Title: STAND ALACRITY CENTER Signature Project: STAND Triaging and Adapting to Level of Care
Lay title: STAND Finding and adapting the level of care
Research study IRB# 22-000635
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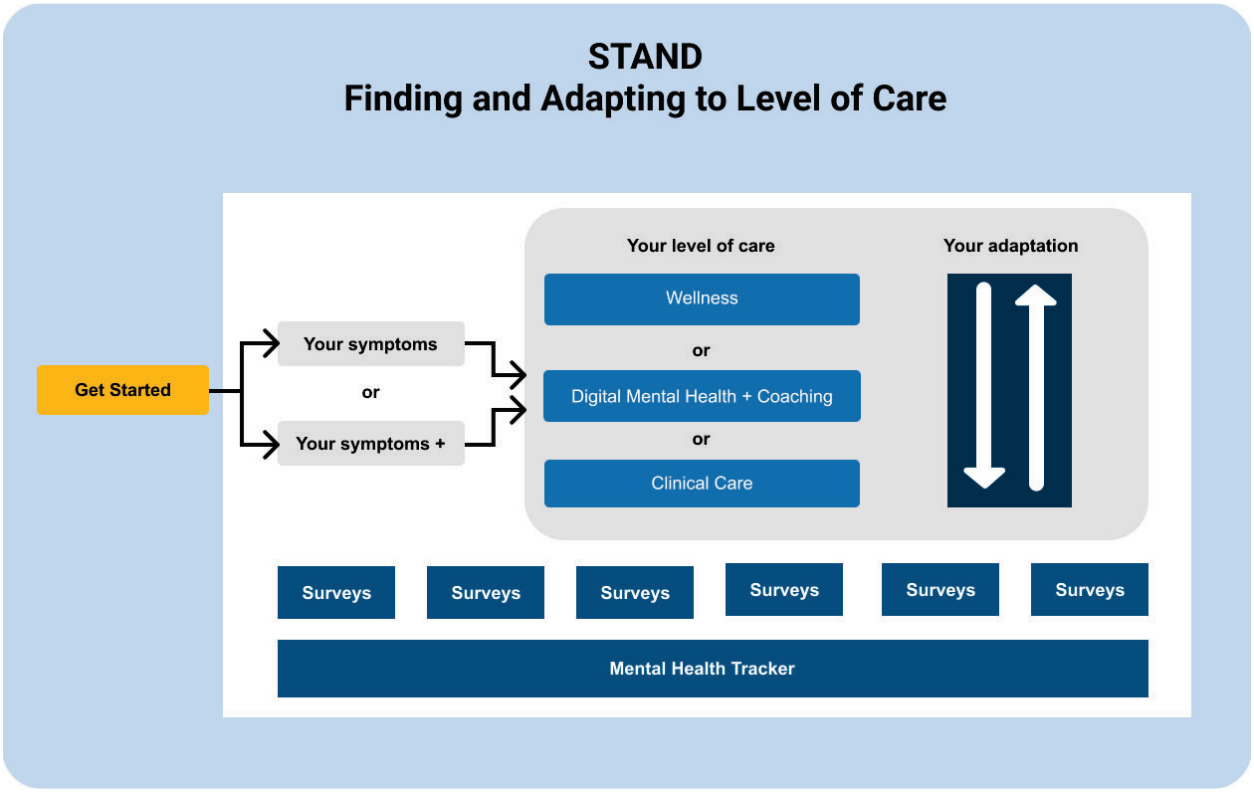
Research Description

The STAND ALACRITY CENTER Signature Project: STAND Triaging and Adapting to Level of Care study is a randomized controlled trial comparing 2 approaches for treatment triaging and adaptation. This study is being conducted among community college students enrolled in the Screening and Treatment for Anxiety and Depression (STAND) initiative at East Los Angeles College (ELAC). 1,000 students who meet study eligibility criteria will be enrolled over 5 years. Participants will be randomized to receive care under 1 of 2 models: symptom severity-based decision making (SSD) or data-driven decision making (DDD). Participation involves completing online self-report assessments in addition to engaging in an assigned depression or anxiety service as provided by this study. See **Figure 1** for general overview of the research design.

This study is funded by the National Institute of Health – National Institute of Mental Health. This research study is conducted by Michelle Craske, PhD, from the Departments of Psychology and Psychiatry, and Kate Wolitzky-Taylor, PhD, from the Department of Psychiatry, at UCLA. This study is affiliated with the UCLA Depression Grand Challenge.

Figure 1



Sample

This study aims to enroll approximately 200 participants per year, for a total sample size of 1,000 participants over five years. To reach this sample size, we expect to consent up to 5,000 students.

Eligibility

Interested individuals are directed to the study webpage to learn about STAND at ELAC, and create an online account. Initial study eligibility is assessed through self-report questions administered during the account creation process. All individuals are informed during screening that they are welcome to sign up for the free virtual wellness program Stand For All, without participating in this research study. If an individual is deemed ineligible at any point during screening, they are notified and offered alternative resources, including Stand For All.

Inclusion criteria:

- Age 18 – 40 years
- Competent to understand informed consent and express willingness to follow study procedures.
- Currently enrolled ELAC student
- Either uninsured or on California Medicaid (Medi-Cal).
- Proficient in English
- Have private access to internet

Exclusion criteria:

- Unable to comprehend the consent form fully, respond adequately to screening questions, or maintain focus or to sit still during assessment.
- Primary psychotic disorder, and disorders requiring more specialized care such as: severe eating disorders, substance use disorders, uncontrolled medical conditions, marked cognitive impairment, or severe neurological disorder.
    - Note: Substance use is expected in this adult population. Exclusion will be only for substance abuse or dependence that is so severe that it interferes or would foreseeably interfere with the ability to complete assessments or intervention.
- Previous participation in STAND research studies

Preliminary eligibility is established during the account creation process. If responses to the self-report questions in screening indicate the individuals may have a substance use disorder, psychosis, or active suicidality, they will be contacted by staff to further assess eligibility for this program, and resources/referrals for care may be provided if they are determined ineligible for this study. If they are found eligible after assessment, they will be provided a link to re-enter the screening process to complete surveys, then receive a randomized condition assignment and information about proceeding to their recommended level of care. Further confirmation of insurance coverage may be required in the case that a participant is assigned to receive clinical care. If they do not have eligible insurance coverage, they are informed of ineligibility at that time. Participants who are treated by a mental health professional (such as a psychiatrist, psychologist, therapist, etc.) during time that treatment is offered through STAND and unwilling to fully transfer care to STAND, will not be eligible to receive clinical services, but may continue participating in the study through receiving surveys. If there are changes to their current treatment status they may be offered to transition care to STAND, or they may be transitioned to other levels of care (tiers 1 or 2) as recommended by their condition assignment (SSD or DDD). Eligibility may be re-assessed throughout the study by research staff, coaches or care providers. If at any time a participant is found to not meet eligibility criteria, they will be informed of ineligibility and removed from study.

Study Overview

Study participation is completely remote and lasts 40 weeks after initial orientation/intake. Participation requires creating an online account on the STAND at ELAC study website in order

to complete eligibility screening. Once initial eligibility is confirmed, those who choose to participate must sign an online consent form and complete baseline assessments. Upon completion of baseline assessments, participants are randomized to 1 of 2 treatment conditions (SSD or DDD), and assigned to a level of care based on their responses to baseline surveys. Participants must attend a remote orientation or intake session for their assigned level of care, and thereafter are asked to complete weekly online surveys over the course of 40 weeks. Participants are considered enrolled after completing consent, baseline assessments, and attending an orientation/intake session for their assigned level of care.

Condition Assignment

Participants in this study will be randomized into one of two conditions which are differentiated by approach for decision making in treatment triage and treatment adaptation. The standard approach used in previous STAND studies is **symptom severity-based decision making (SSD).** SSD participants will be triaged and adapted to level of care based on reported symptom severity only**.**

The experimental approach is **data-driven decision making (DDD)**. DDD participants will be triaged and adapted to a level of care using a multivariate predictive algorithm that is iteratively updated annually. This algorithm determines level of care based on individual participant characteristics, coupled with reported symptom severity. The DDD *triaging* algorithm will be implemented beginning in Year 1 of this project and the DDD *adaptation* algorithm will be implemented beginning in Year 2.

For receiving care, participants will be assigned to one of the three services: Wellness (Tier I), Digital Mental Health and Coaching (Tier II) or Clinical Care (Tier III) based on the criteria of their randomized condition - SSD or DDD. Participants in both conditions will be asked to complete short surveys online weekly, and longer online survey assessments every 8 weeks. At every assessment time point participants are asked to complete the CAT-MH (computer adaptive tests) which provides validated symptom scores for depression, anxiety, mania/hypomania, substance use, psychosis, and suicidality. See **Table 1** for a description of CAT-MH depression and anxiety scores and their clinical interpretation. The information about depression and anxiety symptoms collected during these CAT-MH assessments will be used to inform adaptation of care in accordance with the criteria of participant's randomized condition, SSD or DDD.

Participants assigned to tiers 2 & 3 (in both SSD and DDD conditions) will additionally be randomized to receive usual risk management (URM) or usual risk management with the addition of a technology-enhanced suicide prevention intervention (TE-SPI).

Table 1 CAT-MH Symptom Scores

	Depression (CAT-DI)	Anxiety (CAT-ANX)
Normal	0 - < 35	0 - < 35
Mild	35 - 65	35 - 50
Moderate	> 65 - 75	> 50 - 65
Severe	> 75 - 100	> 65 - 100

In **SSD, triaging** will be determined solely by scores on CAT-DI (depression symptom severity), CAT-ANX (anxiety symptom severity) and CAT-SS (suicide risk severity). CAT-DI and CAT-ANX

provide cutoffs for none, mild, moderate and severe categories. From CAT-SS (suicidality), participants who endorse suicidal ideation with either intention or plan are considered at risk, and are offered Tier III clinical care. Otherwise, Tier assignments in SSD are made based on the following criteria:

- Tier I self-guided prevention (Wellness): Participants with less than mild depression or anxiety and without suicidality.
- Tier II (Digital Mental Health with Coaching): Participants with mild to moderate depression or mild to severe anxiety, without suicidality.
- Tier III (Clinical care): Participants with severe depression or endorsement of suicidality.

