### **How many people will be in this study?**

We expect about 1,500 people will be in this research study.

### **Who is funding this study?**

This research is being funded by the Hope for Depression Research Foundation, UW-Madison, the National Institutes of Health, Joy Ventures, and the Brain & Behavior Research Foundation

### **What will happen to my data and specimens 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. If any amounts of your specimens are left after processing and analyzing the dried blood spot and stool samples for this study, we will store those samples labeled with your participant ID, not name. Your dried blood spot samples will be tested to measure inflammation as well as other signs of your body's immune response. Your stool samples will be tested to measure the type, quality and amount of bacteria in the sample. If you do not want leftover samples to be used in future research, please email the study team at [bewell@chm.wisc.edu](mailto:bewell@chm.wisc.edu) to let them know to withdraw those samples.

We may share your data with other researchers or publish your data on the internet for anyone to use. If we share any information that could identify you such as your name, address, or video, it will only be with researchers who have signed an agreement to protect your privacy. 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**

We will email you a copy of this form, or you can request a copy from us at any time. If you have any questions before proceeding, please reach out to study staff at [bewell@chm.wisc.edu](mailto:bewell@chm.wisc.edu) or 608-890-3073.

By checking this box, I am agreeing to take part in this research study.

☐

Next, you will proceed to the initial surveys and games. Once those are complete, we will mail you the kits to collect dried blood and stool samples as well as schedule your interview.