Cover Page for the Study Protocol

Official Title:	Mobile health (mHealth) application called CBCT Sessions to Treat and Reduce Elevated Stress among Students (C-STRESS)
NCT Number:	NCT05776901
Document Type:	Study Protocol
Document Date:	03/16/2022

PROTOCOLS

Melissa Dawn Pinto

#20195345 - Developing C-STRESS, A Mobile App To Address Mental Health In College Students

Protocol Information

Review Type	Status	Approval Date	Continuing Review Date
Expedited	**Approved**	**Mar 16, 2022**	**--**

Expiration Date	Initial Approval Date	Initial Review Type
Aug 11, 2023	**Aug 12, 2020**	**Expedited**

Feedback

Approval Comment

The IRB Approval Letter and any approved documentation (e.g. stamped consent forms) can be downloaded in the Attachments section of the protocol.

Protocol Amendment Form

Form Navigation

Amendment Screener

Translations: May be submitted without transcription, only when non-English speakers are already included in the approved protocol.

- **If non-English speakers need to be added to the protocol, select either 'minor' or 'major' revisions.**
- **For more information, visit Anticipating the Need for Written Translations.**

Exempt Self-Determinations: The submission of amendments in KRP is NOT required. Amendments are to be tracked by the Lead Researcher independently. If the amendment changes the level of review to where IRB review is required, a new protocol must be submitted in KRP. Please 'Abandon' the amendment for the exempt self-determination.

Yes, changes are required (complete an amendment)

Are you submitting an amendment for an IRB, sIRB, or hSCRO protocol?

IRB (UCI is the IRB of Record)

If this is a legacy protocol (*legacy* = IRB number has 8 digits - 20211234), has Electronic Research Administration (ERA) Transcription *already* transcribed it?

Yes, ERA has transcribed the legacy protocol

When was the initial IRB approval granted?

On or after January 21, 2019 and it adheres to the 2018 Common Rule

Amendment Instructions

- **Complete the amendment form to describe the change(s) and to provide rationale for the change(s).**

- **After the amendment form is complete, review and revise the protocol, as necessary.**
- **Submit all new and/or revised supporting documents in the Attachments section near the end of the protocol.**
- **If the protocol is within 30 days of the expiration date, it is recommended that a renewal be included with the amendment. If Renew & Amend was not initially selected and a renewal is required, please Abandon the draft and start again.**
    - **IMPORTANT! Please refrain from making major changes during a renewal as this could result in a lapse of IRB approval.**
- **REMINDER! Research Personnel (RP) should be removed from the protocol in accordance with the RP Heat Map.**
    - **Active RP removed from the protocol may be tracked through the Study team tracking log (or equivalent) or may be tracked in the Permissions Tab at the top right of the page.**

For more information, visit Protocol Amendment.

IRB Amendment

What type of changes are being proposed for this request?

Minor Revision(s)

Current Status of Enrollments:

Enrollment and research procedures complete - only access to identifiable data / data analysis ongoing

Are there approved Re-Consent Cover Memos on file?

IMPORTANT! To verify, review the 'Approved' documents in the Attachments section.

No

Is there significant new information that would warrant

Is there significant new information that would warrant notification or reconsenting of participants?

No

List of Protocol Changes

- **Select '+Add Line" for each change.**

IMPORTANT! The list below must be complete / comprehensive of all changes as it will be reflected in the IRB Approval Letter. Failure to provide a complete list of changes will delay IRB approval.

Change in Recruitment

Provide the details and reason for the recruitment change:

Expanding age range from 18-25 yrs to 18-30 yrs to capture larger sample of graduate students. New recruitment materials to reflect the expanded protocol narrative.

Change in Research Procedure(s)

Provide the details and reason for the change in research procedures:

This change is an expansion of the original protocol narrative with new aims to examine the C-STRESS application prototype developed based on the feedback from the completed focus groups and design workshops. The prototype C-STRESS mobile application content is based on Cognitively-Based Compassion Training (CBCT©) coursework. An overview of the

content can be found on the CBCT© website - https://www.compassion.emory.edu/ A more detailed description of CBCT© course content can be found in the article “A model for cognitively-based compassion training: theoretical underpinnings and proposed mechanisms” at https://doi.org/10.1057/s41285-019-00124-x There will be 3 steps added to the study protocol: Step 3: We will recruit an independent convenience sample of 8 UCI undergraduate and graduate students aged 18-30 to participate in a Zoom focus group (FG) to provide feedback on low-fidelity wireframes of the C-STRESS mobile application. The participants will complete a short demographic survey prior to the FG and will review the Study Information Sheet at the beginning the FG. Participants will view low-fidelity wireframes of the C-STRESS app (see example attached in packet). Discussion and feedback will be guided by the Low-Fidelity Focus Group Discussion Guide. The FG will last approximately 1 ½ hours. Participants will receive a $30 Amazon Gift Card for participation in the FG. Feedback from this FG will be used to develop high-fidelity wireframes for the next focus group. We will recruit an independent convenience sample of 8 UCI undergraduate and graduate students aged 18-30 to participate in a Zoom focus group (FG) to provide feedback on high-fidelity wireframes of the C-STRESS mobile application. The wireframes will be created based on the feedback from the FG in Step 1. The participants will complete a short demographic survey prior to the FG and will review the Study Information Sheet at the beginning the FG. Participants will view high-fidelity wireframes of the C-STRESS app (see example attached in packet). Discussion and feedback will be guided by the High-Fidelity Focus Group Discussion Guide. The FG will last approximately 1 ½ hours. Participants will receive a $30 Amazon Gift Card for participation in the FG. Feedback from this FG will be used to develop initial content (onboarding and modules 0-3) of the C-STRESS mobile application which will be used in the pilot test (Step 4). Step 4: We will recruit an independent convenience sample of 20 UCI undergraduate and graduate students aged 18-30 to pilot test the initial content (onboarding and modules 0-3) of the prototype C-STRESS mobile application. Participants will complete measures via REDCap survey link: Demographic

Questionnaire, PHQ9, GAD7, Coping 1, Coping 2, CDC HRQOL4). Participants will meet via Zoom with a member of the research team to a) download the prototype app, b) complete app onboarding (eg. indicate reason(s) for using the app, indicate color scheme & frequency of notification preferences, select avatar if desired, etc.), c) begin to explore the app and its functionality with a research team member available to provide technical assistance, and d) complete the SUS and TAM questionnaires via REDCap survey link. This initial download/onboarding meeting will last 20-30 minutes. Participants will receive a $20 Amazon Gift Card for participating in the download/onboarding meeting and completing the measures. Participants will be asked to use the prototype C-STRESS application at least once per day for 8 weeks. Daily usage will range from approximately 2 minutes (opening the app and performing a one-minute meditation) to as much time as the participant desires (opening the app, completing available content, and unlimited meditation/reflection/journaling, etc. multiple times per day). At the end of week 3 (timepoint 1) and week 6 (timepoint 2) the participants will complete measures (PHQ9, GAD7, Coping 1, Coping 2, CDC HRQoL, SUS, TAM) via REDCap survey. Participants will receive a $30 Amazon Gift Card after completing timepoint 1 measures and a $30 Amazon Gift Card after completing timepoint 2 measures. Step 5: At the end of week 8, eight participants will be randomly selected from those who indicated in the Pilot Study Pre-Screener Recruitment Questionnaire they would be interested in participating in a post-pilot interview. Participants will take part in an individual interview via Zoom with questions guided by the Post-Pilot Interview Guide. The interview will last approximately 60 minutes. Participants will receive a $30 Amazon Gift Card for completing the post-pilot interview. Participants may continue using the prototype C-STRESS application after the end of the 8-week pilot test, however the prototype C-STRESS application will not be provided with any updates after the completion of the pilot test. Pilot test participants will be notified via email when the completed C-STRESS mobile application is available for download.

Confirmation of Changes:

Check here to confirm that all changes to the protocol are listed above

End of amendment form!

Project Details

Specify the study title (this title should not exceed more than 100 words):

Developing C-STRESS, A Mobile App To Address Mental Health In College Students

Lead Researcher/Investigator:

Melissa Dawn Pinto

Enter the Lead Unit:

IR-8110 - ADMINISTRATION (Lead Unit)

Project Screener

Submit a Human Subject Protocol for UCI Institutional Review Board (IRB) Review

Will this protocol be reviewed under a sIRB process?

No, there is no reliance involved. UCI serves as the IRB of record

Are the research procedures limited to the use/analysis of identifiable private information

and/or identifiable biospecimens (no subject contact)?
No

Select the required level of review for this protocol:
Minimal Risk (Expedited)

Check all sites where UCI investigator(s) will conduct research activities (e.g., recruitment, informed consent, and research procedures including accessing identifiable, private information about participants):
UCI Facilities or Sites (e.g. school, hospital or clinics, etc.)

