Study title: IntelliCare in College Students - Implementation (ICCS-I)
NCT number: NCT04108429
Date: November 23, 2021
Principle Investigator: Emily Lattie, PhD

Study Protocol:

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.

Phase 2 Aim: Conduct a trial of the SSM program within two university communities. The overall aim of this study is to pilot the SSM program, evaluation metrics, implementation strategies, data collection and assessment procedures for a larger implementation trial. Counseling center utilization will be measured for one academic year to obtain a baseline for both sites. One site will be randomly selected and the SSM program will be implemented, while the other site will continue to collect baseline data. After one academic semester, the additional implementation strategies will be incorporated for an enhanced implementation plan, and both study sites will receive the enhanced implementation plan for one semester. During the implementation phases, counseling center utilization and SSM program use, will be tracked.

Hypothesis 1: Introduction of the SSM program will impact utilization of counseling center resources, and the use of an enhanced implementation plan will increase program penetration (e.g., app downloads) and strengthen its impact on utilization. We will explore multiple metrics to assess program impact on utilization, and hypothesize the number of appointments for crisis and follow-up will 1) be reduced during implementation relative to pre-implementation and 2) will be reduced in enhanced implementation relative to initial implementation. We will also explore the impact of implementation on seasonal variations in

counseling center utilization, level of depressive symptoms (as measured by the PHQ-9) at intake, and any other evaluation metrics identified during Phase 1.

Hypothesis 2: Sustained use of the SSM program will result in reductions in depression and anxiety among individual users, and these reductions will be mediated by increases in mental health literacy, knowledge of mental health care services, and cognitive and behavioral coping skills.

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 $\geq$ 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 $\geq$ 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.

For Phase 2, students must own a smartphone device compatible with the mobile app (an Android-operating or iOS-operating smartphone with a system that operates Android 7 or higher or iOS 11 or higher). During Phase 2, we will also conduct feedback interviews with students who have not used the program. Because Black male students have been the

demographic group who appear least likely to engage with the program, we are recruiting Black male students aged 18-35 years who have not used the program to provide feedback on what they are looking for in technology-based mental health and wellness resources. Therefore, students to be included will be those who self-identify as Black/African American men, between the ages of 18 and 35, English-speaking, familiar with smartphones, and enrolled at University of Illinois at Chicago and Northern Illinois University.

The following 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 Recruitment Methods:

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 after receiving approval from administrators. After receiving permission from administrators, digital signage teaser advertisements (i.e. brief study advertisements to be displayed on televisions across campus) will be used to complement the other advertising methods. Online recruitment will be published to both public spaces and existing private groups with the permission of the private group administrators (including Facebook, Instagram and Reddit). Participants will be directed to a website with study information and from there they will be able to access the study screening form and 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.
For Phase 2 feedback interviews with Black male students who have not used the program, participants will be recruited online, by word-of-mouth and via e-mail at UIC and NIU campuses. After receiving IRB approval and approval from NIU and UIC study organizations, brief study advertisements and recruitment flyers will be used, as well, and published to social media platforms and through email announcements belonging to student organizations that aim to serve students, in general, and those from minority populations, e.g. student wellness, Black student associations and Greek organizations. Recruitment materials will include information about the study and contact information, directing those interested to contact a research team member. For students who express interest and contact the research team member, another email will be sent, containing information about the study, research team

member contact information, and a link prompting students to complete an online consent and eligibility screening measure via REDCap. For those who do not respond to the recruitment email, a "nudge" email will be sent to remind participants 7 days after first contact. The consent form describes the study, discusses participant roles and responsibilities and risks, informs participants that their data will be confidential and de-identified data will be used for research purposes only, and provides important contact information. Participants will agree to participate by checking a "yes" box and typing in their name. Once consent is received, another email will be sent to schedule interviews with students and share Zoom meeting information. Reminder emails will be sent 24-48 hours in advance and day of. These recruitment procedures are similar to those that have been approved by the Northwestern University IRB for prior studies conducted by our lab group.

