Harnessing Mobile Technology to Reduce Mental Health Disorders in College Populations

Principal Investigators:

Denise Wilfley, PhD – Washington University School of Medicine

Craig Barr Taylor, MD – Palo Alto University

Michelle Newman, PhD – Pennsylvania State University

Daniel Eisenberg, PhD – University of California, Los Angeles

Version: 9

FEBRUARY 7, 2022

TABLE OF CONTENTS

A List of Abbreviations

Co-I	Co-Investigator
EDs	Eating Disorders
NIH	National Institute of Health
PAU	Palo Alto University
PSU	Pennsylvania State University
PI	Principal Investigator
UM	Regents of the University of Michigan
WUSM	Washington University School of Medicine

B Introduction

A1 Study Abstract

The prevalence of mental health problems among college populations has risen steadily in recent decades, with one-third of today's college students struggling with anxiety, depression, or an eating disorder. Yet, only 20-40% of college students with mental disorders receive treatment. Inadequacies in mental health care delivery result in prolonged illness, disease progression, poorer prognosis, and greater likelihood of relapse, highlighting the need for new approaches to detect mental health problems and engage students in services.

Our interdisciplinary research team has developed a transdiagnostic, scalable, mobile health prevention and intervention platform. This platform uses population-level screening to engage college students in tailored services that address common mental health problems. This evidence-based approach to care delivery addresses comorbid mental health issues and uses personalized screening and intervention to increase service uptake, enhance engagement, and improve outcomes. Further, our service delivery model harnesses the expertise of our team of leaders in behavioral science, college student mental health, technology, and health economics, and bridges our team's work over the past 25 years in successfully implementing a population-based screening program in over 160 colleges and demonstrating the effectiveness of Internet-based programs for targeted prevention and intervention for anxiety, depression, and eating disorders in over 40 colleges. We propose to test the impact of this mobile mental health platform for service delivery in a large-scale trial across 20 colleges. Students who screen positive or at high-risk for clinical anxiety, depression, or eating disorders

(excluding anorexia nervosa, for which more intensive medical monitoring is warranted), which account for a substantial proportion of the mental health burden on college campuses, and who are not currently engaged in mental health services (N=7,884; of 146,000 initially screened) will be randomly assigned to: 1) intervention via the mobile mental health platform; or 2) referral to usual care (i.e., campus health or counseling center). Our comprehensive mental health care platform can yield clinical benefit to students, appeal to university stakeholders, minimize barriers to implementation sustainability on campuses, and produce an economic return on investment compared to usual care. This population-level approach to service engagement has the potential to improve mental health outcomes for the 20+ million students enrolled in U.S. colleges and universities.

A2 Primary Hypothesis

The mobile mental health platform will yield substantially higher and earlier uptake of services compared to referral to usual care.

B Background

B1 Prior Literature and Studies

Prevalence of mental health problems among college students has risen steadily in recent decades.[9] In national epidemiologic studies, past-year prevalence of mood and anxiety disorders was 11% and 12%, respectively,[16] and 9% of college students screened positively for an eating disorder (ED).[21] Among students with probable disorders, only 20-40% received treatment,[16,22] and this number was even lower among students of color and those from low-income families.[17] With over 20 million people enrolled in U.S. postsecondary education,[23] we can infer an extremely large treatment gap[24,25]—there are at least 6.5 million college students with mental disorders, and at least 4 million college students with untreated mental disorders. Early intervention is particularly important during college ages of 18-24, when mental illnesses account for the largest burden of any disease.[26] Untreated symptoms become more frequent, severe, and persistent over time.[27-29] Students often have difficulty getting appropriate health care,[30] which can have lasting consequences on functioning, physical health, suicidality, social relationships, and educational attainment.[14,15,31] Although many campus counseling and health centers have increased their capacity to provide services,[7] there remain major limitations to access and delivery of mental health services in college populations. For students, important barriers include lack of problem recognition, lack of time, lack of urgency to seek services, and stigma.[32] Increasing the number of providers, by itself, neither addresses the large number who wait until they reach a crisis level to seek mental health support, nor alleviates stigma or campus leaders' concerns about continuing to pour more resources into services without appreciable slowing in demand.[7] These factors highlight the need for a more efficient, proactive, and accessible service delivery model for managing mental health in college student populations through combined targeted prevention and intervention.

B2 Rationale for this Study

mHealth technologies have potential to improve mental health care on college campuses by overcoming treatment barriers and increasing efficiency. Such interventions can offset in-person clinical demands, increase access, enhance treatment precision, and reduce costs.[35] Mobile technologies are efficacious for screening and treatment of anxiety, depression, and EDs across settings and populations, including in college students[1,2,6,36-38] for whom smartphone use is ubiquitous,[39] with high acceptability given their convenience and anonymity. However, these interventions have been primarily delivered independently. A key challenge is delivering these technologies effectively and in combination at a population level. Such an approach would link screening with intervention, maximize engagement, and address comorbid problems.

C Study Objectives

C1 Study Aims

Our study aims are as follows:

1) Aim 1: Examine uptake (i.e., individuals beginning treatment) of the mobile mental health platform compared to referral to usual care.
2) Aim 2: Evaluate the effectiveness of the mobile mental health platform, compared to usual care, in (2a) reducing the number of individuals with mental health disorders (primary outcome); (2b) reducing disorder-specific symptoms (secondary outcome); and (2c) improving quality of life and functioning (secondary outcome).
3) Aim 3: (3a) Examine if the mobile intervention changes targets previously found to be associated with outcomes, both transdiagnostic (i.e., decreased dysfunctional cognitions, increased use of CBT skills) and disorder-specific (i.e., reduced avoidance for anxiety, increased behavioral activation for depression, reduced dietary restraint and weight/shape concerns for EDs); (3b) determine if changes in targets are associated with clinical benefit; and (3c; exploratory) identify other putative mediators of change (e.g., early engagement in help services, rapid response), (3d; exploratory) within-mobile program predictors of outcome (e.g., sessions completed), and (3e; exploratory) treatment moderators.
4) Aim 4 Evaluate stakeholder-relevant outcomes: (4a) costeffectiveness; (4b) students' academic performance; and (4c) attitudes.

C2 Rationale for the Selection of Outcome Measures

As detailed above, we'll be examining uptake of the mobile mental health platform compared to referral to ususal care, as well as effectiveness of the platform in reducing the number of individuals with mental health disorders; reducing disorder-specific symptoms; and improving quality of life and functioning. These are critical outcomes as they will tell us whether the mobile mental health platform is not only more likely to be used by students (uptake) but also whether it is effective on several dimensions.

We also propose several mediators, which fall into: 1) primary intervention targets/mechanisms, considered most essential to outcomes (some of which are transdiagnostic and some disorder-specific; and 2) other mediators—early engagement in services and rapid response. CBT theory posits that the most important ways to change symptoms are by changing cognitions and/or changing behaviors. Thus, our transdiagnostic targets are decreased dysfunctional cognitions and increased use of CBT skills. Empirical support for cognitive changes suggests that they are central to reduction in anxious[113] and depressive[114] symptoms. For EDs, although only a few studies have examined change in cognition,[115] it is worth including given its emphasis in CBT theory.[116] There is evidence that acquisition of CBT skills (e.g., challenging thoughts) is another critical target at least for anxiety and depression.[117-122] Our disorder-specific, evidence-based targets are as follows: reducing avoidance, associated with changing anxiety;[123-125] increasing behavioral activation, associated with reducing depressive symptoms[126-128]; and reducing dietary restraint and weight/shape concerns for reducing EDs.[61,102,115,129] We will examine whether the mHealth platform leads to change in the targets listed above and whether target change is associated with clinical benefit. Use of any potentially helpful services (e.g., Lantern, self-help, face-to-face therapy, medication) is also likely to lead to change, particularly in the first 6 weeks. Thus, while not a specific target of intervention, early engagement in help services is a potential mediator of symptom reduction[130] and will be tested. Rapid response in symptoms, with rapid response usually defined as ≥50% reduction in symptoms occurring within the first 4-6 weeks of treatment,[131,132] predicts longer-term outcome in anxiety, depression, and EDs and is considered a mediator.[97,100-102,133-138] Within-mobile program indices will be tested as predictors of outcome, including sessions completed, number of messages sent by user and coach, techniques completed, time spent with the program, and coach personalization (i.e., assessed through users' perception and coding a subset of messages. Finally, data will be used to explore moderators—subgroups for whom further tailoring or more intensive services are needed in future iterations. Moderators exploratory and based on prior work; they are: gender, race/ethnicity, expectancy/credibility,[139-143] symptom severity,[142,144-147] duration of problem,[142,145,148-150] comorbidity,[142,145,149,151-153], disorder for which the person sought treatment,[144,152,154] degree of cognitive distortion,[142] impairment,[145] family income,[142] and motivation.[155]

D Study Design

D1 Overview or Design Summary

At each of the participating campuses, we will recruit students from the undergraduate population. Some campuses may decide to provide us with with a random sample (requesting from the Registrar [or equivalent campus unit] which isoversampled by gender, race/ethnicity, and socioeconomic status [e.g., Pell grant recipients] to ensure that participant samples are diverse and representative on these dimensions).

Students will be recruited via emails to their campus email address to participate in the screen.

Students will be asked at the start of the screen if they would like to opt out of receiving information about potential future studies. We will create an entire new registry of students from those who **do not select to opt out** of future studies, ensuring we will not be able to contact those who opted out of future contact from the new registry.

Following the screen students will receive personalized feedback about their results. The personalized feedback will be automated through Qualtrics,allowing for an efficient yet individualized feedback approach. The personalized feedback will include either an end of survey message thanking the individual for their participation (and a referral for treatment if applicable) or an invitation to participate in the full study as follows:

1. No symptoms or low risk for depression, anxiety, and EDs - they will not be eligible to participate in the next phase of the study.
2. Low risk with trauma, insomnia, or substance abuse - receive referral for clinical evaluation and intervention.
3. At high risk for or with clinical anxiety, depression, or an ED not currently in treatment; own a smartphone - will be invited to participate in phase 2 of the study.
4. At high risk for or with clinical anxiety, depr ession, or an ED currently in treatment and/or without a smartphone – will be encouraged to continue in treatment provided with a referral for clinical evaluation and intervention.
5. Anorexia nervosa - receive referral for clinical evaluation and intervention.

Following the personalized feedback, students meeting study eligibility criteria will receive a brief statement of eligibility for and description of the study purpose and duration, activities involved, and assessment time points. Students will be asked to confirm their willingness to continue. If they agree students will be asked for their email address and phone numbers, and will be provided a link to the Phase 2 survey. After giving online consent, participants will be randomized via a code through Qualtrics into one of two conditions:

1) Intervention: receiving access to our mobile coached self-help program for 6 months.
2) Control: Receiving information on how to receive treatment at the student's counseling center on campus.

Participants will then complete the baseline survey, which will assess treatment expectancy/credibility, cognitive distortion, impairment/quality of life, motivation for treatment, and mental health treatment utilization. After completing these measures students will be made aware of the condition they were randomized into and asked to complete a short Treatment Credibility and Expectancy Questionnaire.

Individuals who choose not to continue will receive their screen feedback through Qualtrics, a recommendation to seek care, and a campus-specific list of resources.

After completing the baseline survey participants will receive an email and text message with information about their screen responses and either a link to the mobile intervention or information on how to access clinical services, based on their randomized condition. Individuals who screen positive or at high risk for more than one of the three mental health disorders (anxiety, depression, EDs) will be asked to select which problem is most bothersome or impairing to their everyday functioning, which has been shown to correlate with provider ratings,and will then be directed to focus primarily on that problem using either the mobile app or in-person services.

All students in the usual care condition will receive a recommendation to seek care and will be given a list of resources available through their respective health or counseling center, including contact information to make an appointment and any other relevant resources on campus. Participants who will be completing the mobile interventions will be given a link to the program, hosted on a platform by our technology partners SilverCloud Health, and a program description. They will also be provided with instructions to download the SilverCloud Health program app, through which they can access the intervention, as well. Students are encouraged to log in to the intervention, create an anonymous username and password, and begin the program.

Both intervention and control groups will be asked to complete assessments at 6 weeks, 6 months, and 2 years after completing the baseline screen. 6 week assessments will ask participants to complete assessments of anxiety, depression, EDs, motivation for treatment, and mental health treatment utilization. The 6 month and 2-year follow-ups will include assessments of anxiety, depression, EDs, comorbidities, impairment/quality of life, motivation for treatment, mental health treatment utilization, and screening and treatment feedback. In addition, alternate contact information will be requested at baseline, 6, and 12 month follow-ups in order to maximize the likelihood that participants can be reached at the next follow-up assessment, including cell phone number for receiving SMS text-message reminders for follow-up surveys to be sent from the Qualtrics platform. Follow-up emails and SMS may also use images or other media to increase the students' attention and likelihood of reponse. In order to increase the response rate at 2-year follow-up the study team may call participants to remind them to complete the survey, the study team may leave a voicemail if the participant does not respond. All assessments will be conducted using Qualtrics survey platform.

Participants will be compensated by receiving an electronic gift card for completing the Baseline ($5), 6 week ($5), 6 month ($10), and 2-year ($20) follow-up assessments. Particpants will be entered into a sweepstakes to win one of five $50 gift cards after completing the Baseline, 6 week, 6 month, and 2-year surveys. In addition, once particpants complete all four surveys, they will be entered into a sweepstakes to win one of ten $100 gift cards.
All students who receive a recruitment email will be automatically entered into a sweepstakes for one of 40 $100 electronic gift card prizes.

