Digital health platform (DHP) to deliver Mindfulness as a Stress Management Intervention Leveraging Electronic (SMILE) health records for racial and ethnic populations during the COVID-19 pandemic: Clinical Trial

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REDCap introduction:

"You are eligible to participate in the SMILE study! If you are interested in participating, please re-watch the Information Video before reading and signing the Consent document below. [insert link to Consent video]"

University of North Carolina at Chapel Hill
Consent to Participate in a Research Study and Addendum for Unencrypted Communication Adult Participants
Consent Form Version Date: Version 6, 9/04/2024
IRB Study # 23-0154
Title of Study: Digital health platform (DHP) to deliver Mindfulness as a Stress Management Intervention Leveraging Electronic (SMILE) health records for racial and ethnic populations during the COVID-19 pandemic: Clinical Trial
Principal Investigator: Dr. Susan Gaylord
Principal Investigator Department: Physical Medicine and Rehabilitation
Principal Investigator Phone number: (919) 966-8586
Principal Investigator Email Address: susan_gaylord@med.unc.edu
Funding Source and/or Sponsor: National Institutes of Health (NIH)

Concise Summary

The purpose of this research study is to determine whether a training program can help you feel calmer and more relaxed during times of stress, worry or concern. The program we are testing is called mindfulness. Mindfulness training helps you learn to focus on what is happening here and now without judging your experience or getting lost in guilt about the past or worry about the future. Mindfulness training also includes learning how to treat yourself and others with kindness and compassion. In this research, we are creating mindfulness training programs that are geared specifically towards adults who are African American, Black, Hispanic or Latino. We will be testing 2 versions of an 8-week mindfulness training program—one delivered once weekly online by an instructor with a group of participants, and one delivered through an app. A third group will wait for 12 weeks prior to having access to the app. Results will be evaluated by asking you to complete questionnaires and record your heart rate using an app (i.e., the SMILE app) that is installed on a computer tablet we ship to your home. It may take 1-2 months for your part of the study to start after you join. The active part of the study takes about 3 months, which includes 8 weeks of a mindfulness training program and 4 weeks after the end of the training program. During that time, you will be asked to complete 6 research assessments using the tablet and heart monitor.
If you are interested in learning more about this study, please continue to read below.

What are some general things you should know about research studies?
You are being asked to take part in a research study. To join the study is voluntary.
You may choose not to participate, or you may withdraw your consent to be in the study, for any reason, without penalty.

Research studies are designed to obtain new knowledge. This new information may help people in the future. You may not receive any direct benefit from being in the research study. There also may be risks to being in research studies. Deciding not to be in the study or leaving the study before it is done will not affect your relationship with the researcher, your health care provider, or the University of North Carolina-Chapel Hill. If you are a patient with an illness, you do not have to be in the research study in order to receive health care.
Details about this study are discussed below. It is important that you understand this information so that you can make an informed choice about being in this research study.
You will be able to download a copy of this consent form. You should ask the researchers named above, or staff members who may assist them, any questions you have about this study at any time.

What is the purpose of this study?
For many people, particularly those who are African American, Black, Hispanic or Latino(a/e/x), the COVID pandemic has created an increase in economic, social and physical stress. The purpose of this research study is to see whether a home-based mindfulness training program, adapted for adults who are African American, Black, Hispanic or Latino, can help reduce everyday stress, concern or worry.

How many people will take part in this study?
Approximately 404 people at this institution will take part in this study.

How long will your part in this study last?
Your total participation in the study is approximately 4-5 months. Regardless of your group assignment, you will complete 6 research assessments using the tablet and heart monitor, each lasting 30-60 minutes. If you are assigned to group mindfulness training, you will meet once per week for 75-90 minutes over 8 weeks (about 2 months). If you are assigned to app-based mindfulness training, you will be encouraged to engage with training through the app for 60-75 minutes once per week for 8 weeks. You will also be encouraged to practice what you have learned every day for at least 10 minutes.