In **SSD adaptation,** scores on these CAT scales will determine whether participants move to a different level of care following their week 16 assessment: if participants who began in Tier I show mild to moderate depression or mild to severe anxiety without suicidality, they will be moved to Tier II, or if they show severe depression or suicidality, they will be moved to Tier III. Similarly, if participants who began in Tier II show severe depression or suicidality, they will be moved to Tier III. If a participant skips this assessment, the latest available CAT-MH scores are used.

In **DDD, triaging** will be determined by symptom scores from the CAT-MH in conjunction with variables from four overlapping, mutually reinforcing clusters. These clusters are: (1) social determinants of mental health, (2) early life adversity/stress, (3) predisposing, enabling and need influences upon health services use, (4) comprehensive mental health status. These clusters were selected based on available empirical evidence and theory. Statistical models that bridge the gap between traditional statistical models and machine learning models will be used for identify the minimum needed variables for these models. Data from prior STAND studies and implementations will inform the specific set of variables used for DDD during Year 1 of the present study. In subsequent years (Years 2-5), the algorithm will be updated and refined annually to optimize the predictive accuracy and utility of the decision-making tool.

The **DDD adaptation** algorithm will be put into practice in Year 2 of this study. During Year 1, all participants will receive SSD adaptation**,** while statistical models are used to develop DDD adaptation algorithm using the data from Year 1 of the present study, combined with data from prior STAND studies and implementations. In the DDD condition, participants in year 2 of the study are evaluated for treatment adaptation every 4 weeks. Participants in years 3-5 are evaluated for treatment adaptation every 8 weeks based on the output of the DDD adaptation algorithm, which will use data from the latest available CAT-MH scores and other relevant variables from the latest completed self-report measures.

Levels of Care

Participants in this study will be allocated to one of three service tiers. Allocation will be determined at triage and adaptation time points in accordance with their study condition as described above. All of the services use evidence-based practices which have been shown to be effective for anxiety, depression and related conditions. Below is a summary of each tier.

I. **Wellness -** self-guided online education about CBT prevention strategies, with demonstrated efficacy for depression and anxiety in college samples.
II. **Digital mental health with coaching -** online CBT modules supported by coaches through videochats. All online CBT is evidence-based and formatted into a unified approach for depression, anxiety and worry, panic, social anxiety, trauma and sleep dysregulation (developed as part of the UCLA Depression Grand Challenge). Responses on validated symptoms questionnaires (e.g., PHQ-14, FQAS, PDSS-SR-7, GAD-7, SAD-D, PCL-5, PROMIS) determine the content presented to each particular student. Students complete a

30-40 minute online lesson that teaches skills through text, graphics, audio, animated video, and quiz content, all designed with cognitive principles to facilitate memory of the presented content. Animated videos/audio involve characters (avatars) created to maximize diversity across race, ethnicity, gender, sex, religion and age. Homework exercises are supported by an app toolbox accessible through smartphone/mobile devices. Participants might additionally receive coaching. Coaches provide up to 8, 30 minute videochats. At completion of each digital lesson, students indicate their interest in a coaching session which is then automatically scheduled. Coaches use motivational interviewing to increase engagement, encourage CBT skills and problem solve barriers to skill utilization. Coaches are trained and certified over 12 weeks in basics of CBT skills, active listening, empathic responding, motivational support, confidentiality and ethical decision making. Coaches are required to engage in 5-10 hours per week of instruction and assignments including weekly group lessons, role-play practice, and independent study. Certification is not automatic, and specific thresholds of competency must be demonstrated to become certified for coaching. Coaches are trained and supervised under a tiered model overseen by a licensed clinician. All coaches receive weekly supervision from a licensed professional.

III. **Clinical care** – participants with severe depressive symptoms or significant suicidality on the CAT-MH will be allocated to access clinical care, which provides weekly psychotherapy sessions and - if indicated - psychiatric care may additionally be provided. While clinical care will be available for the entire length of the study, participants will be informed that on average therapy is completed within 13 sessions. The schedule of psychiatric care will be determined by the provider. Information from treatment appointments will be collected for use as study data. Treatment appointments take place via phone, secure videochat or in person, in accordance with local public health guidelines and clinical considerations. Clinical care will be provided by DMH Clinicians at the UCLA Tele-Mental Health Clinic, who will follow standard of care clinical protocols developed by STAND and the clinical operational protocols established within their institutions (modified for this implementation).

Service eligibility is confirmed throughout the participation by research staff, coaches and clinicians associated with participants' care. If a participant becomes ineligible to continue clinical care through STAND (e.g., endorses psychosis or severe substance use disorder), they will be referred out to alternative care providers, but may continue to receive surveys and for the duration of the study. These individuals may also be offered re-entry to appropriate levels of care once their completion of outside care is confirmed.

Participants might receive treatment adaptation during their participation in the study. Treatment adaptation involves moving to a different level of care if indicated by the criteria of the participant's assigned condition, SSD or DDD. In any case that a participant endorses suicidality they are offered adaptation to receive clinical care.

Study participation lasts 40 weeks, and the average length of intervention is less than 13 weeks. Once participants complete their assigned level of care (Wellness, Coaching, or Clinical care) they will continue to receive weekly surveys until the end of their 40 week participation period. Responses will continue to be monitored in this period, and additional care and resources will be offered if survey responses indicate need.

Technology-enhanced suicide prevention intervention (TE-SPI):
Beginning July 8, 2025, participants in the ALACRITY Signature protocol that are initially assigned to Tier 2 or Tier 3 (in both SSD and DDD conditions) will additionally be randomized to one of two

conditions to examine the effect of a technology-enhanced suicide prevention intervention (TE-SPI) on suicide and self-harm risk. The two conditions will be:

I. **Usual risk management (URM)** is the current standard of care in the project where participants receive outreach from ProtoCall Services and the study team after endorsing suicidal ideation in the weekly surveys.

II. **URM + TE-SPI** adds a technology-enhanced suicide prevention intervention to the URM. The TE-SPI involves "caring contacts" messages sent to participants, and the use the eTUDES BRITE phone app, which provides users with a tailored coping plan, coping exercises to try in the moment, and a mood thermometer to log daily moods.

Aims

Specific Aim 1:

Triaging level of care - Evaluate whether data-driven algorithms for triaging to level of care lead to greater treatment adherence and outcomes than symptom severity triaging (Years 1-5). Hypothesis a: DDD will show greater adherence (session/lesson completion), greater improvements in depression and anxiety symptoms, and greater improvement in social, occupational and family functioning compared to SSD at 8 weeks. Hypothesis b: between-group differences will increase annually with refinements to DDD algorithms.

Analysis:

- Triaging Algorithm Development - The models we will explore bridge the gap between traditional statistical models and machine learning models which identify a subset of predictors that form a model that accurately predicts week 8 outcomes. This leads to approaches such as regularized regression models, including ridge regression, lasso regression, and elastic net regression that will allow us to identify a smaller and more manageable fixed set of baseline predictors that preserve the predictive accuracy enjoyed by the total set of predictors. At the end of each year, variables included in the predictive modeling will be reviewed for trimming or addition of new variables to be included.
- We will statistically compare the symptom outcomes (depression, anxiety) at 8 weeks between the SSD and DDD adaptation arms using linear regression models. The same general strategy will be used for functioning outcomes. In terms of treatment adherence, we will use generalized linear models (Poisson and negative-binomial regression models) that are appropriate for count outcomes such as number of sessions completed. Outcome analyses will be conducted in three different ways. (1) Our primary analysis will be an intent-to-treat (ITT) analysis. (2) Our second set of analyses is a "per protocol" (PP) analysis. (3) Finally, our "as-treated" (AT) analysis will include all data, but a covariate will be added describing any off-protocol shift in treatment (yes=1; else=0).
- Note that for Aim 1, outcomes will be assessed weekly through week 8. Therefore, the power analysis is essentially identical.

Specific Aim 2:

Adaptation Algorithm Development - Develop a predictive algorithm (Year 1) that combines individual baseline characteristics with time-varying symptom response, perceived support, and life stressors, during discrete 4-week periods to predict depression and anxiety symptom outcomes 4 weeks later. Over Years 2-5, algorithm generation and testing will be iteratively refined, and tested for racial/ethnic and other modifiers.

Analysis:

- We will use linear mixed-effects regression models with weekly assessments at baseline through week 8 to initially calibrate the predictive algorithm, separately for the depression and anxiety outcomes. To predict a future outcome (e.g. 16-week

outcome) from baseline data, current tier and weeks 1-12 outcomes, we will use the model-based estimates for the fixed-effects (baseline and current tier), and the empirical Bayes estimates (see Hedeker and Gibbons, 2006189) for the random effects that describe the trajectory of the outcome based on the repeated assessments through 12 weeks. These fixed and random coefficient estimates will then be used to predict the distal endpoint (16 weeks) and based on this estimated outcome, treatment adaptation will be performed. Model selection will be based on minimizing the root mean square error (RMSE) between the actual observed 8-week outcomes and the estimated outcomes. Once calibrated, we will use this predictive model to set thresholds on what level of change or lack thereof will lead to adaptation of level of care (tier shift) at 4-week intervals of treatment rather than having to wait for several months to evaluate outcomes. The algorithm will be designed such that it will predict the lowest level of care that would produce improvement in symptoms at the outcome point.

Specific Aim 3:

Adapting Level of Care - Evaluate whether data-driven algorithms for adapting level of care lead to greater treatment adherence and outcomes than symptom severity adaptation (Years 2-5). Hypothesis a: Compared to SSD, DDD will show greater treatment adherence (session/lesson completion), greater improvements in depression and anxiety symptoms and social, family and academic functioning at 16 weeks, 24 weeks, 32 weeks, and 40 weeks. Hypothesis b: between-group differences will increase annually with refinements to DDD algorithms.

Analysis:

- Adaptation Outcomes: Outcome analyses will be conducted in three different ways similarly to the analyses planned for the triaging treatment outcomes. Secondary analyses will also be performed. These include 1) using a linear mixed model to explore mediating factors and 2) performing cost-effectiveness analyses of the adaptation algorithm.

