Official Title: Remote Mindfulness Training Following Early Life Adversity (ReMind)

ClinicalTrials.gov ID (NCT number): NCT05516108

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University of Pittsburgh

Kenneth P. Dietrich School of Arts & Sciences
Department of Psychology

3137 Sennott Square
210 South Bouquet Street
Pittsburgh, PA 15260
Phone: 412-624-4500
Fax: 412-624-4428
www.psychology.pitt.edu

CONSENT TO ACT AS A PARTICIPANT IN A RESEARCH STUDY

STUDY TITLE: ReMind Study

PRINCIPAL INVESTIGATOR:
Emily Lindsay, PhD
Department of Psychology
600 Old Engineering Hall
3943 O'Hara Street
Pittsburgh, PA, 15213
emily.lindsay@pitt.edu
(412) 346-1416

CO-INVESTIGATORS:
Anna Marsland, PhD (marsland@pitt.edu)
Carissa Low, PhD (lowca@upmc.edu)

SOURCE OF SUPPORT: National Institutes of Health

KEY INFORMATION:

- **Voluntary research study**:
  - You are being asked to take part in a research study. Research studies include only people who choose to take part. The study team members will explain the study to you and will answer any questions you might have. You should take your time to make your decision. If you join this study, you can still stop at any time.
- **Summary of the research**:
  - Purpose: The purpose of this study is to (1) evaluate whether smartphone-based attention training programs are beneficial for stress and well-being, and (2) compare different ways of measuring stress and well-being.
  - Duration: 8 weeks
  - Study Procedures:
    - Complete a 14-day attention training program on your smartphone
    - Answer brief daily surveys on your smartphone for 5 weeks
    - Answer questions about your thoughts, feelings, and experiences at study visits at the beginning, middle, and end of the study
    - Provide a blood sample at the beginning, middle, and end of the study
    - Wear a Fitbit wristband activity tracker
    - Keep a study app installed on your smartphone to collect sensor data

- Possible risks or discomforts:
    - The potential risks of this study are no greater than those encountered in daily life.
    - Acute pain may be felt when your blood is drawn or for a few hours afterward, and there is a negligible risk of tissue damage or infection.
    - Other infrequent risks and discomforts may include the activity monitoring device being uncomfortable, experiencing discomfort when answering questions about physical or mental health, or breach of confidentiality.
    - The smartphone application could potentially drain your phone's battery more quickly than usual or reduce the performance of the local Wi-Fi network.
    - The steps we take to minimize these risks are explained in this consent form.

QUESTIONS ABOUT THE STUDY:
Questions about this research study can be directed to the Principal Investigator, whose contact information is listed above. If you have any questions about your rights as a research subject or wish to talk to someone other than 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 develop efficient ways of delivering stress management programs and measuring stress.

Who is being asked to take part in this research?
Adults ages 18–29 years who are able to read and write in English and who own data-enabled smartphones may be eligible to participate in this study. Eighty participants will be invited to participate in the study.

How long will your part in this study last?
You will be asked to participate for 8 weeks. You will be asked to wear the activity tracker and keep the application installed on your smartphone for the entire study. You will be asked to complete a 14-lesson training program on your phone, plus one week of daily surveys before and after the program and one month later. We will meet with you in-person at the beginning, middle, and end of the study; these study visits will take about 2 hours.

What procedures will be performed for research purposes?
The study takes place over the course of 8 weeks, during which time we ask that you carry your phone with you wherever you go.

<table>
<tr><td></td><td>Visit 1</td><td colspan="5"></td><td>Visit 2</td><td colspan="3"></td><td>Visit 3</td></tr>
<tr><td>@ Pitt</td><td colspan="11"></td></tr>
<tr><td>Week:</td><td>1</td><td colspan="2">2</td><td>3</td><td colspan="2">4</td><td>5</td><td>6</td><td>7</td><td colspan="2">8</td></tr>
<tr><td rowspan="3">@ home</td><td colspan="2">Stress/mood surveys</td><td colspan="3">Training program + surveys</td><td colspan="2">Stress/mood surveys</td><td></td><td></td><td></td><td colspan="2">Stress/mood surveys</td></tr>
<tr><td colspan="11">Fitbit wristband activity tracker</td></tr>
<tr><td colspan="11">Smartphone sensor data</td></tr>
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- Three study visits (each lasting 2 hours) will take place at University of Pittsburgh in our laboratory in Old Engineering Hall, Suite 600:

    - Today, we will confirm that you are eligible for the study; there is a possibility that you may not qualify. If eligible, you will hear an outline of the study procedures in more detail, learn how to complete surveys and the training program on your own, complete questionnaires about your thoughts, feelings, and experiences, and provide a small amount of blood from your fingers (5 drops) so that we can measure markers of inflammation in your immune system.
    - You will be asked to come back to the lab in 4 weeks for a mid-point study visit and again in 8 weeks for a final study visit. You will again complete questionnaires and provide a small amount of your blood. During your final study visit, we will have a chance to discuss your experiences in the study.
- We will ask you to complete 5 weeks of surveys on your smartphone as you go about your daily life:
    - We will signal you to complete 5 brief (2-5 minute) surveys on your phone each day for one week before the training program, for one week after, and for another week one month later. These surveys will ask you about your experiences of stress, mood, and social interactions.
    - We will ask you to complete brief (2-3 minute) surveys each day during your 14-day attention training. These surveys will ask about your stress and mood.
- We will ask you to complete 14 days of attention training on your smartphone at home:
    - You will be asked to complete a 20-minute attention training session and 3 brief (3-minute) homework practice assignments (which will be delivered via text) each day for this 14-day period. You will have access to the training program at the end of the study.
- We will ask you to wear a waterproof wristband activity tracker (Fitbit) for the duration of the study as you go about your daily life:
    - This device will assess sleep and activity levels as well as heart rate. We will install an application on your phone to permit wireless syncing of your data, and we will ask you to charge the device as needed (approximately once every 4-5 days).
- We will install an application on your smartphone that will collect sensor data for the duration of the study as you go about your daily life:
    - This software will collect information several times per hour that may include: movement, approximate location of the phone, screen status (on/off), battery level, list of currently running applications, timezone, weather, and call and SMS events.
    - **Please note**: All data captured for the research will be linked only to your participant ID and will not include any personally identifiable information about you.
    - The application will store this information on the device and transmit this information to one of our secure servers at least once a week.
    - We are only collecting meta-data, such as timestamp of when texts were sent/received, timestamp of when a call was received/initiated, and timestamp of when a call ended.
        - We do not collect the names or phone numbers of individuals who you are calling/texting.

        - Each person with whom you communicate via smartphone will be assigned a unique ID number so that we know frequency of contact with each person but not the identity of anyone with whom you communicate.
        - We will not be recording any audio data or collecting any data about the content of your messages or anything else you type on your phone.
    - The data plan requirements of the application are not significantly different from what most smartphone users would require if they use their device to access the Internet for web searching.
    - At the end of the data collection (during the final study visit), we will uninstall the software from your smartphone.

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

Risks of collecting blood samples: Some participants may feel uncomfortable around blood. Acute pain may be experienced when your finger is pricked and for several hours following. There is a negligible risk of lasting tissue damage or infection. Staff are trained in standard clinical procedures to minimize these risks.

Risks of the attention training program: Some people may feel uncomfortable, bored, or aggravated while completing the attention training. Many people enjoyed and found the training programs useful in a previous study.

Risks of completing questionnaires: You will be asked to complete questionnaires about your thoughts, feelings, and experiences and daily surveys about your experiences of stress and mood. Some people may find this to be upsetting. You may refuse to answer any of the questions and you may take a break at any time during the study. In the unlikely event that you are significantly distressed by any aspect of study participation, you will be offered the opportunity to discuss these issues, for no fee, with a licensed clinical psychologist.

Risks of collecting smartphone sensor data: The risks associated with participation in this study are no greater than those ordinarily encountered during smartphone use in daily life. There is a risk that the sensors could drain the device's battery more quickly than usual. When the phone uploads data, it might reduce the performance of the local Wi-Fi network. You are encouraged to call the study team if you notice problems thought to be related to the sensor data collection so that steps can be taken to address the issue.

Risks of wearing the Fitbit activity monitoring device: Wearing the activity monitoring device may be uncomfortable for some people who are not accustomed to wearing a wristwatch and/or may cause skin irritation. You may discontinue the use of the activity monitoring device if you are unable to wear it comfortably on either wrist.

Risks of loss of confidentiality of research data: Although every reasonable effort has been taken, confidentiality during Internet communication activities cannot be guaranteed. All data will be stored in secure locations, including locked file cabinets and password-protected computers and databases, and identified only by study ID numbers. You are encouraged to use a password for your smartphone. Text messages used for study reminders are not encrypted or secure during their transmission, and could be intercepted. We will make every attempt to protect

your privacy and the confidentiality of your records, as described in this document, but cannot guarantee the confidentiality of your research records.