What will happen if you take part in the study?
Once you agree to be in the study (by signing the last page of this form), you may have to wait 1 month or two before you are assigned to a group. The researchers will randomly assign you to 1 of 3 groups (such as by flipping a coin) and you will not get to choose into which group you are placed. Once you are assigned to a group, we will mail the equipment that you need to your

home. The equipment includes: (1) a computer tablet; and (2) a heart monitor. The tablet and heart monitor will already be set up for you with the SMILE app and you will be provided instructions to practice using the heart monitor. You will be asked to mail the equipment back (postage paid) in the provided packaging at the end of the study.

- ***Explanation of groups***

Group mindfulness training: In this version, you will attend online group sessions (via Zoom), guided by a mindfulness instructor.
App-based mindfulness training: In this version, you will not attend online group sessions. Instead, you will be given video presentations/instructions to complete mindfulness training sessions on your own.
Wait-group: if you are assigned to this group, you will not receive mindfulness training until after you complete your role in the research. At that time, you will be given access to the app-based mindfulness training, but no further research sessions will occur.

- ***Schedule***

The following is a schedule of sessions that will occur once you have been placed into a group. All sessions will be conducted while you are at home, and all participants in all groups will be asked to complete all 6 research assessments with the tablet and heart monitor. You will be compensated for completion of each research assessment. With your permission, we will send you reminders before each research assessment session.
Initial research assessment. This will include questionnaires about your age, marital status, and your health. It will also include wearing a heart monitor while playing a computer game and shifting your position from sitting to standing. This assessment will take approximately 60 minutes.
o If you are assigned to Group mindfulness training, you will meet with the group, including instructors for 60-75 minutes once a week for 8 weeks (about 2 months). You will be asked to complete shorter mindfulness exercises during the week as well.
o If you are assigned to the App-based mindfulness training program, you will be asked to view the videos on the app each week and complete the shorter mindfulness exercises.
o If you are assigned to the Wait group, you will complete the research assessments only.
Every 2 weeks during the 8 weeks (about 2 months) of the mindfulness training you will be asked to complete a short research assessment (about 30 minutes each). The short research assessment will include fewer questionnaires and the same heart monitoring as the initial research assessment.
At the end of the 8 weeks and again 1 month later, you will be asked to complete a slightly longer set of questionnaires along with the heart monitoring. These last research assessments will take approximately 45 minutes each.

- ***Questionnaires***

The questionnaires were selected as they may indicate whether the mindfulness training programs are having a positive effect on your life. The questionnaires include items related to COVID, stress, anxiety, concern, sleep, quality of life, and your impressions of the training programs. You will be provided with the option to skip questions that you do not want to answer. The questionnaires will be included in the SMILE app that is installed on the computer tablet that we will ship to you. You will keep the tablet for the duration of the program and return it in the prepaid shipping box.

You will be sent a brief (2-question) check-in survey each week to make sure that you are not experiencing any negative effects from your participation. If you are assigned to the Group mindfulness training or the app-based mindfulness training program, you will be asked to complete additional bi-weekly brief questionnaires regarding your daily mindfulness practices. Additionally, at Week 2, you will be asked to complete a brief questionnaire about your expectancy of the mindfulness program, and at Week 8, you will be asked to complete a brief questionnaire about your satisfaction with the training.

- ***Heart monitoring***

To test the effects of mindfulness training on your body's ability to relax, we would like to record your heart rates during 2 tasks: (1) during a brief computer game; (2) while you shift positions from sitting to standing up. In the SMILE app, you will be provided with instructions for how to use the included heart rate monitor, which will fasten around your chest like a belt. Before you begin each Heart Monitoring, you will be asked about your current medication use, and will be asked to refrain from alcohol (12 hours) and caffeine (3 hours).

What are the possible benefits from being in this study?

Research is designed to benefit society by gaining new knowledge. You may find that your mindfulness training helps you to reduce feelings of stress, tension, and worry.

What are the possible risks or discomforts involved from being in this study?

There is minimal risk to you for participating in the study. All research is subject to a risk of loss of privacy and confidentiality. We try to minimize this risk by including only study ID numbers on anything we collect from research participants. For all participants, there is a risk that you will experience discomfort using the heart monitor. If you experience discomfort using the heart monitor, we ask that you contact the researchers for guidance.