In order to assess mental health treatment utilization, in addition to assessing this via-self-report, we will obtain aggregate counts of participants in therapy from campus counseling/health centers, by random assignment group at baseline, 6 months, and 2 years. To assess academic outcomes, including term by-term GPA and enrollment status (to assess drop-out), at the end of the 2 years we will obtain aggregate data of participants from Registrars by semester/term to include GPA and attrition rate by condition.

D2 Subject Selection and Withdrawal

2.a Inclusion Criteria

Screening survey inclusion criteria: Undergraduate students at participating colleges and universities who are 18 years old and older.

Full study inclusion criteria:

- Students who screen has high risk or clinical/subclinical for anxiety, depression, and, EDs
- Students who are not currently in treatment, i.e., in the past month.
- Own a smartphone.

Students who endorse suicidal ideation in the baseline screening assessment will be given a referral to seek in-person care, however, we decided not to exclude students with suicidality, given that only 20-40% of college students with mental health problems receive treatment. As such, we deemed it insufficient to exclude such individuals from receiving the intervention and only providing an in-person referral, given the goal of this proposal to narrow the treatment gap for mental health problems among college students.

2.a Exclusion Criteria

For the full study we will exclude students who do not own a smartphone since the intervention is a mobile app. We will also excludes students who are currently engaged in mental health treatment given the goal to increase access to services for those not receiving help.

2.b Ethical Considerations

All key personnel involved in the design or conduct of research involving human subjects will receive the required education on the protection of human research participants prior to the start of the study. Participants will be informed that they do not have to answer any questions that make them uncomfortable. There are minimal risks for participants in the mobile health intervention. Coaches in SilverCloud Health will be recruited at the study four participating sites. Coaches will be students in a graduate program in psychology, counseling, or social work. Coaches will be trained and under the close supervision of a coach supervisor, at WUSM and PAU who licensed psychologists, as well as the Fidelity Monitoring Center.

Given national data showing that nearly 10% of students have seriously considered suicide in the past year and that rates of suicide on university campuses continue to increase, suicidality will be consistently monitored throughout the study, including within the mobile intervention itself and through the completion of the baseline and 6-week, 6-month, and 2-year follow-up assessments. Students who endorse any suicidality on these assessments will receive immediate follow-up, including a referral to seek in-person care. Despite the perceived risk that assessing suicidality will increase suicidality, research supports that asking about this does not increase suicidality and, among those who may endorse active suicidal plans or intent, may lead to improvements in health seeking behaviors and increased safety. Notably, we decided not to exclude students with suicidality, given that only 20-40% of college students with mental health problems receive treatment. As such, we deemed it insufficient to exclude such individuals from receiving the intervention and only providing an in-person referral, given the goal of this proposal to narrow the treatment gap.

Participant safety is of utmost clinical import, and several safety precautions and procedures will be implemented.
1) SilverCloud Health flags and notify coaches when a user responds positively to the PHQ-9 item about suicidality. Coaches will monitor the platform weekly to assess for significant changes in symptoms (e.g., increased purging). Any participant deemed unsafe or needing more intensive clinical intervention will be given a referral by their coach as well as contacted directly via telephone. Appropriate follow-up (e.g., contacting the university's on-call clinical staff or local police) will be implemented if participants are deemed to be at imminent risk and no response is provided by the participant indicating their safety. This protocol is to safeguard against concerns with keeping individuals in guided self-help care when more intensive services are warranted.
2) Individuals who remain in the clinical symptom range, in both the intervention and control conditions, at the 6-month or 2-year follow-up assessments, will be offered a referral for in-person treatment. For individuals in the intervention condition, in line with a stepped care model, those who do not demonstrate symptom improvement by 6 weeks will be referred to in- person care but can still engage in the program.

In the case of imminent risk, such as in the extremely rare case of a user reporting plans of suicide or homicide, there are several steps that coaches for students engaging in the mobile program are mandated to take as mandated reporters. First, coaches contact a coach supervisor and the Fidelity Monitoring Center either by phone or an email marked URGENT to consult about how to proceed as soon as possible. If coaches do not receive a response within an hour, they will reach out to a back-up coach supervisor. Second, coaches identify the appropriate local agency such as the campus police at the user’s college or university to prepare for possibly making a report. Next, they provide the user with a variety of emergency options such as counseling center information, suicide hotline phone number, emergency room location, or local police information and encourage clients to seek additional support or hospitalization through these options. Coaches also gather relevant information by reviewing the coaching record for all identifying information available such as name, age, phone number, and email address to provide to the agency when making a report. If it is deemed appropriate by the coaching supervisor, coaches call in the report as soon as possible to the identified local agency. They also follow up with the user, express concern, provide support, and let him/her know a report has been made. In addition, coaches follow up with the coach supervisor and the Fidelity Monitoring Center via email to let him/her know the report was made. Finally, coaches continue to monitor the user for emerging or worsening risks, as demonstrated by information the user inputs into the program or messages to the coach, and they continue to keep in close contact with the coaching supervisor. Should the user continue to worsen and be deemed at continued imminent risk, the coach and coach supervisor may make a decision to withdraw the participant from the program.

In the case that individuals endorse criteria for possible AN (low weight and significant weight shape concerns) at the 6-month or 2-year follow-up assessments, they will be offered a referral for in-person treatment.

The Fidelity Monitoring Center will conduct fidelity checks on the coaching data from SilverCloud Health to ensure that coaches are following protocol (e.g., referrals given if lack of symptom improvement). In general, the Fidelity Monitoring Center will oversee regular review of coaches using quantitative and qualitative metrics that include tone and

style (authentic, personalized) of their interactions with clients, content (depth, goal orientation), efficiency (response time), user engagement, outcomes, and accuracy rate for risk management. Coaches that do not meet the metrics will be put on a performance improvement plan and may be terminated if improvement is not demonstrated.

IRB of Record
The use of a single IRB model is designed to enhance and streamline the process of IRB review and reduce inefficiencies without compromising ethical principles and protections within this multi-site clinical study. Each site signs an IRB Authorization Agreement to document the delegation of responsibilities of IRB review to WUSM and demonstrate WUSM's acceptance of these responsibilities.

2.c Subject Recruitment Plans and Consent Process

Each participating school will provide us with a database of students from their registrar or academic information office. The database will contain a full population sample or random sample of undergraduate students. The database will include demographic information about students such as first name, email address, sex, race/ethnicity.

Students will be recruited via emails to their campus email address to participate in the screenning assessment. Students will first receive a brief "pre-notification" email, which lets them know that an invitation to the study will be coming soon. Two to three days later, we will send the screening assessment recruitment email with a link to the online survey, and we will follow-up with reminder emails to non-responders. The emails will note that students can reply to decline participation (and any further reminders); they may also select this option on the consent form page of the screening survey.

Once students click on the survey link, students will be asked to review the consent information sheet, they will have all the time they need to review it. Full disclosure of the purpose of the study, the benefits and risks to individuals who participate, and the confidential nature of information obtained during the study will be explained to participants. Participants will be aware from the outset that they could be eligible for phase 2 of the study. Participants will be consented according to the policies and procedures of the WUSM IRB, the IRB of Record for the study. A trained study staff member will be available to students via phone to answer any questions they may have about their participation in the study.

We will follow-up with reminder emails to non-responders. The emails will note that students can reply to decline participation (and any further reminders); they may also select this option on the consent form page of the baseline survey.

For phase 2 eligible participants, following the personalized feedback , they will receive a brief statement of eligibility for and description of the study purpose and duration, activities involved, and assessment time points. Students will be asked to confirm their willingness to continue. If they agree students will be asked for their email address and phone numbers, and will be provided a link to the Phase 2 baseline survey. People who do not complete the baseline survey will be sent an email reminder to complete the survey.

Once students click on the survey link, students will be asked to review the informed consent before continuing with the baseline survey. Student will have all they time they need to review it. Full disclosure of the purpose of the study, the benefits and risks to individuals who participate, and the confidential nature of information obtained during the study will be explained to participants. Participants will be aware from the outset that they could be randomly assigned to a mobile health platform or referral to usual care. They will also be aware that their expected participation will last up to two years, including three additional follow-up assessments. Participants will be consented according to the policies and procedures of the WUSM IRB, the IRB of Record for the study. A trained study staff member will be available to students via phone to answer any questions they may have about their participation in the study.

2.d Randomization Method

In phase 2, participants will be randomized after giving online consent, participants will be randomized via a code through Qualtrics into one of two conditions:

1) Intervention: receiving access to our mobile coached self-help program for 6 months.
2) Control: Receiving information on how to receive treatment at the student's counseling center on campus.

Participants will be made aware of the condition they were randomized into after completing the baseline survey.

2.e Risks and Benefits

Risks

There are minimal risks for participants.

The assessment process may carry potential risks. For example, some of the questions may be upsetting to participants, and there may be some risk of breach of confidentiality if the suicide or crisis assessment protocols need to be deployed.

There are no high-risk or hazardous aspects of our proposed mobile intervention program; however, we recognize that programs to treat mental health problems may promote increased focus on mental health symptoms, more than that which may exist before starting the program.

Coaches in SilverCloud Health will be recruited from the institutions of the study team members (i.e., WUSM, PAU, PSU, UM). Coaches will be students in a graduate program in psychology, counseling, or social work. Coaches will be trained and under the close supervision of coach supervisors, at WUSM and PAU, as well as the Fidelity Monitoring Center. Given national data showing that ~10% of students have seriously considered suicide in the past year, suicidality will be consistently monitored throughout the study, including within the program itself and through the completion of all assessments. Students who endorse any suicidality on these assessments will receive immediate follow-up, including a referral to seek in- person care. Participant safety is of utmost clinical import, and several safety procedures will be implemented.

1) SilverCloud Health flags and notify coaches when a user responds positively to the PHQ-9 item about suicidality. Coaches will monitor the platform weekly to assess for

significant changes in symptoms (e.g., increased purging). Any participant deemed unsafe or needing more intensive clinical intervention will be given a referral by their coach as well as contacted directly via telephone. Appropriate follow-up (e.g., contacting the university's on-call clinical staff or local police) will be implemented if participants are deemed to be at imminent risk and no response is provided by the participant indicating their safety. This protocol is to safeguard against concerns with keeping individuals in guided self-help care when more intensive services are warranted.
2) Individuals who remain in the clinical symptom range, in both the intervention and control conditions, at the 6-month or 2-year follow-up assessments, will be offered a referral for in-person treatment. For individuals in the intervention condition, in line with a stepped care model, those who do not demonstrate symptom improvement by 6 weeks will be referred to in- person care but can still engage in the program.

In the case of imminent risk, such as in the extremely rare case of a user reporting plans of suicide or homicide, there are several steps that coaches are mandated to take as mandated reporters. First, coaches contact a coach supervisor and the Fidelity Monitoring Center either by phone or an email marked URGENT to consult about how to proceed as soon as possible. If coaches do not receive a response within an hour, they will reach out to a back-up coach supervisor. Second, coaches identify the appropriate local agency such as the campus police at the user's college or university to prepare for possibly making a report. Next, they provide the user with a variety of emergency options such as counseling center information, suicide hotline phone number, emergency room location, or local police information and encourage clients to seek additional support or hospitalization through these options. Coaches also gather relevant information by reviewing the coaching record for all identifying information available such as name, age, phone number, and email address to provide to the agency when making a report. If it is deemed appropriate by the coaching supervisor, coaches call in the report as soon as possible to the identified local agency. They also follow up with the user, express concern, provide support, and let him/her know a report has been made. In addition, coaches follow up with the coach supervisor and the Fidelity Monitoring Center via email to let him/her know the report was made. Finally, coaches continue to monitor the user for emerging or worsening risks, as demonstrated by information the user inputs into the program or messages to the coach, and they continue to keep in close contact with the coaching supervisor. Should the user continue to worsen and be deemed at continued imminent risk, the coach and coach supervisor may make a decision to withdraw the participant from the program.

In addition, Dr. Newman will hold monthly meetings with coach supervisors. Furthermore, the Fidelity Monitoring Center will conduct fidelity checks on the coaching data from SilverCloud Health to ensure that coaches are following protocol (e.g., referrals given if lack of symptom improvement). In general, the Fidelity Monitoring Center will oversee regular review of coaches using quantitative and qualitative metrics that include tone and style (authentic, personalized) of their interactions with clients, content (depth, goal orientation), efficiency (response time), user engagement, outcomes, and accuracy rate for risk management. Coaches that do not meet the metrics will be put on a performance improvement plan and may be terminated if improvement is not demonstrated.

Benefits

The benefits to participants in this study and to society are expected to be great. In terms of potential benefits to participants, these include: improved uptake of services, reduced anxiety, depressive, and/or ED symptoms, and improved quality of life. The treatment may also improve academic impairment and reduce likelihood of dropout from college as well as stress on the individual posed by the burden of mental health problems. In addition, it is possible that skills to solve ongoing problems that may maintain mental health problems may improve. The growing prevalence and burden of mental health problems on the college campus highlight the need for a new approach for detecting mental health problems and engaging college students in services. Therefore, the potential risks that are associated with this study are reasonable when considering the many benefits that the participants and society may gain.

