**FULL PROTOCOL TITLE:** Mobile Health to Monitor Risk for COVID-19 and Improve Mental Health during the Pandemic

**ClinicalTrials.gov Identifier:** NCT05074693

**DOCUMENT DATE:** October 13, 2023

UNIVERSITY of HOUSTON
A CARNEGIE-DESIGNATED TIER ONE PUBLIC RESEARCH UNIVERSITY

# Consent to Take Part in a Human Research Study

***Title of research study:*** Mobile Health to Monitor Risk for COVID-19 and Improve Mental Health during the Pandemic

Investigators: Michael Zvolensky, Ph.D., and Michael Businelle, Ph.D.

## *Key Information:*

The following information is presented to assist you in understanding the key elements of this study, as well as the basic reasons why you may or may not wish to participate. This section is only a summary; more detailed information, including how to contact the research team for additional information or questions, follows within the remainder of this document under the "Detailed Information" heading.

## *What should I know about a research study?*

- Taking part in the research is voluntary; whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide, and can ask questions at any time during the study.

We are inviting you to take part in a research study testing our mobile application designed to reduce ongoing mental health concerns among Black, Latinx, White, and American Indian individuals during the COVID-19 pandemic because you stated that you feel anxious or depressed.

In general, your participation in the research involves using our mobile application to complete a series of questionnaires, and provide us with feedback on how helpful the app is with helping to reduce your mental health concerns. In addition to today, we will also ask you to complete brief daily surveys and follow-up questionnaires 3-months and 6-months from today using our app. Further, 3-months and 6-months from today, selected participants will be asked to take part in an interview over the phone so that we may gather feedback regarding the app, how easy it is to use, and how well it functioned during your participation.

The primary risk to you in taking part is potential discomfort while answering some of our questions, which you can compare to the possible benefit of improving your ability to manage your mood through the intervention program. You will receive compensation for participation.

This research is being funded by the National Institutes of Health.

## *Detailed Information:*

The following is more detailed information about this study, in addition to the information above.

## Consent to Take Part in a Human Research Study

### *Why is this research being done?*

The main goal of this study is to target health inequalities in behavioral health care during the COVID-19 pandemic among White, Black, Latinx, and American Indian (BLAI) individuals with elevated anxiety and/or depressive symptoms by testing a mobile application our team has developed to reduce ongoing mental health concerns among individuals with elevated anxiety and/or depressive symptoms.

### *How long will the research last?*

We expect that you will be in this research study for 6 months. During this time, you will be asked to complete three study sessions which will all be completed virtually and will take about 30 minutes to 60 minutes to complete.

### *How many people will be studied?*

We expect to enroll about 900 people in this research study.

### *What happens if I say yes, I want to be in this research?*

We will ask you to download the Insight™ app to your phone. We will loan you a study phone if you do not have one for study participation. After downloading the app, we will ask you to complete today's study session using your phone. You will be asked to give information about yourself including your birth date, your race, ethnicity, gender, social security number, date of birth, and U.S. residency status. You will also be asked about your medical and mental health history, any medications you have been taking or illnesses that you may have, and about your experiences during the COVID-19 pandemic. You may skip questions that you do not feel comfortable answering. In addition, the mobile app you download will prompt you twice per day (i.e., morning and evening) to complete brief surveys about COVID-19, stress, and mood for 6 months. You will be compensated for completing these daily surveys.

We will also ask you to use the app to complete longer follow-up surveys 3- and 6-months from today using your phone or a study phone that is loaned to you via the app. Some participants will also be asked to complete an interview via phone or online platform (e.g., Zoom) during the 3-month and 6-month follow-up assessments. If you do not respond to the app prompts to complete the follow-up assessment, you will be contacted via call, text, and/or email to receive a reminder from our research team, and carrier messaging rates will apply.

The phone that is provided to you (if needed) has other applications on it like a calendar, phone book, messages, etc. You are allowed to make outgoing phone calls, receive phone calls and send and receive text messages. The other applications may be used but please keep in mind that the phone must be turned back in to our team at the end of the study. After your last follow-up session, you will return the phone to us, and the phone you were loaned will be factory reset and assigned a new phone number. This phone is loaned to you so that you can participate in the study, and it is not meant to replace a phone you may currently have.

The treatment you get will be chosen by chance, like flipping a coin. You will have an equal chance of being given each treatment either (a) the Insight™ app with EASE intervention components, or (b) the Insight™ app.

You will be compensated for completing the study assessments. Please keep in mind that your name, date of birth, and address will be collected from our research team and that information will be shared with the Greenphire company so that you can be compensated for completing study questionnaires on

a convenient reloadable MasterCard. Our research team has a business agreement with Greenphire and all information will be kept confidential.

We will collect geolocation data on the phone when you interact with the app. The geolocation data will be used to identify effects of specific places on thoughts, mood, and behaviors that are related to mental health symptom exacerbation. This information will also be useful in advancing our knowledge of thoughts, feelings, locations, behaviors, and events that link anxiety sensitivity to mental health symptom exacerbation.