Emotional discomfort or distress may arise during mindfulness training. This is due to an increased awareness of negative emotions, thoughts or physical sensations. This discomfort usually lasts a very short time and tends to go away entirely with increased mindfulness practice. However, you can contact the researchers and avoid any mindfulness practices leading to more than transient discomfort. For the group mindfulness sessions, we will use Zoom, a videoconferencing program with end-to-end encryption. Although every reasonable effort is taken, confidentiality during

internet communication cannot be guaranteed. It is possible that additional information beyond that collected for research purposes may be taken and used by others not associated with the study. If you are placed in the group mindfulness program, please note that other participants in the group will be able to see and/or hear you on the Zoom video. We ask that you respect the privacy and confidentiality of others in your group. You must agree not to reveal anything you learn from group discussions during the online sessions. To minimize risks, we will provide you with earbuds or earphones. You may also choose to be known by a nickname or made-up name during the training sessions.

What if we learn about new findings or information during the study?
You will be given any new information gained during the course of the study that might affect your willingness to continue your participation.

How will information about you be protected?
Participants will not be identified in any report or publication about this study. We may use deidentified data from this study in future research without additional consent. In addition, the National Institutes of Health which funds this study requires that the information we collect from the study be shared with other researchers through a secure online research repository. The purpose of this sharing is for people in the future to be able to answer additional research questions. All of your personal identifiers will be removed from the data before being placed in the repository.
Although every effort will be made to keep research records private, there may be times when federal or state law requires the disclosure of such records, including personal information. This is very unlikely, but if disclosure is ever required, UNC-Chapel Hill will take steps allowable by law to protect the privacy of personal information. In some cases, your information in this research study could be reviewed by representatives of the University, research sponsors, or government agencies (for example, the NIH) for purposes such as quality control or safety.
With the permission of everyone in the group, we will record the group mindfulness training sessions (Sessions 1,2,3, and 7 or 8). The purpose of the recording is to ensure that the instructors are teaching mindfulness in the agreed-upon ways. Since the recording will occur via Zoom, a video and an audio recording will be automatically produced. The video recordings will be immediately deleted, and the audio recordings will be stored in a secure online site (Microsoft Teams) until they can be reviewed by the study fidelity monitors. The audio recordings will not be deleted until the end of the study, even if you or the researchers terminate your participation in the study early. You can request that audio recordings be turned off during times when you would like to share something that you do not want to be reviewed by the research team.

Please check one of the following:
_____ok to record me during the group mindfulness training sessions
_____not ok to record me during the group mindfulness training sessions

Alternatively, the group mindfulness sessions may be attended by the study fidelity monitor. Names (or other identifiable information) will not be used or recorded on any of your data or

questionnaire files. You will be assigned an ID number when you enroll in the study, and all files will be labeled with your ID number only. The master file that links name and ID will be stored on a password-protected computer at UNC, and will ONLY be accessible by individuals who are part of the research. All data files will be stored on a secure cloud or network that can only be accessed by researchers on the study. Electronically-signed consent forms will be stored in REDCap and will only be accessible to UNC researchers who are involved in the research.

What is a Certificate of Confidentiality?

This research is covered by a Certificate of Confidentiality. With this Certificate, the researchers may not disclose or use information, documents or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings in the United States, for example, if there is a court subpoena, unless you have consented for this use. The Certificate cannot be used to refuse a request for information from personnel of a federal or state agency that is sponsoring the study for auditing or evaluation purposes or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law, such as mandatory reporting requirements for child abuse or neglect, disabled adult abuse or neglect, communicable diseases, injuries caused by suspected criminal violence, cancer diagnosis or benign brain or central nervous system tumors or other mandatory reporting requirement under applicable law. The Certificate of Confidentiality will not be used if disclosure is for other scientific research, as allowed by federal regulations protecting research subjects or for any purpose you have consented to in this informed consent document. 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 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.