What are possible benefits from taking part in this study?
There may or may not be personal benefit from your participation in the study. You may find the attention trainings useful and decide to continue practicing upon completion of the study. We will provide you with the audio-guided trainings upon completion of the study if you do wish to continue practicing. A potential benefit of study participation includes the contribution to knowledge in delivering stress management programs more widely.

If I agree to take part in this research study, will I be told of any new risks that may be found during the course of the study?
You will be promptly notified if any new information we learn during this research study may cause you to change your mind about continuing to participate in the study.

Will I be paid if I take part in this research study?
For your participation today, you'll receive $10. At your next study visit after the training program, you will receive an additional $60, plus up to $65 in bonuses for completing >85% of the daily surveys and >90% of attention training lessons. At your final study visit, you will receive another $50, plus up to $20 in bonuses for completing >85% of the daily surveys. In total, you will be compensated up to $205, including bonus payments. You will also have the option to keep the wristband device free of charge; the approximate value of the device is $100.

If you complete >85% of the daily surveys and >90% of the attention training lessons, you will also have a chance to receive one of five $100 Giant Eagle gift cards. Your chances of receiving a gift card are at least 1 in 16.

If you do not choose to complete the entire study, you will be compensated for your partial participation as follows: $20 each for completing the attention training, each set of daily surveys, and the second study visit.

All compensation is taxable income to the participant regardless of the amount. 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. 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?
Any information about you obtained from this research will be kept as confidential (private) as possible. Your consent form and data will be kept separate. All paper records related to your involvement in this research study will be stored in locked filing cabinets. Your identity on all records will be indicated by a study number rather than by your name, and the information linking these study numbers with your identity will be kept separate from the research records. You will not be identified by name in any publication of the research results. Your information or biospecimens collected as a part of this research, after removal of identifiers, could be used for

future research studies or distributed to another investigator for future research studies without additional informed consent.

Who will have access to identifiable information related to my participation in this research study?

In addition to the investigators listed on the first page of this authorization (consent) form and their research staff, the following individuals will or may have access to identifiable information related to your participation in this research study:

- Authorized representatives of the University of Pittsburgh Office of Research Protections may review your identifiable research information for the purpose of monitoring the appropriate conduct of this research study.
- In unusual cases, the investigators 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.
- To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. The researchers can use this Certificate to legally refuse to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, for example, if there is a court subpoena. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below.
    - The Certificate cannot be used to resist a demand for information from personnel of the United States Government that is used for auditing or evaluation of federally-funded projects or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA).
    - You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information.
    - The Certificate of Confidentiality will not be used to prevent disclosure to state or local authorities of child abuse and neglect or harm to self or others.

For how long will the investigators be permitted to use and disclose identifiable information related to my participation in this research study?

The investigators may continue to use and disclose, for the purposes described above, identifiable information related to your participation in this research study for at least 7 years following final reporting or publication of a project.

Can my information be used for any other purposes?

Your data and specimens 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.

Although we have no plans at this time to use the blood you provide for whole genome sequencing, it is possible that your data, samples, and genetic data generated from your samples may be shared with other researchers and with federal repositories. 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?
Your participation in this research study is entirely voluntary. You may want to discuss this study with your family and friends before agreeing to participate. If there are any words you do not understand, feel free to ask us. The investigators will be available to answer your current and future questions. Whether or not you provide your consent for participation in this research study will have no effect on your current or future relationship with the University of Pittsburgh.

Can my participation in this study be discontinued?
You may be removed from the research study by an investigator if, for example, you are non-adherent as defined as no survey or sensor data received for 14 consecutive days.

May I withdraw, at a future date, my consent for participation in this research study?
You may, at any time, withdraw your consent for participation in this research study. This means that you will also be withdrawn from further participation in this research study. Any identifiable research information obtained as part of this study prior to the date that you withdrew your consent will continue to be used and disclosed by the investigators for the purposes described above.

To formally withdraw your consent for participation in this research study, you should provide a written and dated notice of this decision to the principal investigator of this research study at the address listed on the first page of this form. Your decision to withdraw your consent for participation in this research study will have no effect on your current or future 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 markers are sometimes used clinically to indicate infection or disease risk, we will not disclose your individual research results.

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