2.f Early Withdrawal of Subjects

The recruitment emails will note that students can reply to decline participation (and any further reminders); they may also select this option on the consent form page of the screening survey.

2.g When and How to Withdraw Subjects

Taking part in this research study is voluntary. Participants may choose not to take part in this research study or may withdraw their consent at any time. They may withdraw by telling the study team they are no longer interested in participating in the study or they may send in a withdrawal letter. There will be no penalty or loss of benefits to which they were otherwise entitled.

2.h Data Collection and Follow-up for Withdrawn Subjects

When a participant withdraws from the study, the research team will stop collecting data from them.

D3 Study Intervention

SilverCloud Health Guided Self-Help Mental Health Programs

The SilverCloud Health platform provides three self-help guided interventions, one for each disorder (both for those with clinical symptoms and at high risk). The interventions were derived from evidence based guided self-help treatments that were efficacious in traditional efficacy trials, specifically for anxiety, depression, and EDs. Each session takes about 20 minutes. To maximize efficacy, key targets (i.e., decreased avoidance for anxiety disorders; increased behavioral activation for depression; decreased dietary restraint and weight/shape concerns for EDs; and decreased dysfunctional thoughts and increased use of Cognitive behavioral treatment skills for all three disorders) are addressed, which include the following content to address the targets: Anxiety: Psychoeducation on anxiety and avoidance, goal setting, self-monitoring and cognitive restructuring (to identify and alter negative automatic thoughts), exposure therapy, mindfulness/relaxation. Depression: Psychoeducation on the cognitive-behavioral theory of depression, goal setting, identifying and engaging in enjoyable activities (behavioral activation), emotion regulation and distress tolerance skills, self-monitoring and cognitive

restructuring (to identify and alter negative automatic thoughts). EDs: Psychoeducation on the cognitivebehavioral theory of EDs, self-monitoring, goal setting, meal planning and tracking, cognitive and behavioral strategies to improve body image, eating, and coping skills.

Participants completing the mobile intervention who screened positive or at high risk for 2 or more disorders (i.e., of depression, anxiety, and EDs) will be asked to choose a focus based on which problem is most bothersome or impairing to their everyday functioning, and will be assigned that program as their primary track. Incorporating participant preference in our approach is designed to enhance the students' involvement as stakeholders and to increase their engagement. As they progress through the intervention, they also will be assigned the components presumed to be essential to intervention effects for the comorbid disorder.

Participants completing the mobile intervention will receive the support from a coach. Their role includes supporting and enhancing user motivation; monitoring progress; facilitating goal setting and offering accountability; providing feedback on technique usage and encouraging practice; answering user questions; and monitoring for/responding to clinical risk. Communication with users is primarily via two-way, asynchronous messaging, with optional, supplementary phone calls to enhance goal setting. Coach messaging is done via a web-based "dashboard," and delivered to users within the SilverCloud Health app. Coaches have participants' baseline screen results so they can personalize treatment and help the user apply skills learned to comorbid problems. Moreover, coaches will monitor symptoms using the following assessments built into the SilverCloud Health programs:

1) For individuals with depression, depression is assessed weekly using an abbreviated version of the measure used for assessing depression at baseline (i.e., PHQ-2).
2) For individuals with anxiety, anxiety is assessed weekly using a short, validated measure of anxiety (i.e., GAD-2).
3) For individuals with eating disorders, weekly monitoring includes three questions based on the EDE-Q assessing eating disorder behaviors (i.e., binge eating, purging) and weight/shape concerns.

Note: When individuals have more than one of these problems, they complete weekly monitoring for each comorbidity.

If the coach feels the online program cannot adequately address comorbidity, participants are referred to appropriate campus/community resources.

The program will be accessible via smart phone app or their desktop. Program access will be password protected.

3.a COVID-19 Specific SilverCloud Module

During the COVID-19 pandemic, coaches in the SilverCloud intervention will be randomized into either condition:

1. Give the COVID-19 modules to their users in addition to their assigned SilverCloud modules to treat depression, anxiety, and/or eating disorders, following the same schedule as for transdiagnostic modules.
2. Only providing their users with their assigned SilverCloud modules to treat depression, anxiety, and/or eating disorders.

E Participants will not be aware of this randomization to prevent bias when answering surveys.Study Procedures

E1 Screening for Eligibility

Eligibitlity will be assessed using the measures and cut-offs in the table below.

Table 3. Screening Measures and Cut-Offs for Anxiety, Depression, and Eating Disorders

Construct	Measure	Cut-off score	Projected prevalence
Anxiety disorders			
Generalized anxiety disorder, at high risk	GAD-Q-IV	5.7	14%
Generalized anxiety, clinical	GAD-Q-IV	diagnostic criteria	8%
Social anxiety disorder, at high risk	SPDQ	7.4	15%
Social anxiety disorder, clinical	SPDQ	diagnostic criteria	9%
Panic disorder, at high risk	PDSR	8.8	2%
Panic disorder, clinical	PDSR	diagnostic criteria	2%
Depression			
Depression, at high risk	PHQ-9	6-10	15%
Depression, clinical	PHQ-9	11	15%
Eating disorders			
Eating disorder, at high risk	WCS, EDE-Q	WCS of 47, plus non-clinical level of compensatory behaviors	10%
Eating disorder, clinical	EDE-Q	2.3 plus diagnostic criteria	8%
Overall projected prevalence			
At high risk for ≥1 condition (none clinical)	see above	see above	25%
No current treatment			15%
Clinical for ≥1 condition	see above	see above	30%
No current treatment			15%

Notes: GAD-Q-IV=Generalized Anxiety Disorder Questionnaire-IV; SPDQ=Social Phobia Diagnostic Questionnaire; PDSR=Panic Disorder Self-report; PHQ-9=Patient Health Questionnaire; WCS = Weight Concerns Scale; EDE-Q= Eating Disorders Examination-Questionnaire. Data source for projected prevalence numbers: Healthy Minds Study 2014-2016 (*N*=66,633)

Participants will also be asked if they own a smartphone and if they are currently in treatment for mental health.

E2 Schedule of Measurements

Participants will be assessed at screening, baseline, 6 weeks, 6 months, and 2 years. All surveys will be administered via Qualtrics. Participants will be compensated by receiving an electronic gift card for completing the Baseline ($5), 6 week ($5), 6 month ($10), and 2-year ($20) follow-up assessments. Particpants will be entered into a sweepstakes to win one of five $50 gift cards after completing the Baseline, 6 week, 6 month, and 2-year surveys. In addition, once particpants complete all four surveys, they will be entered into a sweepstakes to win one of ten $100 gift cards.

All students who receive a recruitment email will be automatically entered into a sweepstakes for one of 40 $100 electronic gift card prizes.

See table below for schedule of assessments:

	Baseline Screen	Intervention Period	Post-Screen Assessments			Primary Purpose
			6 wks	6 mos	2 yrs	
PARTICIPANTS						
Demographics	x					Mod
Expectancy/credibility	x					Mod
Degree of cognitive distortion	x					Mod
Anxiety: Generalized anxiety; social phobia; panic	x		x	x	x	TO/Mod (symptom severity; comorbidity)
Depression	x		x	x	x	TO/Mod (symptom severity; comorbidity)
Eating disorders	x		x	x	x	TO/Mod (symptom severity; comorbidity)
Chronicity	x					Mod
Comorbidities: Trauma; insomnia; substance use	x			x	x	Mod
Impairment/quality of life	x			x	x	TO/Mod
Motivation for treatment	x		x	x	x	Mod
Mental health treatment utilization	x		x	x	x	TO
Academic impairment (obtained from colleges)	x			x	x	TO
Target engagement *Transdiagnostic:* dysfunctional cognitions; CBT skills *Disorder-specific:* avoidance; behavioral activation; restraint; weight/shape concerns	x		x			Med
Early engagement			x			Med
Rapid response			x			Med
Screening and treatment feedback				x	x	--
TREATMENT PROCESS (INTERVENTION CONDITION)						
Mobile treatment process (e.g., sessions completed, messages with coach)		x				Pred
Fidelity/personalization of coaching (i.e., user perception and coder ratings)		x	x	x		Pred
STUDENT MENTAL HEALTH SERVICES CENTERS						
Attitudes toward mobile mental health platform	x					--
Perceptions of mobile mental health platform				x		--
Intended adoption					x	--
Mental health service utilization	x				x	TO

Notes: Light gray shading = occurring during intervention period. Mod = moderator; TO = treatment outcome; Med = mediator; Pred = predictor.

2.a Data Collection Procedures for Adverse Events

For the purpose of this study, adverse events will be defined as unanticipated problems involving risks to the study participant. A serious adverse event will be defined as any untoward occurrence that results in death, is life threatening, or creates persistent and

significant disability. The initial step in reporting adverse events of any kind is to consult with Dr. Newman, PI at PSU, who will be providing oversight for adverse event reporting for the study. Additionally, adverse events will be reported to PIs at the other sites, Drs. Wilfley (WUSM), Eisenberg (UM) and Taylor (PAU), who will decide if the event is serious enough to warrant treatment discontinuation or participant withdrawal. Any potentially adverse events will be evaluated by the PIs within 72 hours. All serious adverse events will be immediately reported to the IRB of Record. All adverse events and study withdrawals, together with a detailed explanation of the event and withdrawal, will be forwarded to the Human Subjects Committee and the DSMB. In addition, at its regular meeting, the DSMB will summarize all adverse events of any severity, to be forwarded to the IRB of Record via Dr. Wilfley.

2.b Reporting Procedures

Because the online interventions follow standard practice guidelines that have been used in research trials without significant adverse events, we do not anticipate any significant adverse events. However, coaches will be trained to monitor for adverse events, including Serious Adverse Events (SAEs) such as deaths, hospitalizations, and life threatening events and Unanticipated Problems (UPs), and will report any potential adverse events immediately upon their identification to the FMC. We will also monitor for adverse events at all follow-up assessments and via all other communication with study participants. Any potentially adverse events will be evaluated by the PIs within 72 hours. Serious adverse events will be promptly reported to the study IRB. Study-related serious adverse events will be reported to the NIMH within 2 weeks; all others will be included in the annual report to the NIMH.

2.c Adverse Event Reporting Period

2.d Post-study Adverse Event

E3 Study Outcome Measurements and Ascertainment

Study outcomes includes the following:

- Reducing the number of individuals with mental health disorders.
- Reducing disorder-specific symptoms
- improving quality of life and functioning

F Statistical Plan

F1 Sample Size Determination and Power

Sample size was based on achieving greater than 80% power to detect minimally meaningful differences in primary and secondary outcomes. We will include 20 colleges with approximately equal numbers of participants per campus, and approximately 3,154 high risk and 3,154 clinical participants with complete follow-up data. All power estimates were derived from Monte Carlo simulations (a gold standard in power estimation)[214,215]. For all analyses, power estimation is based on an effect size of .2 (i.e., for the primary

outcome, a differential change of .2 in the treatment vs. control group; for moderator analyses, effect size was .2 for each moderation effect; for mediator analyses, each pathway within the mediation was estimated at .2). We thus have power to detect smaller differences than we anticipate based on assumptions; this extra power is important, given that smaller differences would still be clinically meaningful at a population scale, particularly considering the modes t cost of this online intervention. Power for all secondary outcomes was also estimated within the Monte Carlo simulation using all moderators within the same model; and all mediators within the same model targeting a .2 effect size, reflecting a conservative approach to power calculation and model estimation. Results of the Monte Carlo simulations suggested we had greater than 90% power to detect all primary outcomes and greater than 80% power to detect all secondary outcomes.

F2 Interim Monitoring and Early Stopping

The DSMB will provide oversight and ongoing monitoring of participant safety, quality of data collection, and integrity of the study on a yearly basis. The DSMB will receive a report from the study Screening Implementation and Data Coordinating Center approximately four weeks before each review date. These reports will include the major variables necessary for monitoring safety, quality of data collection, and integrity of the study and will include otherwise blinded outcome data. The DSMB will prepare a report after every meeting based on the material received from the Screening Implementation and Data Coordinating Center, which will be forwarded to the PIs to review at Study Executive Committee meetings and also forwarded to the IRB of Record by Dr. Wilfley.

F3 Analysis Plan

To evaluate efficacy of the mHealth platform vs. usual care, in engaging participants (Aim 1) we will use hierarchical logistic regression to examine uptake (i.e., individuals beginning any sort of treatment). Outcome will be at least one session of mental health services use (either online or in-person) assessed at 6 weeks, 6 months, and 2 years. Using hierarchical logistic regression, we will also examine efficacy in reducing or preventing number of students with mental health disorders (i.e., a positive screen for at least one of anxiety, depression, or ED as the outcome reflecting a "clinical case")assessed at 6 weeks, 6 months and 2 years, with a primary endpoint of 2 years. This allows for a single, universal outcome applicable to everyone in the study. Both logistic regression models will include random intercepts for colleges and for students nested within colleges, and account for repeated assessments within students, and will estimate the following fixed effects: main effect of time (coded as a factor variable, including baseline, 6-weeks, 6-months, and 2 years), treatment condition, and two-way interaction between time and treatment condition.