Provide a non-technical summary of the proposed research that can be understood by IRB/hSCRO members with varied research backgrounds, including non-scientists and community members (this summary should not exceed more than 250 words):
Psychological distress among college students is increasing, and more than 50% of U.S. college students report significant symptoms of depression, anxiety or stress. Many of these students do not receive professional help due to the long waiting time and lack of resources for mental health services at universities. As a result, they may experience poor performance in college, drop out of college, or even die of suicide. It is thus crucial to provide new interventions that are aligned with the needs of college students. C-STRESS addresses the mental health needs of college students with an innovative mobile application to deliver Cognitively-Based Compassion Training (CBCT®), a mind-training intervention that builds skills of attention, mindfulness, and traditional cognitive behavioral techniques, actualized through meditation, to cultivate compassion for self and others. The ultimate goal of C-STRESS is to revolutionize the delivery of CBCT and strengthen college students' cognitive resilience to stress and improve mental health outcomes. C-STRESS, a potential digital treatment intervention for depressive symptoms. This research project involves:s a)a focus groups and design workshops with 24 students in which they will discuss their experiences with mental health and complete a brief demographic survey and a survey about their experience participating in a

focus group via Zoom; b) focus groups with an independent sample of 16 students in which they provide feedback on low-fidelity or high-fidelity C-STRESS wireframes; c) a pilot study of the prototype C-STRESS app with an independent sample of 20 students during which they use the app daily and complete 7 measures of physical/mental health and coping styles at three timepoints; and d) a post-pilot semi-structured interview to obtain qualitative data to add in further app development with 8 of the 20 participants. All participants complete a demographic survey.

Instructions

IRB Protocol Instructions

- **For research with a Master Protocol or with a detailed project proposal, specify this in the protocol and an abbreviated protocol will be generated.**
- **Submit all new and/or revised supporting documents in the Protocol Attachments section near the end of the protocol.**
- **The Lead Researcher (LR) is responsible for maintaining all supplemental documentation (as indicated in the form) in the research records. This documentation may be requested by Human Research Protections for quality assurance review.**

For regulatory or institutional guidance:

- **Visit Human Research Protections**
- **Contact the Human Research Protections staff**

For technical issues or questions:

- **Visit the Kuali Research Protocols (KRP) User Guide**
- **Contact Electronic Research Administration (ERA)**

Type of Research

The purpose, specific aims or objectives of the research is:

Social/Behavioral/Educational

The research protocol is:
Investigator-Initiated

Does the investigator-initiated study have any industry support?
No

Is this study an extension of a UCI IRB approved study (e.g., resubmission of ongoing exempt research; Open Label Extension) or is it otherwise related to a UCI IRB approved study?
No

Does this research meet the definition of a clinical trial that requires adherence to Clinicaltrials.gov?
No

Level of Review

Minimal Risk - No more than minimal risk to subjects

Select the applicable category(ies):
6. Collection of data from voice, video, digital, or image recordings made for research purposes
7. Research on individual or group characteristics or behavior (including,but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies

Study Funding

Select the funding source(s) (check all that apply):

Select the funding source(s) (**check all that apply**):

Grant/Contract

Select the sponsor type(s) (**check all that apply**):

Health and Human Services (HHS) (includes National Institutes of Health (NIH)

List below all extramural proposals or awards that will support the study (if applicable):

IMPORTANT! **Skip this table if extramural funding is not available.**

Sponsor Name

National Institutes of Health

Title of Proposal/Award (if different from study title):

Proposal or Award #:

Scientific/Scholarly Review

Is the research Sponsor-Initiated?

Yes

The proposed research qualifies as minimal risk research. The Department Chair, Division Chief, or Institute Director provides assurance that the research uses procedures consistent with sound research design, the study design can be reasonably expected to answer the proposed question, and the importance of the knowledge expected to result from the research is known.

Check here to confirm the above assurance

Potentially Hazardous Materials

If any of the following hazardous materials are involved in this research please check below:
N/A

Other UCI Committee Reviews

Check all ancillary committees that apply:
N/A

Study Team

Study Team:

- **List only study team members who are engaged in human subjects research below.**
    - **Administrative Contact (AC): Do not add ACs to the study team table. To add ACs, navigate to the Permissions tab on top-right-hand-side of form. All ACs must complete the requisite Human Research Protections CITI Training.**
- **Lead Researcher (LR): LRs must meet requirements specified on the Lead Researcher Eligibility page for study to be approved.**
    - **Select 'Oversight of Research' along with other applicable duties.**
    - **Select 'Full Access'.**
- **Faculty Sponsor (FS): FSs are required when the person serving the LR role is not qualified to serve as LR-- the FS must be eligible to be LR.**
    - **Select 'Oversight of Research' along with other applicable duties.**
    - **Select 'Full Access'.**
- **Co-Researcher (CR): CRs are faculty, staff, students and other academic appointees who the LR considers to be key personnel for conducting the research study. These individuals work closely with the LR to design, conduct, and/or report on the research.**
- **Research Personnel (RP): List RP as required per the Research Personnel Heat Map.**

For those RP who do not need to be listed on the protocol, they may be tracked by alternative methods, see below.

- **IMPORTANT! Do NOT list non-UCI researchers below, in the Permissions tab at top or on the Study Team Tracking Log (or equivalent); instead, follow the Single IRB Reliance (sIRB) process.**

- **Collaborative Institutional Training Initiative (CITI) Human Research Protections Training Courses**
  - **Confirm CITI training is complete and current for all study team members.**
  - **Incomplete or expired CITI training will delay IRB approval.**
  - **For more information, visit HRP Training and Education.**

Researcher

Melissa Dawn Pinto

Training

Social/Behavioral Investigators - Refresher Course 11/06/18 - 11/05/23	Research and HIPAA Privacy Protections 11/06/18 - 11/05/23
IRB-Mandated Compliance - Social/Behavioral 11/06/18 - 11/05/23	

To promote the objectivity of the research, all researchers are required to disclose their **related disclosable financial interests**, per the IRB COI Policy. If you have any questions about the COI process in general, contact the COI team.

Each member of the study team for this protocol must be asked the following question to comply:

"Do you, your spouse/registered domestic partner, and dependent children have any disclosable financial interests* (i) that would reasonably appear to be affected by this research study; or (ii) in entities whose financial interests would reasonably appear to be affected by this research study?"

No

Degree

PhD

Position/Title

Faculty, School of Nursing

Department

IR-8110 - ADMINISTRATION (Lead Unit)

Affiliation

UCI Faculty

Researcher Role

Lead Researcher

Permissions

Full Access

Duties

Specify relevant training and experience for the referenced duties/responsibilities:

1. All study team members will be trained by Dr. Pinto (PI) on the protocol, and will be required to demonstrate their ability to perform study procedures by practicing with team members. A checklist consisting of the different steps in the research protocol based on this IRB application will be developed to ensure ongoing fidelity of the protocol, and will be completed by all study personnel. Dr. Pinto will also provide ongoing oversight with research staff on a weekly basis through team meetings.
2. Not applicable

Researcher

Candace W Burton

Training

Social/Behavioral Investigators - Refresher Course
11/23/16 - 11/22/21
Expired

Biomedical Investigators - Refresher Course
11/23/16 - 11/22/21
Expired

To promote the objectivity of the research, all researchers are required to disclose their related disclosable financial interests, per the IRB COI Policy. If you have any questions about the COI process in general, contact the COI team.

Each member of the study team for this protocol must be asked the following question to comply:

"Do you, your spouse/registered domestic partner, and dependent children have any disclosable financial interests* (i) that would reasonably appear to be affected by this research study; or (ii) in entities whose financial interests would reasonably appear to be affected by this research study?"

No

Degree

PhD

Position/Title

Faculty, School of Nursing

Department

IR-8110 - ADMINISTRATION (Lead Unit)

Affiliation

UCI Faculty

Researcher Role

Co-Researcher

Permissions

Full Access

Duties

Specify relevant training and experience for the referenced duties/responsibilities:

see above

Researcher

Jonathan Roland Stewart McIntyre

Training

Jonathan McIntyre has no training courses on file.

To promote the objectivity of the research, all researchers are required to disclose their related disclosable financial interests, per the IRB COI Policy. If you have any questions about the COI process in general, contact the COI team.

Each member of the study team for this protocol must be asked the following question to comply:

"Do you, your spouse/registered domestic partner, and dependent children have any disclosable financial interests* (i) that would reasonably appear to be affected by this research study; or (ii) in entities whose financial interests would reasonably appear to be affected by this research study?"

No

Degree

Other

Degree Other

CNRA, PhD Student

Position/Title

PhD Student at UCI School of Nursing

Department

IR-8110 - ADMINISTRATION (Lead Unit)

Affiliation

UCI Grad Student

Researcher Role

Co-Researcher

Permissions

Full Access

Duties

Specify relevant training and experience for the referenced duties/responsibilities:

see above

Researcher

Rebecca W Black

Training

Social/Behavioral Investigators - Basic Course	Research and HIPAA Privacy Protections
02/12/17 - 02/11/22	02/02/21 - 02/01/26
Expired	

To promote the objectivity of the research, all researchers are required to disclose their related disclosable financial interests, per the IRB COI Policy. If you have any questions about the COI process in general, contact the COI team.