Specific Aim 4:

Emotion Regulation Diversity - Examine the association between emotion regulation (ER) diversity and symptoms and functioning in individuals of minority racial and ethnic backgrounds. Hypothesis a: ER diversity will be more strongly associated with depressive and anxiety symptoms as well as functioning level compared to traditional ER indices, such as the sum score. Hypothesis b: The association between ER diversity and symptom and functioning will be stronger as life stress increases. For Aim 4, Participants will complete self-report assessments on racial and ethnic background, use of emotion regulation (ER) strategies, life stress, symptoms, and functioning, using measures already implemented in the protocol. Measures of symptoms, functioning, and life stress will be completed weekly; measures of ER strategy use will be completed every 8 weeks; measures of race, ethnicity, and citizenship will be completed at baseline. The ER diversity index will be computed based on emotion regulation strategy use, resulting in an index every eight weeks for the duration of one year.

Analysis:

- To examine the association between ER diversity and outcomes in individuals of minority racial and ethnic backgrounds, multilevel models will be conducted with ER diversity as the predictor. Analyses will include participants who identify as Latinx. Separate models will be run for depressive and anxiety symptoms as well as work, academic, and social functioning over the course of one year. The large Latinx student population at ELAC may allow for the examination of the link between ER diversity and symptoms and functioning across cultural backgrounds (e.g., Mexican American, Cuban/Dominican American). If the sample has adequate representation of multiple

cultural groups, then cultural background will be included as a moderator in the multilevel models. Power analyses will be conducted prior to the start of the study to determine the sample size needed to detect the effect sizes for the main and moderator analyses.

- Assuming a sample size of n=1000 (500 per group [SSD v. DDD], a drop-out rate of 5% between assessment periods, a Type 1 error rate of 5% for a one-sided test, power of 80%, a linearly increasing effect size (difference between SSD and DDD groups), outcomes will be assessed for Aim 3 at week 16, week 24, week 32, and week 40, and first order autocorrelation of rho=0.3, we will be able to detect a linearly increasing effect size culminating in 0.26 standard deviation unit difference between SSD and DDD groups. Note that these are linearly increasing effect sizes over time with trends that end at these levels of separation, so even smaller differences earlier in time, that increase in magnitude over time, are captured by these analyses with adequate statistical power.

Specific Aim 5:

Recruitment Uptake - Multiple strategies to improve recruitment will be tested throughout the study lifetime.

During Years 2 - 3, the standard advertisement campaign for STAND (that was delivered in Year 1) will be supplemented with community informed video testimonials to facilitate indirect social contact with students who have lived experiences of depression and anxiety. The content of the social contact videos will be informed by extant research on help-seeking interventions and findings from focus groups; selected testimonials will be those that present potentially important themes (stigma, benefits of treatment, treatment hesitancy, etc.). The utility of the videos will be assessed by comparing screening rates across selected years of the project. Community input via focus groups (conducted through IRB-22-0220) will guide potential adaptations to the videos and engagement interventions for Years 3 and 4.

Analysis:

- Analyses will be primarily descriptive and will include chi-square tests to compare screening rates during Year A when recruitment did not use video testimonials with Year B, when video testimonials were used.

During Year 3 of recruitment, we will test two specialized processes designed to increase participant uptake into the STAND program. Upon enrollment, participants will be initially randomized to one of three conditions: (1) Emotion Regulation Uptake, (2) Text Messaging Uptake or (3) STAND as usual. This randomization will occur prior to their randomization into SSD and DDD conditions. The Emotion Regulation and Text Messaging Uptake conditions are designed to test two separate methods to increase the rates that participants schedule and attend a STAND orientation. Hypothesis a: The two recruitment uptake conditions will lead to higher rates of completed orientations. Hypothesis b: The two recruitment uptake conditions will not lead to any differences in the rates of completed orientations.

Analysis:

- To examine whether the two recruitment uptake conditions lead to higher rates of completed orientations, t-tests will be conducted to analyze whether significant differences in the rates of completed orientations are found, compared against the STAND as usual control condition.

Specific Aim 6:

To evaluate a technology-enhanced suicide prevention intervention (TE-SPI) that includes treatment components with demonstrated benefits in prior research (safety planning, BRITE app, caring contacts to support safety plan use, hope, and reasons for living) and leverages mobile technology to deliver just-in-time adaptive interventions when intervention is most needed. Using Tier II and Tier III from the Signature Project, which include students for whom

additional intervention for SU/SH risk is indicated, this work will use a rapid prototyping and testing model to develop and test an adaptation of the existing BRITE app plus safety planning for the ELAC population. We will evaluate the TE-SPI with STAND usual risk management protocol (URM) compared to STAND URM alone. We hypothesize that TE-SPI will a) lead to increased treatment engagement/contacts (i.e. app, STAND); b) demonstrate safety as indicated by low levels of self-harm related adverse events (e.g. hospitalizations, ED visits); c) be associated with fewer SU/SH events and greater improvement in suicidality, compared to URM; and d) that intervention engagement/dose received will lead to reduced SU/SH behavior.

Study Procedures

Recruitment

Multiple strategies are used for the recruitment of participants. When this study is open for enrollment, information about the study will be provided to potential participants via flyers, email messaging, online and in-person materials or by ELAC staff.

During active study enrollment, we will also distribute targeted recruitment materials for this study. These strategies are outlined below.

- *Referrals*
    - ELAC staff will be trained to refer students to STAND via professional development training (open to faculty and staff as well as mini roadshows to services offices, departments and the chair's council).
- *Direct recruitment & advertisements/flyers distribution*
    - We will host 3 all-campus recruitment events per year, which would ideally take place outdoors where all could participate. For example, having a DJ play music, handing out food, and having people explaining STAND. Study flyers will be provided at these events.
    - We will participate in orientation programs for incoming freshmen. Study flyers will be provided at these events.
    - A communication campaign will include a college-wide email sent by the President or Vice President of Student Services, flyers and postcards in all staff offices and ELAC hotlines and resources.
    - Social media campaign via Instagram and Facebook consisting of various videos and text and graphic posts about the study.
    - Targeted text messaging to ELAC students via the ELAC Student Health Center and Basic Needs Center
    - A promotional website is available for students to learn more about the study
    - Participants who started the enrollment process but did not complete it will be sent automatic reminders to return and complete the process if desired
    - Classroom presentations to ELAC students both in-person and virtually
- *Drawings*
    - We will host drawings periodically throughout each year to increase recruitment, including at each of the 3 all-campus recruitment events. We will inform potential participants that they may be entered into a drawing to receive a $50 Amazon e-Giftcard if they register or complete orientation for STAND. Language about the drawing will be included in flyers as well as via emails, texts and social media communications. Individuals interested in entering the drawing, but who decline to participate in the research project or fail to complete the project, will still be eligible to be entered into the drawing. The procedure for an individual who does not wish to participate in the study but wishes to be included in the drawing involves sending research staff an email to enter their contact information.

Drawing winners will be chosen using a random number generator and will be notified via email.

- *Refer-A-Friend*
    - We will enact a refer-a-friend program where current Tier 1 and Tier 2 STAND participants can refer their friends to the STAND Program. Upon their completion of the program, participants will be asked during a closeout session whether they would like to refer a friend who is an ELAC student to the STAND Program. If they would like to refer a friend, then we will send them a secure REDCap form that allows them to provide their friend's name and phone number and/or email address to us. Following this, our team will outreach to the referred student and provide them with information about joining the STAND Program. Our outreach will also reference the name of the friend who referred them.
- *Video Testimonials*
    - We will utilize video testimonials recorded from our previous Tier 1 & Tier 2 participants who have completed the program as well as our past and present coaches. The videos will include their experiences with the program, what they learned from the program, and how the program helped their lives. These video testimonials will be hosted on our main webpage (https://stand.ucla.edu/elac) and will be visible for potential participants to watch.

Additional recruitment strategies will be developed through STAND ALACRITY Project 001: Promoting Recruitment and Initial Uptake of STAND among ELAC students (IRB#22-000220) throughout the duration of the present study.

Active recruitment will take place during each academic year at ELAC. Promotional activities as outlined above will continue during the rest of the academic year as necessary for maintaining awareness about the study on the college campus. Materials related to these strategies and specific to this research study are uploaded to the online IRB application. Note that in these materials, we have explicitly limited the times we discuss the affiliation of the study with UCLA. Many community college students seek admission to UCLA and might become concerned about disclosing mental health information prior to learning about the confidentiality limits discussed in the informed consent form, and thus not engage with the present research study.

Prospective participants who have provided their contact information will be contacted (via email, phone call or text message) by study staff within 14 business days to review study eligibility and research procedures. Participants in this stage may be guided by staff or automated prompts to continue their enrollment process as needed.

Study enrollment has a target sample of approximately 200 participants per year. Additionally, for this study, we require the following allocation per service across both conditions per year: n = 20 for Wellness, n = 120 for Digital Mental Health + Coaching, n= 60 for Clinical Care. Once the desired sample size per service is reached for the research study, upon review, enrollment may conclude for the academic year and students will be referred out for alternative services if needed. Care may continue to be available through the STAND for All (non-research) program. Participants may be placed on a wait list for the research study in the case that a spot in their recommended care service is expected to become open within a clinically acceptable timeframe.

Consent

Participants sign research consent prior to their assignment to the recommended level of care. This study utilizes the REDCap eConsent framework to collect electronic signatures from

participants on self-administered consent forms. Copies of the signed consent form are saved in the REDCap database and the consent form is available for participants to access/download through a web link. As part of the consent workflow, participants will be presented with the informed consent form, including their rights as a research participant, and will be asked to acknowledge their receipt of a Notice of Privacy Practices. To enroll in the study participants provide electronic signature using their mouse and enter date and time on the last page of the electronic consent. Participants additionally are asked to provide consent to use of recordings for training and education, or research purposes. Participants are additionally asked to either consent or decline being contacted in the future for other research studies. Participants are not required to consent to this future contact in order to enroll in this study. Participants assigned to receive clinical care through TeleHub are additionally asked to sign the Los Angeles County Department of Mental Health (LACDMH) client statement, indicating who they should contact in the even that they have questions or concerns about the services they are receiving from the LACDMH legal entity, TeleHub, during their study participation.