To evaluate reduction in disorder-specific symptoms (Aim 2b) and improvement in quality of life (Aim 2c), multilevel models will be used. Analyses of symptom change will be conducted within each clinical disorder subgroup separately with relevant symptoms as the response variables. We will also use a z-score to standardize primary symptom measures to obtain an estimate for a unified intervention effect. All symptom models will include random intercepts for colleges and for students nested within colleges, account for repeated assessments within students, and will estimate the following fixed effects: main effect of time, treatment condition, and two-way interaction between time and treatment condition. Parameter estimates from these models will allow separately

comparing change between arms from pre to 6 weeks, pre to 6 months, and from pre to 2-year follow-up. Each model will use dummy-coded factor terms as a stringent test of the treatment to ensure that: 1) treatment was associated with significantly greater change from pre to post than the control group; and 2) gains made in treatment at 6 weeks are maintained and significantly greater than baseline at each follow-up.

Analyses for Aim 3 (targets, other mediators, within-mobile program predictors, moderators). Potential mediators,are categorized into three groups: 1) clinical targets (Aim 3a and Aim 3b); 2) early engagement with services (Aim 3c); and 3) early clinical response/rapid response (Aim 3c). We will test for mediation using structural equation models (SEM) with confidence intervals derived from bootstrapping of indirect effects and total effects. We will examine targets and mediators preceding changes in outcomes. To draw more informative and coherent conclusions across the three disorders, we will explore meaningful transdiagnostic clinical targets as well as disorder specific targets. For transdiagnostic mediator outcomes, binary clinical case status and quality of life measures are natural outcome measures, but for symptom outcomes, we will use standardized symptom scores (for transdiagnostic outcomes) and nonstandardized symptoms scores (for disorder-specific outcomes). Moderated mediation (with treatment vs control as the moderator) will be tested by constraining the indirect effect to be equal across treatment and control groups and testing differences in chi-square fit. Any significant misfit caused by specifying the indirect effect of each mediator to be equal suggests that there are significant differences in this mediational path between the treatment and control. All mediational paths between the primary predictor and outcome will be estimated simultaneously to account for any and all interdependence between paths and to ensure these interdependencies do not bias estimation. Note that in applying moderated mediation analyses to both transdiagnostic and disorder-specific targets, we will be simultaneously testing whether the intervention engages the targets (Aim 3a) and whether intervention-induced changes in targets are associated with clinical benefit (Aim 3b). Putative moderators (Aim 3e) will examine interaction terms with time point and random assignment in regressions to identify subgroups that benefit most from treatment, and others for whom additional tailoring may be necessary in future refinements of the delivery model. In cases where moderators are significant, we will then conduct mediator analyses separately by subgroups defined by these moderators, because different intervention effects often imply different mechanisms by which effects are occurring[216].In moderation models, results will estimate the following fixed effects: 1) main effect of time, treatment condition, and each proposed moderator; 2) two-way interactions between time and treatment condition, treatment condition and each moderator, and time and each moderator; and 3) three way interactions between time, treatment condition, and each moderator. The models will also estimate random effects of time nested within individuals, and intercepts nested within campuses. Within-mobile treatment predictors of change (Aim 3d) will use multilevel models using the fixed effects of maineffects of time, and each within-mobile program predictor, and the interaction between within-mobile program predictors and time estimating random effect of time nested within individuals and intercepts nested within campuses.

Analyses for Aim 4: Economic evaluation analyses (Aim 4a) were designed to provide information for stakeholders considering implementing the mobile platform[217]. As such, analyses will be conducted from the payer's perspective to reflect opportunity cost for the payer. We will use TreeAge software, taking a multistep approach. Overall, the model will be evidence-based and fully validated using study data. A decision analytic

model using a microsimulation approach[218] will be used to provide the most flexibility for testing model assumptions and provide clear evidence to decision-makers concerning reliability of results. Internal validation of the model will be conducted by comparing outcomes of participants whose data were used to construct the model to their predicted outcomes. Model fit will be tested using the R2 statistic for continuous data and the chi-squared statistic for categorical data. External validity will be tested by comparing the model's predicted outcome to actual for participants who were "excluded" from the model-building process. The outcome of interest is the net benefit of the intervention compared to usual care at 2 years. Sensitivity of the decision model to the assumptions, including time frame, discount rate, and perspective, will be thoroughly tested using deterministic and probabilistic sensitivity analyses.[219,220] We will also calculate incremental cost-effectiveness ratios, corresponding to the incremental difference (intervention vs. control) in costs divided by the incremental difference in the primary outcome, the number of clinical cases at 2-year follow-up. Monte Carlo simulations and cost-effectiveness acceptability curves will be used to present uncertainty around this estimate. Academic outcomes (Aim 4b) will be analyzed using the methods described for the primary outcomes under Aim 1. Academic outcomes will also be included into cost analyses, by translating drop-outs from college into losses in tuition (for institutions) and losses in lifetime expected productivity. Stakeholder attitudes (Aim 4c) will be assessed for variation using descriptive statistics, and will be used to predict intention to adopt the platform using ordered probit regressions (with Likert categorical variables corresponding to intention to adopt).

F4 Missing Outcome Data

All analyses will be intent-to-treat analyses, using full-information maximum likelihood to handle missing data.

G Data Handling and Record Keeping

G1 Confidentiality and Security

All surveys will be completed on the secured survey platform Qualtrics. Survey data will be directly downloaded by our Screening Implementation and Data Coordinating site, UM, onto a protected server.

The data coordinating center will store the study data on secure, password-protected servers, with identifying information always kept separate from other study data (such as assessment responses). The data will only be accessible at any given time to the small number of study team members who need to use the data at that time. Data will be stored separately by participating institution until de-identified analytic files are assembled after data collection.

Data will be transmitted betweem sites using the secured file share program Box.

In order for the Fidelity Monitoring site, PSU, to review coach messages and data, SilverCloud Health will send PSU the data using Box. The data will be stored on password protected computers.

SilverCloud Health's privacy is aligned with US personal data protection principles and is HIPAA compliant.

All of our surveys will be completed using Qualtrics. Within Qualtrics we will create a contact list based on the registrar office database sent by the universities, which will allow Qualtrics to send out personalized email invitation to students. Only our Data Coordinating Center, the University of Michigan, will have access to the identifying information and will create an anonymous study ID for each participant who agrees to participate in the study. With the assistance of SilverCloud we were able to create a code to automatically link the anonymous Qualtrics Response ID from the survey with the self-selected username in SilverCloud. SilverCloud will only have access to limited data from Qualtrics for people who were randomized into the SilverCloud program. The data they will receive will help inform the coach on how to best support participants such as disorder risk level, suicide risk, gender, school, and co-morbidities. SilverCloud will also receive the email address of the participants in order to send them an automatic email to sign-up for the program."

G2 Training

All staff personnel are trained and comply with HIPAA regulations. All study team members will complete the CITI training and Good Clinical Practice training.

G3 Performance Monitoring

The Data and Safety Monitoring Plan for this trial includes close monitoring by the principal investigators (PIs) and four independent safety officers through the DSMB.

H Study Monitoring, Auditing, and Inspecting

H1 Study Monitoring Plan

Data Safety and Monitoring Board (DSMB)
An independent panel of experts with experience in clinical trials, health services research, biostatistics, and college mental health, consisting of four members who are not affiliated with the study – including an intervention researcher, a counseling center director, a biostatistician, and a patient advocate – will be appointed to constitute a Data Safety and Monitoring Board (DSMB). Members will be named prior to the commencement of the study. In addition, the study PIs (Drs. Wilfley, Eisenberg, Newman, and Taylor) and designated staff will attend the DSMB meetings (as non-voting participants) and will be responsible for preparing and presenting data reports from the study. The DSMB will provide oversight and ongoing monitoring of participant safety, quality of data collection, and integrity of the study on a yearly basis. The DSMB will receive a report from the study Screening Implementation and Data Coordinating Center approximately four weeks before each review date. These reports will include the major variables necessary for monitoring safety, quality of data collection, and integrity of the study and will include otherwise blinded outcome data. The DSMB will prepare a report after every meeting based on the material received from the Screening

Implementation and Data Coordinating Center, which will be forwarded to the PIs to review at Study Executive Committee meetings and also forwarded to the IRB of Record by Dr. Wilfley.

The DSMB will provide the following functions:

- Review of data (including masked data) over the course of the trial relating to efficacy, recruitment, randomization, adherence, retention, operating procedures, forms completion, intervention effects, ethnic/racial minority inclusion, and participant safety.
- Identification of problems relating to safety over the course of the study. Study PIs and Program Administrators will be informed by phone and via written report of their findings and recommendations.
- Identification of needs for additional data relevant to safety issues and request of these data from the study investigators.
- Selection of appropriate analyses and periodic review of data on safety and outcomes.
- Recommendations regarding recruitment, treatment effects, adherence, retention, safety issues, and continuation of the study.
- Provision of written reports to the Project Officer and the PIs following each DSMB meeting. These reports will summarize the key issues reviewed by the DSMB.

The frequency and type of data review is summarized in the following table, with additional information following:

Data	Review Frequency
Participant accrual (with demographic data)	Semiannually
Adverse events	Within 72 hours
Adverse and other events review	Annually
Intervention compliance	Annually
Discontinuation rules report regarding statistical power implications of drop-outs and missing data	Annually

I Study Administration

I1 Organization and Participating Centers

Overall responsibility for this project falls under PIs Denise E. Wilfley, PhD, Craig Barr Taylor, MD, Michelle Newman, PhD, and Daniel Eisenberg, PhD, continuing a long-standing collaboration between them and their respective institutions. Each PI offers unique strengths to the proposed project.

To conduct this trial, we propose a Clinical Coordinating Center, a Screening Implementation and Data Coordinating Center, a Fidelity Monitoring Center, a Technology Monitoring Center, and a Technology Partner, as well as a Study Executive Committee and expert consultants.

Clinical Coordinating Center, headed by Dr. Wilfley, with the support of co-I Dr. Fitzsimmons-Craft at WUSM will be responsible for study oversight, including site recruitment, coordination and monitoring of study procedures and progress across sites, and collection of follow-up data.

Screening Implementation and Data Coordinating Center, headed by Dr. Eisenberg at UCLA, with the support of co-Is Drs. Lipson, Justin Heinze, and Hyungjin Kim at UM, at well as Dr. Newman at PSU, will be responsible for administering the online screen at each study site, identifying students who are eligible for the full study and overseeing referrals to the mobile platform or campus treatment options, data coordination and monitoring, and data analysis.

Fidelity Monitoring Center, headed by Dr. Newman at PSU, will ensure the integrity of coach training activities and fidelity monitoring of the coaching.

Technology Partner SilverCloud Health will oversee the maintenance of the platform software.

Technology Monitoring Center, headed by Dr. Taylor at PAU, will oversee the study's use of technology, including monitoring and recording real-time technological improvements and ensuring that any platform changes (to keep pace with modern advances) sustain core intervention principles and follow proposed Consort standards.[157] This site will be the primary contact for SilverCloud Health and will ensure all withinprogram data are adequately labeled and tracked.

Expert Consultation from Dr. Andrea Kass regarding cost analyses and mobile health delivery and evaluation, and from Dr. Helena Kraemer on methodological and statistical issues.

I2 Funding Source and Conflicts of Interest

This study is funded by NIH. Any potential financial conflicts of interest for individual research team members are reported according to the site-specific IRB requirements and procedures.

I3 Committees

Study Executive Committee will consist of PIs Drs. Wilfley, Eisenberg, Newman, Taylor, and co-Is Fitzsimmons-Craft, Lipson, and Kim. The PIs will be primarily responsible for decision-making related to the overall scientific conduct of the study and monitoring the overall study progress to ensure its timely completion, and the co-Is will assist in this process. Throughout the study, the committee will communicate weekly by teleconference to make study-related decisions. Daily communication about the project will be made by email and phone.

I4 Subject Stipends or Payments

All students who receive a recruitment email will be automatically entered into a sweepstakes for one of 40 $100 electronic gift card prizes.

Participating universities and colleges will have the option to offer their own incentives to their students. The incentives offered by the school will be reviewed by the research team to make sure they are compliant with the IRB regulations, i.e., not coercive.

Participants in the full study will be compensated by receiving an electronic gift card for completing the Baseline ($5), 6 week ($5), 6 month ($10), and 2-year ($20) follow-up assessments. Particpants will be entered into a sweepstakes to win one of five $50 gift cards after completing the Baseline, 6 week, 6 month, and 2-year surveys. In addition, once particpants complete all four surveys, they will be entered into a sweepstakes to win one of ten $100 gift cards.

I5 Study Timetable

The table below summarizes the timeline for the proposed five-year study. Each wave includes 5 campuses, for a total of 20 campuses across 4 waves. The waves are staggered by 6 months each, with the exception that the second wave will start a full year after the first wave to allow for careful adjustments in sampling (e.g., the size of the initial samples) if necessary. Data analysis and write-up will begin in month 43 so as to allow 18 months for these activities.

