PROTOCOL TITLE: Expanding College Student Mental Health with Stress Management Mobile Technologies – Extended Usability Pilot Trial

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VERSION DATE:
June 26, 2020

Objectives:

This research project aims to develop and test a Student Stress Management (SSM) mobile program, a suite of apps based within the framework of an evidence-based treatment for depression and anxiety that will be integrated within a student health system. This program will improve engagement with mental health services by serving as an access point to mental health treatment options, and providing an opportunity for self-guided treatment. The SSM program will feature components known to be effective both for engagement (symptom assessment and promotion of care accessibility) and treatment (thought restructuring, relaxation exercises, and behavioral activation). Within the suite, students will be prompted to complete symptom assessments on a weekly basis, and those with elevated symptom scores will be provided with feedback and recommendations for on-campus services. All users will be able to access and use interactive treatment apps. The program will be developed with the University of Illinois at Chicago (UIC) and Northern Illinois University (NIU) counseling centers, and will be made available to all UIC and NIU students. These studies will establish a research program that will expand the reach of services and ease the burden of untreated depression and anxiety for college students.

Phase 1 Aim: Develop the SSM program by refining a mobile smartphone intervention and develop an optimized multi-component implementation strategy using a user-centered design process. We will start from a suite of apps developed for a general population and, based on needs reported by current students and mental health care providers, they will be optimized for the college student population alongside development of an implementation plan and evaluation metrics. Laboratory-based usability testing and an 8-week field trial will be included as part of the iterative design process to ensure that SSM works optimally both in individual interactions, as well as cumulatively over time.

Background:

College student mental health problems. With rising rates of students demonstrating clinically significant symptoms of depression and anxiety, there has been a broadly recognized college student mental health crisis in recent years. As students face increased stress and academic pressures, 85% of college students report feeling overwhelmed by demands over the last year. In a national survey of college students, 20% screened positive for moderate-severe depressive symptoms, and 20% screened positive for moderate-severe anxiety symptoms. However, many students have low mental health literacy as they do not recognize a need for treatment, believing that these depression and anxiety symptoms are typical college stress. As nearly 70% of Americans enroll in college following high school (and even more in subsequent years), this is an important point for intervention. At this life phase, untreated mental illness can have life-long impacts, including increased risk of substance use, academic failure, and impaired

relationships. Untreated depression is the number one cause of suicide, which is the second leading cause of death for this age group.

Insufficient access to mental health resources for college students. While many students do not recognize a need for treatment, students who do recognize a need often endorse difficulties accessing care, perceive care available as inconvenient, and are skeptical about the efficacy of care. Campus counseling centers are well-positioned to provide mental health care. For many students, particularly those from low-income backgrounds without access to a parent's insurance plan, these centers are the main option for affordable care. However, many counseling centers across the country are under-resourced, have difficulty reaching students in need of treatment, and while there are seasonal variations in capacity, are at full capacity during much of the year. Students are increasingly being seen in crisis, rather than when symptoms are moderate. Over the last 6 years, rates of students presenting to these clinics with symptoms of depression and anxiety trended upward, and utilization of crisis services have increased by 28%. ***There is a clear, immediate need to develop accessible methods for delivering effective mental health care to college students.***

Need for alternative methods of care delivery Developing accessible and effective interventions could facilitate early management and treatment of symptoms – saving many individuals from the detrimental impact of untreated mental illness including social, emotional, and financial costs. Behavioral intervention technologies (BITs), including smartphone apps, offer the possibility to expand treatment options and to reduce barriers to services. Internet-based CBT has demonstrated efficacy for treating a wide range of mental health concerns, and self-guided treatments are known to be effective for treating common mental health problems such as depression. Early work suggests that programs delivered via mobile phone are comparably efficacious while circumventing some barriers to computer-based treatments. As smartphones are often carried throughout the day, apps provide access in the real-world conditions of individuals with mental health concerns. Thus making apps an accessible method for delivering mental health care to students, which could keep students with lower levels of distress well-managed and not in need of counseling center appointments.