Procedures Involved:
Monthly data on engagement with counseling center services will be collected from the counseling center's Titanium Electronic Medical Record (EMR) to serve as a predeployment "baseline" for Phase 2. For the primary outcome of counseling center resource utilization, we will compare the predeployment phase (the 2 semesters prior to program implementation) to the implementation phases. During the predeployment phase, weekly data will be collected from existing service records at the counseling centers at UIC and NIU on new counseling appointments, follow-up appointment, group therapy appointments and crisis appointments. The data will be reported in aggregate and will not include individual personal identifiers. The SSM program will first be implemented in one study site (UIC or NIU – chosen via random selection) using the initial implementation plan (e.g. advertisements, identification of early adopters, identification of student leaders to serve as champions) designed in Phase 1. Data from individual interviews will be gathered from the first study site will inform an enhanced implementation plan. During this third semester, predeployment data will also be collected at Site #2. Then, the enhanced implementation plan, updated based on the semester 3 deployment at Site #1, will be deployed at both study sites and data will be collected for an additional semester. When the implementation begins on each campus, the program will be made freely available to download, and counseling center intake paperwork will be modified to ask students if they used the SSM program which allows for tracking of counseling center referrals while maintaining patient confidentiality. This design allows us to examine: a predeployment phase for both sites, an initial phase of implementation for Site #1, and an enhanced implementation phase for Site #1 and for Site #2. A strength of this implementation design is that is allows for learning within itself by comparing initial implementation strategies with an enhanced implementation plan. This process of learning and adapting is key for effective and sustainable implementation. Staggering the start times of implementation allows for within-site targeted comparisons of effect of introducing the SSM program on utilization of the counseling center in each site, and for an exploration of between-site differences in the impact of the enhanced implementation plan.

The study utilizes an interrupted time-series design, which offers a number of benefits over large-N designs and has been shown to be an acceptable approach for examining treatment efficacy as well as a useful design for rigorous implementation research when few sites are

involved. There are both scientific and pragmatic benefits to introducing a program into a system with this design approach. Since these time-series measurements are recorded on a weekly basis, one can observe how change unfolds across time, examine seasonal effects to better evaluate change in these centers that are often at capacity, and investigate the trajectory of change. Because all members of the campus community are granted access to the program, this design meets the needs of community stakeholders.

To examine outcomes for Hypothesis 2 (sustained use of the SSM program will result in reductions in depression and anxiety among individual users, and will be mediated by increases in mental health literacy, knowledge of mental health care services, and cognitive and behavioral coping skills), we will examine longitudinal data from individual users regarding depression and anxiety symptoms, mental health literacy, knowledge and beliefs about mental health care services, barriers to mental health care, and cognitive and behavioral coping skills to determine if sustained program use is associated with changes in these measures.
SSM Program: The program will prompt users to complete repeated symptom assessments and provide psychoeducation regarding current symptoms while encouraging students in need to utilize available campus services. Upon download, the Student Hub app will prompt users to complete the PHQ-8 and GAD-7 and will provide feedback on symptoms. Based on symptom scores, users will receive automated feedback about depression/anxiety, availability of mental health and wellness services on campus, and information and interactive digital tools to support continued stress management and wellness. Users will be prompted with ability to use interactive self-help tools within the app suite. Interactive, clinical apps (designed for daily use) are included to facilitate engagement with mood monitoring, and to appeal to a preference for self-reliance.

Risks of the intervention: The primary risk of the intervention is participants being distracted by their mobile phones while engaged in activities that demand their complete attention. Participants occasionally try to use mobile apps while driving motor vehicles, and therefore will be instructed never to use the mobile phone while driving. Participants will be made aware of the physical, financial, and legal risks associated with using the phone while driving. If the research team becomes aware of a participant engaging in this behavior, the PI and mentors will consult to determine the most appropriate way to eliminate this risk.

Protection for risks of worsening mental or emotional state and or self-harm thoughts/events: Some participants may show a worsening of depressive symptoms, suicidality or problems during the study period. Consistent with past research on internet-based mental health screening and intervention for college students, participants will receive automated messages information on available resources (e.g. local emergency services, the Crisis Text Line, National Suicide Prevention Lifeline, and on-campus crisis counseling). These are risks inherent in the population and would occur whether or not they were enrolled in the study. We do not believe that the risk of these depressive, suicidal, or other adverse outcomes are increased as a function of being enrolled in this study or receiving the mobile application. All potential risks associated with participation in this study will be disclosed in consent documents.

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

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.

Statistical Analysis Plan:

We used a mixed-methods approach to analyzing the impact of the IntelliCare for College Students program, in that we analyzed quantitative data on app usage and counseling center utilization alongside qualitative data generated through interviews with students and staff.