Study Timeline	Pre-award	1-6	7-12	13-18	19-24	25-30	31-36	37-42	43-48	49-54	55-60
Finalize procedures and protocol											
Finalize the study procedures	X	X									
Finalize assessment protocols	X	X									
Confirm and prepare study sites											
Step 1a. Confirm diverse set of 20 campuses		X	X								
Step 1b. IRB and institutional approvals		X									
Wave 1 campuses											
Baseline survey, 6-week follow-up, intervention			X								
6-month follow-up				X							
2-year follow-up						X					
Wave 2 campuses											
Baseline survey, 6-week follow-up, intervention				X							
6-month follow-up					X						
2-year follow-up							X				
Wave 3 campuses											
Baseline survey, 6-week follow-up, intervention					X						
6-month follow-up						X					
2-year follow-up								X			
Wave 4 campuses											
Baseline survey, 6-week follow-up, intervention						X					
6-month follow-up							X				
2-year follow-up									X		
Data analysis and write-up									X	X	X
Preparation of de-identified data set for sharing										X	X

J Publication Plan

Access to data is made equally available to the site PIs: Drs. Wilfley, Taylor, Newman, and Eisenberg and their teams. A publication plan will be formulated within the first two years of the trial to determine authorship order and responsibilities. Publication authorship will be based on the relative scientific contributions of the PIs, Co-Is, key personnel, and other members of the research team.

K References

1. Davies EB, Morriss R, Glazebrook C. Computer-delivered and web-based interventions to improve depression, anxiety, and psychological well-being of university students: A systematic review and metaanalysis. *J Med Internet Res.* 2014;16(5):e130. PMCID: PMC4051748
2. Melioli T, Bauer S, Franko DL, et al. Reducing eating disorder symptoms and risk factors using the internet: A meta-analytic review. *Int J Eat Disord.* 2016;49(1):19-31. PMID: 26607683
3. Hofman J, Pollitt A, Broeks M, Stewart K, van Stolk C. Review of computerised cognitive behavioural therapies: Products and outcomes for people with mental health needs. *Rand Health Q.* 2017;6(4):12. PMCID: PMC5627641
4. Andersson G, Cuijpers P. Internet-based and other computerized psychological treatments for adult depression: a meta-analysis. *Cogn Behav Ther.* 2009;38(4):196-205. PMID: 20183695
5. Spek V, Cuijpers P, Nyklicek I, Riper H, Keyzer J, Pop V. Internet-based cognitive behaviour therapy for symptoms of depression and anxiety: a meta-analysis. *Psychol Med.* 2007;37(3):319-328. PMID: 17112400
6. Kass AE, Trockel M, Safer DL, et al. Internet-based preventive intervention for reducing eating disorder risk: A randomized controlled trial comparing guided with unguided self-help. *Behav Res Ther.* 2014;63C:90-98. PMCID: PMC4383716
7. Reetz DR, Krylowicz B, Bershad C, Lawrence JM, Mistler B. The Association for University and College Counseling Center Directors Annual Survey: Reporting period: September 1, 2014 through August 31, 2015. 2015. http://www.aucccd.org/assets/documents/aucccd%202015%20monograph%20-%20public%20version.pdf.
8. Center for Collegiate Mental Health (CMMH). Center for Collegiate Mental Health: 2016 Annual Report. 2016.

9. Twenge JM, Gentile B, DeWall CN, Ma D, Lacefield K, Schurtz DR. Birth cohort increases in psychopathology among young Americans, 1938–2007: A cross-temporal meta-analysis of the MMPI. *Clin Psychol Rev.* 2010;30(2):145-154. PMID: 19945203
10. Kessler RC, Berglund P, Demler O, Jin R, Merikangas KR, Walters EE. Lifetime prevalence and age-ofonset distributions of DSM-IV disorders in the National Comorbidity Survey Replication. *Arch Gen Psychiatry.* 2005;62(6):593-602. PMID: 15939837
11. Arria AM, Caldeira KM, Vincent KB, Winick ER, Baron RA, O'Grady KE. Discontinuous college enrollment: Associations with substance use and mental health. *Psychiatr Serv.* 2013;64(2):165-172. PMCID: PMC3609033
12. De Hert M, Correll CU, Bobes J, et al. Physical illness in patients with severe mental disorders. I. Prevalence, impact of medications and disparities in health care. *World Psychiatry.* 2011;10(1):52-77. PMCID: PMC3048500
13. Kafali N, Cook B, Wang S, Martinez PG, Selke Z, Blanco C. Impact of mental disorders on employment and receipt of public assistance: An instrumental variables approach. *J Ment Health Policy Econ.* 2015;18(3):137-145. PMID: 26474049
14. Kessler RC, Foster CL, Saunders WB, Stang PE. Social consequences of psychiatric disorders, I: Educational attainment. *Am J Psychiatry.* 1995;152(7):1026-1032. PMID: 7793438
15. Kessler RC, Walters EE, Forthofer MS. The social consequences of psychiatric disorders, III: Probability of marital stability. *Am J Psychiatry.* 1998;155(8):1092-1096. PMID: 9699699
16. Blanco C, Okuda M, Wright C, et al. Mental health of college students and their non-college-attending peers: Results from the National Epidemiologic Study on Alcohol and Related Conditions. *Arch Gen Psychiatry.* 2008;65(12):1429-1437. PMCID: PMC2734947
17. Eisenberg D, Hunt J, Speer N. Mental health in American colleges and universities: Variation across student subgroups and across campuses. *J Nerv Ment Dis.* 2013;201(1):60-67. PMID: 23274298
18. Auerbach RP, Alonso J, Axinn WG, et al. Mental disorders among college students in the World Health Organization World Mental Health Surveys. *Psychol Med.* 2016;46(14):2955-2970. PMCID: PMC5129654
19. Zivin K, Eisenberg D, Gollust SE, Golberstein E. Persistence of mental health problems and needs in a college student population. *J Affect Disord.* 2009;117(3):180-185. PMID: 19178949
20. National Institute of Mental Health. *Strategic Research Priorities Overview*. 2017. https://www.nimh.nih.gov/about/strategic-planning-reports/strategic-research-priorities/index.shtml. Accessed 10/6/2017.
21. Eisenberg D, Nicklett EJ, Roeder K, Kirz NE. Eating disorder symptoms among college students: Prevalence, persistence, correlates, and treatment-seeking. *J Am Coll Health.* 2011;59(8):700-707. PMCID: PMC3721327
22. Eisenberg D, Hunt J, Speer N, Zivin K. Mental health service utilization among college students in the United States. *J Nerv Ment Dis.* 2011;199(5):301-308. PMID: 21543948
23. Aud S, KewalRamani A, Frohlich L. America's youth: Transitions to adulthood. National Center for Education Statistics. 2012. http://ies.ed.gov/pubsearch/pubsinfo.asp?pubid=2012026
24. Kazdin AE. Addressing the treatment gap: A key challenge for extending evidence-based psychosocial interventions. *Behav ResTher.* 2017;88:7-18. PMID: 28110678
25. Kazdin AE, Fitzsimmons-Craft EE, Wilfley DE. Addressing critical gaps in the treatment of eating disorders. *Int J Eat Disord.* 2017:n/a-n/a. PMID: 28102908

26. Michaud CM, McKenna MT, Begg S, et al. The burden of disease and injury in the United States 1996. *Popul Health Metr.* 2006;4:11. PMCID: PMC1635736
27. Wang PS, Berglund P, Olfson M, Pincus HA, Wells KB, Kessler RC. Failure and delay in initial treatment contact after first onset of mental disorders in the National Comorbidity Survey Replication. *Arch Gen Psychiatry.* 2005;62(6):603-613. PMID: 15939838
28. Gelenberg AJ. The prevalence and impact of depression. *J Clin Psychiatry.* 2010;71(3):e06. PMID: 20331925
29. Yonkers KA, Bruce SE, Dyck IR, Keller MB. Chronicity, relapse, and illness--course of panic disorder, social phobia, and generalized anxiety disorder: findings in men and women from 8 years of follow-up. *Depress Anxiety.* 2003;17(3):173-179. PMID: 12768651
30. Hargreaves DS, Greaves F, Levay C, et al. Comparison of health care experience and access between young and older adults in 11 high-income countries. *J Adolesc Health.* 2015;57(4):413-420. PMID: 26205758
31. Ettner SL, Frank RG, Kessler RC. The impact of psychiatric disorders on labor market outcomes. *ILR Review.* 1997;51(1):64-81.
32. Eisenberg D, Speer N, Hunt JB. Attitudes and beliefs about treatment among college students with untreated mental health problems. *Psychiatr Serv.* 2012;63(7):711-713. PMID: 22752036 33. Riley WT, Nilsen WJ, Manolio TA, Masys DR, Lauer M. News from the NIH: Potential contributions of the behavioral and social sciences to the precision medicine initiative. *Transl Behav Med.* 2015;5(3):243-246. PMCID: PMC4537462
34. National Institutes of Health. NIH-Wide Strategic Plan, Fiscal Years 2016-2020: Turning Discovery into Health. Bethesda, MD: National Institutes of Health; 2015.
35. Kumar S, Nilsen WJ, Abernethy A, et al. Mobile health technology evaluation: the mHealth evidence workshop. *Am J Prev Med.* 2013;45(2):228-236. PMCID: PMC3803146
36. American College Health Association. American College Health Association-National College Health Assessment II: Reference Group Executive Summary Spring 2015. Hanover, MD: American College Health Association; 2015.
37. Jones M, Kass AE, Trockel M, Glass AI, Wilfley DE, Taylor CB. A population-wide screening and tailored intervention platform for eating disorders on college campuses: the healthy body image program. *J Am Coll Health.* 2014;62(5):351-356. PMCID: PMC4031301
38. Andrews G, Cuijpers P, Craske MG, McEvoy P, Titov N. Computer therapy for the anxiety and depressive disorders is effective, acceptable and practical health care: a meta-analysis. *PLoS One.* 2010;5(10):e13196. PMCID: PMC2954140
39. Harris poll. Pearson student mobile device survey 2015: National report: College students. 2015. http://www.pearsoned.com/wp-content/uploads/2015-Pearson-Student-Mobile-Device-Survey- College.pdf.
40. Kanuri N, Taylor CB, Cohen JM, Newman MG. Classification models for subthreshold generalized anxiety disorder in a college population: Implications for prevention. *J Anxiety Disord.* 2015;34:43-52. PMID: 26119139
41. Kass AE, Balantekin KN, Fitzsimmons-Craft EE, Jacobi C, Wilfley DE, Taylor CB. The economic case for digital interventions for eating disorders among United States college students. *Int J Eat Disord.* 2017;50(3):250-258. PMCID: PMC5391044
42. Munoz RF. Using evidence-based internet interventions to reduce health disparities worldwide. *J Med Internet Res.* 2010;12(5):e60. PMCID: PMC3057307
43. Mohr DC, Cheung K, Schueller SM, Hendricks Brown C, Duan N. Continuous evaluation of evolving behavioral intervention technologies. *Am Journal Prev Med.* 2013;45(4):517-523. PMCID: PMC3828034

44. Eisenberg D, Golberstein E, Hunt JB. Mental health and academic success in college. *B E J of Econom Anal Policy.* 2009;9(1):Article 40.
45. Lipson SK, Jones JM, Taylor CB, et al. Understanding and promoting treatment-seeking for eating disorders and body image concerns on college campuses through online screening, prevention and intervention. *Eat Behav.* 2016. PMID: 27117825
46. Kanuri N, Cohen JM, Jones M, Ruzek J, Taylor CB, Newman MG. Coached self-help: Notes from the field. In M. Moessner (Chair). Moving beyond efficacy: Investigation of settings, processes, and training in Internet based interventions. 45th Annual Meeting of the Society for Psychotherapy Research; June, 2015; Philadelphia, PA.
47. Newman MG, Kenardy J, Herman S, Taylor CB. Comparison of palmtop-computer-assisted brief cognitive-behavioral treatment to cognitive-behavioral treatment for panic disorder. *J Consult Clin Psychol.* 1997;65(1):178-183. PMID: 9103747
48. Kenardy JA, Dow MGT, Johnston DW, Newman MG, Thomson A, Taylor CB. A comparison of delivery methods of cognitive-behavioral therapy for panic disorder: An international multicenter trial. *J Consult Clin Psychology.* 2003;71(6):1068-1075. PMID: 14622082
49. Newman MG, Przeworski A, Consoli AJ, Taylor CB. A randomized controlled trial of ecological momentary intervention plus brief group therapy for generalized anxiety disorder. *Psychotherapy (Chic).* 2014;51(2):198-206. PMCID: PMC4440457
50. Gruber K, Moran PJ, Roth WT, Taylor CB. Computer-assisted cognitive behavioral group therapy for social phobia. *Behav Ther.* 2001;32(1):155-165.
51. Dow MGT, Kenardy JA, Johnston DW, Newman MG, Taylor CB, Thomson A. Prognostic indices with brief and standard CBT for panic disorder: II. Moderators of outcome. *Psychol Medicine.* 2007;37(10):1503-1509. PMID: 17493295
52. Kanuri N, Newman MG, Ruzek JI, et al. The feasibility, acceptability, and efficacy of delivering Internetbased self-help and guided self-help interventions for generalized anxiety disorder to Indian university students: Design of a randomized controlled trial. *JMIR Res Protoc.* 2015;4(4):e136. PMCID: PMC4704912
53. Kanuri N, Newman MG, Ruzek JI, et al. Implementing a stepped-care model of digital mental health interventions in Indian universities: The role of engagement in development. Eighth Scientific Meeting of the International Society for Research on Internet Interventions; April, 2016; Seattle, Washington.
54. LaFreniere LS, Newman MG. A brief ecological momentary intervention for generalized anxiety disorder: A randomized controlled trial of the worry outcome journal. *Depress Anxiety.* 2016;33(9):829- 839. PMID: 27062682
55. Newman MG, Kanuri N, Ruzek JI, et al. A randomized controlled trial of feasibility, acceptability, and efficacy of online, CBT-based guided self-help programs to reduce anxiety among students in India. 36th Annual Convention of the Anxiety and Depression Association of America; March, 2016; Philadelphia, PA.
56. Newman MG, Szkodny LE, Llera SJ, Przeworski A. A review of technology-assisted self-help and minimal contact therapies for anxiety and depression: Is human contact necessary for therapeutic efficacy? *Clin Psychol Rev.* 2011;31(1):89-103. PMID: 21130939
57. Hunkeler EM, Hargreaves WA, Fireman B, et al. A web-delivered care management and patient selfmanagement program for recurrent depression: A randomized trial. *Psychiatr Serv.* 2012;63(11):1063- 1071. PMID: 22983558
58. O'Neil A, Taylor B, Sanderson K, et al. Efficacy and feasibility of a tele-health intervention for acute coronary syndrome patients with depression: results of the "MoodCare" randomized controlled trial. *Ann Behav Med.* 2014;48(2):163-174. PMID: 24570217