Each member of the study team for this protocol must be asked the following question to comply:

"Do you, your spouse/registered domestic partner, and dependent children have any disclosable financial interests* (i) that would reasonably appear to be affected by this research study; or (ii) in entities whose financial interests would reasonably appear to be affected by this research study?"

No

Degree

PhD

Position/Title

Department of Informatics/Donald Bren School of ICS; Faculty

Department

IR-8062 - INFORMATICS

Affiliation

UCI Faculty

Researcher Role

Research Personnel

Permissions

Full Access

Duties

Specify relevant training and experience for the referenced duties/responsibilities:

see above

Researcher

Gillian R Hayes

Training

Social/Behavioral Investigators - Refresher Course
04/21/16 - 04/20/21
Expired

Social/Behavioral Investigators - Basic Course
11/05/21 - 11/04/26

Biomedical Investigators - Refresher Course
03/25/16 - 03/24/21
Expired

To promote the objectivity of the research, all researchers are required to disclose their related disclosable financial interests, per the IRB COI Policy. If you have any questions about the COI process in general, contact the COI team.

Each member of the study team for this protocol must be asked the following question to comply:

"Do you, your spouse/registered domestic partner, and dependent children have any disclosable financial interests* (i) that would reasonably appear to be affected by this research study; or (ii) in entities whose financial interests would reasonably appear to be affected by this research study?"

No

Degree

PhD

Position/Title

Department of Informatics/Donald Bren School of ICS; School of Education; School of Medicine Robert A. and Barbara L. Kleist Professor of Informatics;Faculty

Department

IR-8122 - GRADUATE DIVISION-OPERATIONS (Lead Unit)

Affiliation
UCI Faculty

Researcher Role

Co-Researcher

Permissions

Full Access

Duties

Specify relevant training and experience for the referenced duties/responsibilities:
see above

Researcher

Sharnnia Artis

Training

Social/Behavioral Investigators - Refresher Course
09/17/20 - 09/16/25

To promote the objectivity of the research, all researchers are required to disclose their related disclosable financial interests, per the IRB COI Policy. If you have any questions about the COI process in general, contact the COI team.

Each member of the study team for this protocol must be asked the following question to comply:

"Do you, your spouse/registered domestic partner, and dependent children have any disclosable financial interests* (i) that would reasonably appear to be affected by this research study; or (ii) in entities whose financial interests would reasonably appear to be affected by this research study?"

No

Degree

PhD

Position/Title

Dean of Office of Access and Inclusion for Engineering and Information Sciences

Department

IR-7343 - DO STUDENT AFFAIRS

Affiliation

UCI Faculty

Researcher Role

Research Personnel

Permissions

Full Access

Duties

Specify relevant training and experience for the referenced duties/responsibilities:
see above

Researcher

Heather Lynn Abrahim

Training

Heather Abrahim has no training courses on file.

To promote the objectivity of the research, all researchers are required to disclose their related disclosable financial interests, per the IRB COI Policy. If you have any questions about the COI process in general, contact the COI team.

Each member of the study team for this protocol must be asked the following question to comply:

"Do you, your spouse/registered domestic partner, and dependent children have any disclosable financial interests* (i) that would reasonably appear to be affected by this research study; or (ii) in entities whose financial interests would reasonably appear to be affected by this research study?"
No

Degree

Other

Degree Other

RN PhD Student

Position/Title

PhD Student at UCI School of Nursing

Department

IR-8110 - ADMINISTRATION (Lead Unit)

Affiliation

UCI Grad Student

Researcher Role

Co-Researcher

Permissions

Full Access

Duties

Specify relevant training and experience for the referenced duties/responsibilities:

see above

Researcher

Lucretia Williams

Training

Social/Behavioral Investigators - Basic Course 07/12/19 - 07/10/24	**Research and HIPAA Privacy Protections** 02/01/21 - 01/31/26

To promote the objectivity of the research, all researchers are required to disclose their related disclosable financial interests, per the IRB COI Policy. If you have any questions about the COI process in general, contact the COI team.

Each member of the study team for this protocol must be asked the following question to comply:

"Do you, your spouse/registered domestic partner, and dependent children have any disclosable financial interests* (i) that would reasonably appear to be affected by this research study; or (ii) in entities whose financial interests would reasonably appear to be affected by this research study?"

No

Degree

Other

Degree Other

PhD Student

Position/Title

PhD Student at UCI Department of Informatics

Department

IR-8062 - INFORMATICS

Affiliation

UCI Grad Student

Researcher Role

Co-Researcher

Permissions

Full Access

Duties

Specify relevant training and experience for the referenced duties/responsibilities:
see above

Are RP tracked outside the approved protocol, in accordance with the RP Heat Map?
Yes, RP are tracked on a Study Team Log or other comparable log

Supplemental Documents

Does this study include supplemental documents?
No

Background & Purpose of the Research

Describe the purpose, specific aims or objectives and specify the hypotheses or research questions to be studied:
Employ user-centered design (UCD) methodology, to develop a prototype C-STRESS that leverages focus group sessions with 40 subjects (college students) , a series of three design workshops with selected participants from focus group sessions. The second part of this project involves additional focus groups with an independent sample (n=16) college students to obtain additional feedback before pilot. A pilot test with an independent sample (n=20) of college students in which subjects will use the app and complete 5 measures at 3 timepoints(Baseline, 3 and 6 weeks after beginning to use the app).. Of the 20 participants who participated in

the pilot, 8/20 will be invited to complete individual an approximately 60minute semi-structured interview regarding the app.

Provide the scientific or scholarly rationale for the research and describe the relevant background information and the specific gaps in current knowledge that this study intends to address:

More than half of U.S. college students experience significant symptoms of depression, anxiety or stress, and three-fourths of these college students do not obtain professional help due to overburdened mental health services at universities and colleges. Prevalence of mental disorders and inadequate utilization of mental health services is a particularly severe problem for minority students and community college students. CBCT has been administered to a variety of populations, including college students (undergraduate students, medical school students) and younger adolescents in prior completed studies, that collectively showed that CBCT can significantly strengthen cognitive resilience to stress and substantially reduce depressive symptoms, stress-associated systemic inflammation (pro-inflammatory markers), improved emotional regulation (including impulse control) and mindfulness; increase compassion, and improve empathetic accuracy (measured by fMRI) - a critical skill that aims at cultivating relationships and connection to others. Currently, as a face-to-face program, CBCT certification at Emory takes 1 year to complete, and there are only 48 CBCT instructors. Due to the course duration, location, and time-intensive requirement for certification, CBCT has limited reach and scalability in its current instructional model despite growing demands. This prompted us to explore the possibility of incorporating CBCT in a mobile app and we intend to use the ADAPT-ITT model, the most widely used model for behavioral intervention adaptation, to successfully adapt the existing CBCT curriculum for C-STRESS.

Provide relevant preliminary data (animal and/or human):

please complete

Describe the primary outcome variable(s), secondary outcome variables, and predictors

and/or comparison groups as appropriate for the stated study objectives/specific aims:
please complete

List up to ten relevant references/articles to support the rationale for the research:
1. Thielking M. A dangerous wait: Colleges can’t meet soaring student needs for mental health care. STAT. https://www.statnews.com/2017/02/06/mental-health-college-students/. Published 2017. 2. Pinto MD, DiClemente RJ, Higgins MK, Greenlatt AM, Negi LT, Abbott KL KA. Cognitively-Based Compassion Training (CBCT®): Promising intervention to improve depressive symptoms, self-regulation, attention, and executive function. Rev. 3. Jennifer S. Mascaro, Sean Kelley, Alana Darcher, Lobsang Tenzin Negi, Carol Worthman AM& CR. Meditation buffers medical student compassion from the deleterious effects of depression. J Posit Psychol. 2016;(1743-9760 (Print) 1743-9779 (Online)). http://www.tandfonline.com/loi/rpos20. 4. Desbordes G, Negi LT, Pace TWW, Wallace BA, Raison CL, Schwartz EL. Effects of mindful-attention and compassion meditation training on amygdala response to emotional stimuli in an ordinary, non-meditative state. Front Hum Neurosci. 2012;6. doi:10.3389/fnhum.2012.00292. 5. Eisenberg D, Goldrick-Rab S, Lipson SK, Broton K. Too Distressed to Learn? Wisconsin HOPE LAB. 2016;(March). 6. Rebecca A. Vidourek, Keith A. King, Laura A. Nabors and ALM. Students’ benefits and barriers to mental health help-seeking. Heal Psychol Behav Med. 2014;2(1):1009-1022. 7. Paola Pedrelli, Maren Nyer, Albert Yeung, Courtney Zulauf and TW. College Students: Mental Health Problems and Treatment Considerations. Acad Psychiatry. 2015;39(5):503-511. 8. CB D. Processes of mental health service use by adolescents with depression. J Nurs Sch. 2005;37(2):155-162. 9. Liu CH, Chen JA, Stevens C, Wong SHM, Yasui M. The prevalence and predictors of mental health diagnoses and suicide among U . S . college students : Implications for addressing disparities in service use. Anxiety Depress Assoc Am. 2018;(January):1-10. doi:10.1002/da.22830. 10. Suicide. National Institute of Mental Health (NIMH). https://www.nimh.nih.gov/health/statistics/suicide.shtml. Accessed January 3, 2018.