Uptake

Pilot Interventions

During Year 3-4 of recruitment (November 2024-September 2025), we will test two specialized processes designed to increase participant uptake into the STAND program. Upon enrollment, all participants, initially randomized to one of three *uptake* conditions: (1) Emotion Regulation Uptake, (2) Text Messaging Uptake or (3) STAND as usual. This randomization will occur prior to their randomization into SSD and DDD conditions. The Emotion Regulation and Text Messaging Uptake conditions are designed to test two separate methods to increase the rates that participants schedule and attend a STAND orientation.

- The Emotion Regulation Uptake condition introduces participants to personalized animations that highlight helpful and unhelpful coping strategies. This condition aims to educate and persuade participants to continue enrolling in STAND by offering a preview of the program's content before they are enrolled. Participants randomized into this uptake condition will see an additional time commitment of 3 - 6 minutes.
- The Text Messaging Uptake condition uses personalized text messages to identify and address participants' perceived barriers to enrollment. Participants who haven't yet scheduled their orientation will receive an automated text message prompt asking if they are ready to do so. If they decline, they will be asked about their possible concerns and options will include: (1) *I don't know if I need treatment*, (2) *I have other ways of coping*, (3) *I'm concerned others will find out*, (4) *I don't have time to participate in this program* and (5) *I am not sure if this program will work*. Based on their responses, participants will receive targeted resources through text, infographics, and videos to overcome these barriers. Participants will also have the option to schedule a call with a STAND staff member to discuss any questions or concerns they have.The STAND as usual condition does not include any additional methods to increase uptake and will serve as a control condition to which the two additional uptake methods will be compared. Participants randomized into this uptake condition will see an additional time commitment of 5 - 10 minutes.

Project 1 Engagement Interventions:

During Year 4-5 (September 2025 – end of enrollment) we will test two specialized processes designed to increase participant uptake into the STAND program. Upon enrollment, all participants will be randomized to one of three *uptake* conditions: (1) STAND Fotonovela (2) Engagement Navigators or (3) STAND as usual. This randomization will occur prior to their randomization into SSD and DDD conditions. The STAND Fotonovela and Engagement Navigator

conditions are designed to test two separate methods to increase the rates that participants schedule and attend a STAND orientation. The fotonovela or peer navigator interventions will be administered to those respectively assigned, if they have consented and have not yet attended an intake or orientation. After participants receive one of these interventions, they may be asked to provide qualitative feedback on the engagement experience, through a phone or video interview with staff. They would be compensated $40 for completion of this interview.

- The Fotonovela Uptake condition introduces participants to a fotonovela, an online booklet that portrays a dramatic story using animated characters and captions. Participants randomized to this condition will be provided the fotonovela in addition to the text and email reminders already used to remind participants to re-engage in the enrollment process. The content of the fotonovela provides psychoeducation about mental health treatment and ways to overcome barriers to service use. The fotonovela will take approximately 10 minutes to view.
- STAND Engagement Navigator Uptake condition includes a brief telephone contact (approximately 10-15 minutes) with an engagement navigator from the STAND program, in addition to the text and email reminders already used to remind participants to re-engage in the enrollment process. The engagement navigator will follow a guide to address potential barriers to service uptake. The engagement navigator will provide an education to: 1) clarify goals of mental health treatment and perceived need, 2) improve self-efficacy, 3) address negative mental health attitudes, and 4) problem-solve barriers to STAND.
- STAND as usual: Participants randomized to the condition “STAND as USUAL” will not receive additional engagement interventions. These participants will continue to receive the text and email reminders to complete baseline assessments and schedule orientation/intake if they have stopped the enrollment process midway.

URM+TE-SPI

Following assignment to signature project tier, eligible participants (those assigned to tiers 2 and 3) will be additionally randomized to either URM or URM+TE-SPI. Those assigned to URM will proceed according to the usual protocol. Those assigned to URM+TE-SPI will be asked to schedule a time to meet with staff via zoom or phone, when staff will introduce the participant to the TE-SPI intervention components. Participants will be contacted to schedule this introduction at least 1x/week for up to 4 weeks before participants are considered non-responsive. Contact may occur via phone call, text, and/or email.

TE-SPI components will be added to existing usual risk management procedures for those randomized to URM+TE-SPI. The TE-SPI components include 1) BRITE app 2) coping plan 3) caring contacts messaging:

1) Participants will be asked to download the BRITE app which includes access a customized coping plan (see component 2 below) mindfulness exercises, a mood log, and selected social support contacts. Staff will provide instruction on logging in and navigating the app.
2) Coping plans will be individually tailored by staff to each participant during the BRITE app registration process. The coping plan is programmed into the app for participants to use at will. This coping plan includes strategies for regulating painful, distressing, or dysregulating emotions that can lead to unsafe behaviors, urges, or thoughts, intense distress, emotional dysregulation and/or other problems.

3) “Caring Contacts” messages will be sent to participants at least monthly throughout the study. These include text and email messages that communicate care with the goal of enhancing feelings of connectedness/reminding participants that the study team cares and is interested in their well-being.

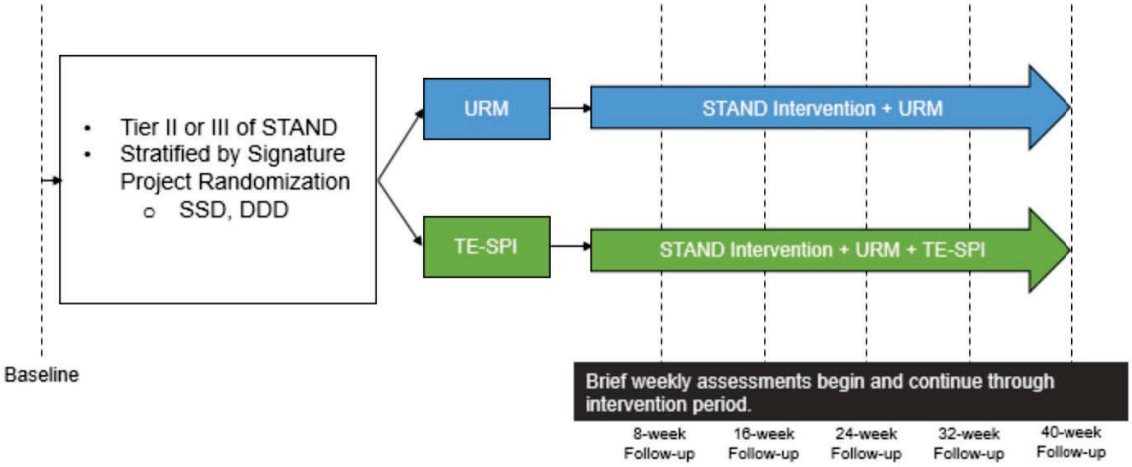
BRITE App & Coping Plan: Staff will work with participants to initially set up their BRITE app account. This includes staff following prompts and working with the participant to build participants’ personal coping plans (10-20 minutes). Individual coping plans are stored in the participant’s BRITE account. The participant will then be guided to download the BRITE app to their phone and their personal coping plan will be accessible in the app. This plan will be developed to focus on coping with intense distress, depression/mood, anxiety, and/or unsafe (suicidal/self-harm) thoughts or urges as appropriate given the participant’s presentation which will be stored in the participant’s BRITE+ app. For participants who present with some SI risk, the coping plan will focus on coping around SI risk/triggers. For those without reported SI risk, the coping plan will focus on their identified treatment target (i.e. anxiety, mood).
Participants can further customize the app by uploading support materials (videos, websites, photos) which are saved to the participants phone and not on the app server. Students can set up their own reminders in the app to receive prompts to use the app and can also access the app at any time. After rating their distress level (1-5, 5=most upset), the app offers the student skills and strategies based on these ratings and their coping/safety plan. For participants at the highest distress levels, the app presents the coping/safety plan, including interpersonal support (i.e., contact options for a nominated person of support).

The BRITE app has been approved by the UCLA TRO Risk Assessment team. All data collected by the app will be stored in a secure research environment, UCLA AWS server. The only data that will be stored in the AWS campus cloud server will be the mood thermometer daily log ins and any text that is entered into the app. Participants will be allowed to upload pictures to the app; however, these pictures are not stored on the cloud and are stored locally on their phone. Data on app use (i.e., time spent on app) will be collected through the app and used to describe intervention uptake/use which will be important for evaluating the intervention feasibility and outcome data. We will also collect data on implementation of the coping planning and caring contacts intervention components (e.g. responses received).

Caring Contacts Messages: Additionally, participants randomized to URM+TE-SPI, will also receive caring contact messages via text. Participants will be informed that messages will not be monitored on a 24/7 basis. Staff will communicate that these messages are intended for support only and are not a substitute for therapy or comprehensive interventions. If participants respond to caring contacts messaging requesting additional support or resources, staff may direct participants to their personal coping plans or the usual risk and case management procedures will be followed, and staff may provide referrals to community resources.

Figure 2 URM & URM+TE-SPI

Figure 3. Overview of Project 3 Design for RCT (Years 3 - 5) Comparing Technology-Enhanced Suicide Prevention (TE-SPI) to Usual Risk Management (URM).



Abbreviations. URM, Usual Risk Management; TE-SPI, Technology-Enhanced Suicide Prevention; SSD, Symptom-Severity Decision Making; DDD, Data-Driven Decision Making.

Participants who were randomized to URM+TE-SPI will receive 1 additional survey (BRITE Satisfaction & Usability Survey) at weeks 12 and 40, asking them to rate the perceived helpfulness of the intervention components (BRITE app, coping plan, caring contacts). Data on app use and responses to caring contacts will also be stored.

Assessments

Once participants complete enrollment, they are directed to a unique link to complete baseline assessments. Participants are instructed to complete the baseline assessments before they can be assigned to a service, and may receive reminders from staff to complete their baseline assessments. Participants may be asked to re-do baseline surveys if > 4weeks has passed between baseline completion and initiation of care in their assigned service tier.

