Consent to Participate in Research

Title of Research Study: Expanding College Student Mental Health with Stress Management Mobile Technologies

Investigator: Emily Lattie, PhD

Supported By: This research is supported by National Institute of Mental Health and Northwestern University.

Financial Interest Disclosure: The following disclosure is made to give you an opportunity to decide if this relationship will affect your willingness to participate in this research study: Emily Lattie has received consulting fees from Actualize Therapy, LLC, the company that holds the license to the IntelliCare app platform.

Before you get started with the Expanding College Student Mental Health with Stress Management Mobile Technologies study, we would like to share some important information about this research study and obtain your consent to participate. Please take the time to read the information carefully. If you have any questions feel free to discuss this with research study staff.

Key Information about this research study:

The following is a short summary of this study to help you decide whether to be a part of this study. This study is part of a series of studies aimed at developing a university student-facing stress management mobile app program that will serve as both a self-help tool and as a bridge to connecting students in need with mental health services on campus. The purpose of this 8 week trial is to identify software bugs and usability problems that emerge over extended use, and to examine preliminary effects of program use. You will be asked to do three main things;

1. Interact with **smartphone apps and education and tools designed to provide mental health support over an 8 week period.**
2. Complete **research surveys on the smartphone app.**
3. Complete **user feedback interviews via telephone.**

Your participation does not involve any significant risks. You may feel emotional discomfort or increased anxiety as a result of reading, logging or talking about mental health. You are not likely to have any direct benefit from being in this research study. The main benefit is helping researchers resolve any problems with this college student mobile stress management program

Why am I being asked to take part in this research study?

We are asking you to take part in this research study because you are a student at the University of Illinois at Chicago or at Northern Illinois University. You have a smartphone that operates Android 7 (or higher) or iOS 11 (or higher) and have expressed interest in using a smartphone app to track and manage stress.

How many people will be in this study?

We expect about 20 people here will be in this research study.

What should I know about participating in a research study?

- 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.

If you say that "Yes, you want to be in this research," here is what you will do

After you read this consent form and agree to participate by signing the form, you will have an opportunity to speak with the study staff and ask any questions before you get started with the study. After you speak with study staff, and it has been determined that you are eligible to participate and would like to continue in the study, you will receive information and instructions about how to download the study app onto your personal smartphone. You will be asked to use the app in your daily life and to complete weekly mood symptom assessements. At the beginning of the study, at 4 weeks, and at 8 weeks, you will be prompted to complete a slightly longer set of questionnaires through the app. You will also be asked to complete a user feedback interview over the phone at 4 weeks and 8 weeks. These interviews should take no more than 30 minutes each.

Mental Health App tools

As a participant in the study, you will be also able to use the IntelliCare suite of mobile applications developed by researchers at the Center for Behavioral Intervention Technologies (CBITs). The IntelliCare apps teach people skills they can use to manage stress, depression and anxiety. You will be encouraged to use the study app a few minutes each day.

If you do not wish to participate in this research study, you will have the option to download the IntelliCare apps and use them on your own.

Will being in this study help me in anyway?

We cannot promise any benefits to you or others from your taking part in this research. However, possible benefits include:

- Learning helpful strategies to manage stress and mood.
- Access to tools and lessons that may help you develop positive health behaviors and habits.

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

As noted above, the risks of harm from being in this study are minimal. The most apparent risk in the proposed study is that the study app might not be effective at managing stress, depression, and anxiety. There is therefore a risk that the program might not fully meet every participant's needs. We consider this risk to be minimal however, because all programs come with the risk that they will not work for some. Participants might also experience distress reading, or logging information about mental health. The study app is not intended to replace the need for contacting a mental health provider or emergency services if you are at risk of harm to yourself or to others.

There are additional risks due to the nature of this intervention being delivered via smartphone. Depending on the nature of your smartphone service plan, there is the potential for data plan overages. We encourage you to discuss your plan with research staff before enrolling in the study. There is also the potential for loss of confidentiality if someone else were to use your phone and read information you have entered into the app/s. We recommend password protecting your phone to reduce confidentiality risks.

