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CONSENT TO ACT AS A PARTICIPANT IN A RESEARCH STUDY

STUDY TITLE: ReMind 2 Study

PRINCIPAL INVESTIGATOR:
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SOURCE OF SUPPORT: University of Pittsburgh

KEY INFORMATION:

- **Voluntary research study**:
  - You are being asked to take part in a research study. Research studies include only people who choose to join. The research team will explain the study and answer any questions you have. Take your time to decide. If you choose to join this study, you can still stop at any time.
- **Summary of the research**:
  - Purpose: The purpose of this study is to (1) see if an online group program called Mindfulness-Based Stress Reduction (MSBR) helps people manage stress and improve their well-being, and (2) compare different ways of measuring stress and well-being.
  - Duration: 14 weeks of active participation
  - Study Procedures:
    - Before and after the MBSR program:
      - Come to two study visits that each last 1 to 2 hours
        - Answer questions about your thoughts, feelings, and experiences
        - Give a small blood sample
      - Daily life assessments
        - Fill out short surveys on your phone each day for one week

- Wear a Fitbit to track your activity for one week
- Join a 10-week online MBSR group program
  - Attend a 2-hour orientation session
  - Join weekly group meetings that last 2.5 hours for 10 weeks
  - Practice meditation at home for 30-45 minutes each day
  - Take part in a full-day group practice session

- Possible risks or discomforts:
  - The risks in this study are not greater than what you might face in everyday life.
  - You may feel a quick, sharp pinch when a few drops of blood are taken from your finger using a small needle (a finger prick). Your finger might feel sore for a short time afterward. There is a very small risk of tissue damage or infection.
  - The mindfulness program (MBSR) includes meditation and gentle movement (like yoga). These may cause physical or emotional discomfort as you explore your thoughts and feelings in new ways. You can stop at any time if anything feels uncomfortable or unsafe.
  - MBSR is not recommended for people who have recently had serious mental health problems like severe depression, substance abuse, suicidal thoughts, post-traumatic stress disorder (PTSD), psychosis, or social anxiety. MSBR is not a substitute for medical or mental health treatment.
  - Other infrequent risks may include discomfort wearing the Fitbit device, discomfort answering personal questions about your health, or breach of confidentiality.
  - **Text Messages:** Text messages may not be encrypted or secure during their transmission or storage and it is possible they could be intercepted and used by others not associated with this study.
  - **Email**: Emails may not be encrypted during transmission or storage and may be intercepted and used by others not associated with this study.
  - We will take steps to reduce these risks, and those steps are explained in this consent form.

QUESTIONS ABOUT THE STUDY:
If you have questions about this study, you can contact the Principal Investigator using the information listed above. If you have questions about your rights as a research participant, or if you want to talk to someone who is not part the research team, please call the University of Pittsburgh Human Subjects Protection Advocate toll-free at 866-212-2668.

Why is this research being done?
The goal of this research is to find better ways to teach people how to manage stress and better ways to measure stress.

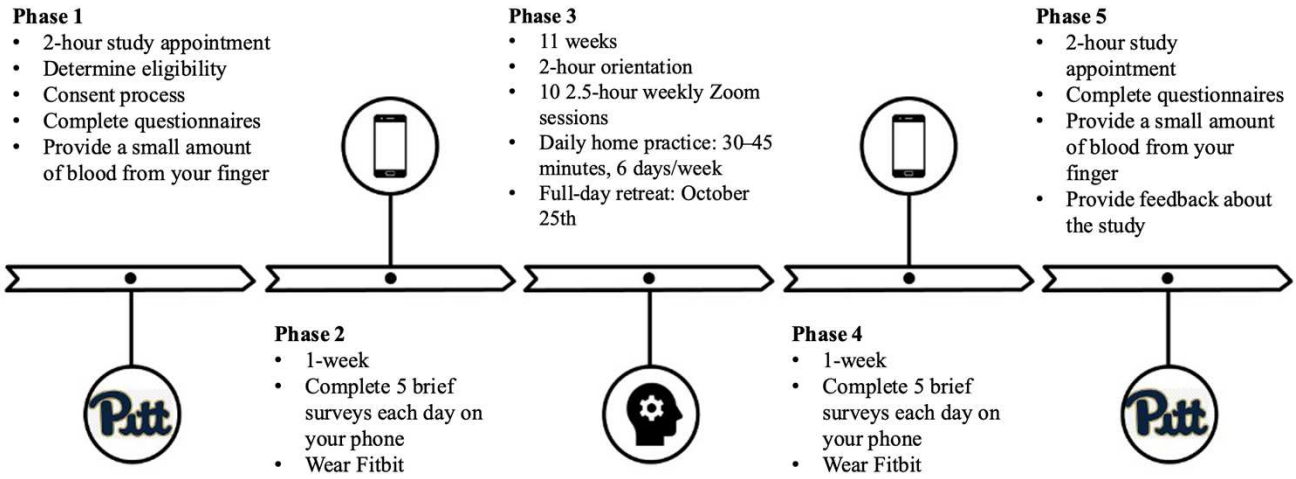
Who is being asked to take part in this research?
Adults between the ages of 18 and 29 who can read and write in English and have a data-enabled smartphone may be eligible to join this study. Up to 15 people will be invited to participate in the study.

