

UNIVERSITY OF CALIFORNIA LOS ANGELES
STUDY INFORMATION SHEET

STAND Program
Tracking Study

This study is a part of the **Screening and Treatment for Anxiety and Depression (STAND) Program**, funded by the UCLA Depression Grand Challenge. Michelle Craske, Ph.D. from the Department of Psychology and Elizabeth Gong-Guy, Ph.D. from the Office of Campus and Student Resilience are conducting a research study.

The STAND Tracking study is a condition of the STAND Program Online Therapy with Certified Support study (see below for more detail). The STAND Program also includes another study focused on clinical care for individuals suited for this level of care.

Why have I been invited to participate in this study?

You are invited to be a possible participant in this study because you are a UCLA student, aged 18 years or older, and are not currently experiencing any symptoms of depression or anxiety. Your participation in this study is entirely voluntary. Please read the information below and refer to the contacts at the end of this form if you would like to ask questions about anything you do not understand before deciding whether you will participate.

Why is this study being done?

We aim to track symptoms of depression and anxiety over the course of ten months in order to assess the best methods to monitor these symptom changes in UCLA students. Students who are experiencing symptoms of depression and anxiety are additionally offered access to online Cognitive Behavioral Therapy (CBT). You will not be offered access to this program, but by sharing information with us about your symptoms over the course of ten months, you will help us understand the impact of online CBT in students with anxiety and/or depression.

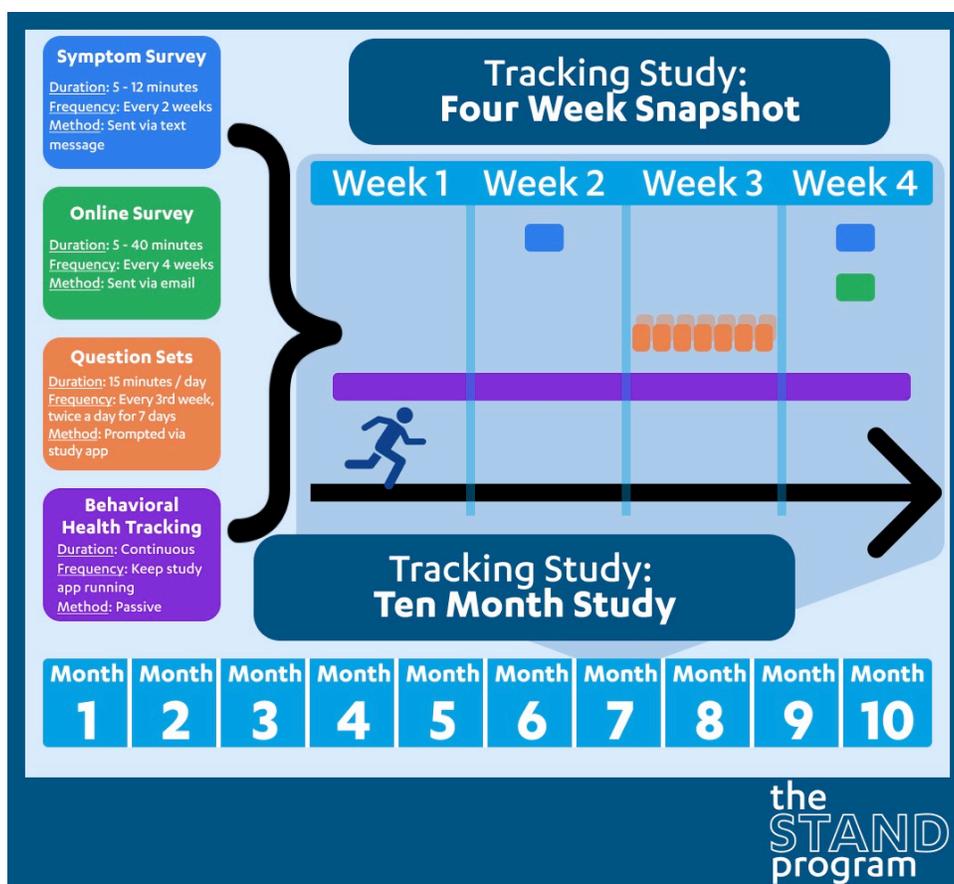
What does this study involve?

You have already completed the online screening process as part of IRB#17-001938 and have been deemed eligible to participate in this study. If you agree to take part in the study, you will be asked to read and sign this online consent form. Once completed, you can sign up for an orientation visit with a study team member to start the study, which will include the following over a 10-month period:

- Initial meeting with a STAND team member (staff or trained and certified student) for orientation to the research study
- Signing a HIPAA authorization form that allows us to review your medical record to obtain information such as your age, sex, diagnosis and current medications.