Appointment reminders

To remind you of appointments, the study team would like to message you by text notifications. You may say “no” to receiving these messages and still participate in this study. If you say “yes”, messages may contain personal information about you (e.g., your name, your participation in the SMILE study) and may be sent or received by the university’s devices or in a method that is not able to be encrypted (protected) and there is the risk your information could be shared beyond you and the study team. This information may include information such as reminders and notifications to contact the study team. If you wish to stop receiving unprotected communication from the study team or have lost access to your device, please notify the study team using the study contact information on the first page of this consent form. After the study is complete and all research activities finished, or you withdraw from the study or request to stop receiving unprotected communication, you will no longer receive un-encrypted (un-protected) messages specific to this study.

_____ Yes, I consent to the study team utilizing my cell phone number for text messages for appointment reminders. Please provide your cell-phone # _____

_____ No, I do not consent to receive un-protected communication from the study team.

What will happen if you are injured by this research?
Even though the procedures in the study are low risk, all research involves a chance that something bad might happen to you. If you are hurt, become sick, or develop a reaction from something that was done as part of this study, the researcher will help you get medical care, but the University of North Carolina at Chapel Hill has not set aside funds to pay you for any such injuries, illnesses or reactions, or for the related medical care. Any costs for medical expenses will be billed to you or your insurance company. You may be responsible for any co-payments and your insurance may not cover the costs of study-related injuries.
If you think you have been injured from taking part in this study, call the Principal Investigator at the phone number provided on this consent form. They will let you know what you should do. By signing this form, you do not give up your right to seek payment or other rights if you are harmed as a result of being in this study.

What if you want to stop before your part in the study is complete?
You can withdraw from this study at any time, without penalty. The investigators also have the right to stop your participation at any time. This could be because you have had an unexpected reaction, or have failed to follow instructions, or because the entire study has been stopped.
If you withdraw or are withdrawn from this study all data collected up until the point of withdrawal will be retained, however no additional information will be collected unless you provide additional written permission for further data collection at the time of your withdrawal.

Will you receive anything for being in this study?
You can receive up to $135 for completing all research sessions ($30 for session with the longer questionnaires and $15 for sessions with the shorter questionnaires). Payments will be made at week 6 for sessions completed up until that point ($75) and at week 12 ($60).

Will it cost you anything to be in this study?
It will not cost you anything to be in this study.

What if you are a UNC student?
You may choose not to be in the study or to stop being in the study before it is over at any time. This will not affect your class standing or grades at UNC-Chapel Hill. You will not be offered or receive any special consideration if you take part in this research.

What if you are a UNC employee?
Taking part in this research is not a part of your University duties, and refusing will not affect your job. You will not be offered or receive any special job-related consideration if you take part in this research.

Who is sponsoring this study?

This research is funded by the National Institutes of Health. This means that the research team is being paid by the sponsor for doing the study. The researchers do not, however, have a direct financial interest with the sponsor or in the final results of the study.

What if you have questions about this study?
You have the right to ask, and have answered, any questions you may have about this research. If you have questions about the study (including payments), complaints, concerns, or if a research related injury occurs, you should contact the researchers listed on the first page of this form. A description of this clinical trial will be available on www.clinicaltrials.gov, as required by U.S. 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.

What if you have questions about your rights as a research participant?
All research on human volunteers is reviewed by a committee that works to protect your rights and welfare. If you have questions or concerns about your rights as a research subject, or if you would like to obtain information or offer input, you may contact the Institutional Review Board at 919-966-3113 or by email to IRB_subjects@unc.edu.

Participant's Agreement:
I have read the information provided above. I have asked all the questions I have at this time. I voluntarily agree to participate in this research study.

_____
Signature of Research Participant

_____
Date

_____
Printed Name of Research Participant

_____
Signature of Research Team Member Obtaining Consent

_____
Date

_____
Printed Name of Research Team Member Obtaining Consent

REDCap message after the e-sign is complete:
"Thank you for consenting to participate in the SMILE Study! You will be contacted by the research team once we are ready to begin your role in the study. It may take up to 2 months before you are contacted."