Demographic data were examined primarily in the form of descriptive statistics, and chi-square tests and a student's t-test were used to examine potential demographic differences between the participants who consented to the study that did (n=117) and did not (n=65) download and register their participant ID to the IntelliCare for College Students app. App usage data were examined in the form of descriptive statistics.

Due to missing data throughout the trial, multiple imputation methods and separate generalized linear mixed models to account for repeated measures from each participant over time, were used to examine symptoms of depression and anxiety at baseline, week 1, week 2, week 4, week 6 and week 8, and anxiety literacy, depression literacy, and cognitive and behavioral coping skills at baseline, month 1 and month 2.

To examine symptom assessments longitudinally, we fit the available weekly symptom assessment data into a structure of baseline, week 1, week 2, week 4, week 6 and week 8 timepoints. Only 2 individuals had complete data. A total of 48 participants only completed the symptom assessment at one time period, 16 (17) completed 2 of the 6 assessments (16 for GAD, 17 for PHQ), 3 (2) completed 3 of the 6 assessments, 5 had 4 of the 6 assessments, and 5 were missing just one assessment. Multiple imputation methods were used to account for missing data. Participants were also prompted to complete measures of our mental health intervention targets on a monthly basis within the app. Many participants did not complete these assessments, and data were examined at baseline, month 1, and month 2. Multiple imputation methods were used to account for missing data.

As originally planned for this project, counseling center utilization data were examined using Simulation Modeling Analysis (SMA) for Time-Series data to determine if there were changes in utilization between the pre-implementation and implementation phases. Because we were unable to enact an enhanced implementation strategy during the second semester of program implementation, we examined implementation as a single phase. SMA evaluates the statistical significance of between-phase changes in data streams and also accounts for the presence of autocorrelation (the non-independence of data points in time-series data streams). A phase effect size (Pearson's R) is produced for each phase-comparison that is then compared to a distribution of data streams, using bootstrapping, resulting in an empirical estimate of the probability of the observed effect occurring by chance.

Interviews were transcribed and coded using a thematic analysis approach. The interview transcripts were first reviewed for thematic content. In creating the codebook, coders met to review their initial codes to reach initial consensus and identified the primary themes that were used to create a codebook. Then, a second round of review took place as the coders reviewed the codebook, refined codes as needed, and completed a final round of coding. The coders met regularly throughout the analytic process to discuss these codes with the study principal investigator, check codes between coders, come to consensus, and ensure validity.

Consent form:

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

IRB Study Number: STU00205589

Principal Investigator: Emily Lattie, PhD

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

Financial Interest Disclosure: The following disclosure is made to give you an opportunity to decide if this relationship will affect your willingness to participate in this research study: Emily Lattie has received consulting fees in the past (last received in May 2018) from Actualize Therapy, LLC (now Adaptive Health, Inc.), the company that holds the license to the IntelliCare app platform.

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

Key Information about this research study:

The following is a short summary of this study to help you decide whether to be a part of this study. This study examines usage of a university student-facing stress management mobile app program that can serve as both a self-help tool and as a bridge to connecting students in need with mental health services on campus. The purpose of this study is to examine use of a stress management mobile app program developed for college students, the impact the program has

on mood symptoms and mental health knowledge, and the impact that program introduction has on campus counseling center utilization. You will be asked to download and use a stress management app known as the IntelliCare Hub for College Students. Activities within this app include taking brief assessments, journaling, or accessing contact information for various campus resources that can be helpful in stress management.
We expect that you will be in this research study throughout the academic year, and you can discontinue participation at any time by removing the app from your phone.

The primary risks of participation are breaches in privacy and/or confidentiality. The information collected may only be protected to the extent technologically possible. is participants being distracted by their mobile phones while engaged in activities that demand their complete attention. ***You may also feel emotional discomfort or increased anxiety as a result of reading, logging or talking about mental health.*** The main benefit of participation is helping researchers understand the impact IntelliCare for College Students can have on student mental health and counseling center utilization.

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

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

How many people will be in this study?

We expect about 3000 people here will be in this research study.

What should I know about a research study?

- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.

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

After you read this consent form and agree to participate by signing the form, you will receive information and instructions about how to download the study app onto your personal smartphone. You will be asked to use the app in your daily life, to complete weekly mood symptom assessments, and monthly mental health knowledge assessments.