How long will you be in this study?
You will take part in the study over about 4 months, ending in November or December 2025. This includes 14 weeks of active participation.

- For one week before and one week after the mindfulness program, you will get 5 text messages a day asking you to complete short surveys. You will also wear a Fitbit activity tracker during this time.
- During the 10-week mindfulness program (MSBR), you will join weekly online group classes on Zoom. A professional instructor will guide you in learning mindfulness meditation techniques.
- You will also come to two in-person study visits—one at the beginning and one at the end of the study. Each visit will take about 1 to 2 hours.

What procedures will be performed for research purposes?

The study lasts about 4 months, with 14 weeks of active participation:



- Two in-person visits at the University of Pittsburgh (Old Engineering Hall, Suite 600):
  - First visit (about 2 hours): We will check if you are eligible for the study (there is a possibility that you may not qualify). If you are eligible, we will explain the study in more detail, show you how to complete surveys and access the MBSR program, ask you to fill out questionnaires about your thoughts and feelings, and take a small blood sample from your fingers (5 drops) so that we can measure markers of inflammation in your immune system.
  - Final visit (about 1 hour, in November or December): After the MBSR program, you come back to the lab to answer questionnaires and give another small blood sample. We will also talk about your experience in the study.
- One week of surveys on your smartphone (before and after the training program):
  - We will send you 5 text messages each day for one week before and after the mindfulness program (MBSR). Each text message will ask you to complete a short survey (2-5 minutes) about your stress, mood, and social interactions.
- Wear a waterproof Fitbit activity tracker for one week before and after the mindfulness program:
  - The Fitbit will track your sleep, activity, and heart rate. We will install the Fitbit app on your phone to send us the data. You will need to charge the Fitbit about once every 4-5 days.

What are the possible risks, side effects, and discomforts of this research study?

Risks of collecting blood samples: Some people feel uncomfortable around blood. You may feel a quick, sharp pinch when your finger is pricked, and your finger might be sore for a few hours afterward. There is a very small risk of lasting tissue damage or infection. The study staff are trained

to follow safe medical steps to keep these risks low.

Risks of the MBSR training program: MSBR is not a substitute for medical or mental health care. It is not recommended for people who have recently had severe depression, substance abuse, thoughts of suicide, PTSD, psychosis, or social anxiety. Some possible risks include:

- Physical pain or injury from gentle mindful yoga exercises. You can change or skip any movement that hurts or doesn't feel right for your body.
- Emotions like sadness, anger, or fear might get stronger as you practice mindfulness and pay attention to your emotions in new ways. You may find it challenging or uncomfortable to face these feelings or learn new things about yourself. Sometimes these feelings get worse at first or it may feel like nothing is changing. If you feel upset during the program, we encourage you to seek additional support from a licensed therapist. If you have a therapist, we will ask for their contact information. This information will be kept confidential and can only be accessed by the research team. We will only contact your therapist with your permission or if we are worried about your immediate safety.
- Changes in how you act or communicate might make your family, friends, or coworkers uncomfortable.
- Finding time to practice mindfulness regularly can be hard.