Potential in Mental Health Apps Commercially available mental health apps have been rapidly emerging over recent years, and demand for them is high. In the U.S., 85% of 18-29 years olds own a smartphone, and more than 75% of Americans are interested in free mobile apps aimed at mental health management and treatment. While interest exists, few existing apps have been subject to empirical evaluation, fewer have demonstrated clinical efficacy, and those that demonstrated efficacy are typically not available to the general public. Appropriate mental health apps are challenging for individuals to locate, leading users to face significant barriers to find something trustworthy and useful. Empirically tested app-based programs are needed to fully realize the promise and potential for their use in clinical care.

Mental Health Technologies for College Students. College students are ideal candidates for mental health technologies. Research on mental health help-seeking in young adults has identified a preference for self-reliance and low mental health literacy, resulting in a failure to recognize symptoms as signs of treatable mental health conditions, as the most important barriers to seeking care. These barriers are a toxic combination but are prime targets in which BITs can facilitate mental healthcare. By providing a program that includes self-guided treatment, we can appeal to a preference for self-reliance and facilitate program engagement to promote mental health literacy and provide further referrals when students need services. A recent RCT of a web-based suicide risk screening program for college students found that the provision of personalized feedback, with the option of online counseling based on motivational interviewing, had a significant impact on students' readiness to consider mental health treatment, and these students were more likely to link up with mental health services. However, there were relatively low levels of engagement with the site, and authors noted the site's subpar user interface likely contributed to low utilization by students.

BITs for college students need to be strategically designed to promote use. College students today are digital natives confident about their ability to access and navigate digital interfaces, and, counter to older adults, tend to view usability issues as the fault of the program or website. There are challenges in engaging these users to continue to interact with new technologies. Young adults are seen to exhibit distinct preferences in interface design relative to both teenagers and older adults, and they are quick to dismiss tools that do not meet their expectations. In the general population, 1 of 5 apps downloaded are only used once. The risks of BIT rejection/non-use are greater among young adults, and can likely be prevented with appropriate design. User centered design processes and usability testing, widely used methods from the field of Human-Computer Interaction (HCI), are vitally important to develop usable, useful programs. Once developed, it can be a challenge to get these programs into the hands of people who could benefit from them. Thus, implementation plans must be carefully developed and iterated upon as necessary. Implementation scientists have outlined 73 discrete implementation strategies; however, use of a single strategy is rare and a multicomponent implementation plans are typically developed to address multiple barriers within a system. Identification of implementation strategies likely to be successful in a setting is key to program success.

To evaluate the needs and preferences of college students seeking digital mental health resources, I conducted a pilot study of an internet-based cognitive-behavioral therapy (iCBT) program with 15 college students and collected user feedback. The iCBT program was rated usable and useful, with an average of 12 logins over the 6-week trial period (range: 2–35 logins), and nearly three-quarters of participants indicated that they would recommend it to a friend. From baseline to end of treatment, students reported an increase in use of cognitive-behavioral coping strategies, $t(10)=3.40, p=.007$, and a trend was observed for decreased levels of stress, $t(11)=2.12$, $p=.058$. However, many students reported that making time to be in front of a computer was a barrier to program use. A majority reported interest in app-based programs, noting a greater likelihood of frequently utilizing program content and tools if easily accessible on their phones. Based on these data, the proposed project will use smartphone apps to deliver program content and tools.

Apps used in this study are drawn from IntelliCare and will be optimized based on feedback from participants in Phase 1. IntelliCare is a suite of clinical apps, developed at CBITs, that feature different methods of managing mental health. To fit with standard app use patterns, the apps are lightweight and designed to be used in short bursts of time. In conjunction with ongoing trials, the IntelliCare apps were made freely available. In the first 18 months of public availability, 8,293 individuals downloaded one or more of the apps, for a total of 19,852 downloads.

Inclusion and Exclusion Criteria:

Participants include both students, counselors, and administrative staff members of the University of Illinois at Chicago and Northern Illinois University. Students, to be included in all phases of the study, will be 18 years of age or older, English-speaking, familiar with smartphones, and living in the university communities (e.g. not studying abroad). Counselors and administrative staff members will be current employees at the University of Illinois at Chicago Counseling Center or at Northern Illinois University's Counseling & Consultation Services. Potential participants for Phase 1 will be excluded for visual, hearing, voice, or motor impairment that would prevent completion of the study procedures or use of mobile phone; diagnosis of a psychotic disorder, dissociative disorder, or other diagnosis for which participation in this trial is inappropriate, or severe suicidality (has ideation, plan, and intent). For

Phase 1, Stages III and IV, student participants will have clinically elevated symptoms (defined by scores ≥ 10 on the PHQ-9 or GAD-7). For Phase 1, Stage V, half of the participants will have elevated symptoms of depression or anxiety as measured by scores ≥ 10 on either the PHQ-9 or GAD-7, and half of the participants will not have elevated scores on either measure. Participants in Phase 1, Stage V will also need to own an Android-operating or iOS-operating smartphone with a system that operates Android 7 or higher or iOS 11 or higher.