This information will be recorded in a separate file that will be coded, de-identified and kept confidential.

- Signing a release of information form allowing us to communicate with your medical provider if needed
- Completion of online surveys every four weeks via a link sent to your email (these will take between 10 and 45 minutes to complete, depending on the time point)
- A repeat of the online Mental Health Tracker every other week, with links sent by text
- Installing an app on your phone and leaving it on for the duration of the study, which will provide information about activity and phone usage; the app will additionally present a series of questions daily for seven days, every three weeks, to learn more about your activity over the course of a given day



The total time that these assessments are estimated to take is approximately 2.93 hours over the 40-week study, with some weeks including more assessments than others.

Completing questionnaires is an important aspect of participating in a research study. They help us monitor your current symptoms and behaviors, and they provide us with valuable information necessary to evaluate and improve the treatment we offer. If you decide to proceed with assessment, we will kindly ask that you are willing and committed

to completing these questionnaires. If you are not willing to complete the study questionnaires, you may withdraw your consent to participate in this study. As we review these data, we may contact you to follow-up on recently reported symptoms or behaviors, and may offer you access to treatment options in response to symptom changes.

Research Assessments

By agreeing to participate in the study, you will be agreeing to provide the following types of data, in addition to regularly scheduled online surveys sent to your email every four weeks:

Behavioral Health Tracking: Completing assessments is an important aspect of participating in the research study. If you decide to proceed with assessment, we will kindly ask that you are willing and committed to completing these assessments and leave the app installed and running on your phone. If you are not willing to comply, you may withdraw your consent to participate in this study.

Upon enrollment, you will be asked to download an app onto your smartphone, which will pick up information from the sensors already in your smartphone. The app will run in the background unless forcefully closed. We will ask you to keep the app open at all times so data may be collected. This data will be sent to study staff as part of the research study daily. The minimum amount of information we are asking for your permission to passively gather is described in the table below.

What we’re trying to understand	Examples of information gathered	Sensors/plugins used to gather information
How you interact with your smartphone	Screen interactions, how close you hold the phone to your face, how you use other apps	Applications, Device Usage, Gyroscope, Installations, Magnetometer, Proximity, Rotation, Screen
Your movement	Your speed, direction, balance, physical activity, mode of transportation (still, walking, running, biking, in vehicle)	Accelerometer, Activity Recognition, Gravity, Linear Accelerometer
Your environment/ surroundings	The lighting around you, brief samples of sounds in your environment, temperature and humidity, air pressure, time zone	Ambient Noise, Barometer, Light, Temperature, Time zone

Locations you visit	GPS coordinates of places you've been along with information from Google's Fused Location API (if available)	Location, Google Fused Location
Your call and text habits	The frequency and duration of calls and the number of text messages sent and received. Please note that information about your contacts is de-identified. No person or entity involved in the study can see the names or numbers of your friends and family or what you say to them over text or calls.	Communication
Capabilities & functioning of your Smartphone	Battery level, processor usage, running applications, network connections	Battery, Network, Processor, Telephony, WiFi

In addition, the app may prompt you to answer brief daily questions on occasion. This may occur 1-2 times per day, for 7 days in a row, once every three weeks while you are enrolled in the study. Answering these prompts will help the researchers relate the information passively gathered through the app(s) to the context of your life. Here are some examples of the topics we may ask about:

- Your mood
- Your daily routines
 - Times you wake up, go to sleep, work, attend school or engage in other daily routines
 - The places you visit and reasons for going to certain locations
- Your relationship to people you've contacted. For instance, if you called your best friend, the app would ask who this number belongs to. You would indicate the person's relationship to you, and the app would then know in the future the nature of your relationship. However, no one, including the researchers, would ever see your best friend's number or name, and we cannot access content of the phone call. The research team would simply know that you called your best friend.
- How you've been feeling physically

Remote mood assessments: You will also be sent a text message every two weeks with a link to our online symptom assessment survey, which will ask questions about your mood during the previous 2 weeks.

Study Conditions: Upon entry into the study, you will be randomized into one of two study conditions. If you are randomized into the first study condition, all of your survey scores will be monitored throughout the study and you may receive follow-up from our clinical

team in response to survey scores if it is indicated that additional treatment options are needed. If you are randomized into the second study condition, a subset of your survey scores will be monitored throughout the study and you may receive follow-up from our clinical team in response to these survey scores if it is indicated that additional treatment options are needed.

