

Art and Science of Human Flourishing Microsupport Study

NCT06630897

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University of Wisconsin-Madison Consent to Participate in Research

Study Title: Art and Science of Human Flourishing Microsupport 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 if providing small amounts of digital support may improve wellbeing. We are doing this research because we believe it will help us understand how to support college students' wellbeing and mental health.

We invite you to take part in this research study because you are ≥ 18 years old and are enrolled in the Art and Science of Human Flourishing class in the fall of 2024.

What will I need to do in this study?

If you decide to join the study, you will be asked to complete three online surveys which will take between 15-30 mins. The first one will be now, the second survey will be 1 month from now and the third survey will be three months after the second survey.

You will also be asked to complete brief (1-2 minutes) surveys in the morning and evening daily during the first month of the study. You will also be randomly assigned to either receive or not receive messages on your phone to help support your practice during the first month of the study. If you are randomized to receive text messages, you will receive them approximately every other day. Standard text message / data costs may apply.

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?

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.

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, class grade 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?

Everything that is required for completion of this study can be done online / remotely. 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. This will include a demographic questionnaire.

Daily Surveys: You will complete brief (1-2 minutes) surveys in the morning and evening daily throughout the study for one month. The surveys will ask you about your mental health and wellbeing.

First Follow-Up Survey: At the end of the month, you will receive another set of online surveys which will take about 15-30 minutes to complete.

Second Follow-Up Survey: About three months later, 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.

Healthy Minds Program App: We will access all usage data gathered through the Healthy Minds Program app, including data which was collected prior to the start of the study.

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 and any data collected through the Healthy Minds Program app.

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 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 or illegal behavior (e.g., underage drinking) 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. We will also share your name and email address with our partner non-profit, Healthy Minds Innovations, in order to access data gathered through the Healthy Minds Program app.

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.

Will I receive anything for participating?

If you agree to take part in this research study, we will pay you up to \$200 for your time and effort. Payment will be provided via a check or via a debit card at the end of the study. Below is the payment schedule for this study:

- \$0 for initial survey
- \$30 for the first follow up survey
- \$70 for the second follow up survey
- \$100 bonus if you complete at least 75% of the daily surveys

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

Attention International Students: study compensation for you requires the submission of additional documents, including but not limited to a copy of the passport, W8BEN, I-94 with passport stamp or ESTA with homeland security stamp, and I-20. We will not be able to process payments without these additional documents.

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) 265-9530.

How many people will be in this study?

We expect about 300 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/> or <https://www.uhs.wisc.edu/mental-health/> 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. All data you share may be stored indefinitely. 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.

Attention International Students: study compensation for you requires the submission of additional documents, including but not limited to a copy of the passport, W8BEN, I-94 with

passport stamp or ESTA with homeland security stamp, and I-20. We will not be able to process payments without these additional documents.

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 ashfmicro@chm.wisc.edu or (608) 265-9530. Your signature (i.e., typing your name) indicates that you have read this consent form and voluntarily consent to participate.

☐ By checking this box and typing my name below, I confirm I am ≥ 18 years old, enrolled in the Art and Science of Human Flourishing class in the fall of 2024 and I voluntarily consent to participate, and I am electronically signing this consent form.

Signature (Please type first and last name): _____

Email address: _____

Date: _____

Next, you will proceed to the initial surveys.