The follow populations will be excluded from the study:

a. Adults unable to consent

b. Individuals who are not yet adults (minors): infants, children, teenagers

c. Pregnant women (where the activities of the research may affect the pregnancy or the fetus.)

d. Prisoners or other detained individuals.

Study-Wide Number of Participants:
In Phase 1, a total of 48 students and 20 counseling center staff members will participate in user-centered design for, and usability testing of, a mobile app intervention aimed at facilitating engagement with existing services, and at reducing depressive and anxious symptoms through self-guided treatment tools.

Stage I is a co-design workshop will involve 28 students and 12 counseling center staff members in order for both parties to share their design ideas with each other in order to better inform the design of the program.
Stage II is an online questionnaire that will be sent to counseling center staff members at both counseling centers. We anticipate that 20 staff members will complete the questionnaire.
Stage III consists of individual semi-structured interviews (n = 20) which will occur in single sessions. Similar to Stage I, students and counseling center staff members will share their needs, preferences, and implementation ideas for the mobile app program and its development on an individual and confidential basis.
Stage IV consists of laboratory-based usability testing (n=15) in which we will gain user feedback of an interactive model of the mental health mobile app program. These usability sessions will be approximately 45 minutes long and will be conducted on an individual and confidential basis.
Stage V, as part of extended usability testing, 20 students will be enrolled in an 8-week feasibility field trial of the intervention once all major issues identified by usability testers from Stage IV have been addressed. 10 students from each institution will be recruited for the trial. Each sample of ten will be composed of 5 students with elevated symptoms of depression or anxiety as measured by scores ≥ 10 on either the PHQ-9 or GAD-7, and 5 without elevated scores on either measure.

Study-Wide Recruitment Methods:
Stage I (co-design workshop): participants will be recruited via hard copy study advertisements, and via email by a member of the study team.
Stage II (online questionnaire to counseling center staff): participants will be recruited via email.
Stage III (individual semi-structured interviews): participants will be recruited in-person, via e-mail, and via hard copy study advertisements at the University of Illinois at Chicago (UIC) and Northern Illinois University (NIU) campuses. Individuals interested in participating will be able to call or e-mail study staff for more information, and students interested in participating will be

emailed a link to the study eligibility screening measure. Counseling center staff will not need to complete the eligibility screening measure as all counseling center staff members will be eligible to participate. Potential student participants recruited via non-electronic means (e.g. they contact the study staff by telephone) will be asked for their email address so that the consent and survey link will be emailed to them.
Stage IV (laboratory-based usability testing): participants will be recruited in-person, via e-mail, and via hard copy study advertisements at the University of Illinois at Chicago (UIC) and Northern Illinois University (NIU) campuses. Individuals interested in participating will be able to call or e-mail study staff for more information, and students interested in participating will be emailed a link to the study eligibility screening measure. Potential student participants recruited via non-electronic means (e.g. they contact the study staff by telephone) will be asked for their email address so that the consent and survey link will be emailed to them. Eligible participants will be scheduled for a usability session at their college counseling center. At this appointment, participants will read and sign a paper copy of the informed consent form and be provided a copy for their own records.
Stage V (8-week extended feasibility trial): Participants will be recruited in-person, online, via e-mail, and via hard copy study advertisements at the University of Illinois at Chicago (UIC) and Northern Illinois University (NIU) campuses. Online recruitment will be published to both public spaces and existing private groups with the permission of the private group administrators. Individuals interested in participating will be able to call or e-mail study staff for more information, and students interested in participating will be emailed a link to the study eligibility screening measure. Potential student participants recruited via non-electronic means (e.g. they contact the study staff by telephone) will be asked for their email address so that the consent and survey link will be emailed to them. Eligible participants will be emailed a link to the digital consent form. Subjects agree to participate by checking a “yes” box and typing in their name. They are instructed to print out the consent form for their records. Participants are enrolled remotely to avoid excluding participants with access barriers who are among those who would be likely end users. The digital consent form will describe the mobile app program, show participants how to add a PIN to their phone, and inform participants that data entered into the phone will be de-identified to the research team, those it cannot replace the need for contacting a mental health provider in the case of an emergency. These recruitment procedures are similar to those that have been approved by the Northwestern University IRB for prior studies conducted by our lab group.