Participants will be asked to complete a brief symptom survey (CAT-MH) as part of their baseline assessment and weekly thereafter. Additionally, they will be asked about current stress (1 item), current financial, housing and food insecurity, and perceived social support.

Online surveys will be administered on a predetermined schedule at baseline, week 8, week 16, week 32 and week 40 post baseline, and will be sent to the participant by email or text message. An additional battery of online assessments will be administered immediately upon treatment termination. Please see **Table 2** for a detailed schedule of assessments. **Table 3** provides a description for each assessment administered in this protocol. Participants may be additionally contacted by staff for qualitative data collection through interviews over the phone or via zoom. Participants who are interested in providing feedback about study procedures may be compensated an additional $40 for up to 1 hour of interview and discussion.

Although previous work suggests that there is a low likelihood that any of our assessments will result in significant emotional distress, several steps will be taken to provide additional protection against risk. Both at the outset and following completion of the major assessments, participants will be asked if they are experiencing marked distress. In the event that participants endorse significant distress due to the assessments, they will be given the option to be contacted by the study team. Individuals who are very distressed and indicate that they would like contact will be

told that a member of the project team will contact them to make sure they are okay. A member of the project team will contact the participant, ascertain their current condition, determine the need for escalation to the project investigators, or the need for clinical intervention, and arrange appropriate mental health referral (if the patient is not eligible for or interested in participating in the trial), if necessary.

All assessments will be administered online and data will be collected remotely. The STAND technical infrastructure has been developed by the UCLA Depression Grand Challenge. It has undergone security review by both UCLA Information Services and Solutions (ISS) and Los Angeles County Department of Mental Health (LADMH) and has been approved for providing services and collecting assessment data.

Table 2: Schedule of Assessments

Form Name	Baseline*	Orientation	W 1	W 2	W 3	W 4	W 5	W 6	W 7	W 8	Continued frequency
Demographics	X										
HMS Citizenship	X										
Country & City of birth	X										
Ethnic Identity/Racial Identity	X										
Family Pride	X										
Major Experiences of Discrimination	X										
HMS Beliefs About Mental Health	X									X	
HMS Therapy Seeking Preferences And Satisfaction	X										
Preference Scale	X										
HMS Physical Health Survey	X										
DERS 16	X										
HMS Insurance	X										
Sensory Experiences Screener	X										
PQ-B Psychosis	o										
SUD Screener	X										
LCSWA Assessment SA	o										
Treatment Utilization Form											
Recent Treatment History						X				X	weeks 16, 20, 24, 28, 32, 36, 40
HMS Employment	X									X	weeks 16, 24, 32, 40
WSAS	X									X	weeks 16, 24, 32, 40
Impact and GPA	X									X	weeks 16, 24, 32, 40

Family Cultural Conflict	X									X	weeks 16, 24, 32, 40
HMS Needs Assessment	X										week 40
MOS Support	X		X	X	X	X	X	X	X	X	weekly
Everyday Discrimination Scale	X									X	weeks 16, 24, 32, 40
Early and Recent Adversity Questionnaire	X										
Perceived Need	X		X	X	X	X	X	X	X	X	weekly
Willingness to Pay for Mental Health Treatment, Insurance Status	X										
Weekly Stress (Life Stress)	X		X	X	X	X	X	X	X	X	weekly
PHQ Screen	X										
PHQ Short	o			o		o		o		o	o-biweekly
GAD Screen	X										
GAD Short	o			o		o		o		o	o-biweekly
SADD Screen	X										
SADD Short	o			o		o		o		o	o-biweekly
Sleep Screen	X										
Sleep Short	o			o		o		o		X	weeks 16, 24, 32, 40; AND o-biweekly
Agora Screen	X										
Agora Short	o			o		o		o		o	o-biweekly
PCL Screen	X										
PCL Short	o			o		o		o		o	o-biweekly
PDSS Screen	X										
PDSS Short	o			o		o		o		o	o-biweekly
BRITE Satisfaction & Usability^{+}											weeks 12^{+}, 40^{+}
Suicide and Self-Harm Measures	X									X	weeks 16, 24, 32, 40

Credibility/Expectancy Questionnaire		X									
DSM-5 Self Rated Cross cutting symptom measure		X									
WHODAS 2.0		X									
Social Needs Utilization Questionnaire										X	weeks 16, 24, 32, 40
Modified Cox Treatment Satisfaction Questionnaire										X	weeks 16, 24, 32, 40
Test My Brain (post registration)	X										
CERQ9	X									X	weeks 16, 24, 32, 40
SAGE Self Report Diagnostic Screen (post registration)	X										
CAT-MH	X		X	X	X	X	X	X	X	X	weekly

***** Baseline occurs after consent. The remaining assessment time points are relative to the date of baseline completion of CAT-MH (e.g., 8 weeks after baseline).

o = only administered if indicated as a treatment target for individual participant. Treatment target defined by: baseline "screen" scores for this measure are above defined thresholds

+ only administered to those randomized to receive TE-SPI

Table 3 Description of Assessments

Form Name	Description
Demographics	Healthy Minds Survey (HMS) - 4 Items assessing self-reported Age, Sex at Birth, Gender Identity, Race/Ethnicity
HMS Citizenship	HMS - 2 items questionnaire assessing self-reported citizenship/Immigrant Status and Acculturation
Country & City of birth	HMS - 1 item questionnaire assessign self-reported country & City of Birth
Ethnic Identity/Racial Identity	Multigroup Ethnic Identity Measure - 6 item questionnaire about relationship to ethnic identity
Family Pride	Family Pride (Familismo) - 7 item questionnaire about familial relationships
Major Experiences of Discrimination	12 Item self-report about lifetime experiences with discrimination
HMS Beliefs About Mental Health	10 item questionnaire assessing personal beliefs about mental health treatment
HMS Therapy Seeking Preferences And Satisfaction	7 item questionnaire assessing mental health treatment history
Preference Scale	1 item questionnaire assessing preferred service from presented options for mental health treatment and resources
HMS Physical Health Survey	2 item self-report scale assessing perceived quality of health and diagnosis of select medical diseases/conditions
DERS 16	16 item self-report scale assessing Difficulties in Emotion Regulation (DERS)
HMS Insurance	1 item self-report assessment of Insurance coverage
Sensory Experiences Screener	4 item self-report questionnaire about sensory experiences, used to screen for psychosis
PQ-B Psychosis	40 item self-report questionnaire asking about experiences of psychotic symptoms in the past month
SUD Screener	4 item self-report questionnaire about experiences with substance use in the past month, used to screen for substance use disorders
LCSW Assessment SA	11 item self-report questionnaire about experiences with substance use in the past month
Treatment Utilization Form	Custom, 4 item questionnaire asking if participants received any mental health care external to this study
Recent Treatment History	Custom, 2 item questionnaire asking if participants are receiving mental health care external to this study
HMS Employment	HMS - 1 Item questionnaire assessing employment

WSAS	5 item questionnaire assessing symptom impact on work, school, and relationships
Impact and GPA	HMS - 2 item questionnaire assessing symptom impact on school
Family Cultural Conflict	5 item self-report scale about perceived conflict in family relationships
HMS Needs Assessment	USDA Housing/Food Security questionnaire and Financial Stress questionnaire - 7 item questionnaire assessing food and housing security, financial and personal wellbeing,
MOS Support	4 item self-report questionnaire about perceived availability of social support
Everyday Discrimination Scale	11 item self-report scale assessing frequency of experiences with discrimination
Early and Recent Adversity Questionnaire	Trauma History Questionnaire
Perceived Need	Healthy Minds Survey (1 item), HMS Needs Assessment
Willingness to Pay for Mental Health Treatment, Insurance Status	1 item self-report question about the amount one is willing and able to pay for mental health treatment in a year
Weekly Stress (Life Stress)	1 Item self-report assessment of current stress level
PHQ Screen	Patient Health Questionnaire-2: 3 item self-report survey screening for depressive symptoms
PHQ Short	Patient Health Questionnaire-14:14 item self-report survey assessing depressive symptoms
GAD Screen	Generalized Anxiety Disorder-2: 2 item self-screener for generalized anxiety, customized for this project
GAD Short	Generalized Anxiety Disorder-7, 7 item self-report assessment of generalized anxiety symptoms
SADD Screen	Social Anxiety Disorder Dimensional scale Screener -3 item self-report screening for social anxiety disorder
SADD Short	Social Anxiety Disorder Dimensional scale-10 item self-report assessment of symptoms of social anxiety disorder
Sleep Screen	Custom, 1 item self-report assessing sleep
Sleep Short	PROMIS 7 item self-report sleep disturbance questionnaire
Agora Screen	DIAMOND Agoraphobia Screener, 1 item
Agora Short	Fear Questionnaire (Agoraphobia subscale), 5 item self-report assessment for experiences of agoraphobia
PCL Screen	PTSD Check List- 5 item self-report screening for PTSD
PCL Short	PTSD Check List, Short: 20 item self-report assessing symptoms of PTSD
PDSS Screen	Panic disorder severity scale self-report, brief - 2 item self-report screening for panic disorder
PDSS Short	Panic disorder severity scale self-report - 7 item self-report assessment for symptoms of panic disorder
BRITE Satisfaction and Usability	23 item self-report about experience using the BRITE app and receiving caring contacts messages

Suicide and Self-Harm Measures	Columbia Suicide Severity Scale (11-31 items), adaptive questionnaire assessing suicidal ideation
Credibility/Expectancy Questionnaire	4 item questionnaire assessing treatment expectations
DSM-5 Self Rated Cross cutting symptom measure	23 item scale used to screen for major DSM-5 diagnoses through self-reported symptom experiences
WHODAS 2.0	World Health Organization Disability Assessment schedule – 11 item self-report assessment instrument for health and disability
Social Needs Utilization Questionnaire	17 item questionnaire about personal utilization of social support services available to participants in this program
Modified Cox Treatment Satisfaction Questionnaire	5 item questionnaire about satisfaction with treatment received
CERQ9	Self report 9 items about responses to negative or unpleasant responses
Test My Brain	self-administered online tasks assessing neurocognitive function including: TMB Digit Symbol Matching, TMB Vocabulary, TMB Matrix Reasoning, TMB Choice Reaction Time, TMB Gradual Onset Continuous Performance Test, TMB Multiple Object Tracking, TMB Multiracial Emotion Identification
SAGE Self-Report Diagnostic Screen	Comprehensive, self-report behavioral health diagnostic tool measuring: Depressive Disorders, Manic + Hypomanic, GAD, Panic Disorder, Agoraphobia, Social Anxiety, PTSD, Alcohol use, Cannabis use
CAT-MH	computer adaptive tests which provide validated symptom scores for depression, anxiety, mania/hypomania, substance use, psychosis, and suicidality

Management of Suicidality

Participants complete suicidality assessment as part of the CAT-MH survey in their weekly assessments. In the event that a participant endorses suicidality in any of these assessments, we will implement a multi-level response, starting with an automated alert system built into the online symptom assessment. Upon survey completion, the participant endorsing suicidal ideation will receive an automatic notification that they will be contacted shortly by the study team. Alerts triggered by responses on the assessments indicating an endorsement of significant suicidal ideation will be automatically sent to ProtoCall Services, a 24/7 triage and crisis intervention service provided through contract. ProtoCall Services will initiate outreach with the participant to assess suicidality and provide urgent intervention if needed. ProtoCall services is contracted to provide 3 follow-up contact attempts within 48 hours of alert (6 contact attempts over 72 hours during weekends and holidays.)