Student Education Records: By consenting to participate in this study, the researchers will have permission to access your student record for the duration of your enrollment at UCLA. The researchers will use your student record, including academic and demographic information, to examine academic performance and enrollment status in all study participants. No further action is required on your part for us to collect these data.

Web analytics: We also automatically collect data about your activity and usage of our website. This information includes, for example, the information you provide to us, information about your device, web browser, operating system, and your actions while interacting with our website.

How long will I be in the study?

In total, you will participate in this study for approximately 40 weeks (10 months).

Are there any potential risks or discomforts that I can expect from this study?

There are no anticipated risks or discomforts. Some unanticipated risks may include:

Psychological Risks: Some questions about your mood may bring up uncomfortable feelings. You can choose not to answer any question, and discontinue your participation at any time.

Loss of confidentiality: As this study involves the use of your identifiable, personal information, there is a chance that a loss of confidentiality will occur. The researchers have procedures in place to lessen the possibility of this happening (see “Will information about my participation and me be kept confidential?” section below).

Worsening of Mood: It is possible that your mood may get worse during the course of the study. Your mood and anxiety symptoms will be closely monitored as part of this research study. **Please note that, once you are admitted to the study, if any of your responses are potentially concerning (e.g., you are suicidal and with a plan to harm yourself), your information is forwarded to our clinical team for confidential review. A clinician will contact you to determine if you have safety concerns that require immediate help. If deemed necessary, additional clinical care will be offered.**

Risks associated with smartphone app installation: Your smartphone battery may drain more quickly than usual while the study apps are installed on your device. While the study apps have been designed to use a minimal amount of data, there is a small chance you could experience an increase in data plan usage during the study period.

Can the researchers remove me from this study?

The researchers may end your participation in this study for a number of reasons, such as if your safety and welfare are at risk, or if you miss completing online questionnaires. Note, that if you decide to stop being in the study, or are removed from the study, or the study is stopped, the data collected about you up to that point will remain part of the study and may not be removed from the study database.

Are there any benefits to participating in this study?

Possible benefits to me: You will not directly benefit from your participation in the research.

Possible benefits to others or society:

This study aims to further medical knowledge and may improve future treatment of Anxiety and Depression.

What other choices do I have if I choose not to participate?

Your participation in the study is entirely voluntary. Your decision not to participate has no impact on resources that are available to you through your enrolment in medical plans or other counselling services offered by the University.

Will taking part in this study cost me anything, and will I be paid?

Participation in this study will not cost you anything other than the costs associated with using your computer or accessing the internet (including completing online questionnaires).

How will my information be kept confidential?

This section of the consent form describes how your information will be protected and handled.

Privacy: We take your privacy very seriously. As part of our commitment to your privacy, you have been assigned a unique study ID that will follow you throughout the course of the study. Study data containing your name or other information that could directly identify you is kept in secure, password-protected, and locked locations and will only be accessed by individuals who have been trained to protect your privacy.

There are also steps you can take to protect your privacy. You will likely be answering questions and completing tasks in this study that relate to your mood and mental health. Because this information can be sensitive, the study team will ask you to password protect your personal phone on which the apps will be used.

Sharing of identifying information: Your unique identifier, name, phone number and e-mail will be shared with a third-party scheduling system, which will allow you to schedule appointments directly with STAND Program staff, and with our external crisis response

team, in cases when your responses on the online surveys are concerning (i.e., suicidality risk has been detected). This communication has been approved by UCLA Health Compliance and UCLA Health ISS and secure methods are used whenever possible. These parties will not receive any other information you provide to us.

Emergency contact: We ask you to provide us with your emergency contact. We will contact your emergency contact only if we have consistently failed to reach you using a variety of channels (phone, email) and if we are concerned about your safety. We will disclose to your emergency contact only that you are participating in a UCLA research study and that we have been trying to reach you but failed to do so. We will disclose that we are concerned about your safety if that is the case. We will not disclose the nature of the study or any other information you have provided to us.

Mandated reporting: We may release identifying information in some circumstances. Specifically, the STAND Program team members are legally required to report known or reasonable suspicion of abuse to a child, elder, or dependent adult and serious threats against a reasonable identifiable victim or victims. Information will be released only to responsible agencies and others we are mandated by law or the university to report to (e.g., potential victims of violence). We also might need to release information about you if you are in danger and need emergency care (e.g., imminent threat of suicide or serious self-harm). Any and all relevant information obtained during the course of the study can be used in mandated reporting if indicated (e.g., emergency contact).

E-mail and texting policy: By agreeing to participate, you provide your consent to receive appointment reminders and other communication regarding the STAND Program sent to me via texting or e-mail. Texting and email are not secure communication methods as unencrypted messages could be intercepted. The STAND Program team commits to using the minimum necessary standard when communicating with you using these methods (i.e., providing only essential information).