59. Trockel M, Manber R, Chang V, Thurston A, Taylor CB. An e-mail delivered CBT for sleep-health program for college students: effects on sleep quality and depression symptoms. *J Clin Sleep Med.* 2011;7(3):276-281. PMCID: PMC3113967
60. Redzic NM, Taylor K, Chang V, Trockel M, Shorter A, Taylor CB. An Internet-based positive psychology program: Strategies to improve effectiveness and engagement. *The Journal of Positive Psychology.* 2014;9(6):494-501.
61. Taylor CB, Bryson S, Luce KH, et al. Prevention of eating disorders in at-risk college-age women. *Arch General Psychiatry.* 2006;63(8):881-888. PMCID: PMC3837629
62. Taylor CB, Kass AE, Trockel M, et al. Reducing eating disorder onset in a very high risk sample with significant comorbid depression: A randomized controlled trial. *J Consult Clin Psychol.* 2016;84(5):402- 414. PMCID: PMC4836995
63. Wilfley DE, Agras WS, Taylor CB. Reducing the burden of eating disorders: A model for populationbased prevention and treatment for university and college campuses. *Int J Eat Disord.* 2013;46(5):529- 532. PMCID: PMC3703768
64. Jones M, Luce KH, Osborne MI, et al. Randomized, controlled trial of an Internet-facilitated intervention for reducing binge eating and overweight in adolescents. *Pediatrics.* 2008;121(3):453462. PMID: 18310192
65. Völker U, Jacobi C, Taylor CB. Adaptation and evaluation of an Internet-based prevention program for eating disorders in a sample of women with subclinical eating disorder symptoms: A pilot study. *Eat Weight Disord.* 2011;16(4):e270-e273. PMID: 22526132
66. Saekow J, Jones M, Gibbs E, et al. StudentBodies-eating disorders: A randomized controlled trial of a coached online intervention for subclinical eating disorders. *Internet Interv.* 2015;2(4):419-428.
67. Wilfley DE, Welch RR, Stein RI, et al. A randomized comparison of group cognitive-behavioral therapy and group interpersonal psychotherapy for the treatment of overweight individuals with binge-eating disorder. *Arch Gen Psychiatry.* 2002;59(8). PMID: 12150647
68. Wilson GT, Wilfley DE, Agras WS, Bryson SW. Psychological treatments of binge eating disorder. *Arch Gen Psychiatry.* 2010;67(1):94-101. PMCID: PMC3757519
69. Borkovec TD, Newman MG, Pincus AL, Lytle R. A component analysis of cognitive-behavioral therapy for generalized anxiety disorder and the role of interpersonal problems. *J Consult Clin Psychol.* 2002;70(2):288-298. PMID: 11952187
70. Newman MG, Przeworski A, Fisher AJ, Borkovec TD. Diagnostic comorbidity in adults with generalized anxiety disorder: Impact of comorbidity on psychotherapy outcome and impact of psychotherapy on comorbid diagnoses. *Behav Ther.* 2010;41(1):59-72. PMCID: PMC2827339
71. Newman MG, Castonguay LG, Borkovec TD, et al. A randomized controlled trial of cognitive-behavioral therapy for generalized anxiety disorder with integrated techniques from emotion-focused and interpersonal therapies. *J Consult Clin Psychol.* 2011;79(2):171-181. PMCID: PMC3078794
72. Brown GK, Karlin BE, Trockel M, Gordienko M, Yesavage J, Taylor CB. Effectiveness of cognitive behavioral therapy for veterans with depression and suicidal ideation. *Arch Suicide Res.* 2016;20(4):677-682. PMID: 26983897
73. Karlin BE, Trockel M, Brown GK, Gordienko M, Yesavage J, Taylor CB. Comparison of the effectiveness of cognitive behavioral therapy for depression among older versus younger veterans: results of a national evaluation. *J Gerontol B Psychol Sci Soc Sci.* 2015;70(1):3-12. PMID: 24218096
74. Strachowski D, Khaylis A, Conrad A, Neri E, Spiegel D, Taylor CB. The effects of cognitive behavior therapy on depression in older patients with cardiovascular risk. *Depress Anxiety.* 2008;25(8):E1-10. PMID: 17377961

75. Eisenberg D, Hunt J, Speer N. Help seeking for mental health on college campuses: review of evidence and next steps for research and practice. *Harv Rev Psychiatry*. 2012;20(4):222-232. PMID: 22894731 76. Killen JD, Taylor CB, Hayward C, et al. Pursuit of thinness and onset of eating disorder symptoms in a community sample of adolescent girls: A three-year prospective analysis. *Int J Eat Disord.* 1994;16(3):227-238. PMID: 7833956
77. Killen JD, Taylor CB, Hayward C, et al. Weight concerns influence the development of eating disorders: A 4-year prospective study. *J Consult Clin Psychol.* 1996;64(5):936-940. PMID: 8916622
78. Jacobi C, Fittig E, Bryson SW, Wilfley D, Kraemer HC, Taylor CB. Who is really at risk? Identifying risk factors for subthreshold and full syndrome eating disorders in a high-risk sample. *Psychol Med.* 2011;41(9):1939-1949. PMCID: PMC3782385
79. Ohlmer R, Jacobi C, Taylor CB. Preventing symptom progression in women at risk for AN: Results of a pilot study. *Eur Eat Disord Rev.* 2013;21(4):323-329. PMID: 23520152
80. Jacobi C, Völker U, Trockel MT, Taylor CB. Effects of an internet-based intervention for subthreshold eating disorders: A randomized controlled trial. *Behav Res Ther.* 2012;50(2):93-99. PMID: 22137366
81. Ruscio AM, Chiu WT, Roy-Byrne P, et al. Broadening the definition of generalized anxiety disorder: Effects on prevalence and associations with other disorders in the National Comorbidity Survey Replication. *J Anxiety Disord.* 2007;21(5):662-676. PMCID: PMC2475335
82. Hayward C, Killen JD, Kraemer HC, Taylor CB. Linking self-reported childhood behavioral inhibition to adolescent social phobia. *J Am Acad Child Adolesc Psychiatry.* 1998;37(12):1308-1316. PMID: 9847504
83. Hayward C, Killen JD, Kraemer HC, Taylor CB. Predictors of panic attacks in adolescents. *J Am Acad Child Adolesc Psychiatry.* 2000;39(2):207-214. PMID: 10673832
84. Karsten J, Hartman CA, Smit JH, et al. Psychiatric history and subthreshold symptoms as predictors of the occurrence of depressive or anxiety disorder within 2 years. *Br J Psychiatry.* 2011;198(3):206-212. PMID: 21357879
85. Karsten J, Penninx BWJH, Verboom CE, Nolen WA, Hartman CA. Course and risk factors of functional impairment in subthreshold depression and anxiety. *Depress Anxiety.* 2013;30(4):386-394. PMID: 23165799
86. Shankman SA, Lewinsohn PM, Klein DN, Small JW, Seeley JR, Altman SE. Subthreshold conditions as precursors for full syndrome disorders: A 15-year longitudinal study of multiple diagnostic classes. *J Child Psychol Psychiatry.* 2009;50(12):1485-1494. PMCID: PMC2804772
87. American Psychological Association. *Clinical implications of "subthreshold" depressive symptoms*. 2000.
88. Fergusson DM, Horwood L, Ridder EM, Beautrais AL. Subthreshold depression in adolescence and mental health outcomes in adulthood. *Arch Gen Psychiatry.* 2005;62(1):66-72. PMID: 15630074
89. Cuijpers P, Smit F. Subthreshold depression as a risk indicator for major depressive disorder: A systematic review of prospective studies. *Acta Psychiatr Scand.* 2004;109(5):325-331. PMID: 15049768
90. Asselmann E, Wittchen H-U, Lieb R, Höfler M, Beesdo-Baum K. Associations of fearful spells and panic attacks with incident anxiety, depressive, and substance use disorders: A 10-year prospectivelongitudinal community study of adolescents and young adults. *J Psychiatr Res.* 2014;55:8-14. PMID: 24774646

91. Angst J, Merikangas K. The depressive spectrum: Diagnostic classification and course. *J Affect Disord.* 1997;45(1-2):31-40. PMID: 9268773
92. Goodwin RD, Lieb R, Hoefler M, et al. Panic attack as a risk factor for severe psychopathology. *Am J Psychiatry.* 2004;161(12):2207-2214. PMID: 15569891
93. Newman MG, Kanuri N, Ruzek JI, et al. A randomized controlled trial of feasibility, acceptability, and efficacy of online, CBT-based guided self-help programs to reduce anxiety among students in India. 36th Annual Convention of the Anxiety and Depression Association of America; March, 2016; Philadelphia, PA.
94. Richards D, Richardson T. Computer-based psychological treatments for depression: a systematic review and meta-analysis. *Clin Psychol Rev.* 2012;32(4):329-342. PMID: 22466510
95. Durham RC, Allan T, Hackett CA. On predicting improvement and relapse in generalized anxiety disorder following psychotherapy. *Br J Clin Psychol.* 1997;36(1):101-119. PMID: 9051282
96. Lutz W, Hofmann SG, Rubel J, et al. Patterns of early change and their relationship to outcome and early treatment termination in patients with panic disorder. *J Consult Clin Psychol.* 2014;82(2):287-297. PMCID: PMC3966935
97. Lewis CC, Simons AD, Kim HK. The role of early symptom trajectories and pretreatment variables in predicting treatment response to cognitive behavioral therapy. *J Consult Clin Psychol.* 2012;80(4):525- 534. PMID: 22730951
98. Moscovitch DA, Gavric DL, Senn JM, et al. Changes in judgment biases and use of emotion regulation strategies during cognitive-behavioral therapy for social anxiety disorder: Distinguishing treatment responders from nonresponders. *Cognit Ther Res.* 2012;36(4):261-271.
99. Bradford A, Cully J, Rhoades H, et al. Early response to psychotherapy and long-term change in worry symptoms in older adults with generalized anxiety disorder. *Am J Geriatr Psychiatry.* 2011;19(4):347- 356. PMCID: PMC3058752
100. Munsch S, Meyer AH, Biedert E. Efficacy and predictors of long-term treatment success for cognitivebehavioral treatment and behavioral weight-loss-treatment in overweight individuals with binge eating disorder. *Behav Res Ther.* 2012;50(12):775-785. PMID: 23099111
101. Vall E, Wade TD. Predictors of treatment outcome in individuals with eating disorders: A systematic review and meta-analysis. *Int J Eat Disord.* 2015;48(7):946-971. PMID: 26171853
102. Wilson GT, Fairburn CC, Agras WS, Walsh BT, Kraemer H. Cognitive-behavioral therapy for bulimia nervosa: Time course and mechanisms of change. *J Consult Clin Psychol.* 2002;70(2):267-274. PMID: 11952185
103. Buntrock C, Ebert D, Lehr D, et al. Effectiveness of a web-based cognitive behavioural intervention for subthreshold depression: Pragmatic randomised controlled trial. *Psychother Psychosom.* 2015;84(6):348-358. PMID: 26398885
104. Imamura K, Kawakami N, Furukawa TA, et al. Does Internet-based cognitive behavioral therapy (iCBT) prevent major depressive episode for workers? A 12-month follow-up of a randomized controlled trial. *Psychol Med.* 2015;45(9):1907-1917. PMID: 25562115
105. Thompson NJ, Patel AH, Selwa LM, et al. Expanding the efficacy of Project UPLIFT: Distance delivery of mindfulness-based depression prevention to people with epilepsy. *J Consult Clin Psychol.* 2015;83(2):304-313. PMCID: PMC4380523
106. American Medical Association. *Stepped-care prevention of anxiety and depression in late life: A randomized controlled trial*. 2009.