Subject Population(s) (Individuals/Records/Biospecimens)

Check all subject populations/data sources that apply to the research:

Adults Competent to Provide Informed Consent

UCI Students/Staff/Faculty

Use of identifiable or coded data, specimens, records, charts

Maximum and Expected Number of Persons/Records/Biospecimens to be Enrolled

1. **Click "Add Line" button above Enrollment Table to add a Category/Group**
    a. **To change visibility of columns, click "Columns" button above Enrollment Table and select which Column rows to view.**
2. **Specify the maximum and expected numbers of individual-level information and/or biospecimens to be accessed/analyzed within each Category/Group**

Category/Group

Undergraduate or graduate college students (focus groups)

Age Range

18-25 years

Maximum Number of Subjects, Subjects to be Consented or Reviewed/Collected

50

Number Expected to Complete the Study or Needed to Address the Research Question

24

Category/Group

Undergraduate or graduate college students (design workshops)

Age Range

18-25 years

Maximum Number of Subjects, Subjects to be Consented or Reviewed/Collected
50

Number Expected to Complete the Study or Needed to Address the Research Question
24

Category/Group

Undergraduate or graduate students (focus groups)

Age Range

18-30

Maximum Number of Subjects, Subjects to be Consented or Reviewed/Collected
30

Number Expected to Complete the Study or Needed to Address the Research Question
16

Category/Group

Undergraduate or graduate studentsn(pilot test)

Age Range

18-30

Maximum Number of Subjects, Subjects to be Consented or Reviewed/Collected
40

Number Expected to Complete the Study or Needed to Address the Research Question
20

Will this study only take place at UCI and does not involve other sites?

Yes

Eligibility Factors (Inclusion/Exclusion Criteria)

1. Click "Add Line" button above Eligibility Factors Table to add a inclusion/exclusion criteria
    a. To change visibility of columns, click "Columns" button above Eligibility Factors Chart and select which Column rows to view.
2. Identify the factors for limited eligibility and provide a scientific rationale. Include additional rows for factors, as needed.

Category/Group Eligibility

Undergraduate or graduate students

Inclusion Criteria

Inclusion criteria: Young adults must be (a) undergraduate or graduate students; (b) enrolled at University of California Irvine (UCI),); (c) between the ages of 18-30, which is representative of the age group for the target population i.e. young adults; (d) speak and understand English; (e) have access to the internet for 8 weeks to participate in study activities via Zoom or attend in person (if safe and feasible given Covid-19 pandemic) (f) report clinically significant depression (scores ≥ 10 on the PHQ-9),and (g) have a smartphone with either iOS or android operating system.

Exclusion Criteria

Exclusion criteria: (a) Potential subjects who report active suicidal ideation will be excluded unless they obtain a written note from a psychiatric provider; (b) Female student who self-report pregnancy or plans to become pregnant within the next 3 months

Is eligibility based on age, gender, pregnancy/childbearing potential, social/ethnic group, or language spoken (e.g., English Speakers only)?

Yes

Limited Eligibility Factors (Special Populations)

1. Click "Add Line" button above Limited Eligibility Factors Table to add a special population
    a. To change visibility of columns, click "Columns" button above Limited Eligibility Factors Table and select which Column rows to view.
2. Identify the special populations and provide a scientific rationale. Add additional rows, as needed.

Eligibility Limited to the Following Factors

Other Factors

Specify the rationale for this group:

Subject eligibility is based on a numbers of factors including: age – we plan on recruiting young adults between the ages 18-30 years as our focus is on mental health among young adults, and proficiency in English – we will only recruit individuals who can speak and understand English; we do not expect this criterion to discriminate against potential subjects since the study is set in a college that provides instructions in English. We also plan on excluding females who self-report pregnancy or plans to become pregnant to avoid inclusion of post-partum depression, which is thought to have a potentially different biological etiology/contributors than depression from non-childbearing women.

Pre-Screening and Determining Eligibility without Informed Consent

Will Identifiable information be obtained for the purpose of screening, recruiting, or determining eligibility of prospective subjects?

No

Recruitment Methods

Will this study involve NO direct contact with participants (i.e., passive observation of public behavior)?

No

Indicate all methods that will be used to recruit subjects for this study:

Recruitment Method

Flyers/Brochures

Specify Where Posted

Part One: Focus Group Potential subjects will be approached through print ads or email ad or electronic posting of flyer on UCI websites or affiliated social media and locations in and around UCI campus. Emails (email will use the flyer, and a short message from me, the investigator (see attachment labeled “email/social media message”), will be sent on behalf the investigator through individuals working in student services in different departments on UCI campus. Our student services director at the school of nursing is able to connect with other departments and ask if they would be willing to send a flyer out on my behalf to invite interested students to contact the investigative team. Also, the school of nursing social media accounts will be used and the flyer will be used to

notify followers who may meet criteria are aware of the potential study. Our school social media colleague in the school of nursing has connections across and we will push out the study flyer on UCI social media accounts. Potential subjects will contact us via telephone or email. Potential subjects will be provided a link to a secure Red Cap survey which will describe the study,askscreening questions for eligibility, and provide a list of mental health resources. If subjects are eligible and interested in participating, they will select a date/time for focus group participation and provide the research team their email or phone contact information. Part Two: Design Oriented Focus Groups Focus group participants will be invited to continue with this project by participating in up to three more focus groups, which will have a focus on co-design activities. Potential subjects will be contacted via email following the focus group if stated interest in design workshop proposes at the end of focus group. Part Three: Focus Groups Potential subjects will be

approached through print ads or email and/or electronic posting of flyer on UCI websites or affiliated social media and locations in and around UCI campus. Emails (email will use the flyer, and a short message from me, the investigator (see attachment labeled “email/social media message”), will be sent on behalf the investigator through individuals working in student services in different departments on UCI campus. Our student services director at the school of nursing is able to connect with other departments and ask if they would be willing to send a flyer out on my behalf to invite interested students to contact the investigative team. Also, the school of nursing social media accounts will be used and the flyer will be used to notify followers who may meet criteria are aware of the potential study. Our school social media colleague in the school of nursing has connections across and we will push out the study flyer on UCI social media accounts. Potential subjects will contact us via telephone or email. Potential subjects will be provided a link to a secure Red Cap survey which will describe the study, ask screening questions for eligibility, and provide a list of mental health resources. If subjects are eligible and interested in participating, they will select a date/time for focus group participation and provide the research team their email or phone contact information by phone or email. Eight participants will be included in the first focus group which will provide the research team with feedback on low-fidelity wireframes. Based on feedback from focus group one participants, the research team will create high-fidelity wireframes. Eight participants will participate in the second focus group which will provide the research team with feedback on high-fidelity wireframes. Part Four: Pilot Testing Potential subjects will be approached in the same manner as prior parts of this protocol. If subjects are eligible and interested in participating, they will select a date/time to meet with a member of the study team to download the C-STRESS application, complete the app on-boarding process, and receive pilot test instructions. At the time of enrollment, participants will be asked if they would like to be involved in one follow-up interview (Part Five) for approximately 60 minutes about their experience using the app. Part Five: 8 participants will be randomly selected from the Part 4 participants who expressed

interest in the follow-up interview. These 8 participants will complete a post-pilot interview lasting approximately 60 minutes.