*Follow up Assessments*

You will be asked to complete surveys on the smartphone (i.e., your personal phone or one we loan to you) during your first study visit, 3 months from now, and 6 months from now. The 3- and 6-month follow up assessments will ask you to complete many of the same tests and surveys as the first survey, as well as some additional tests and surveys about the study.

*Study Groups*

**EASE App.** Study participants randomized to the EASE group will download the Insight app with EASE intervention components onto their personal phone or a study provided phone. The EASE app focuses on reducing anxiety and depression. The EASE app will prompt (i.e., phone will ring/vibrate) two daily surveys (one in the morning and one in the evening). The app will use the answers to these surveys to create tailored messages that are designed to help participants cope with symptoms of anxiety and depression. Messages may address you by your first name. Participants can also use the smartphone app functions to: 1) watch videos that address anxiety and depression, 2) get easy access to local resources (e.g., housing, job placement, food), 3) tips on coping with distress, stress, challenging thoughts, depression, etc., 4) access relaxation exercises and videos, and 5) report COVID-19 symptoms and receive help with getting tested for the COVID-19 virus.

**Insight App.** Study participants randomized to the Insight group will download the Insight app with Insight intervention components onto their personal phone or a study provided phone. The Insight app focuses on reducing anxiety and depression. The app will prompt (i.e., phone will ring/vibrate) two daily surveys (one in the morning and one in the evening). Participants can use the smartphone app functions to: 1) access relaxation exercises and videos, and 2) report COVID-19 symptoms and receive help with getting tested for the COVID-19 virus.

## *What are my responsibilities if I take part in this research?*

If you take part in this research, you will be responsible for completing the surveys, and returning your study phone at the end of the study if a study phone is loaned to you.

To ensure data protection, if you are eligible to receive a study phone, we will ask you to please act as the sole user of the study phone.

## *What happens if I do not want to be in this research?*

You can choose not to take part in the research and it will not be held against you. Choosing not to take part will involve no penalty or loss of benefit to which you are otherwise entitled.

If you are a student, a decision to take part or not, or to withdraw from the research will have no effect on your grades or standing with the University of Houston, or University of Oklahoma.

### *What happens if I say yes, but I change my mind later?*

You can leave the research at any time and it will not be held against you.

If you decide to leave the research, you may not receive all of the possible benefits from the treatment. You will receive payment for the parts of the study that you have completed, but you will not be paid for what you have not completed. If you decide to leave the research, contact the investigator so that the investigator can remove you from the study.

If you stop being in the research, already collected data will not be removed from the study record.

### *Is there any way being in this study could be bad for me?*

Risks to people who take part in this study are minimal. Still, efforts will be made to lower the risks for each person who takes part in this study. You will be informed of the nature of the investigation, the types of assessments and procedure, and the potential risks associated with these procedures. You will be given an opportunity to have any questions answered to your satisfaction and will be asked to sign an informed consent statement prior to participating in the project. The risks involved in study are listed below:

- You may experience discomfort or mild distress as a result of responding to sensitive questions or laboratory procedures. This may include feeling uncomfortable answering questions about sensitive, personal information. However, this discomfort is expected to be relatively minimal.
- The loss of confidentiality regarding research information is a possibility, although, the risk is small. The investigators and their research staff will make every effort to maintain the confidentiality of study participants. The privacy of people who take part in this study will be carefully protected. All data which might link a person to the information provided during the study will be stored in locked files. We will also ensure that all study staff and people who take part are well informed about confidentiality rules and laws. We will use identification numbers and not names on all data forms.

### *Will I receive anything for being in this study?*

You will be compensated $20 for completing the baseline survey, and $50 for completing each of the 3- and 6-month appointments. Each appointment will include a self-report follow-up assessment via the app and, if selected, an interview over the phone about the app; the assessment and, if selected, the interview must be completed to receive compensation. Participants will also be compensated for completing daily phone assessments for 6-months. Specifically, those who complete 50%-74% of prompted assessments each month (2 per day x 30 days = 60 monthly assessments) will receive $20, those who complete 75%-89% of assessments will receive $30, and those who complete 90% or more of their assessments will receive a total of $40 for that month. Additionally, participants can receive $10 for every individual they refer to this study that is successively enrolled up to a total of $50. Participants receive compensation via reloadable Greenphire MasterCards. These cards can be used anywhere MasterCard is accepted and you may also use these cards to withdraw your compensation from a bank. Your card will be purchased by our research team and mailed to you once you complete your baseline assessment, and reloaded following each month. Per the policy of the University of Oklahoma Health Sciences Center, gift card payments are limited to U.S. Citizens and Permanent Residents. Those who fall under the category of Resident Aliens and Non-Resident Aliens will receive

compensation via a check. Per the Oklahoma Taxpayer and Citizen Protection Act of 2007, undocumented immigrants are prohibited from receiving payment, and thus will not be included in this study.

### *Will being in this study help me in any way?*

We cannot promise any benefits to you or others from your taking part in this research. However, possible benefits include the opportunity to examine and improve your ability to effectively manage your mood through the intervention program. Additionally, the findings of this research may be used to improve future COVID-19-specific mental health interventions for those who identify as White, African American, Latinx, or American Indian.