107. Titov N, Andrews G, Davies M, McIntyre K, Robinson E, Solley K. Internet treatment for depression: a randomized controlled trial comparing clinician vs. technician assistance. *PLoS One.* 2010;5(6):e10939. PMCID: PMC2882336
108. Robinson E, Titov N, Andrews G, McIntyre K, Schwencke G, Solley K. Internet treatment for generalized anxiety disorder: A randomized controlled trial comparing clinician vs. technician assistance. *PLoS One.* 2010;5(6):e10942. PMCID: PMC2880592
109. Johansson R, Sjoberg E, Sjogren M, et al. Tailored vs. standardized internet-based cognitive behavior therapy for depression and comorbid symptoms: a randomized controlled trial. *PLoS One.* 2012;7(5):e36905. PMCID: PMC3352859
110. Titov N, Andrews G, Johnston L, Robinson E, Spence J. Transdiagnostic internet treatment for anxiety disorders: A randomized controlled trial. *Behav ResTher.* 2010;48(9):890-899. PMID: 20561606
111. Carrard I, Crépin C, Rouget P, Lam T, Golay A, Van der Linden M. Randomised controlled trial of a guided self-help treatment on the Internet for binge eating disorder. *Behav Res Ther.* 2011;49(8):482- 491. PMID: 21641580
112. Ruwaard J, Lange A, Broeksteeg J, et al. Online cognitive–behavioural treatment of bulimic symptoms: A randomized controlled trial. *Clin Psychol Psychother.* 2013;20(4):308-318. PMID: 22298417
113. Smits JA, Julian K, Rosenfield D, Powers MB. Threat reappraisal as a mediator of symptom change in cognitive-behavioral treatment of anxiety disorders: a systematic review. *J Consult Clin Psychol.* 2012;80(4):624-635. PMCID: PMC3404225
114. Lemmens LHJM, Müller VNLS, Arntz A, Huibers MJH. Mechanisms of change in psychotherapy for depression: An empirical update and evaluation of research aimed at identifying psychological mediators. *Clin Psychol Rev.* 2016;50:95-107. PMID: 27770716
115. Linardon J, de la Piedad Garcia X, Brennan L. Predictors, moderators, and mediators of treatment outcome following manualised cognitive-behavioural therapy for eating disorders: A systematic review. *Eur Eat Disord Rev.* 2017;25(1):3-12. PMID: 27862611
116. Fairburn CG. *Cognitive Behavior Therapy and Eating Disorders.* New York, NY: The Guilford Press; 2008.
117. Hundt NE, Williams AM, Mendelson J, Nelson-Gray RO. Coping mediates relationships between reinforcement sensitivity and symptoms of psychopathology. *Personality and Individual Differences.* 2013;54(6):726-731.
118. Hundt NE, Calleo JS, Williams W, Cully JA. Does using cognitive-behavioural therapy skills predict improvements in depression? *Psychol Psychother.* 2016;89(2):235-238. PMID: 26173639
119. Jacob KL, Christopher MS, Neuhaus EC. Development and validation of the cognitive-behavioral therapy skills questionnaire. *Behav Modif.* 2011;35(6):595-618. PMID: 21893554
120. Meuret AE, Wolitzky-Taylor KB, Twohig MP, Craske MG. Coping Skills and Exposure Therapy in Panic Disorder and Agoraphobia: Latest Advances and Future Directions. *Behavior Therapy.* 2012;43(0):271-284. PMCID: PMC3327306
121. Webb CA, Beard C, Kertz SJ, Hsu KJ, Björgvinsson T. Differential role of CBT skills, DBT skills and psychological flexibility in predicting depressive versus anxiety symptom improvement. *Beh ResTher.* 2016;81:12-20. PMCID: PMC4860036
122. Schmidt NB, Woolaway Bickel K. The effects of treatment compliance on outcome in cognitivebehavioral therapy for panic disorder: Quality versus quantity. *J Consul Clin Psychol.* 2000;68(1):13-18. PMID: 10710836
123. Cuming S, Rapee RM, Kemp N, Abbott MJ, Peters L, Gaston JE. A self-report measure of subtle avoidance and safety behaviors relevant to social anxiety:

Development and psychometric properties. *J Anxiety Disord.* 2009;23(7):879-883. PMID: 19556098
124. Chu BC, Harrison TL. Disorder-specific effects of CBT for anxious and depressed youth: A metaanalysis of candidate mediators of change. *Clin Child Fam Psychol Rev.* 2007;10(4):352-372. PMID: 17985239
125. Aderka IM, McLean CP, Huppert JD, Davidson JRT, Foa EB. Fear, avoidance and physiological symptoms during cognitive-behavioral therapy for social anxiety disorder. *Behav Res Ther.* 2013;51(7):352-358. PMCID: PMC3669252
126. Bewernick BH, Urbach AS, Broder A, Kayser S, Schlaepfer TE. Walking away from depression-motor activity increases ratings of mood and incentive drive in patients with major depression. *Psychiatry Res.* 2017;247:68-72. PMID: 27865100
127. Ryba MM, Lejuez CW, Hopko DR. Behavioral activation for depressed breast cancer patients: the impact of therapeutic compliance and quantity of activities completed on symptom reduction. *J Consult Clin Psychol.* 2014;82(2):325-335. PMID: 24364801
128. Manos RC, Kanter JW, Luo W. The Behavioral Activation for Depression Scale–Short Form: Development and Validation. *Behav Ther.* 2011;42(4):726-739. PMID: 22036000
129. Spangler DL, Baldwin SA, Agras WS. An examination of the mechanisms of action in cognitive behavioral therapy for bulimia nervosa. *BehavTher.* 2004;35(3):537-560.
130. Sharry J, Davidson R, McLoughlin O, Doherty G. A service-based evaluation of a therapist-supported online cognitive behavioral therapy program for depression. *J Med Internet Res.* 2013;15(6):e121. PMCID: PMC3713925
131. Erekson DM, Horner J, Lambert MJ. Different lens or different picture? Comparing methods of defining dramatic change in psychotherapy. *Psychother Res.* 2016:1-11.
132. Lambert MJ. Early response in psychotherapy: further evidence for the importance of common factors rather than "placebo effects". *Journal of clinical psychology.* 2005;61(7):855-869. PMID: 15827996
133. Aaronson CJ, Shear MK, Goetz RR, et al. Predictors and time course of response among panic disorder patients treated with cognitive-behavioral therapy. *J Clin Psychiatry.* 2008;69(3):418-424. PMID: 18278989
134. Aderka IM, Nickerson A, Boe HJ, Hofmann SG. Sudden gains during psychological treatments of anxiety and depression: a meta-analysis. *J Consult Clin Psychol.* 2012;80(1):93-101. PMID: 22122290
135. Bohn C, Aderka IM, Schreiber F, Stangier U, Hofmann SG. Sudden gains in cognitive therapy and interpersonal therapy for social anxiety disorder. *J Consult Clin Psychol.* 2013;81(1):177-182. PMID: 23244366
136. Norton PJ, Klenck SC, Barrera TL. Sudden gains during cognitive-behavioral group therapy for anxiety disorders. *J Anxiety Disord.* 2010;24(8):887-892. PMCID: PMC2956855
137. Lutz W, Stulz N, Kock K. Patterns of early change and their relationship to outcome and follow-up among patients with major depressive disorders. *J Affect Disord.* 2009;118(1-3):60-68. PMID: 19217669
138. Tang TZ, DeRubeis RJ. Sudden gains and critical sessions in cognitive-behavioral therapy for depression. *J Consult Clin Psychol.* 1999;67(6):894-904. PMID: 10596511
139. Borkovec TD, Nau SD. Credibility of analogue therapy rationales. *J Behav Ther Exp Psychiatry.* 1972;3(4):257-260.
140. Borkovec TD, Sides JK. The contribution of relaxation and expectancy to fear reduction via graded, imaginal exposure to feared stimuli. *Behav Res Ther. 1*979;17(6):529-540. PMID: 43126

141. Brown LA, Wiley JF, Wolitzky-Taylor K, et al. Changes in self-efficacy and outcome expectancy as predictors of anxiety outcomes from the CALM study. *Depress Anxiety.* 2014;31(8):678-689. PMCID: PMC4244230
142. Curry J, Rohde P, Simons A, et al. Predictors and moderators of acute outcome in the Treatment for Adolescents with Depression Study (TADS). *J Am Acad Child Adolesc Psychiatry.* 2006;45(12):1427- 1439. PMID: 17135988
143. Westra HA, Dozois DJ, Marcus M. Expectancy, homework compliance, and initial change in cognitivebehavioral therapy for anxiety. *J Consult Clin Psychol.* 2007;75(3):363-373. PMID: 17563153
144. Brown TA, Barlow DH. Long-term outcome in cognitive-behavioral treatment of panic disorder: clinical predictors and alternative strategies for assessment. *J Consult Clin Psychol.* 1995;63(5):754-765. PMID: 7593868
145. Dow MG, Kenardy JA, Johnston DW, Newman MG, Taylor CB, Thomson A. Prognostic indices with brief and standard CBT for panic disorder: II. Moderators of outcome. *Psychol Med.* 2007;37(10):1503- 1509. PMID: 17493295
146. Hilbert A, Saelens BE, Stein RI, et al. Pretreatment and process predictors of outcome in interpersonal and cognitive behavioral psychotherapy for binge eating disorder. *J Consult Clin Psychol.* 2007;75(4):645-651. PMID: 17663618
147. Lelliott PT, Marks IM, Monteiro WO, Tsakiris F, Noshirvani H. Agoraphobics 5 years after imipramine and exposure. Outcome and predictors. *J Nerv Ment Dis.* 1987;175(10):599-605. PMID: 3309186
148. Basoglu M, Marks IM, Swinson RP, Noshirvani H, O'Sullivan G, Kuch K. Pre-treatment predictors of treatment outcome in panic disorder and agoraphobia treated with alprazolam and exposure. *J Affect Disord.* 1994;30(2):123-132. PMID: 7911132
149. Dow MGT, Kenardy JA, Johnston DW, Newman MG, Taylor CB, Thomson A. Prognostic indices with brief and standard CBT for panic disorder: I. Predictors of outcome. *Psychol Med.* 2007;37(10):1493- 1502. PMID: 17493294
150. Newman MG, Fisher AJ. Mediated moderation in combined cognitive behavioral therapy versus component treatments for generalized anxiety disorder. *J Consult Clin Psychol.* 2013;81(3):405-414. PMCID: PMC4432847
151. Heldt E, Manfro GG, Kipper L, et al. Treating medication-resistant panic disorder: predictors and outcome of cognitive-behavior therapy in a Brazilian public hospital. *Psychother Psychosom.* 2003;72(1):43-48. PMID: 12466637
152. Newman MG, Przeworski A, Fisher AJ, Borkovec TD. Diagnostic comorbidity in adults with generalized anxiety disorder: impact of comorbidity on psychotherapy outcome and impact of psychotherapy on comorbid diagnoses. *Behav Ther.* 2010;41(1):59-72. PMCID: PMC2827339
153. Scheibe G, Albus M. Predictors of outcome in panic disorder: a 5-year prospective follow-up study. *J Affect Disord.* 1996;41(2):111-116. PMID: 8961038
154. Tsao JC, Lewin MR, Craske MG. The effects of cognitive-behavior therapy for panic disorder on comorbid conditions. *J Anxiety Disord.* 1998;12(4):357-371. PMID: 9699119
155. Westra HA. Comparing the predictive capacity of observed in-session resistance to self-reported motivation in cognitive behavioral therapy. *Behav Res Ther.* 2011;49(2):106-113. PMCID: PMC3037024
156. Versluis A, Verkuil B, Spinhoven P, van der Ploeg MM, Brosschot JF. Changing mental health and positive psychological well-being using ecological momentary interventions: A systematic review and meta-analysis. *J Med Internet Res.* 2016;18(6):e152. PMCID: PMC4940607

157. Eysenbach G. CONSORT-EHEALTH: Implementation of a checklist for authors and editors to improve reporting of web-based and mobile randomized controlled trials. *Stud Health Technol Inform.* 2013;192:657-661. PMID: 23920638
158. Lipson SK, Speer N, Brunwasser S, Hahn E, Eisenberg D. Gatekeeper training and access to mental health care at universities and colleges. *J Adolesc Health.* 2014;55(5):612-619. PMCID: PMC4209329
159. Eisenberg D, Golberstein E, Whitlock JL, Downs MF. Social contagion of mental health: Evidence from college roommates. *Health Econ.* 2013;22(8):965-986. PMCID: PMC4381550
160. Crawford SD, Couper MP, Lamias MJ. Web surveys: Perception of burden. *Soc Sci Comput Rev.* 2001;19(2):146-162.
161. American College Health Association-National College Health Assessment. Undergraduate Student Reference Group. 2016. http://www.acha-ncha.org/docs/NCHAII%20SPRING%202016%20UNDERGRADUATE%20REFERENCE%20GROUP%20DATA%20REPORT.pdf.
162. Eisenberg D, Golberstein E, Gollust SE. Help-seeking and access to mental health care in a university student population. *Med Care.* 2007;45(7):594-601. PMID: 17571007
163. Lipson SK, Gaddis SM, Heinze J, Beck K, Eisenberg D. Variations in student mental health and treatment utilization across US colleges and universities. *J Am Coll Health.* 2015;63(6):388-396. PMID: 25942473
164. Furner CP, Racherla P, Babb JS. Mobile app stickiness (MASS) and mobile interactivity: A conceptual model. *Market Rev.* 2014;14(2):163-188.
165. Connolly Gibbons MB, Rothbard A, Farris KD, et al. Changes in psychotherapy utilization among consumers of services for major depressive disorder in the community mental health system. *Adm Policy Ment Health.* 2011;38(6):495-503. PMCID: PMC3350098
166. Olfson M, Marcus SC. National trends in outpatient psychotherapy. *Am J Psychiatry.* 2010;167(12):1456-1463.PMID: 20686187
167. Fridberg DJ, Cao D, King AC. Integrating alcohol response feedback in a brief intervention for youngadult heavy drinkers who smoke: A pilot study. *Drug Alcohol Depend.* 2015;155:293-297. PMCID: PMC4582006
168. Norman P, Cameron D, Epton T, et al. A randomized controlled trial of a brief online intervention to reduce alcohol consumption in new university students: Combining self-affirmation, theory of planned behaviour messages, and implementation intentions. *Br J Health Psychol.* 2017. PMID: 28941040
169. Pedersen ER, Neighbors C, Atkins DC, Lee CM, Larimer ME. Brief online interventions targeting risk and protective factors for increased and problematic alcohol use among American college students studying abroad. *Psychol Addict Behav.* 2017;31(2):220-230. PMCID: PMC5344728
170. Sainfort F, Becker M, Diamond R. Judgments of quality of life of individuals with severe mental disorders: Patient self-report versus provider perspectives. *Am J Psychiatry.* 1996;153(4):497-502. PMID: 8599397
171. Newman MG, Llera SJ, Erickson TM, Przeworski A, Castonguay LG. Worry and generalized anxiety disorder: A review and theoretical synthesis of evidence on nature, etiology, mechanisms, and treatment. *Annu Rev Clin Psychol.* 2013;9:275-297. PMCID: PMC4964851
172. Buntrock C, Ebert DD, Lehr D, et al. Effect of a web-based guided self-help intervention for prevention of major depression in adults with subthreshold depression: A randomized clinical trial. *JAMA.* 2016;315(17):1854-1863. PMID: 27139058
173. Titov N, Dear BF, Staples LG, et al. Disorder-specific versus transdiagnostic and clinician-guided versus self-guided treatment for major depressive disorder and