Type of Space

Public (i.e., site/media that allows open access to content)

Recruitment Method

Online/Social Media

Specify Where Posted

Part One: Focus Group Potential subjects will be approached through print ads or email ad or electronic posting of flyer on UCI websites or affiliated social media and locations in and around UCI campus. Emails (email will use the flyer, and a short message from me, the investigator (see attachment labeled “email/social media message”), will be sent on behalf the investigator through individuals working in student services in different departments on UCI campus. Our student services director at

the school of nursing is able to connect with other departments and ask if they would be willing to send a flyer out on my behalf to invite interested students to contact the investigative team. Also, the school of nursing social media accounts will be used and the flyer will be used to notify followers who may meet criteria are aware of the potential study. Our school social media colleague in the school of nursing has connections across and we will push out the study flyer on UCI social media accounts. Potential subjects will contact us via telephone or email. Potential subjects will be provided a link to a secure Red Cap survey which will describe the study,askscreening questions for eligibility, and provide a list of mental health resources. If subjects are eligible and interested in participating, they will select a date/time for focus group participation and provide the research team their email or phone contact information. Part Two: Design Oriented Focus Groups Focus group participants will be invited to continue with this project by participating in

up to three more focus groups, which will have a focus on co-design activities. Potential subjects will be contacted via email following the focus group if stated interest in design workshop proposes at the end of focus group. Part Three: Focus Groups Potential subjects will be approached through print ads or email and/or electronic posting of flyer on UCI websites or affiliated social media and locations in and around UCI campus. Emails (email will use the flyer, and a short message from me, the investigator (see attachment labeled “email/social media message”), will be sent on behalf the investigator through individuals working in student services in different departments on UCI campus. Our student services director at the school of nursing is able to connect with other departments and ask if they would be willing to send a flyer out on my behalf to invite interested students to contact the investigative team. Also, the school of nursing social media accounts will be used and the flyer will be used to notify followers who may meet criteria are aware of the potential study. Our school social media colleague in the school of nursing has connections across and we will push out the study flyer on UCI social media accounts. Potential subjects will contact us via telephone or email. Potential subjects will be provided a link to a secure

Red Cap survey which will describe the study, ask screening questions for eligibility, and provide a list of mental health resources. If subjects are eligible and interested in participating, they will select a date/time for focus group participation and provide the research team their email or phone contact information by phone or email. Eight participants will be included in the first focus group which will provide the research team with feedback on low-fidelity wireframes. Based on feedback from focus group one participants, the research team will create high-fidelity wireframes. Eight participants will participate in the second focus group which will provide the research team with feedback on high-fidelity wireframes. Part Four: Pilot Testing Potential subjects will be approached in the same manner as prior parts of this protocol. If subjects are eligible and interested in participating, they will select a date/time to meet with a member of the study team to download the C-STRESS application, complete the app on-boarding process, and receive pilot test instructions.

At the time of enrollment, participants will be asked if they would like to be involved in one follow-up interview (Part Five) for approximately 60 minutes about their experience using the app. Part Five: 8 participants will be randomly selected from the Part 4 participants who expressed interest in the follow-up interview. These 8 participants will complete a post-pilot interview lasting approximately 60 minutes.

Type of Space

Private (i.e., site/media that allows control of access to content)

Recruitment Method

Email/Postal Mail/Phone

Specify how contact information will be obtained:

Informed Consent Process

Does this study involve the creation, use, or disclosure of Protected Health Information (PHI)?
No

Methods of Informed Consent

Identify the consent or assent process as applicable for each participant population (check all that apply):
Oral/Implied informed consent/assent (no signature)

Oral/Implied Informed Consent/Assent

Indicate the waiver of signed informed consent/assent (check all that apply):
Waiver of Signed Informed Consent (oral consent obtained)

Does this oral consent process include all subjects?

No

Specify cohort:

please complete previous question / verify for accuracy

REQUIRED! Submit a Study Information Sheet in the Attachments Section

UCI IRB requires ALL of the following:

- **An IRB-approved Study Info Sheet will be presented prior to administering research procedures,**
- **Subjects verify they meet the eligibility criteria,**
- **Subjects indicate their willingness to participate in the research (e.g., click "Yes")**

You selected Minimal Risk (Expedited) or Greater than Minimal Risk (Full Committee) Research for the Level of Review.

Check here to confirm you will complete the Waiver of Documentation Section

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Circumstances of Consent

Indicate the location where the consent process will take place (check all that apply):

Internet

Specify how the research team will assure that subjects, their parents, or their legally authorized representative (LAR) have sufficient time to consider whether to participate in the research:

Other

Specify 'Other' timeframe:

Focus Group and Pilot Test: The study team will screen for the inclusion/exclusion criteria using a secure REDCap survey, and the study will be described in the survey narrative. Potential focus group participants who select a date/time or potential pilot study participants who select a date/time to meet with a study team member for onboarding will receive

an electronic copy of the Study Information Sheet ahead of time via email prior to the focus group/meeting with study team member. The potential participant will be given the opportunity to request a copy of the study information sheet in the mail as well.

This study does NOT include Non-English Speaking Participants. Scientific justification/rationale is required in the Eligibility Criteria Section for Subject Populations.

Waiver of Documentation

Select the option for the Waiver of Documentation (Signed) Informed Consent:

OPTION B (*Most Common*): The research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context

OPTION B (*Most Common*): The research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context

Does the research involve no more than Minimal Risk? [45 CFR 46.116(f)(3)(i)]

Yes

Will the subject be provided with a Study Information Sheet or other document that addresses the basic elements of informed consent?

Yes

Would the research procedures normally require a signed consent form outside the research environment?

No

Select the following research procedures that do not normally require signed consent (Check all that apply):

Specify and provide the rationale for 'Other' research procedures:

Discussing one's experience with

Interview/Focus Group/Survey/Questionnaire Other research procedures	mental health and providing information about their experience of engaging with a focus group could be topics that individuals discuss in daily life, and really pose minimal risk, and would not require consent to engage in these activities in daily life.

Research Procedures

Check all boxes that apply to the research:

Audio, Video, Digital or Image Recording and/or Photography for Collection of Research Data

Surveys/Questionnaires/Interviews/Oral Histories

Will deception or incomplete disclosure be involved in the research?

No

Study Design

Include an explanation of the study design (e.g., randomized placebo-controlled, cross-over, cross-sectional, longitudinal, etc.) and, if appropriate, describe stratification/ randomization/blinding scheme:

Focus groups, questionnaires, and semi-structured interviews

Provide precise definitions of the study endpoints and criteria for evaluation; if the primary outcomes are derived from several measurements (i.e., composite variables) or if endpoints are based composite variables, then describe precisely how the composite variables are derived:

Study endpoints are completion of focus group(s), end of pilot test, and end of semi-structured interviews. Outcomes are derived from thematic analysis of focus group and interview narratives and from results of usability/acceptability measures.

Statistical Considerations

Is a statistical analysis plan appropriate for this qualitative study design?
No

Specify a non-statistical analysis plan for assessing study results:
please complete previous question/verify for accuracy

Research Procedures

Provide a detailed chronological description of the clinical or treatment plan:
Part One: Focus Group- This research will be conducted at UCI via Zoom (because of Covid, there is a low potential for face-to-face data collection without increasing risk). Each subject will participate in only one focus group, but there will a series of focus groups conducted to obtain data for the number of potential subjects outlined in this application. Each focus group will be approximately an hour and a half long in duration. As part of participating in these focus group sessions, subjects will also complete a short demographic survey (age, gender, race, ethnicity, education, and socioeconomic status) via RedCap as well as brief survey about their experience of participating in a focus group via Zoom. Part Two: Design-Oriented Focus Groups - A series of 3 design workshop settings will be conducted at UCI via Zoom (because of COVID, there is a low potential for face-to-face data collection without increasing risk). Each participant will be asked to participate in all three sessions, but they will not be required to attend all three. Each design workshop will be approximately 90 to 120 minutes. As a part of participating in these groups, participants will be asked to revisit some of the themes discussed in their initial focus groups as well as to view and critique existing mental health apps available in the app store – a sample list of questions is attached, but that list will be curated based on the results of the focus groups – and discuss what technologies might be most useful to them. Between focus groups, the research team will sketch and design prototype versions of the concepts discussed during the groups and then return these prototypes for critique

and discussion at the following session. Part Three: Focus Group - This research will be conducted at UCI via Zoom (because of Covid, there is a low potential for face-to-face data collection without increasing risk). Each subject will participate in only one focus group.There will be two focus groups to obtain data for the number of potential subjects outlined in this application. The first focus group will view and be asked to provide feedback on low-fidelity wireframes of the C-STRESS mobile application being developed. The feedback from the first focus group will be used by the research team to develop high-fidelity wireframes. The second focus group will view and be asked to provide feedback on the high-fidelity wireframes. Each focus group will be approximately an hour and a half long in duration. As part of participating in these focus group sessions, subjects will also complete a short demographic survey (age, gender, race, ethnicity, education, and socioeconomic status) via REDCap. Part Four: Pilot Test – This research will be conducted at UCI via Zoom (because of COVID, there is a low potential for face-to-face data collection without increasing risk). Participants will complete a short demographic survey (age, gender, race, ethnicity, education, and socioeconomic status) and 5 brief online questionnaires (PHQ9, GAD7, CDC HRQOL4, Coping Styles 1 and Coping Styles 2) via REDCap. Participants will meet with a study team member who will walk them through the process of downloading the C-STRESS mobile application to their personal smart phone (prototype application will be available for both iOS and android operating systems) and initial application on-boarding. Participants will be provided an opportunity to orient themselves/interact with the application for approximately 5-15 minutes with the study team member available to answer questions/provide technical assistance. After onboarding and app orientation, the participant will complete usability and acceptability measures (SUS and TAM) (baseline measurement). This initial meeting and completion of online survey/questionnaires will last approximately 1 hour. Participants will be asked to use the C-STRESS app daily for 8 weeks. The minimum amount of time the participants will interact with the app each day is approximately 2 minutes. The participants will be able to interact with the C-STRESS app for longer if they so choose; it is entirely up to them

based on the activities they choose to do in the app. At the end of weeks 3 (data point 2) and 6 (data point 3), participants will complete 7 online measures (SUS, TAM, PHQ9, GAD7, CDC HRQOL4, Coping Styles 1 and Coping Styles 2) (data point 2). These measures will take approximately 30 minutes to complete. Part Five Follow-Up Post-Pilot Semi-Structured Interview-At the end of week 8, eight randomly selected participants who participated in part four will be asked to participate in a post-pilot interview via Zoom. The interview will last approximately 60 minutes.