Mindfulness meditation and yoga involve self-exploration and movement. If you feel like you cannot or should not take part in these exercises, you can stop at any time. You may also communicate with your instructor by phone if needed.

Risks of completing questionnaires: You will be asked questions about your thoughts, feelings, and daily experiences with stress and mood. Some people may find these questions upsetting. You can skip any question or take a break whenever you want. If the study causes strong emotional distress, you can talk for free with a licensed clinical psychologist.

Risks of wearing the Fitbit activity monitoring device: Wearing the Fitbit might feel uncomfortable if you don't usually wear a wristwatch. It may also cause skin irritation. You can stop wearing it if it is uncomfortable on either wrist.

Risks of loss of confidentiality of research data: We will work hard to protect your privacy, but internet communication is not completely secure. All your study data will be kept in secure places like locked cabinets and password-protected computers and databases. Your data will only be identified by a study ID number, not by your name. We encourage you to use a password on your phone. Text messages we send are not encrypted and could be seen by others. We will do our best to keep your information private but cannot guarantee complete confidentiality.

Who is liable if there is an injury during the study?

If you believe that the research procedures have resulted in an injury to you, immediately contact the Principal Investigator who is listed on the first page of this form. Emergency medical treatment for injuries solely and directly related to your participation in this research study will be provided to you by the hospitals of UPMC. Your insurance provider may be billed for the costs of this emergency treatment, but none of those costs will be charged directly to you. If your research-related injury requires medical care beyond this emergency treatment, you will be responsible for the costs of this follow-up care. At this time, there is no plan for any additional financial compensation. You do not waive any rights by signing this form.

What are possible benefits from taking part in this study?

You might find the mindfulness program helpful and may choose to keep practicing mindfulness after the study ends. Some possible benefits include:

- Feeling more aware and focused
- Learning new ways to handle stress
- Taking better care of yourself

Even if you don't notice personal benefits, your participation may help researchers learn how to offer stress management programs to more people in the future.

If I join the study, will I be told of any new risks that may be found during the study?

Yes. If we learn anything new during the study that might make you change your mind about staying in the study, we will tell you right away.

Will I be paid if I take part in this research study?

Yes, you will be paid for your time in the study. The study team will discuss the payment options with you. Briefly, here is how it works:

- Today's visit:
  - If you are eligible, you will get $20.
  - If you are not eligible, you will still get $10 for your time.
- Daily surveys:
  - You can earn $25 for completing at least 85% of the daily surveys during the first week.
  - During the last week of surveys, you can earn $25 plus a $25 bonus if you complete at least 85% of surveys.
- Final visit:
  - You will get $25 when you come back for the last visit.
  - You can keep the Fitbit you wear during the study (valued at $100).
- MSBR training program:
  - You will get $50 for participating.
  - You can also earn a bonus based on how many sessions you attend:
    - $50 if you attend at least 9 of 11 sessions
    - $75 if you attend 10 of 11 sessions,
    - $100 if you attend all 11 sessions

In total, you could earn up to $270 (plus the Fitbit) for participating in this study. If you don't complete the whole study, you will still be paid for the parts you do complete.

Compensation for your participation in research is considered as taxable income. If a participant receives $600 or more in a calendar year from one organization, that organization is required by law to file a Form 1099 – Miscellaneous with the IRS and provide a copy to the taxpayer. To receive the full amount of compensation for this study, you would need to provide your name, address, and social security number. Individuals who do not provide a social security number may still participate in the research, but the IRS requires that 24% of the payment be sent by the institution to the IRS for 'backup withholding;' thus you would only receive 76% of the expected payment.

Who will know about my participation in this research study?

We will do our best to keep your information private. Your name will not be used in any research reports. Instead, we will give you a study ID number, and we will keep your name and that ID number in separate, secure places. Paper files will be stored in locked cabinets. Your signed consent form will also be kept separate from your study data. Only the research team will have access to your information. If we share your data with other researchers in the future, we will first remove anything

that could identify you. This means your information or blood samples might be used in future studies without asking you again, but your name and personal details will not be shared.