Study Endpoints:
The primary study endpoint for Phase 1 is the development of the Student Stress Management program.

Procedures Involved:

***For Phase 1*:**

User-centered design and usability testing will be conducted in 5 iterative stages.

Stage I of user-centered design will consist of a 2 hour co-design workshop at each study site, a participatory design method with demonstrated ability to engage young adults to develop acceptable, efficacious technologies. The goal of this workshop will be to develop prototypes of the managing hub app and advertising materials of the SSM program. See attached for a proposed schedule of the co-design workshop and proposed design activities. Two workshops will occur at each study site, and at each of the 4 workshops, we aim to recruit 7 students and three mental health counselors will be recruited at each site for this stage, for a total of 40

participants. Participants will be given the option of receiving a text message reminder about the co-design workshop. Sessions will be video- and/or audio-recorded. While the end users of the SSM program will be students, input and expertise from mental health providers from the UIC and NIU counseling centers will be used to inform the design process to promote meaningful integration into the center's existing services. *Through the co-design workshop, we will bring together students and counselors to integrate stakeholder input into the final design of the program.*

Stage II is an online questionnaire in which counseling center staff members will complete implementation readiness and capacity assessments on their needs and goals, as well as the organizational factors that could facilitate or impede integration of the SSM program into the counseling center. This questionnaire will be sent to all counseling center staff mental health providers. We anticipate that 20 staff members will complete the questionnaire.

The goal of Stage III of user-centered design is to further identify needs and preferences for SSM program tools and implementation procedures. During recruitment for Stage III, interested students will be prompted to complete an online consent for Stage III and a survey determining depression and anxiety symptomology and eligibility before being invited to participate in an interview. The individual interviews will be 30-45 minutes with students with clinically elevated symptoms (defined by scores $\geq$ 10 on the PHQ-9 or GAD-7), and counseling center staff members (both mental health providers and administrative staff), who will complete a semi-structured interview and view advertising materials and low-fidelity paper prototypes of tools to be included in the SSM program. Staff members will be prompted to generate ideas and give feedback on metrics for assessing impact of the program on counseling center utilization (e.g. the number of appointments for crises, intakes, and follow-up therapy sessions, and level of depressive symptoms [as measured by the PHQ-9)] at intake). This stage guides our evaluation plan and proposed data informed implementation process in Phase 2 (described below). Recruitment will continue at each study site until we reach data saturation. We estimate a sample size of 10 participants per site, for a total of 20 participants, based on research demonstrating 95% of usability problems can be identified with 10 users. Use of paper prototypes, or mock-ups, is an established, cost-effective method for gaining user experience and usability data early in the design process. *This step will identify any design flaws before app development and programming are completed and will identify metrics for assessing program impact on utilization in Phase 2.*

Stage IV: Following app development and initial quality assurance testing by the research team, the next stage will consist of laboratory-based usability testing sessions. Student participants with elevated symptoms ($\geq$ 10 on either the PHQ-9 or GAD-7) will be recruited for 45 minute testing sessions. Participants will be audiotaped while using a "think aloud" framework to have them verbalize their thoughts when using the program to complete a set of tasks. For each task, we will use standard objective measures to empirically evaluate recommended attributes of system usability. Following the think aloud protocol, participants will complete a brief structured interview on the user experience of the program, including learnability, acceptability, and usefulness, and overall satisfaction with aesthetics and perceived efficiency. Recruitment will continue at each study site until we reach data saturation, and we estimate a sample size of 15. Participants will also complete brief quantitative questionnaires. Problems will be addressed as they are identified. This will ensure the apps are usable and acceptable for single use.