Certificate of Confidentiality: Information about you is protected by a federal Certificate of Confidentiality. This means that we can't be forced to release information about you for any legal proceeding, even if a court of law asks.

The Certificate allows us to use information about you for purposes of this research, or to disclose it for other research when allowed by law. The Certificate requires other researchers to also protect information we share with them.

There are limits to this protection. The Certificate does not protect your information when:

- You or your family voluntarily release information about yourselves.
- You consent to release of information (for example, the uses described in this form, or if you sign release forms for employment, insurance or medical

care).

- A federal agency audits or evaluates research that it funds.
- Researchers are required to report possible intent to harm yourself or others, child abuse, or elder/dependent adult abuse

Data storage & security: Your information will be stored on multiple secure databases. These databases are secured by multi-tiered information technology security infrastructures. Access to these databases is on a “need to know” basis and only for the execution of research and supporting job functions. Study databases have strict security provisions, including but not limited to multiple firewalls, separate servers, and data encryption protocols. The researchers intend to keep the research data and records until analysis of the information is completed. In the future, data collected for this study may be shared with other researchers for other studies that are unknown at this time (see below).

Data sharing & broad consent: By signing this consent form, you will give us permission to share your information with people other than the researchers who are conducting this study.

The data that we will share will remain de-identified, meaning they will not contain identifying information. These data will be available to other investigators through one or more ‘controlled-access’ databases. This means that people who want to see that data have to be approved by the Principal Investigator before they can have access. These other investigators may be at other research centers (academic or commercial) around the world. You will not be informed of the details of any specific research studies that might be conducted using your data, including the purposes of the research, and it is possible that you might not have chosen to consent to some of those specific research studies. Results from these studies may not be disclosed to you.

Data used, created, or collected in the research study may be shared with the following groups:

- The study team members.
- Other investigators working at other research centers (academic or commercial) who are working on this study and who 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. Note that publications and/or presentations that result from this study will not identify you by name.
- Data Archive repositories, for example The National Institutes of Health (NIH) and NIMH have developed a federation of data repositories called the NIMH Data Archive (NDA) to store the collection of de-identified data from participants in

research studies related to mental health. The extensive information collected by these studies provides a rare and valuable scientific resource to the largest possible number of qualified investigators in an effort to achieve rapid scientific progress.

Data sharing with you: We are unable to share your individual results from the study with you or your provider. This includes, but is not limited to, behavioral health tracking data obtained from your phone sensors.

Who can I contact if I have questions about this study?

The Research Team:

If you have any questions, comments or concerns about the research, you can talk to one of the researchers. Please contact one of the study investigators below:

Michelle Craske, Ph.D. (310) 825-8403

Elizabeth Gong-Guy, Ph.D. (310) 486-8387

UCLA Office of the Human Research Protection Program (OHRPP):

If you have questions about your rights while taking part in this study, or you have concerns or suggestions and you want to talk to someone other than the researchers about the study, you may contact the UCLA OHRPP by phone (310) 825-5344 or email: mirb@research.ucla.edu.

UCLA Office of the Human Research Protection Program
11000 Kinross Ave., Suite 211, Box 951694
Los Angeles, CA 90095-1694.

What are my rights if I take part in this study?

Taking part in this study is your choice. You can choose whether or not you want to participate. Whatever decision you make, there will be no penalty to you, and no loss of benefits to which you were otherwise entitled. Your decision whether or not to participate in the study will have no effect on your status at UCLA.

- You have a right to have all of your questions answered before deciding whether to take part.
- If you decide to take part, you can leave the study at any time.
- If you decide to stop being in this study you should notify the research team right away. The researchers may ask you to complete some procedures in order to protect your safety.
- If you decide not to participate, it will not affect the treatment you receive in the future.

HOW DO I INDICATE MY AGREEMENT TO PARTICIPATE?

Agreement to participate: If you agree to participate in this study you should agree to the procedures outlined here and click the Next button below. You can print a copy of this information sheet for your records. You will be asked to sign a separate form authorizing access, use, creation, or disclosure of health information about you.

Consent to Audio/Video Recording and Observation: By agreeing to participate, you acknowledge that any video chat sessions will be recorded for clinical supervision purposes using a secure mobile app.

Data Sharing: By agreeing to participate, you are also agreeing to allow your data and/or specimens to be kept for use in future research to learn about, prevent or treat depression or other health-related problems.

Future Contact: By agreeing to participate, you are also agreeing to be contacted by UCLA researchers in the future to take part in other research studies, or to follow-up on your participation in this study.