Who will have access to identifiable information related to my participation in this research study?
In addition to the researchers listed on the first page of this consent form and their research staff, the following people may see information that could identify you:

- Authorized representatives of the University of Pittsburgh Office of Research Protections may review your identifiable research information to make sure the study is being done correctly and safely.
- In unusual cases, the researchers may be required to release identifiable information related to your participation in this research study in response to an order from a court of law. If the investigators learn that you or someone with whom you are involved is in serious danger or potential harm, they will need to inform, as required by Pennsylvania law, the appropriate agencies.

How long can the researchers use and disclose identifiable information related to my participation in this research study?
The researchers may use and share information that could identify you for at least 7 years after the study ends or after the results are published. They will only use it for the purposes explained in this consent form.

Can my information be used for any other purposes?
Your data and blood samples used in this research study may contribute to a new discovery or treatment. In some instances, these discoveries or treatments may be of commercial value and may be sold, patented, or licensed by the investigators and the University of Pittsburgh for use in other research or the development of new products. You will not retain any property rights nor

will you share in any money that the investigators, the University of Pittsburgh, or their agents may realize.

Right now, we do not plan to do a full reading of your DNA (called whole genome sequencing). But your samples or data might be shared with other researchers and with federal repositories in the future. The risks associated with genetic studies include the potential for a breach of confidentiality which could affect future insurability, employability, or reproduction plans, or have a negative impact on family relationships and/or result in paternity suits or stigmatization. A Federal law, called the Genetic Information Nondiscrimination Act (GINA), generally makes it illegal for health insurance companies and group health plans to use genetic information in making decisions regarding your eligibility or premiums. GINA also makes it illegal for employers with 15 or more employees to use your genetic information when making decisions regarding hiring, promoting, firing, or setting the terms of employment. This new Federal law does not protect you against genetic discrimination by companies that sell life, disability, or long-term care insurance.

Is my participation in this research study voluntary?
Being in this study is completely your choice. You can talk it over with your family or friends before agreeing to participate. If there's anything you do not understand, please ask us. You can ask questions now or later. Whether or not you consent to participate in this research study will not affect your relationship with the University of Pittsburgh.

Can my participation in this study be discontinued?
Yes, a researcher may remove you from the research study. For example, you might be taken out of the study if we don't receive any data from you or if you don't respond to our messages or calls for 3 weeks.

May I withdraw, at a future date, my consent for participation in this research study?
Yes, you can stop being in the study at any time. If you stop, you won't take part in any more study activities. The researchers will still use the information they collected from you before you stopped, as explained earlier.

To formally withdraw your consent for participation in this research study, please send an email or letter (with the date) to the principal investigator. Their contact information is listed on the first page of this form. Your decision to leave the study will have no effect on your relationship with the University of Pittsburgh.

How can I find out about the results of this research study?
A description of this clinical trial will be available on http://www.clinicaltrials.gov, as required by US 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.

Your blood will be drawn so that we can measure markers of inflammation in your body. Although these results are sometimes used by doctors to show signs of illness, we will not share your individual lab results with you.

VOLUNTARY CONSENT TO PARTICIPATE

The above information has been explained to me and all of my current questions have been answered. I understand that I am encouraged to ask questions, voice concerns or complaints about any aspect of this research study during the course of this study, and that such future questions, concerns or complaints will be answered by a qualified individual or by the investigator(s) listed on the first page of this consent document at the telephone number(s) given. I understand that I may always request that my questions, concerns or complaints be addressed by a listed investigator. I understand that I may contact the Human Subjects Protection Advocate of the IRB Office, University of Pittsburgh (1-866-212-2668) to discuss problems, concerns, and questions; obtain information; offer input; or discuss situations that occurred during my participation. By signing this form I agree to participate in this research study. A copy of this consent form will be given to me.

Participant's Signature	Printed Name of Participant	Date

INVESTIGATOR CERTIFICATION OF INFORMED CONSENT:

I certify that I have explained the nature and purpose of this research study to the above-named individual(s), and I have discussed the potential benefits and possible risks of study participation. Any questions the individual(s) have about this study have been answered, and we will always be available to address future questions, concerns or complaints as they arise. I further certify that no research component of this protocol was begun until after this consent form was signed.

Printed Name of Person Obtaining Consent	Role in Research Study

Signature of Person Obtaining Consent	Date