For Stage V, students will be recruited for an 8-week field trial in which they will be given the SSM program and encouraged to use it daily. To ensure a sample representative of likely end users, 10 students from each site will be recruited: 5 with elevated distress as measured by

scores ≥ 10 on either the PHQ-9 or GAD-7, and 5 without elevated scores on either measure, for a total of 20 participants. The rationale for 10 participants in each group is based on past usability research indicating saturation is typically reached within 10 participants. The aim of this trial is to identify software bugs and usability problems that emerge over extended use, and to examine preliminary effects of program use. During the trial, participants will be prompted to complete the PHQ-8 and GAD-7 on a weekly basis. At baseline, 4 weeks, and 8 weeks, participants will be prompted within the app to complete the Depression Literacy Questionnaire and Anxiety Literacy Questionnaire to measure mental health literacy, the Knowledge and Beliefs about Services scale to measure knowledge of campus mental health services, the Barriers to Mental Health Help-Seeking questionnaire to measure treatment barriers, and the Cognitive and Behavioral Response to Stress Scale to measure cognitive and behavioral coping skills. Additionally, at weeks 4 and 8 of the 8-week trial, we will conduct 30-minute semi-structured user feedback interviews to gain insights on the use of the study app. These interviews will be audio-recorded and conducted via telephone.

Data and Specimen Banking: N/A

Data and Specimen Management:
Data analysis plan for Phase 1: Qualitative data from interviews and quantitative data from questionnaires and video recordings from usability testing will be incorporated for mixed methods data analysis. This mixed methods approach was chosen because, while quantitative data can identify usability errors and dissatisfaction with program components, qualitative data provides guidance to the root of those errors and methods for program optimization. Qualitative data will be analyzed using a grounded theory approach, in which interviews will be analyzed using iterative codes that are used to identify core concepts, from which we will determine the needs, concerns, and impressions of our prototypes, implementation strategies and evaluation metrics. This analytic approach was selected due to the expectation that participants will raise unanticipated needs. Mean rating values of app components from the quantitative data will be calculated, and the components will lowest rated values will be flagged for further refinement. Video recordings of usability testing sessions will be coded for navigation errors (difficulty locating a function), content errors (difficulty due to labeling of information), and usage errors (improper tool use). For the extended usability study, app usage data will be examined in the form of descriptive statistics. Due to the small sample size of each symptom group (higher symptoms and lower syptoms), we will examine symptoms of depression and anxiety by subgroup in the form of descriptive statistics. Measures of our treatment targets (anxiety literacy, depression literacy, cognitive and behavioral coping skills) will be analyzed using Wilcoxon signed rank tests across higher symptom and lower symptom participants.Qualitative data will be analyzed using a thematic analytic approach.
Prior to moving to the hybrid implementation-effectiveness study, we will ensure that the program does not have a detrimental impact on students' self-reported symptoms, needs initially reported by the students and counselors are represented as components in the SSM program, and the components have a satisfactory rating or greater.

Protection for risks associated with potential loss of confidentiality. Data for all participants will be kept strictly confidential, except as mandated by law. All research files are kept on secure, password protected departmental and medical school servers. All electronic data will be stored on secure servers behind firewalls meeting all security requirements of the medical school. Any paper documentation is kept in locked file cabinets or a locked file room. Participants will be assigned a numerical code for identification in the files. Names and other identifiers will be kept

in separate password protected files. Audio data will be stored on secure servers and will only be available for coding by study staff. Online assessments will be conducted through REDCap. This platform uses up to date security measures that are consistent with those used by Electronic Medical Records and are HIPAA compliant. In Stages III - V of Phase 1, data for all participants who consent to participate in the screening will be kept, including those participants who are found ineligible to participate in these stages of the study and those participants who are eligible but decline to participate in these stages of the study.

Provisions to Monitor the Data to Ensure the Safety of Participants:
Adverse events will be reported by the PI to the Northwestern IRB, the NIMH Program Officer, and clinicaltrials.gov where the trials will be registered. The PI will closely monitor all incoming data, recruitment progress, and retention in assessments and treatment. For the eligibility screening measures for Phase 1, Stages III-V, student participants will respond to a question on suicidality, with suicidal ideation considered to be a score of 1 or higher on the ninth question of the Patient Health Questionnaire-9 (i.e., "Over the last 2 weeks, how often have you been bothered by thoughts that you would be better off dead or of hurting yourself in some way"). If a participant responds to the PHQ-9 item 9 with a score of 1 or higher, then the REDCap questionnaire will branch to item 9 from the Beck Depression Inventory:

0 I don't have any thoughts of killing myself.
1 I have thoughts of killing myself, but I would not carry them out.
2 I would like to kill myself.
3 I would kill myself if I had the chance.