<u>Mental Health App tools</u>

As a participant in the study, you will be also able to use the IntelliCare suite of mobile applications developed by researchers at the Center for Behavioral Intervention Technologies (CBITs). The IntelliCare apps teach people skills they can use to manage stress, depression and anxiety. You will be encouraged to use the study app a few minutes each day.
If you do not wish to participate in this research study, you will have the option to download the IntelliCare apps and use them on your own. In this case, the developers of the app will receive your usage data but it will not be used for this research study.

Will being in this study help me in any way?

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

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

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

The risks from being in this study are minimal. The primary risks of the study are breaches in privacy and/or confidentiality. The information collected may only be protected to the extent technologically possible. An additional risk of this study is participants being distracted by their mobile phones while engaged in activities that demand their complete attention. Participants might experience distress reading, or logging information about mental health. The study app is not intended to replace the need for contacting a mental health provider or emergency services if you are at risk of harm to yourself or to others. However, the study app provides resources on how to contact a mental health provider. Participants who express distress to research staff will be assessed for suicide risk and provided with both on-campus and off-campus health resources. The study will not provide payment for the use of any additional health resources. There are additional risks due to the nature of this intervention being delivered via smartphone. Depending on the nature of your smartphone service plan, there is the potential for data plan overages. We encourage you to discuss your plan with research staff before enrolling in the study. There is also the potential for loss of confidentiality if someone else were to use your phone and read information you have entered into the app. We recommend password protecting your phone to reduce confidentiality risks.
This study involves the use of your identifiable, personal information and there is a chance that a loss of confidentiality could occur. The researchers have procedures in place to lessen the possibility of this happening. See the section below titled: **"What happens to the information collected for the research?".**

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

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

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

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

What happens to the information collected for the research?

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

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information or documents, that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information or documents protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law of child [or elder] abuse and neglect, or intent to harm self or others.

A description of this study will be available on http://www.ClinicalTrials.gov, as required by U.S. law. The ClinicalTrials.gov identifier is NCT04108429. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

These surveys will be hosted by Adaptive Health, Inc on AWS servers and involves a secure connection. Adaptive Health, Inc will also have access to your app usage data. Terms of service, addressing confidentiality, may be viewed at https://www.actualizetherapy.com/privacy. No personal identifiers are submitted with your survey results and you will only be identified by a unique subject number. All data is kept on a password protected server only accessible by Adaptive Health staff.

Data Sharing

You have the right to decide if we can use and share information gathered about you through this research study with others. By signing this consent form, you will give us permission to share some of your information with the researchers at Northwestern University who are conducting this study.
De-identified data from this study may be shared with the research community at large (listed below) to advance science and health. We will remove or code any personal information that could identify you before files are shared with other researchers to ensure that, by current scientific standards and known methods, no one will be able to identify you from the

information we share. Despite these measures, we cannot guarantee anonymity of your personal data

- The following entities may have access to identifiable information under limited circumstances:
  - Authorized members of the Northwestern University workforce, who may need to see your information, such as administrative staff members from the Office for Research, Office for Research Integrity and members of the Institutional Review Board (a committee which is responsible for the ethical oversight of the study.)
  - Study monitors and auditors, for example from funding agencies, who make sure that the study is conducted properly.

- The following entities may have access to study data without identifiable information.
  - Other researchers and contractors working on this study and other studies who are collaborating to further research and agree to protect the data.
  - Readers and reviewers of scientific journals that may publish the results of this and other studies that involve your data.

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

What else do I need to know?

Compensation: For completing monthly in-app mental health knowledge assessments, participants will be entered into a lottery with the potential to win one of multiple $50 Amazon gift cards. Because the research team does not know how many participants will use the app and complete these assessments, we cannot provide the approximate odds of winning a gift card. Due to payment restrictions, only participants who are U.S. Residents or Citizens are eligible for the gift card lottery. If selected for the lottery, a participant can decline the gift card for any reason, and will not be prompted to further report on their citizenship status.

Who can I talk to?

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

This research has been reviewed and approved by an Institutional Review Board ("IRB") at Northwestern University. You may talk to the Northwestern IRB office at (312) 503-9338 or irb@northwestern.edu if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research participant.
- You want to get information or provide input about this research.

Consent

If you want a copy of this consent for your records, you can print it from the screen.
Agreeing to this consent documents your permission to take part in this research.

[first_name] [last_name], if you wish to participate, please select "I Agree" and you will be taken to the instructions on how to install the app. If you do not wish to participate in this study, please select "I Disagree" or select X in the corner of your browser.

_____
Today's Date