### *What happens to the information collected for the research?*

Efforts will be made to keep your personal information private, including research study records, to people who have a need to review this information. Each subject's name will be paired with a code number, which will appear on all written study materials. The list pairing the subject's name to the code number will be kept separate from these materials. We cannot promise complete secrecy. Organizations that may inspect and copy your information include the Institutional Review Board (IRB) and other representatives of this organization, as well as collaborating institutions and federal agencies that oversee our research. Participant data will only be shared among members of our study team at the University of Houston and Oklahoma Health Sciences Center. The sponsor of this research, the National Institute of Health, may also review research records upon request.

We may publish the results of this research. However, unless otherwise detailed in this document, we will keep your name and other identifying information confidential.

This research is covered by a Certificate of Confidentiality from the National Institute of Health. The researchers with this Certificate may not share or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be shared with anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by the National Institute of Health which is funding this project 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 from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

All of the information you provide will be double-locked (in a locked cabinet, within a locked lab) at all times. The electronic and self-report data obtained will also be assigned an ID number and will be stored on the investigator's computers, which will be password protected.

Results of this research will be published in academic journals and may be used to improve future COVID-19-specific mental health interventions for those who identify as White, African American, Latinx, and/or American Indian.

Additionally, the audio recording collected during your qualitative interview will be shared with Civicom who will be transcribing the audio file. This audio file is the only information that will be shared with Civicom, and it will not be tied to your personal information. Additionally, Civicom has privacy procedures in place to ensure our study data will be kept private and not compromised. For more information on Civicom's privacy policy, you can visit https://www.transcriptionwing.com/privacy-policy/.

The investigator, Dr. Michael Businelle is an inventor of the Insight mHealth Platform, which will be used for this study, and may receive royalties and other compensation from the use of this platform through the University's intellectual property policy.

Data from this study will be submitted to the National Institute of Mental Health Data Archive (NDA) at the National Institutes of Health (NIH). NDA is a large database where deidentified study data from many NIH studies are stored and managed. Sharing your deidentified study data helps researchers learn new and important things about brain science more quickly than before.

The study researchers will never send your personal information to NDA.

It is possible that you will participate in more than one study that sends data to NDA. NDA can connect your data from different studies by matching the code number on your deidentified data from each study. This data matching helps researchers who use NDA data to count you only one time. It also helps researchers who use NDA to better understand your health and behavior without knowing who you are.

During and after the study, the study researchers will send deidentified study data about your health and behavior to the NDA. Other researchers across the world can then request your deidentified study data for different research projects. Every researcher (and the institution to which they belong) who requests your deidentified study data must promise to keep your data safe and promise not to try to learn your identity.

The study data provided to NDA may help researchers around the world learn more about brain science and how to help others who have problems with brain science. NIMH will also report to Congress and on its website about the different studies using NDA data. You will not be contacted directly about the study data you contributed to NDA.

You may decide now or later that you do not want your study data to be added to NDA. You can still participate in this research study even if you decide that you do not want your data to be added to NDA. If you know now that you do not want your data in NDA, please tell the study researcher before leaving the clinic today. If you decide any time after today that you do not want your data to be added to NDA, call or email the study staff who conducted this study, and they will tell NDA to stop sharing your study data. Once your data is part of NDA, the study researchers cannot take back the study data that was shared before they were notified that you changed your mind. If you would like more information about NDA, it is available on-line at http://nda.nih.gov.

I consent to share my study data with the National Institute of Mental Health Data Archive (NDA).

I DO NOT want my study data shared with the National Institute of Mental Health Data Archive (NDA).

## *Who can I talk to?*

If you have questions, concerns, or complaints, or think the research has hurt you, you should talk to the team at the RESTORE Laboratory at uhrestore@gmail.com or by phone at (713) 743-8056. You can also reach this study's staff by calling 346-495-3962.

Participants in Oklahoma may contact the TSET Health Promotion Research Center at Businellelab@ouhsc.edu or by phone at (405) 271-1803.

Dr. Michael Businelle is the primary investigator in charge of the TSET Health Promotion Research Center in Oklahoma. Dr. Michael Zvolensky is the primary investigator for all subsites.

This research has been reviewed and approved by the University of Houston Institutional Review Board (IRB). You may also talk to them at (713) 743-9204 or cphs@central.uh.edu if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research subject.
- You want to get information or provide input about this research.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this website at any time.

## *May we contact you regarding future research opportunities?*

In the future, our research team may be interested in contacting you for other research studies we undertake, or to conduct a follow-up study to this one. There is never any obligation to take part in additional research. Do we have permission to contact you to provide additional information?

Yes
No

## Consent to Take Part in a Human Research Study

**Signature Block for Capable Adult**

Your signature documents your consent to take part in this research.

| | |
|---|---|
| Signature of subject | Date |
| Printed name of subject | |
| Signature of person obtaining consent | Date |
| Printed name of person obtaining consent | |