If a respondent selects a 2 or 3 on this item, they will be prompted with the message "CBITs Health is NOT an emergency service. If you do not feel safe and need immediate police or medical assistance, call 9-1-1 or go directly to your nearest emergency room."

Incoming questionnaires will be monitored daily by study staff, and any participants who have selected a 2 or 3 on item 9 from the Beck Depression Inventory will be contacted via telephone by study staff who will administer the Columbia Suicide Risk Assessment (see attached). This measure has been used telephonically in past studies within the Center for Behavioral Intervention Technologies, and provides instructions on handling psychiatric emergencies.
In the case of a psychiatric emergency, all necessary efforts will be made to ensure the safety of the participant. This may include contacting psychiatric liaison teams in the local police department to conduct a health and safety check and possibly to hospitalize the patient participant. If the person assessing the individual is a staff member (e.g. RA), the staff member will immediately contact the PI. However, all staff will be trained in crisis management, in the event the PI or another licensed clinician on staff cannot be immediately contacted.
For all stages involving participant interviews, the PI (or one of the mentors if the PI is unavailable) will discuss responses to interviews with the assessor immediately after assessments should there be any concerns regarding participant safety or deterioration; otherwise, the PI will examine interview responses the same or next business day.
Participants in the user-centered design and early usability stages of this study will only enter the lab once to review treatment prototypes. This portion of the proposed research does not constitute a clinical trial and poses minimal risk.

For stage V the feasibility trial embedded in usability testing and the pilot study constitute a phase I, and an early phase II, clinical trial respectively. While the risk of this intervention is low, we are proposing use of an independent Data Safety Monitoring Board (DSMB) because there are two clinical sites. The independent Data Safety Monitoring Board (DSMB) that will oversee the study and offer guidance to the PI. The DSMB will meet at the discretion of the chair but not

less that once every 6 months. The chair, Michael Levin, PhD, was selected by Drs. Lattie and Mohr, and is external to Northwestern, UIC and NIU. To ensure that that chair will understand many of the issues we confront in this research and evaluate these issues as related to the safety of trial participants, requirements for the chair will include expertise with implementation trials, the treatment of depression, and digital mental health. Drs. Lattie and Mohr will be a non-voting members of the DSMB and will attend all meetings to provide and receive information. Study data will be reviewed for evaluation of the safety of the intervention and the procedures used to detect and respond to deterioration and/or suicidality. Reports from all meetings will be submitted to the NIMH Program.

Withdrawal of Participants:
Patients can be taken off the study treatment and/or study at any time at their own request, or they may be withdrawn at the discretion of the investigator for safety, behavioral or administrative reasons. The reason(s) for discontinuation will be documented and may include:

Patient voluntarily withdraws from treatment (follow-up permitted);

Patient withdraws consent (termination of treatment and follow-up);
Patient is unable to comply with protocol requirements.

Risks to Participants:
The proposed study poses minimal risks. All potential risks associated with participation in this study will be disclosed in consent documents. Any potential risks that might exist fall into four categories: (a) risks associated with the intervention; (b) risks associated with research assessments, consisting of questions about depression, anxiety, and personal functioning, and other mental and emotional problems; (c) risks associated with potential loss of confidentiality; and (d) risks of worsening mental or emotional state. We address each in turn below.
Risks of the intervention: Mobile phone based mental health intervention programs have not been shown to cause any harm.
Risks associated with research assessments: Research assessments include questions about depression and other mental and emotional problems. Participants will give voluntary responses to interview questions; they are told that they can decline to answer any questions that they choose. The instruments and methodologies are well tested and are not known to cause problems or distress on the part of the participants. All research interview-based assessments are audio-recorded, for the purpose of review to ensure quality assurance ratings of assessment performance, including ensuring that patients are comfortable with the interview procedures. Audiotapes will be maintained on a secure server with no identifying information in the labels for the duration of the funded study, unless other arrangements are made. On occasion patients may request that audio files be deleted before the end of the study, in which case we will comply.
Risks associated with potential loss of confidentiality. There is a slight risk of loss of confidentiality. While transmissions are protected using a Transport Security Layer and communication occurs within a secure messaging platform, there is some possibility that others may see the participant's open webpage or smartphone. Measures to protect security in these instances are described below. Confidentiality may be broken by research staff to ensure the patient's safety if there is an imminent threat to self or others. There is also the remote possibility that research records will be subpoenaed by a court of law. All of these potential losses of confidentiality will be disclosed in the consent documents.
Risks of worsening mental or emotional state and or self-harm thoughts/events: Some participants may show a worsening of depressive or anxious symptoms, suicidality or problems during the study period. The development of suicidal ideation during the study remains the most