This study involves the use of your identifiable, personal information and there is a chance that a loss of confidentiality could occur. The researchers have procedures in place to lessen the possibility of this

happening. See the section below titled: **"What happens to the information collected for the research?".**

What happens if I do not want to be in this research or if I say "Yes", but I change my mind later?

Participation in research is voluntary. You can decide to participate or not to participate.

You can leave the research at any time and it will not be held against you. Your decision to participate in this study will not affect your status at your university.

If you decide to leave the research, contact the investigator so that the investigator is aware. Your authorization of the use of your information will never expire unless you change your mind. You may stop giving permission (and end participation of the research study) by calling Dr. Lattie. Even if you end your permission, the researcher may use your personal information that was collected prior to you stopping permission.

What happens to the information collected for the research?

Efforts will be made to limit the use and disclosure of your personal information, including research study, to people who have a need to review this information. We cannot promise complete secrecy. Organizations that may inspect and copy your information include the IRB and other representatives of this institution and the National Institute of Mental Health.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information or documents, 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 or documents protected by this Certificate cannot be disclosed to 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 of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law of child [or elder] abuse and neglect, or harm to self or others.

Unless you revoke your consent, it will not expire.

Although you may revoke consent to participation in this research at any time and in any format, you must revoke authorization for use or disclosure of your health information in writing. To revoke your authorization, write to:

PI's Name: Emily Lattie
Institution: Northwestern University
Department: Medical Social Sciences
Address: 750 N. Lake Shore Dr., 10th Floor
Chicago, IL 60611

These surveys will be hosted by Actualize Therapy on AWS servers and involves a secure connection. Terms of service, addressing confidentiality, may be viewed at https://www.actualizetherapy.com/privacy. No personal identifiers are submitted with your survey

results and you will only be identified by a unique subject number. All data is kept on a password protected server only accessible by Actualize staff.

Data Sharing:

You have the right to decide if we can use and share information gathered about you through this research study with others. By signing this consent form, you will give us permission to share some of your information with researchers at Northwestern University who are conducting this study.

De-identified data from this study may be shared with the research community at large to advance science and health. We will remove or code any personal information that could identify you before files are shared with other researchers to ensure that, by current scientific standards and known methods, no one will be able to identify you from the information we share. Despite these measures, we cannot guarantee anonymity of your personal data

- Authorized members of the Northwestern University workforce, who may need to see your information, such as administrative staff members from the Office for Research, Office for Research Integrity and members of the Institutional Review Board (a committee which is responsible for the ethical oversight of the study.)
- Other researchers and contractors working on this study and other studies who are collaborating to further research and agree to protect the data.
- Study monitors and auditors, for example from funding agencies, who make sure that the study is conducted properly.
- Readers and reviewers of scientific journals that may publish the results of this and other studies that involve your data.
- The information that we share about you with with the people mentioned above will not include direct identifiers like your name, address, or telephone number.

The consent to share your information will not expire, unless it is revoked by you.

What else do I need to know?

Compensation: Participants will be compensated $10 for each of the monthly in-app assessments, and will be compensated $20 for each of the telephone-based user feedback interviews. Thus, participants are eligible to receive up to $70 for their efforts.

Who can I talk to?

If you have questions, concerns, or complaints, or think the research has affected you in some way, talk to the research team at 312-503-3741.

This research has been reviewed and approved by an Institutional Review Board ("IRB"). You may talk to them at (312) 503-9338 or irb@northwestern.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 participant.
- You want to get information or provide input about this research.

Consent:

If you want a copy of this consent for your records, you can print it from the screen. If you wish to

participate, please click the "I Agree" button and you will be taken to the questionnaire. If you do not wish to participate in this study, please select "I Disagree" or select X in the corner of your browser.