List all procedures involving the use and/or collection of photographs, or audio/video recording:

Part one Focus groups, part two design workshops, part four pilot test on-boarding, and part five post-pilot interviews will be completed via Zoom. The subjects will have the option to turn on their camera if they would like to be seen. If they do not wish to be seen, they will be able to participate using audio only. Prior to the scheduled Zoom session, subjects will be provided information on how to change their screen name if they do not

want their name/full name to be seen by others.. Subjects will be reminded that the Zoom session will be recorded from Zoom--both audio and video.

Specify the total duration of a subject's participation in the study and clearly outline the duration of participation for each study visit and sub-study, as applicable:

Part 1 focus groups = 1 - 1.5 hours Part 2 focus groups = 1.5 - 2 hours Part 2 participants a subgroup of part 1 participants Part 3 focus groups = 1.5 hours Part 3 participants an independent sample Part 4 pilot test = 4 hours (Initial meeting and completion of online survey/questionnaires = 1 hour; Interaction with mobile application = minimum of 2 minutes per day for 8 weeks (total of approx. 2 hours) up to as much time as the participant wants to spend interacting with the mobile application per day for 8 weeks; completion of online measures at data points 2 and 3 = 1 hour total) Part 4 participants an independent sample Part 5 semi-structured interviews = 1 hour Part 5 participants a subgroup of part 4 participants

List data collection tools (e.g., measures, questionnaires, observational tool) below by clicking the 'Add Line' button. Include additional rows for study instruments, as needed:

The 'Columns' button allows you to display or hide columns in the Study Instrument List.

Name of Tool:

Data will be collected through focus groups; an 18-item questionnaire based on the System Usability Scale (SUS), two 6-item scales based on the Technology Acceptance Model (TAM), PHQ9, GAD7, CDC HRQOL4, Coping 1, Coping 2 questionnaires; a demographic survey; and a post-pilot interview All potential subjects will complete the PHQ-9 to determine eligibility.All surveys, measures, and questionnaires will be completed via REDCap link. Part 1 –Focus group participants will complete a short demographic survey and a survey about their experience participating in a focus group via Zoom. Focus groups will be guided by the focus group question guide(s) included with this application Part 2 – Design workshop participants will complete a short demographic survey. Part 3 – Focus group participants will complete a short demographic survey. Focus group will be guided by the focus group guides low-fidelity FG and high-fidelity FG included with this application Part 4 – Pilot test participants will complete a short demographic survey; SUS, TAM, PHQ9,

GAD7, CDC HRQOL4, Coping 1, and Coping 2 questionnaires at baseline, the end of week 3 and the end of week 6 of the pilot study. Part 5 – Post-pilot interview participants will complete a short demographic survey and an approximately 60 minute interview guided by the Post-Pilot Interview guide included with this application.

Is the data collection tool standardized or validated?
No, submit a copy of the draft or final tool in the Attachments Section

Will this study require clinical items/ services from UC Irvine Health?
No

Does the research involve the use of identifiable private information?
No

Sharing Results with Subjects

Will Individual results be shared with subjects?
No

Will overall study results will be shared with subjects?
N/A, final study results will not be shared with subjects

Risk Assessment

Risks and Discomforts

1. Describe and assess any reasonably foreseeable risks and discomforts associated with each procedure for each subject population — physical, psychological, social, legal or other:

2. If this study will involve the collection of identifiable private information, even temporarily, for which the disclosure of the data outside of the research could reasonably place the subjects at risk, include the risk of a potential breach of confidentiality:

Possible risks/discomforts associated with the study are risk for feeling discomfort in discussing (focus group) mental health because some people find this to be a sensitive topic. A second potential risk is breach of confidentiality. However, please know we will safeguard data to the best of our ability, and we will follow all procedures described in this application to protect data and ensure the security of data.

[ü] This study involves the collection of participant identifiable data (even if temporary such as for recruitment or compensation purposes), and as such, a breach of confidentiality is a risk associated with the research.

Discuss what steps have been taken and/or will be taken to prevent and minimize any risks/potential discomforts to subjects:

The two primary potential risks in this study are (1) subject could potentially feel discomfort in discussing mental health—some people find to be a sensitive topic—and (2) potential risk for breach of confidentiality. (1) To minimize potential risk for (1), we will instruct all subjects that they may decline to answer any questions they do not want to answer or makes them feel uncomfortable. Subjects do not have to use their real names and can create an alias name to use for the Zoom focus group and design workshops. All subjects will be supplied with a mental health resource

sheet during initial eligibility screening and at the beginning of the study so they can seek assistance if needed. (2) To minimize potential risk (2), we will ensure the information collected by the C-STRESS application will be protected with password access and designed with security standards that are HIPAA-compliant for security and privacy.

Certificate of Confidentiality

Is the research partially or wholly funded by NIH (including NIH Institutes and Centers), or does the research involve identifiable sensitive information that require CoC protections?

Yes

Indicate whether the research is protected by a NIH Certificate of Confidentiality (CoC):

This research is partially or wholly funded by NIH, including NIH Institutes and Centers. A CoC is automatically issued

Indicate in what situations identifiable private information protected by a CoC will be

Indicate in what situations identifiable private information protected by a CoC will be disclosed (**check all that apply**):

As required by Federal, State, or local laws, excluding instances of disclosure in any Federal, State, or local civil, criminal, administrative, legislative, or other proceeding. Some examples are laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others

When necessary for the medical treatment of the individual to whom the information, document, or biospecimen pertains and disclosed with the consent of such individual

Disclosed with the consent of the individual to whom the information, document, or biospecimen pertains

Disclosed for the purposes of other scientific research that is in compliance with applicable Federal regulations governing the protection of human subjects in research

Potential Benefits

Is there the prospect of a direct benefit anticipated for subjects?

No

Specify the expected potential societal/scientific benefit(s) of this study:

However we believe there are potential benefits to society. The subjects' opinions and feedback will help the study team develop a mobile app that would be available to general public of college students to help them with their mental health. We believe this research could also help advance knowledge in the field of college mental health and the use of mobile applications to better promote the mental health of college students in the future.

Alternatives to Participation

Describe the alternatives to participation in the study available to prospective subjects. Include routine (standard of care) options as well as other experimental options, as applicable (check all that apply):

applicable (**Check all that apply**):

No alternatives exist. The only alternative to study participation is not to participate in the study

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Participant Compensation

Will subjects be compensated or reimbursed?

Yes

Specify whether compensation is applicable and, if so, the method, amount and schedule of compensation (Check all that apply):

Gift Card

Specify gift card type and amount:

Amazon gift cards - see schedule

Gift Card schedule:

Other

Specify 'Other' gift card schedule:

Subjects will be compensated with the following schedule: Part one Focus Group: Subjects will receive $30 monetary compensation in the form of a gift card for focus group participation and brief demographic and Zoom Focus Group Experience survey. Part two Design-Oriented Workshops: Subjects will receive $30 monetary compensation in the form of a gift card for each session in which they participate. Participants that complete the focus group and all design work shops will receive an additional $30 in giftcards. In summary, participants who complete the focus group and all design workshops will for a total max compensation of $150. Part three focus groups: Subjects will receive $30 monetary compensation in the form of a gift card for participating in the focus group session. Part four pilot test: Participants will receive a total of $80 monetary compensation in the form of gift cards for

a total of $80 monetary compensation in the form of gift cards for participation in the pilot study according to the following schedule: $20 gift card after completing demographic survey, downloading C-STRESS app, completing on-boarding, and completing baseline measures (SUS, TAM, PHQ9, GAD7, CDC HRQOL4, Coping 1, Coping 2); $30 gift card after completing 7 measures (SUS, TAM, PHQ9, GAD7, CDC HRQOL4, Coping 1, Coping 2) at end of week 3; $30 gift card after completing 7 measures (SUS, TAM, PHQ9, GAD7, CDC HRQOL4, Coping 1, Coping 2) at end of week 6. Part five - Eight randomly selected pilot study participants will be invited to complete a post-pilot interview to provide feedback about C-STRESS. Participants that take part in this interview will receive a $30 gift card.

Will the gift card compensation method include all subjects?

Yes

Will subjects be reimbursed for out-of-pocket expenses?

No

Confidentiality of Research Data

Information and/or Biospecimens Storage

Indicate how information and/or biospecimens (including signed consent forms) will be stored (check all that apply):

Information will be maintained electronically. Information will be password protected and maintained in an encrypted format

Encrypted Format

Specify where the information will be maintained electronically:

Data will be stored at UCI, in RedCap or Qualtrics. Data will be stored as

Data will be stored at UCI, in RedCap or Qualtrics. Data will be stored as an encrypted file with password protection on a secure drive that is HIPAA-compliant for security and privacy maintained by UCI.