serious risk. However, these are risks inherent in the population and would occur whether or not they were enrolled in the study. It is not believed that the risk of these depressive, anxious, suicidal, or other adverse outcomes are increased as a function of being enrolled in this study. All potential risks associated with participation in this study will be disclosed in consent documents.
Antidepressant medications are permissible within this trial. Treatment alternatives outside of the primary care setting include treatment from an outpatient psychiatrist or psychologist, electroconvulsive therapy, or inpatient treatment. The benefits of these alternatives are that they are evidence-based, more intensive and specialized.

Potential Benefits to Participants:
The potential benefits of participation are that some participants may receive support for their depression and anxiety. The potential to future patients is that the study may provide fundamentally new and more effective low-intensity treatment approaches that would be more widely available.

Vulnerable Populations: n/a

Community-Based Participatory Research: The user-centered design processes described in Phase 1, and the user feedback interviews described in Phase 2 will involve members of the community in both the design and conduct of the research.

Sharing of Results with Participants:
Aggregate results will be shared with participants at the conclusion of the research study through written summaries and infographics.

Setting:
The PI, Dr. Lattie, has an office within the Center for Behavioral Intervention Technologies (CBITs) within the Northwestern University Department of Preventive Medicine and has access to secure data storage through the Feinberg School of Medicine. The majority of research activities will take place online or on site at the University of Illinois at Chicago (UIC) Counseling Center and at Northern Illinois University (NIU) Counseling & Consultation Services.
The UIC Counseling Center has more than 25 rooms for individual therapies, three group therapy rooms, two or more smaller rooms for self-directed programming (e.g. biofeedback), and three furnished conference/multi-purpose rooms for workshops, staff meetings and gatherings that can each accommodate upwards of 25 people. Counseling Center staff also have access to larger conference spaces in their building and elsewhere on campus. NIU Counseling & Consultation Services operates in a space with 19 individual therapy rooms, a relaxation room (capacity 2-3 people, two group therapy rooms (capacity 10-12 people), and a conference room that can accommodate 20 people.

Resources Available:
The PI, Emily Lattie, is a licensed clinical psychologist and research assistant professor within the Department of Preventive Medicine. Dr. Lattie has training and expertise in mobile and web-based interventions, and more recently, has begun working on methods to leverage technologies to expand mental health care accessibility for university students. Dr. Lattie has built strong relationships with the directors of the UIC and NIU counseling centers. The mobile app programmer who is scheduled to work on this project has several years of experience building mobile mental health apps, and has collaborated with researchers from the Center for Behavioral Intervention Technologies for the past 10 years.

Both universities involved in this study have large student bodies, and serve more than 1,000 students per year. Based on the size of these student bodies, it is expected that it will be feasible to recruit the 68 participants proposed in Phase 1 to conduct user centered design work. In Phase 2, we are interested in assessing the uptake of the intervention program and do not have a set number of participants to recruit.

The PI and a research assistant devote full-time effort to this research project. The PI and research assistant have designated office space within the Center for Behavioral Intervention Technologies, along with a personal computer and have access to a printer and scanner (available software includes SPSS/SAS, MS Office, Adobe, etc.). Both have access to research databases, administrative support, hardware, and software assistance available directly within the Department. The Department has a secure server with data security features ensuring confidentiality of participant data. All laptops are encrypted and the network has firewall protection. In addition, Northwestern University's information technology program supports researchers with the software, hardware, and data storage and retrieval facilities to conduct large-scale projects.

Prior Approvals:
Approval will be obtained by the University of Illinois at Chicago and Northern Illinois University prior to commencing research activities.