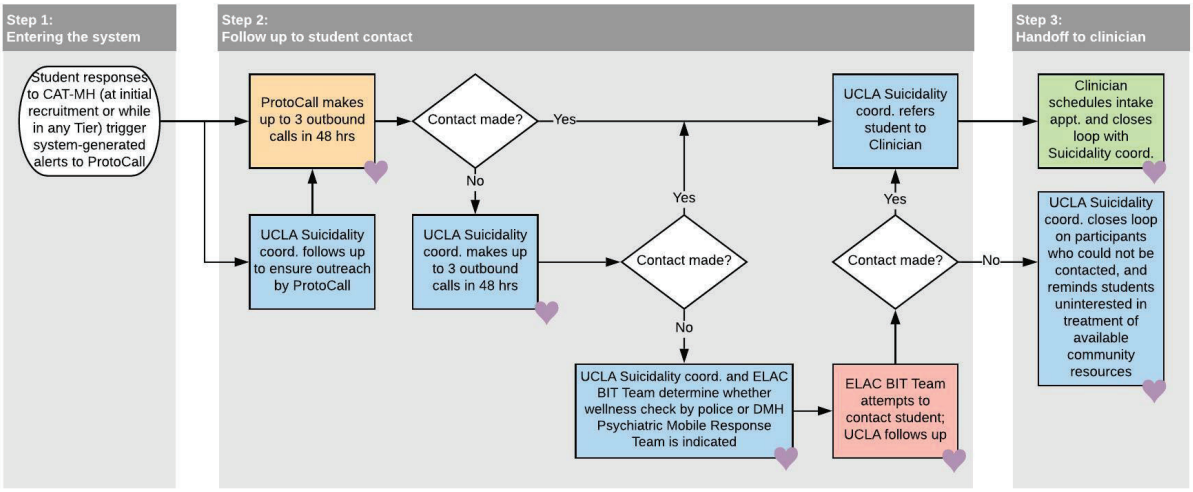
An automated alert is also sent to the study team. Participants will receive a follow-up call from a member of our clinical team within one business day (Monday-Friday, 8am-5pm) if needed based on information provided by ProtoCall Services (e.g., in case of no contact, or need for further assessment and support). Response to these alerts might be escalated (e.g., calling emergency contact or wellness check). Members of the clinical team performing this follow up may coordinate further care with a clinician if judged an appropriate course of action. All actionable alerts will be

fully documented, along with follow-up and outcome reporting. The consent form will advise participants that staff will monitor responses to the screener and any alerts generated by responses to symptom assessments.

In the event that Protocall Services counselors are unable to reach the participant through their three attempts within 48 hours, UCLA staff will make three additional outreach attempts within the next 48 hours. If both Protocall Services and UCLA staff are unable to reach the participant, the available data will be reviewed by a licensed clinician and they will make a determination about whether to contact the LA County Department of Mental Health Psychiatric Mobile Response Team (PMRT) for a safety check. In such cases where a participant's safety cannot be verified by Protocall Services or UCLA, the ELAC Student Health Coordinator and the ELAC Behavioral Intervention Team (BIT) will be notified. The suicide monitoring workflow is shown below in **Figure 2.**

Figure 3 Suicide Response

Protocol for ProtoCall+UCLA+ELAC+Clinician coordinated response to suicidality alerts triggered by ELAC students while taking the CAT-MH online screening



As part of the STAND training protocol, clinicians providing Tier III treatment are trained in suicide risk assessment and management. Clinicians are trained to know when to contact their supervisors to discuss and receive guidance about suicide risk, and will always call their supervisors before making decisions about hospitalization or calling 911. Clinicians and coaches will also be provided with specialty training in conducting these assessments and implementing suicide risk protocols remotely (via teleconference or telephone, depending on tier).

In the digital mental health with coaching service, coaches are trained to identify suicide risk in and contact their supervisors immediately (or any of the Project Leads, i.e., Drs. Craske, Wolitzky-Taylor, Chavira, or Asarnow) for further guidance. All Project Leads have considerable experience in handling high-risk clinical matters.

Participants will be informed about the limits to confidentiality (including endorsement of suicidality) during the informed consent procedures. Other mandated reporting issues may arise (though unlikely, as there is no in-person structured diagnostic interview for PTSD); nonetheless, these limits to confidentiality (e.g., child abuse reporting) will be presented during informed consent. Information about mandated reporting is provided in the informed consent and provided again verbally at multiple occasions during the study.

Time commitment
Total time of participation required is approximately 450 - 510 minutes (8-9 hours). This estimate is based on the time required to complete the following:

- Consent (15 minutes)
- Screening and Baseline assessments (85 minutes)
- Weekly assessments 27 minutes per month, for a total of up to 270 minutes)
- Online surveys at weeks 8, 16, 32 and 40 (20 minutes each; for a total of 80 minutes)
- Optional interview with staff (up to 1 hour)

Participants spend additional time in clinical or coaching appointments, engaging with the Digital Mental Health materials or completing associated practice assignments, which varies per participant and based on clinical recommendations.

Financial obligation and compensation
Participants will be issued compensation via electronic gift cards through Tremendous Research Payment Disbursement Request. Some participants were paid through US Bank debit cards, however this system was discontinued for participants enrolled after 2023. Participants enrolled in 2024 and on will receive Tremendous gift cards for reimbursement.

Participants will receive electronic gift cards after each assessment time point is completed. Participants are informed in the consent that compensation is dependent on completion of assessments. Participants may earn less than the amount below if assessments are not completed within the allotted time frames. Compensation is available as follows:

- $40 for completed baseline assessments
- $20 per each 8-week assessment completed (x5) (up to $100 total),
- $10 per each weekly assessment completed (x35) (up to $350 total)

for up to $490 in total possible incentives per participant for completion of all study procedures. If participants opt to provide qualitative data through interviews with staff, they will receive an additional $40 in compensation.

Participants will be reminded of this compensation schedule multiple times throughout the study.

The study will pay for research-related items and/or services that are provided only because participants are participating in the study. Participants' insurance may be billed for clinical services they receive as a participant in this study. The study will be conducted remotely, so no transportation reimbursement will be provided.

History of revisions to the protocol:

- 01/2025 - Addition of optional interviews for qualitative feedback.

- **08/2025** – Addition of engagement interventions, new consent form, updated recruitment materials. Engagement intervention randomization list generated using:

  Sealed Envelope Ltd. 2024. Create a blocked randomisation list. [Online] Available from: https://www.sealedenvelope.com/simple-randomiser/v1/lists [Accessed 19 Sep 2025].

  Pilot interventions stopped: ??Sep 2025

  Algorithm v8 implemented 11Sep2025

- **04/2025** – Addition of Specific Aim 6, addition of Tier 2&3 participants being randomized to usual risk management (URM) or URM+ technology-enhanced suicide prevention intervention (TE-SPI). Updated recruitment materials to include additional video testimonials, and to advertise available Spanish components in STAND. Updated consent form.

- **10/30/2024** – Inclusion of video testimonials in recruitment materials, addition of pilot interventions to increase uptake of STAND (text messaging around barriers and informative animation). Editorial overhaul to protocol and consent form to provide clarity around research procedures. Updated consent form.

- **8/28/2025** – Addition of Aim 5 - Recruitment Uptake including video testimonials, updated recruitment documents to reflect rebranding from "The STAND at ELAC Research Program" back to "STAND at ELAC." Updated consent form.

- **7/17/2024** – Compensation increased from $475 to $490 and US Bank compensation discontinued, e-gift cards exclusively used to pay compensation. Updated consent form

- **6/5/2024** participants given choice to receive compensation through either e-gift-cards or US Bank, removed enrollment cap of 200 participants/year. Updated consent form

- **12/15/2023** - Compensation increased from $275 to $475. Addition of raffles to recruitment strategies. Updated consent form.

STAND at ELAC Consent Form

UNIVERSITY OF CALIFORNIA LOS ANGELES
CONSENT TO PARTICIPATE IN RESEARCH

Research Study Name: STAND Finding and adapting the level of care

Thank you for your interest in STAND at ELAC! This study is funded with a grant from the National Institute of Mental Health (NIMH) and is being conducted under the UCLA Depression Grand Challenge by Michelle Craske PhD (from the Department of Psychology and the Department of Psychiatry and Biobehavioral Sciences) and Kate Taylor, PhD (from the Department of Psychiatry and Biobehavioral Sciences), at the University of California, Los Angeles (UCLA).

WHAT SHOULD I KNOW ABOUT A RESEARCH STUDY?

- Research studies are voluntary. Whether or not you take part is up to you.
- Someone will explain this research study to you.
- You can discuss this study with friends, family, or your doctor.
- If you have any questions, you can ask the researchers for more information before deciding to participate.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.