Will subject/patient identifiers be collected or retained?

Yes

Subject/Patient Identifiers

Will any subject/patient identifiers be collected or retained for data analysis, recruitment, consenting and/or compensation (check all that apply)?

All elements of dates (except year) for dates that are directly related to an individual: birth date, admission date, discharge date, death date, and all ages over 89
Email addresses
Full-face photographs and any comparable images
Names
Telephone numbers

Will a code be used to link subject/patient identifiers with the information and/or biospecimens?

A code will be used. Subject/Patient identifiers will be kept separately from the information and/or biospecimens. The code key will be destroyed at the earliest opportunity, consistent with the conduct of this research

Will research data/biospecimens be transported or maintained on portable devices (e.g., laptop, smartphone, external hard drive, etc.)?

No

Specify who will have access to subject/patient identifiable information/biospecimens as part of this protocol (check all that apply):

Authorized UCI personnel (such as the research team) and appropriate institutional officials; such as the

Specify 'Other' group or personnel who will have access to subject/patient identifiable information/biospecimens:

Non-UCI collaborating researchers (see Appendix U)

Institutional officials: such as the Office of Human Research Protections (OHRP) Regulatory entities such as the Food and Drug Administration (FDA), the National Institutes of Health (NIH)
Other

Specify whether subject/patient identifiers be disclosed in presentations and/or publications:
Subject/Patient identifiers will not be disclosed

Specify how long all subject/patient identifiers will be retained. This includes identifiers stored in paper format, stored electronically as well as video recordings, audio recordings, photographs, etc.:
Destroyed after publication/presentation or end of protocol

Will any identifiable photos or audio/video recordings be collected or used?
Yes

Collection of Photographs, or Audio/Video Retention & Recording

Will identifiable audio recordings be collected?
Yes

How will the audio recordings be transcribed?
Identifiable audio recordings transcribed by the study team

Specify timeframe for the audio transcription:
60 days

Will the identifiable audio recordings be de-identified?
Yes

Specify timeframe for the audio recordings de-identification and how will the recordings be de-identified:
60 days. Participant name will be replaced with participant study ID# in transcription

Will identifiable video recordings be collected?
Yes

How will the video recordings be transcribed?
Identifiable video recordings transcribed by the study team

Specify timeframe for the video transcription:
60 days

Will the identifiable video recordings be de-identified?
Yes

Specify timeframe for the video recordings de-identification and how will the recordings be de-identified:
Participants 60 days. Participant name will be replaced with participant study ID# in transcription

Will identifiable photographs be collected?
No

Research Information and/or Biospecimens Retention

Indicate how long research information/biospecimens will be retained:
Other

Specify time frame and provide the rationale for research information and/or biospecimens retention:
Audio or video recordings destroyed within 60 days of the completion of final transcription and analyses..

Will research information and/or biospecimens be shared?
No

Attachments

If required documentation is not provided, the submission is incomplete and your Application will be returned to you. Be sure to upload each document as required. If changes are needed, go back to the sub-section to revise your selections.

All UCI templates are available on the Applications & Forms page, subsections "Human Research Protections or Human Stem Cell Research"

To access approval documents where UCI will rely on another IRB, including commercial IRBs, visit their respective online portals. Frequently used commercial IRB portals include:

- WIRB Copernicus Group's WCG IRB Connexus
- Advarra's CIRBI

Attachment

2019-5345 DEMOGRAPHIC BACKGROUND INFORMATION QUESTIONNAIRE 8-12-20_NORMAL_391884.DOC

Attachment Type

File Comments

File Name

Status (IRB/hSCRO Use Only)

Approved

Attachment

2019-5345 FOCUS GROUP ZOOM QUESTIONS 8-12-20_NORMAL_391889.DOCX

Attachment Type

File Comments

File Name

Status (IRB/hSCRO Use Only)

Approved

Attachment

2019-5345 IIA (DICLEMENTE) 8-12-20_NORMAL_391890.PDF

Attachment Type

File Comments

File Name

Status (IRB/hSCRO Use Only)

Approved

Attachment

2019-5345 PHQ-9 8-12-20_NORMAL_391891.PDF

Attachment Type

File Comments

File Name

Status (IRB/hSCRO Use Only)

Approved

Attachment

2019-5345 RESOURCE SHEET 8-12-20_NORMAL_391894.DOCX

Attachment Type

File Comments

File Name

Status (IRB/hSCRO Use Only)

Approved

Attachment

2019-5345 SOCIAL MEDIA RECRUITMENT 8-12-20.DOCX_NORMAL_391895.DOCX

Attachment Type

Recruitment Material

File Comments

File Name

Status (IRB/hSCRO Use Only)

Approved

Attachment

2019-5345 SOCIAL MEDIA RECRUITMENT 8-12-20.DOCX_APPROVED_391895.PDF

Attachment Type

Recruitment Material

File Comments

File Name

Status (IRB/hSCRO Use Only)

Approved

Attachment

2019-5345 MOD 28596 APPROVAL LETTER 3-2-21_APPROVED_405520.PDF

Attachment Type

File Comments

File Name

Status (IRB/hSCRO Use Only)

Approved

Attachment

2019-5345 FOCUS GROUP INTERVIEW GUIDE 3-2-21_NORMAL_405521.DOCX

Attachment Type

File Comments

File Name

Status (IRB/hSCRO Use Only)

Approved

Attachment

2019-5345 FOCUS GROUP RECRUITMENT POSTER 3-2-21_NORMAL_405522.DOCX

Attachment Type

Recruitment Material

File Comments

File Name

Status (IRB/hSCRO Use Only)

Approved

Attachment

2019-5345 FOCUS GROUP RECRUITMENT POSTER 3-2-21_APPROVED_405522.PDF

Attachment Type

File Comments

File Name

Status (IRB/hSCRO Use Only)

Attachment

2019-5345 FOCUS GROUP SOCIAL MEDIA RECRUITMENT 3-2-21_NORMAL_405523.DOCX

Attachment Type

Recruitment Material

File Comments

File Comments

File Name

Status (IRB/hSCRO Use Only)

Approved

Attachment

2019-5345 FOCUS GROUP SOCIAL MEDIA RECRUITMENT 3-2-21_APPROVED_405523.PDF

Attachment Type

Recruitment Material

File Comments

File Name

Status (IRB/hSCRO Use Only)

Approved

Attachment

2019-5345 FOCUS GROUP STUDY INFORMATION SHEET 3-2-21_NORMAL_405524.DOCX

Attachment Type

Study Information Sheet

File Comments

File Name

Status (IRB/hSCRO Use Only)

Approved

Attachment

2019-5345 FOCUS GROUP STUDY INFORMATION SHEET 3-2-21_APPROVED_405524.PDF

Attachment Type

Study Information Sheet

File Comments

File Name

Status (IRB/hSCRO Use Only)

Approved

Attachment

2019-5345 PRE-SCREEN QUESTIONNAIRE 3-2-21_NORMAL_405525.DOCX

Attachment Type

File Comments

File Name

Status (IRB/hSCRO Use Only)

Approved

Attachment

20195345 EXAMPLE OF A LOW-FIDELITY WIREFRAME 03-16-22.DOCX

Attachment Type

Data Collection Tool/Instrument

File Comments

File Name

Status (IRB/hSCRO Use Only)

Attachment

20195345 FG PRE-SCREENER RECRUITMENT QUESTIONNAIRE 03-16-22.DOCX

Attachment Type

Data Collection Tool/Instrument

Data Collection Tool/ Instrument

File Comments

File Name

Status (IRB/hSCRO Use Only)

Attachment

20195345 FG RECRUITMENT POSTER 03-16-22.DOCX

Attachment Type

Recruitment Material

File Comments

File Name

Status (IRB/hSCRO Use Only)

Approved

Attachment

20195345 FG RECRUITMENT POSTER 03-16-22.PDF

Attachment Type

Recruitment Material

File Comments

File Name

Status (IRB/hSCRO Use Only)

Approved

Attachment

20195345 FG SOCIAL MEDIA RECRUIT 03-16-22.DOCX

Attachment Type

Recruitment Material

File Comments

File Name

Status (IRB/hSCRO Use Only)

Approved

Attachment

20195345 FG SOCIAL MEDIA RECRUIT 03-16-22.PDF

Attachment Type

Recruitment Material

File Comments

File Name

Status (IRB/hSCRO Use Only)

Approved

Attachment

20195345 PILOT RECRUITMENT POSTER 03-16-22.DOCX

Attachment Type

Recruitment Material

File Comments

File Name

Status (IRB/hSCRO Use Only)