Confidentiality:
Data for all participants will be kept strictly confidential, except as mandated by law. All research files are kept on secure, password protected Northwestern University departmental and medical school servers. All electronic data will be stored on secure servers behind firewalls meeting all security requirements of the medical school. Any paper documentation is kept in locked file cabinets or a locked file room. Participants will be assigned a numerical code for identification in the files. Names and other identifiers will be kept in separate password protected files. Audio data will be stored on secure servers and will only be available for coding by study staff. Online assessments will be conducted on REDCap. This platform uses up to date security measures that are consistent with those used by Electronic Medical Records and are HIPAA compliant. All data collected via the interventions (e.g. mobile application) and assessments are transmitted using Transport Layer Security (TLS) encryption to prevent eavesdropping and tampering information while it is in the transmission pipeline. In addition, all data stored within the intervention is de-identified with a unique key. We will instruct patients on how to add a PIN to their phone to prevent unwanted access. We will clearly inform the patients of the risk of data insecurity. All data presentation will be of aggregate-level data; participants are never individually named.

Financial Compensation

Participants in the codesign workshop (Stage I) will be offered $30 cash for participation. Financial compensation will not be offered for survey completion (Stage II). Participants in the semi-structured interviews (Stage III) and in the usability testing sessions (Stage IV) will be offered $20 cash for participation. For the Stage V trial, participants will be compensated $10 for each of the monthly in-app assessments, and will be compensated $20 for each of the telephone-based user feedback interviews. Thus, participants are eligible to receive up to $70 for their efforts in the Stage V trial. Participants in the Phase 2 trial will earn entries into a lottery for completing monthly Knowledge Check questionnaires. Lottery winners will be selected on a monthly basis and will win a $50 Amazon giftcard. Participants completing semi-structured interviews during Phase 2 will be compensated $20 cash for in-person interviews or by a $20 Amazon gift card for phone interviews.

Provisions to Protect the Privacy Interests of Participants:
Participation in all aspects of the study is voluntary and data will be stored without personal identifiers. Participants will be reminded of the voluntary nature of study procedures.

Compensation for Research-Related Injury:
n/a

Economic Burden to Participants:
n/a

Consent Process:
For the codesign workshop (Stage I), participants will read and sign a paper copy of the informed consent form and be provided a copy for their own records. They will be given an opportunity to discuss the consent form with a member of the research study staff in private before the start of the codesign workshop.

For the survey sent to counseling center staff (Stage II), participants will read and click “agree” or “do not agree” on an online consent form. They will be encouraged to print the page for their own records, and will be provided with contact information of the PI in case they want to discuss the consent form before agreeing to participate.

For the semi-structured interviews (Stage III), participants will read and sign a paper copy of the informed consent form and be provided a copy for their own records. They will be given an opportunity to discuss the consent form with a member of the research study staff. To determine if students are eligible to participate in the Stage III semi-structured interviews, they will be prompted to complete an online eligibility screening measure. Participants will read and click “agree” or “do not agree” on an online consent form for this screening measure. They will be encouraged to print the page for their own records, and will be provided with contact information of the PI in case they want to discuss the consent form before agreeing to participate.

For the usability testing (Stage IV), to determine if students are eligible to participate in the usability testing session, they will be prompted to complete an online eligibility screening measure. Upon determination of eligibility, study staff will contact eligible participants to schedule a date and time for the participant to come in for the usability session. Before the usability session begins participants will be guided through a written consent and will sign if they agree with the written consent presented to them with research staff signing as witness. Research staff will then copy the consent to provide the participant for their own records as well as be asked if they have any questions before they would like to participate.

For the 8-week feasibility trial (Stage V), to determine if students are eligible to participate in the usability testing session, they will be prompted to complete an online eligibility screening measure. Upon determination of eligibility, study staff will contact eligible participants by email With a link to the digital consent form. Subjects will agree to participate by checking a “yes” box and typing in their name. They will be instructed to print out the consent form for their records. Participants are to be enrolled remotely to avoid excluding participants with access barriers who are among those who would be likely end users. The digital consent form will describe the mobile app program, show participants how to add a PIN to their phone, and inform participants that data entered into the phone will be de-identified to the research team, those it cannot replace the need for contacting a mental health provider in the case of an emergency.