WHAT IS THE STUDY RESEARCHING?

The STAND at ELAC research study is evaluating different methods for finding the most appropriate level of care for each student, and adapting that care to meet individual needs.

WHY IS THIS STUDY BEING DONE?

STAND offers three levels of care: 1) Wellness 2) Digital Mental Health + Coaching 3) Clinical Care. Your responses to surveys about your symptoms and history inform which level of care you receive. We are interested in comparing two methods for assigning the appropriate level of care in STAND. One method is Symptom Severity Decision-making (SSD). The other method is the Data Driven Decision-making (DDD). The difference between the two groups is that individuals in the SSD group are assigned a level of care based on their reported symptoms. Individuals in the DDD group are assigned a level of care using an algorithm that considers reported symptoms as well as individual characteristics. The goal is to compare SSD and DDD methods to find the best system for making treatment decisions. Some participants will be assigned to receive additional supportive resources in order to examine whether this addition leads to safer coping and improved functioning. Findings from this study may help us develop and implement better ways of providing personalized care in the future.

WHAT WILL I NEED TO DO IF I ENROLL IN THIS STUDY?

Research participation is completely remote and lasts for 10 months (40 weeks). During the research study, you may be provided access to online resources and/or mental health care through STAND at ELAC, and you will be asked to complete brief, weekly questionnaires online. Every two months you will be asked to complete a slightly longer set of online questionnaires. We estimate that you may spend one to three hours per week receiving services, depending on the level of care you have been assigned. Typically these services are provided for five to 16 weeks depending on need, but services can be provided for up to the full 40 weeks as needed. We estimate that during the 40 weeks of study participation, you will spend about 8 hours in total responding to online questionnaires. More details about study participation and types of data collected are provided below.

Before you begin the study: If you decide to participate in this research study, you will review and complete this consent form by signing the signature locations below.

- Baseline assessment (about 1.5 hours)
  You will be asked to complete about 1.5 hours of online surveys and computer tasks. Afterwards, you will be randomly assigned to the SSD or DDD group for treatment decision making. You will not be told which group you have been assigned. You may receive reminders from our study team to complete your baseline questionnaires. Our team may contact you to provide more information about enrollment and treatment available through this study.
- Assignment to Treatment
  Based on your responses to the online surveys completed, you will be assigned to a level of care: 1) wellness or 2) digital therapy with coaching or 3) clinical care. If you are assigned to 2) digital therapy with coaching or 3) clinical care, you may additionally be offered supportive resources including access to an app for coping skills that you will be asked to download & set up with support from our staff. After you receive information about your assignment, you will be asked to complete an orientation or intake appointment with our staff.

During the study:

- Orientation and Intake
  You will be asked to schedule and compete an orientation session or intake session with our staff. This session is designed to inform you about what services are available to you. At this time staff can also answer any additional questions you may have about participating in the research study.

- Online questionnaires
  Over the 40 weeks of study participation, the research team will ask you to complete online questionnaires:
  - Short, 5-10 minute questionnaires once every week (40x).
  - Longer 20 minute questionnaires (4x) at weeks 8, 16, 24, 32 and 40.

You may receive reminders from our team if these are not completed. If you provide responses that indicate a need for social services or that you are potentially suicidal with a plan to harm yourself, a member of the extended STAND at ELAC team will reach out to you to check on your safety and connect you to support.

You may receive an invite to provide us feedback about your participation experience. If you decide to provide this feedback during a phone or zoom interview with our staff (1 hour maximum), you may be compensated an additional $40.

- Levels of care

  Services may be provided for the whole duration of the study (40 weeks). However, most participants complete a course of care in the first 16 weeks. You will not be given the choice about which level of care you will receive, though as we track your symptoms, we may recommend changes to your level of care during the study. These recommendations will be based on the decision making associated with the group you are assigned (SSD or DDD group). Your group assignment will be kept confidential so that only STAND at ELAC staff members know which group you are in. Your level of care will be one of the three options below.
  - **Wellness** - An online wellness program, through which you can learn skills for coping with common stressful experiences and build resilience at your own pace.
  - **Digital Mental Health + Coaching** - An online digital therapy program with lessons that are designed to respond to your experiences. You may access the system through any personal device (phone, tablet, or computer), and for each lesson, you also are assigned to a certified student coach who provides support through remote video chat.
  - **Clinical Care** - Connection to a team of clinicians who will evaluate your symptoms and create an individual treatment plan, tailored for you. Your treatment will include weekly sessions delivered through telehealth, and if deemed appropriate, you may also have medication appointments. To be eligible for clinical care through this program, students need to be uninsured or have Medi-Cal or Medicare coverage. There may be costs associated with clinical care depending on your income and other factors.

  Treatment Adaptation: During your participation in the study, your recommended level of care may be changed.

  Eligibility for care: If you are deemed not eligible for the STAND at ELAC services at any point, our team will provide you with information about other resources available.

- Risk Responses:

  We will ask you questions about potentially sensitive topics. If any of your responses are potentially concerning, specifically if you are suicidal with a plan to harm yourself, your information is forwarded to our team for confidential review. A member of our team will contact you for additional assessment to

determine if there are safety concerns that require immediate support or response. If we are unable to reach you, we may contact your emergency contact, and/or ELAC to ensure your safety. If we are concerned that you are going to seriously harm or kill yourself imminently, we may need to share that information with someone outside of our research team to ensure your safety. If we hear during the course of the study of imminent threats of harm against a reasonably identifiable victim or victims, we may need to share that information with someone outside of our research team to ensure the safety of others. If you receive treatment by an external provider (i.e., not associated with STAND at ELAC), you might be asked to provide us with your written permission to share this information with your current provider.

- Identification of Other Significant Needs:

  If your responses indicate that you might have unmet housing/food, financial, abuse and substance use needs, one of the study team members may guide you towards appropriate resources.

- Communication with the study team:

  During your participation in the study, we ask that you agree to receive regular communication via e-mail, phone or text from the study team, including requests for information pertaining to your study eligibility, supportive and motivational messages, and reminders for appointments and questionnaire. Please, see below additional information about using these services as it pertains to your confidentiality.

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

HOW LONG WILL I BE IN THE STUDY?

Participation in this study lasts for 40 weeks. You will receive weekly questionnaires, and services will be available throughout the study as appropriate for your reported symptoms. If at the end of the 40-week period, you are interested in continuing to access online lessons, we will provide you access to the STAND for All program.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?

We aim to recruit approximately two hundred students per year (up to 1000 participants over 5 years) into this research study.

IS THERE A CHANCE I WILL NOT BE ABLE TO PARTICIPATE IN THE RESEARCH PROJECT? IF SO, WHAT WILL HAPPEN?

If your assigned treatment program has no space available, you could be placed on a waitlist. If you are found to not be eligible for the STAND at ELAC research project, our team will provide you with information about other resources available to you.

WHAT KIND OF RISKS OR DISCOMFORTS COULD I EXPECT?

Known risks and discomforts: The possible risks and/or discomforts associated with the procedures described in this consent form include the following:

Risks associated with mood and cognitive assessments: The risks of answering questions about your mood, feelings, thinking or past experiences include fatigue, anxiety or discomfort. You can refuse to answer any question or end any research interview or treatment session, are welcome to discuss your emotions with the researchers or clinicians at any time; and can contact the principal investigators for additional emotional support if needed.

Overall risks of loss of confidentiality: One risk of participating in this study is that confidential information about you may be accidentally disclosed. We will use our best efforts to keep the information about you secure. Please see the Notice of Privacy Practices form to understand our privacy and data security practices.

Unknown risks and discomforts: The services provided through this study may have side effects that no one knows about yet. The researchers will let you know if they learn anything that might make you change your mind about participating in the study.

ARE THERE ANY BENEFITS IF I PARTICIPATE?

Possible benefits to you: The possible benefits you may experience from being in this study might include improvement in depressive symptoms and functioning and earlier interventions. However, a response to treatments offered cannot be guaranteed in any participant and neither the degree of response nor the duration of response to one of the services offered can be reliably predicted at this time.

Possible benefits to others in society: This study aims to further medical knowledge and may improve future treatment of depression and anxiety.

WHAT OTHER CHOICES DO I HAVE IF I DON'T WANT TO OR AM UNABLE TO PARTICIPATE IN THE RESEARCH STUDY?

Your participation in the study is voluntary. If you are not eligible for STAND at ELAC and do not have or cannot afford a private mental health professional (psychologist, psychiatrist, therapist, etc.) we will recommend low-cost treatment centers that may be able to help you. Some specific resources available to you can be in the STAND at ELAC Resource Guide. https://ucla.app.box.com/v/stand-elac-resource-guide.

CAN THE RESEARCHERS REMOVE ME FROM THIS STUDY?

The researchers may end your participation in this study for several reasons, such as if your safety and welfare are at risk, if you do not follow instructions, if you choose to receive treatment elsewhere (e.g., become a participant in another treatment study) or if you miss scheduled visits. The research team will inform you if you are removed from the study. The decision may be made either to protect your health and safety, or to ensure

the integrity of the study. The researchers or the study sponsor might also decide to stop the study at any time. The team will provide you with information about available resources if this occurs.

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.

HOW WILL MY INFORMATION BE KEPT CONFIDENTIAL?

Information about you will be handled as confidentially as possible, but participating in research may involve a loss of privacy and the potential for a breach in confidentiality. Data relating to your participation in this study are stored on multiple, secured databases. Access to these databases is on a "need to know" basis and only for the execution of research and supporting job functions. Study data will be physically and electronically secured. As with any use of electronic means to store data, there is a risk of breach of data security. If you choose to participate in the research project, the following provisions also will apply:

Use of Study ID to protect your identity: 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.
We will replace your name with your Study ID for the records that relate to your questionnaires, but we will maintain your name and contact information on records that involve your treatment.

Retention of your data and records: The researchers intend to keep the research data and records in a repository indefinitely.