Approved

Attachment

20195345 PILOT RECRUITMENT POSTER 03-16-22.PDF

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Recruitment Material

File Comments

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Approved

Attachment

20195345 PILOT SOCIAL MEDIA RECRUIT 03-16-22.DOCX

Attachment Type

Recruitment Material

File Comments

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Status (IRB/hSCRO Use Only)

Approved

Attachment

20195345 PILOT SOCIAL MEDIA RECRUIT 03-16-22.PDF

Attachment Type

Recruitment Material

File Comments

File Name

Status (IRB/hSCRO Use Only)

Approved

Attachment

20195345 STEP 3 03-16-22.PDF

Attachment Type

Data Collection Tool/Instrument

File Comments

File Name

Status (IRB/hSCRO Use Only)

Attachment

20195345 STEP 4 03-16-22.PDF

Attachment Type

Data Collection Tool/Instrument

Data Collection Tool/Instrument

File Comments

File Name

Status (IRB/hSCRO Use Only)

Attachment

20195345 STEP 5 03-16-22.PDF

Attachment Type

Data Collection Tool/Instrument

File Comments

File Name

Status (IRB/hSCRO Use Only)

Attachment

20195345 STUDY INFORMATION SHEET (FG) 03-16-22.DOCX

Attachment Type

Study Information Sheet

Study Information Sheet

File Comments

File Name

Status (IRB/hSCRO Use Only)

Approved

Attachment

20195345 STUDY INFORMATION SHEET (FG) 03-16-22.PDF

Attachment Type

Study Information Sheet

File Comments

File Name

Status (IRB/hSCRO Use Only)

Approved

Attachment

20195345 STUDY INFORMATION SHEET (PILOT) 03-16-22.DOCX

Attachment Type

Study Information Sheet

File Comments

File Name

Status (IRB/hSCRO Use Only)

Approved

Attachment

20195345 STUDY INFORMATION SHEET (PILOT) 03-16-22.PDF

Attachment Type

Study Information Sheet

File Comments

File Name

Status (IRB/hSCRO Use Only)

Approved

Attachment

20195345 AMENDMENT APPROVAL 03-16-22.PDF

Attachment Type

UCI IRB Approval Letter

File Comments

File Name

Status (IRB/hSCRO Use Only)

Approved

Lead Researcher Certification

Investigator's Assurance

As Lead Researcher, I have ultimate responsibility for the performance of this study, the protection of the rights and welfare of the human subjects, and strict adherence by all co-investigators and research personnel to all Institutional Review Board (IRB) requirements, federal regulations, and state statutes for research involving human subjects.

I hereby assure the following:

1. The information provided in this application is accurate to the best of my knowledge.
2. The information provided in this application has been discussed and shared with my Department Chair. Any requests for changes based on this discussion are included in this application upon submission or will be initiated by the research team either during the IRB review process or via an amendment.
3. All named individuals on this project have read and understand the procedures outlined in the protocol and their role on the study.
4. All named individuals on this project have completed the required Educational research tutorials and have been made aware of the "Common Rule" (45 CFR Part 46), applicable Food and Drug Administration (FDA) regulations (21 CFR Parts 50, 56, 312 and 812), have read the Belmont Report, and UCI's Federalwide Assurance (FWA) that are available on the Human Research Protections Program (HRP) website.
5. All experiments and procedures involving human subjects will be performed under my supervision or that of another qualified professional listed on this protocol.

6. I understand that, if the study described in this IRB application is supported by a federal award or used as a basis for a proposal for funding, it is my responsibility to ensure that the description of human subjects activities in the proposal/award is identical in principle to that contained in this application. I will submit modifications and/or changes to the IRB as necessary to assure the proposal/award and application are identical in principle.

I and all co-investigators and research personnel agree to comply with all applicable requirements for the protection of human subjects in research including, but not limited to, the following:

1. Obtaining the legally effective informed consent of all human subjects or their legally authorized representatives (unless waived) and using only the currently approved, stamped consent form (if applicable).
2. Per federal regulations, once a human research study has received IRB approval, any subsequent changes to the study must be reviewed and approved by the IRB prior to implementation except when necessary to avoid an immediate, apparent hazard to a subject. See Reporting of Unanticipated Problems.
3. Reporting any unanticipated problems involving risk to subjects or others, including protocol violations per UCI IRB policy. In addition, HIPAA privacy violations must be PROMPTLY disclosed to the UCI Privacy Officer. There are time requirements for reporting these breaches of confidentiality, which, if not met, may result in monetary damages to the researcher and the institution.
4. Responding appropriately to subjects' complaints or requests for information about the study; and reporting to the IRB any subject complaints that are not resolvable by the study team.
5. Promptly providing the IRB with any information requested relative to the project.
6. Assuring the appropriate administration and control of investigational test articles (i.e., investigational drugs, biologics or devices) by a qualified investigator or other appropriate individual or entity (e.g., UCI Health pharmacy), and assuring use and maintenance of an Investigational Drug/Biologic Accountability Log or Device Accountability Log.
7. Registering applicable clinical trials with clinicaltrials.gov. For more information about this topic, visit the ClinicalTrials.gov web page or the HRP webpage. The consequences of not meeting the registration and reporting requirements include monetary damages to the researcher and the institution.
8. Obtaining continuing review prior to study expiration (I understand if I fail to apply for continuing review, approval for the study will automatically expire, and all human research activities must cease until IRB approval is obtained).
9. Promptly and completely complying with an IRB decision to suspend or terminate its approval for some or all research activities.
10. Submitting to a routine review of human subject research records. The Compliance & Privacy Office at UCI Health performs ongoing routine reviews of open biomedical research protocols, in an effort to ensure in part that human subject research activities

are conducted in accordance with regulations, laws and institutional policies regarding the protection of human subjects. In addition, the HRP unit of the Office of Research has developed the Education Quality and Improvement Program (EQUIP). Through EQUIP, HRP staff conduct periodic quality improvement monitoring and educational outreach.

11. For clinical trials initially approved by the IRB on or after January 21, 2019, posting one (1) IRB-approved clinical trial consent form at a publicly available federal website. The consent form must be posted after recruitment closes, and no later than 60 days after the last study visit. For additional guidance, refer to the OHRP FAQs on Informed Consent.

12. Filing a final report with UCI HRP at the conclusion of this project.

As the Lead Researcher, I assure all of the above

Financial Disclosure

Investigators' Disclosure of Financial Interest

In order to inform research subjects of circumstances that may affect their decision to participate in this study, all researchers are required to disclose their financial interests with outside institutions.

The Lead Researcher of the protocol must ask the following question of all study team members:

"Do you, your spouse/registered domestic partner, and dependent children together have any disclosable financial interests (i) that would reasonably appear to be affected by the research; or (ii) in entities whose financial interests would reasonably appear to be affected by the research?"

A member of the study team who answers in the affirmative will be contacted by the Conflict of Interest Oversight Committee (COIOC) to obtain additional information regarding their specific financial interest(s).

IMPORTANT! If there has been a change in the financial disclosures of the LR or the study team, please also request a 'Change in Financial Interests'.

As Lead Researcher, I certify that the disclosures for all study team members are accurate

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End of form. Please review responses for accuracy and

End of Form. Please review responses for accuracy and completeness.

Please ignore the Admin Details Section below. This section is for IRB/hSCRO use only.

Administrative Details Form

General Information

ERA Transcribed

November 18, 2021

Pre-2018 Common Rule

No

Review Type

Minimal Risk

Research Type

Social/Behavioral/Educational

Study Status

Amendment Type:

Right to Try

No

Clinical Phase of Study

Not Applicable

COVID-19

No

Research Department

Sue and Bill Gross School of Nursing

Author

Investigator Authored

To be Destroyed Date

December 31, 1969

Scientific Scheduled Review Type

Dept

Clinical Trial

No

NCT #

Legacy Systems (HRP/hSCRO Only)

Link to HPS or hSCRO Report

Link to FileNet Documents

Subject Population Tab

Project Allocation

100

Subject Group
NONE - Use of identifiable or coded data, specimens, records, charts

Subject Notes

Subject Group
COMP - Adults Competent to Provide Informed Consent

Subject Notes

Subject Group
UCI - UCI students/staff/faculty

Subject Notes

Procedures Tab

PHI

No

Procedure Type
ISQ Surveys/Questionnaires/Interviews/Oral Histories

Procedures Notes

Procedure Type
DATACOLL Audio, Video, Digital or Image Recording and/or Photography for Collection of Research Data

Procedures Notes

Drugs Tab

Devices Tab

Sites Tab

Sites
UCI Facilities or Sites (e.g. school, hospital or clinics, etc.)

Sites
Locations within the United States

Funding Tab

KR Award Report

https://cognos.oit.uci.edu/ibmcognos/bi/?pathRef=.public_folders%2FOffice%2Bof%2BResearch%2FReports%2FCampus%2FDrill-Through%2BReports%2FINCR-OR-012-Protocol%2BFunding%2BLookup&ui_appbar=true&ui_navbar=false&prompt=false&p_param_Protocol_ID=19471

Consent Tab

Reliance Tab

Agreement

Reviewing Site