Notice of Privacy Practices: As explained in greater detail in the Notice of Privacy Practices, there are a number of different ways that we may need to use or disclose your information for purposes of treatment, payment, operations or other regulatory reasons. Following signing this consent form, you will need to acknowledge your receipt of the

Who will have access to your data: As described below, the team supporting STAND at ELAC including the research study team members and the UCLA Tele-Mental Health Hub ("Care & Study Team") will have access to all of the information related to your participation in this study. Other groups including selected members of the Los Angeles County Department of Mental Health (LACDMH), ProtoCall Services, and East Los Angeles College (ELAC) (collectively "Extended Care & Study Team") will have access to specific data as explained below if needed for your care, safety, or support.

What data is collected:

We will collect the following types of information from you as part of your services and the research project which are accessible by the Care & Study Team. As specified below this information may also be shared with the Extended Care & Study Team:

- **Personally identifiable information**. We collect information such as your name, email address, and telephone number, as well as other information (e.g., survey responses, message content, progress) that you voluntarily provide or receive through the use of our applications*. Shared with Care & Study Team and potentially with LACDMH to confirm eligibility for services. If you agree to be contacted by other researchers for more participation opportunities (pgs 12-13), your contact information may be shared those researchers who are at other universities or organizations.*
- **Mental health surveys to track symptoms, severity, and support care needs**. *Shared with Care & Study Team.* This information and your contact information will be shared with (a) ProtoCall Services if it determined that you are in need of a risk assessment and (b) with ELAC BIT, LACDMH or other applicable crisis response team if we are unable to reach you and are concerned for your safety; and (c) with ELAC and LACDMH if we need to coordinate urgent support services such as housing insecurity, homelessness, food insecurity, presence of ongoing abuse, substance abuse, psychosis or financial duress.
- **Website and e-Learning Use Data**. If you are assigned to Digital Mental Health and Coaching services, we will collect your responses to questions in the materials and information about your progress. *Care & Study Team.*
- **App Use Data.** We offer several apps to support your participation in this study. We will collect the data you enter into study-associated apps including text input, auido recordings, and app use data. *Care & Study Team.*
- **Coaching Session Data**. Information regarding any attempted or successful interactions with coaches may be collected, such as requests for a coaching session, scheduled time for coaching sessions, and cancellations of coaching sessions. Notes from coaching sessions also will be collected. *Shared with the Care & Study Team.*
- **Therapy/Psychiatry Session Data & Information from Risk Assessment Team**. Information will be collected from ProtoCall and the UCLA Tele-Mental Health Hub which will be *shared with the full Care & Study Team*, which might include visit dates, therapy techniques, prescriptions (if applicable) etc. Note that information shared with the Care & Study Team may be only a subset of information that these providers collect and maintain in accordance with their privacy policies that are shared with you.
- **Recorded Sessions**. By agreeing to participate, you understand that your coaching and treatment sessions may be observed in person, via audio or video recording for the purposes of teaching and clinical supervision, research and quality assurance. *Shared with the Care & Study Team.*
- **Messages**. You will receive text, email, and phone communications from the Care & Study Team. You will also have access to a messaging tool to communicate with the Care & Study Team. We will collect and store such messages. *Shared with Care & Study Team*.
- **Automatically Collected Information**. Some information about you may be automatically collected. For example, we may collect information about your computer's operating system, Internet Protocol (IP) address, access times, browser type and language, and the website that referred you to us. We also

collect information about your usage and activity on our Sites. *Shared with Care & Study Team.*

Incidental Third-Party Access. We may need to work with third-party service providers to perform specific aspects of this research (e.g., scheduling). We share the minimal amount of information necessary with these third-party service providers that is essential for providing the service and this information might contain some personally identifiable data. Each of these providers are guided by their own terms of service and privacy policies. The methods of information exchange are vetted by UCLA Office of Compliance Services prior to establishing their use for the purposes of the research. Information transfer is always done in a secure and encrypted manner.

Emergency Contact. As part of your registration information, 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.

Broad consent to Share Data beyond above Uses. By signing here, I also give permission for you to share my information beyond the Care & Study Team, Extended Care & Study Team, and Incidental Third-Party Access uses above ("Broader Consent"). This consent is with the understanding that if the Care & Study Team shares information beyond the above uses, that the data will remain de-identified, meaning they will not contain identifying information.

Groups who may have access to my de-identified information include:

- The study team members working at other research centers (academic or commercial).
- Collaborators at other institutions that conduct additional optional studies.
- Other investigators not affiliated with the project are investigating similar questions and agree to protect the data. 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.
- Study monitors and auditors, for example from the NIMH, who make sure that the study is conducted properly.
- Readers and reviewers of scientific journals may publish the results of this and other studies that involve your data but not your name or likeness.
- 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 to achieve rapid scientific progress.

Data sharing with you: Some information regarding your symptom scores may be shared with you. Other study data will not be shared with you or your provider(s).

Certificate of Confidentiality also protects you: This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that the researchers cannot release or use information, documents, or samples **that may identify you** in any action or suit unless you say it is okay. They also cannot provide them as evidence unless you have agreed. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings. An example would be a court subpoena. While there are these protections, the Certificate will not stop the type of reporting that federal, state, or local laws require and that are outlined in the Notice of Privacy Practices. For example, it won't stop mandated reporting of child or elder abuse or threats to harm yourself or others. The Certificate CANNOT BE USED to stop a sponsoring United States federal or state government agency from checking records or evaluating programs. The Certificate also DOES NOT prevent your information from being used for other research if allowed by federal regulations.

Researchers may release information about you when you say it is okay. For example, by participating in the STAND at ELAC program you have given permission to release certain information to insurers, medical providers or any other persons not connected with the research. The Certificate of Confidentiality does not stop you from willingly releasing information about your involvement in this research. It also does not prevent you from having access to your own information.

WILL I BE PAID FOR MY PARTICIPATION?

You will be compensated for completing research questionnaires in this study. Participants may receive payments totaling up to a possible $490 for completing all assessments during the 40-week study. If participants opt to complete an additional interview with staff to provide feedback about their study experience, they may receive an additional $40 for the completing the interview.

You will receive compensation for completed online questionnaires through an electronic gift card through Tremendous which allows you to select a preferred vendor for your gift card payment. Gift card codes will be emailed to you shortly after completion of each assessment. The compensation amounts are provided as follows:

- $40 total for completed baseline questionnaires and is paid after program orientation is completed
- $10 per each completed weekly questionnaire (x35) (up to $350 total)
- $20 per each 8-week completed questionnaire (x5) (up to $100 total)

FREQUENTLY ASKED QUESTIONS ABOUT COMPENSATION

Q: Why isn't all of my money available at once?

A: Electronic gift cards are emailed to you for each time you complete a weekly questionnaire. Payment is spread out across the 40 weeks of study participation.

Q: Is there any reason I won't receive compensation?

A: You are paid for completion of weekly questionnaires, on an all-or-nothing basis. This means if you do not complete them in full, you will not receive compensation for that that week.

Q: What happens to my money if I withdraw from the study?

A: You will be paid for all questionnaire time points you have completed in full. If you withdraw, you will not be paid for future, incomplete questionnaires.

ARE THERE ANY COSTS FOR TAKING PART IN THIS STUDY?

The study will pay for research-related items and/or services that are provided only because you are participating in the study. These research-related items and/or services are explained in other areas of this consent form.

You or your health plan may be responsible to pay for all the types of items listed below:

- Items and services that would have been provided to you even if you were not in the study
- Health care given during the study as part of your regular care
- Items or services needed to give you study drugs or devices
- Monitoring for side effects or other problems
- Deductibles or co-pays for these items and/or services

If you are receiving wellness or digital mental health services, no costs are anticipated for your participation. If you are receiving clinical care, you or your government insurance policy (if applicable) may be charged for certain services, such as medications or medical visits. The fees will be on a sliding scale and the clinician's office will let you know in advance.

WILL I BE CONTACTED ABOUT OTHER RESEARCH STUDIES?

Studies related to STAND at ELAC: During your participation in this study, we may find that you are eligible for other UCLA studies related to this STAND at ELAC study. If you are eligible, staff will contact you and give you the choice to participate in any of these additional studies.

Other studies: During your participation in this study, we may find that you are eligible for other studies 1) conducted by UCLA Depression Grand Challenge - but not related to STAND at ELAC; or 2) studies conducted by our colleagues at other universities or organizations.

Would you like information about these other studies? *Note: Agreeing to receive this information is not a commitment to participate in another study*

1. I am willing to receive information about other studies by UCLA Depression Grand Challenge

YES / NO / I'm not sure

2. I am willing to receive information about other studies conducted by people who are part of this program but happen to work at other universities or organizations.

YES / NO / I'm not sure

WHO CAN I CONTACT IF I HAVE QUESTIONS ABOUT THIS STUDY?

The Research Team: You may contact the Principal Investigators, Michelle Craske at (310) 825-8403 or Dr. Kate Taylor at kbtaylor@mednet.ucla.edu, (310) 267-5339, or contact our study team at standelac@mednet.ucla.edu with any questions or concerns about the research or your participation in this study.

If you have questions about your rights while taking part in the STAND at ELAC 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) 206-2040 or by email: participants@research.ucla.edu.

WHAT ARE MY RIGHTS IF I TAKE PART IN THIS STUDY?

Rights of research subjects: 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 you will not lose any of your regular benefits.

- 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.

HOW DO I INDICATE MY AGREEMENT TO PARTICIPATE?

Agreement to participate: If you agree to participate in this study, you should sign and date below.

I have read the information about UCLA STAND at ELAC, and I consent to enrolling in the program, receiving wellness, digital therapy, coaching services, referrals for crisis response, support needs and/or clinical treatment, as applicable. Furthermore, I agree and authorize to have the information collected and shared within UCLA and between the participating organizations as described above for my care and safety. I specifically authorize this collection of data and sharing by and between the Care & Study Team and the Extended Care & Study Team.

Furthermore, I understand that 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 must 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. I understand that I will not be informed of the details of any specific research

studies that might be conducted using my data, including the purposes of the research, and it is possible that I might not have chosen to consent to some of those specific research studies. Finally, I understand that results from these studies may not be disclosed to me.

A copy of this document is available for you to download for your own records. The document also may be found online at: https://ucla.box.com/v/STAND-ELAC-Consent. If you have questions regarding this form, please contact standelac@mednet.ucla.edu.