comorbid anxiety disorders: A randomized controlled trial. *J Anxiety Disord.* 2015;35:88-102. PMID: 26422822
174. Lynch FL, Striegel-Moore RH, Dickerson JF, et al. Cost-effectiveness of guided self-help treatment for recurrent binge eating. *J Consult Clin Psychol.* 2010;78(3):322-333. PMCID: PMC2880825
175. Striegel-Moore RH, Wilson GT, DeBar L, et al. Cognitive behavioral guided self-help for the treatment of recurrent binge eating. *J Consult Clin Psychol.* 2010;78(3):312-321. PMCID: PMC2880824
176. Oulasvirta A, Tamminen S, Roto V, Kuorelahti J. Interaction in 4-second bursts: The fragmented nature of attentional resources in mobile HCI. Paper presented at: Proceedings of the SIGCHI conference on Human factors in computing systems; 2005.
177. Vaish R, Wyngarden K, Chen J, Cheung B, Bernstein MS. Twitch crowdsourcing: crowd contributions in short bursts of time. Paper presented at: Proceedings of the 32nd annual ACM conference on Human factors in computing systems; 2014.
178. Nitsch M, Dimopoulos NC, Flaschberger E, et al. A guided online and mobile self-help program for individuals with eating disorders: An iterative engagement and usability study. *J Med Internet Res.* 2016;18(1):e7. PMCID: PMC4726867
179. Donkin L, Glozier N. Motivators and motivations to persist with online psychological interventions: A qualitative study of treatment completers. *J Med Internet Res.* 2012;14(3):e91. PMCID: PMC3414905
180. American College Health Association. American College Health Association-National College Health Assessment II: Reference Group Executive Summary Spring 2015; 2015. https://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=1&ved=0ahUKEwiSeGd1e_RAhWE64MKHaOODFMQFggaMAA&url=http%3A%2F%2Fwww.achancha.org%2Fdocs%2FNCHAII_WEB_SPRING_2015_REFERENCE_GROUP_EXECUTIVE_SUMMARY.pdf&usg=AFQjCNFOBvLJhYp2jlrSHTOxgUbv4tBteQ&sig2=yezVohCSTTBIuRb26TOivA&bvm=bv.146073913,d.amc&cad=rjt
181. Dazzi T, Gribble R, Wessely S, Fear NT. Does asking about suicide and related behaviours induce suicidal ideation? What is the evidence? *Psychol Med.* 2014;44(16):3361-3363. PMID: 24998511
182. Devilly GJ, Borkovec TD. Psychometric properties of the credibility/expectancy questionnaire. *J Behav Ther Exp Psychiatry.* 2000;31(2):73-86. PMID: 11132119
183. Özdel K, Taymur I, Guriz SO, Tulaci RG, Kuru E, Turkcapar MH. Measuring cognitive errors using the Cognitive Distortions Scale (CDS): Psychometric properties in clinical and non-clinical samples. *PLoS One.* 2014;9(8):e105956. PMCID: PMC4149474
184. Newman MG, Zuellig AR, Kachin KE, et al. Preliminary reliability and validity of the Generalized Anxiety Disorder Questionnaire-IV: A revised self-report diagnostic measure of generalized anxiety disorder. *Behav Ther.* 2002;33(2):215-233.
185. Newman MG, Kachin KE, Zuellig AR, Constantino MJ, Cashman-McGrath L. The Social Phobia Diagnostic Questionnaire: Preliminary validation of a new self-report diagnostic measure of social phobia. *Psychol Med.* 2003;33(4):623-635. PMID: 12785464
186. Newman MG, Holmes M, Zuellig AR, Kachin KE, Behar E. The reliability and validity of the Panic Disorder Self-Report: A new diagnostic screening measure of panic disorder. *Psychol Assess.* 2006;18(1):49-61. PMID: 16594812
187. Moore MT, Anderson NL, Barnes JM, Haigh EA, Fresco DM. Using the GAD-Q-IV to identify generalized anxiety disorder in psychiatric treatment seeking and primary care medical samples. *J Anxiety Disord.* 2014;28(1):25-30. PMID: 24334213

188. Roemer L, Borkovec M, Posa S, Borkovec TD. A self-report diagnostic measure of generalized anxiety disorder. *J Behav Ther Exp Psychiatry.* 1995;26(4):345-350. PMID: 8675722
189. Kroenke K, Spitzer RL, Williams JB. The PHQ-9: Validity of a brief depression severity measure. *J Gen Intern Med.* 2001;16(9):606-613. PMID: 11556941
190. Kroenke K, Spitzer RL. The PHQ-9: A new depression diagnostic and severity measure. *Psychiatr Ann.* 2002;32(9):509-515.
191. Kroenke K, Spitzer RL, Williams JBW, Löwe B. The Patient Health Questionnaire somatic, anxiety, and depressive symptom scales: A systematic review. *Gen Hosp Psychiatry.* 2010;32(4):345-359. PMID: 20633738
192. Mond JM, Hay PJ, Rodgers B, Owen C, Beumont PJV. Validity of the Eating Disorder Examination Questionnaire (EDE-Q) in screening for eating disorders in community samples. *Behav Res Ther.* 2004;42(5):551-567. PMID: 15033501
193. Berg KC, Peterson CB, Frazier P, Crow SJ. Psychometric evaluation of the eating disorder examination and eating disorder examination-questionnaire: A systematic review of the literature. *Int J Eat Disord.* 2012;45(3):428-438. PMCID: PMC3668855
194. Prins A, Ouimette P, Kimerling R, et al. The primary care PTSD screen (PC-PTSD): Development and operating characteristics. *Primary Care Psychia.* 2003;9(1):9-14.
195. Morin CM, Belleville G, Bélanger L, Ivers H. The Insomnia Severity Index: Psychometric indicators to detect insomnia cases and evaluate treatment response. *Sleep.* 2011;34(5):601-608. PMCID: PMC3079939
196. Bradley KA, Bush KR, Epler AJ, et al. Two brief alcohol-screening tests from the alcohol use disorders identification test (audit): Validation in a female veterans affairs patient population. *Arch Intern Med.* 2003;163(7):821-829. PMID: 12695273
197. Bush K, Kivlahan DR, McDonell MB, Fihn SD, Bradley KA. The AUDIT alcohol consumption questions (AUDIT-C): An effective brief screening test for problem drinking. *Arch Intern Med.* 1998;158(16):1789- 1795. PMID: 9738608
198. Ware J Jr., Kosinski M, Keller SD. A 12-Item short-form health survey: Construction of scales and preliminary tests of reliability and validity. *Med Care.* 1996;34(3):220-233. PMID: 8628042
199. Gandek B, Ware JE, Aaronson NK, et al. Cross-validation of item selection and scoring for the SF-12 Health Survey in nine countries: Results from the IQOLA Project. *J Clin Epidemiol.* 1998;51(11):1171- 1178. PMID: 9817135
200. Wells KB, Sturm R, Burnam A. *National Survey of Alcohol, Drug, and Mental Health Problems [Healthcare for Communities], 2000-2001.* Ann Arbor, MI: Inter-university Consortium for Political and Social Research; 2012.
201. Brown GK, Karlin BE, Trockel M, Gordienko M, Yesavage J, Taylor CB. Effectiveness of cognitive behavioral therapy for veterans with depression and suicidal ideation. *Arch Suicide Res.* 2016;20(4):677-682. PMID: 26983897
202. Jarrett RB, Vittengl JR, Clark LA, Thase ME. Skills of Cognitive Therapy (SoCT): A new measure of patients' comprehension and use. *Psychol Assess.* 2011;23(3):578-586. PMCID: PMC3144321
203. Brown GK, Thase ME, Vittengl JR, Borman PD, Clark LA, Jarrett RB. Assessing cognitive therapy skills comprehension, acquisition, and use by means of an independent observer version of the Skills of Cognitive Therapy (SoCT-IO). *Psychol Assess.* 2016;28(2):205-213. PMCID: PMC4564865
204. Campbell-Sills L, Norman SB, Craske MG, et al. Validation of a brief measure of anxiety-related severity and impairment: The Overall Anxiety Severity and Impairment Scale (OASIS). *J Affect Disord.* 2009;112(1-3):92-101.

205. Norman SB, Hami Cissell S, Means-Christensen AJ, Stein MB. Development and validation of an overall anxiety severity and impairment scale (OASIS). *Depress anxiety.* 2006;23(4):245-249. PMID: 16688739
206. Bragdon LB, Diefenbach GJ, Hannan S, Tolin DF. Psychometric properties of the Overall Anxiety Severity and Impairment Scale (OASIS) among psychiatric outpatients. *J Affect Disord.* 2016;201:112- 115. PMID: 27195516
207. Norman SB, Allard CB, Trim RS, et al. Psychometrics of the Overall Anxiety Severity and Impairment Scale (OASIS) in a sample of women with and without trauma histories. *Arch Womens Ment Health.* 2013;16(2):123-129. PMID: 23296334
208. Berg KC, Peterson CB, Frazier P, Crow SJ. Convergence of scores on the interview and questionnaire versions of the Eating Disorder Examination: A meta-analytic review. *Psychol Assess*. 2011;23(2):714- 724. PMCID: PMC3437603
209. Killen JD, Taylor CB, Hayward C, et al. Weight concerns influence the development of eating disorders: A 4-year prospective study. *J Consult Clin Psychol.* 1996;64(5):936-940. PMID: 8916622
210. Newman MG, Fisher AJ. Expectancy/credibility change as a mediator of cognitive behavioral therapy for generalized anxiety disorder: Mechanism of action or proxy for symptom change? *Int J Cogn Ther.* 2010;3:245-261. PMCID: PMC2995495
211. Reinecke A, Waldenmaier L, Cooper MJ, Harmer CJ. Changes in automatic threat processing precede and predict clinical changes with exposure-based cognitive-behavior therapy for panic disorder. *Biol Psychiatry.* 2013;73(11):1064-1070. PMID: 23510582
212. Tang TZ, DeRubeis RJ, Beberman R, Pham T. Cognitive changes, critical sessions, and sudden gains in cognitive-behavioral therapy for depression. *J Consult Clin Psychol.* 2005;73(1):168-172. PMID: 15709844
213. Scott SD, Plotnikoff RC, Karunamuni N, Bize R, Rodgers W. Factors influencing the adoption of an innovation: An examination of the uptake of the Canadian Heart Health Kit (HHK). *Implement Sci.* 2008;3(1):41. PMCID: PMC2567341
214. Abraham WT, Russell DW. Statistical power analysis in psychological research. *Soc Personal Psychol Compass.* 2008;2(1):283-301.
215. Arnold BF, Hogan DR, Colford JM, Jr., Hubbard AE. Simulation methods to estimate design power: An overview for applied research. *BMC Med Res Methodol.* 2011;11:94. PMCID: PMC3146952
216. Kraemer HC. Messages for clinicians: Moderators and mediators of treatment outcome in randomized clinical trials. *Am J Psychiatry.* 2016;173(7):672-679. PMID: 26988629
217. Drummond M, Sculpher M, Torrance G, O'Brien B, Stoddart G. *Methods for the Economic Evaluation of Health Care Programmes*. 3rd ed. Oxford, England: Oxford University Press; 2005.
218. Kymes SM. An introduction to decision analysis in the economic evaluation of the prevention and treatment of vision-related diseases. *Ophthalmic Epidemiol.* 2008;15(2):76-83. PMID: 18432490
219. O'Hagan A, McCabe C, Akehurst R, et al. Incorporation of uncertainty in health economic modelling studies. *Pharmacoeconomics.* 2005;23(6):529-536. PMID: 15960550
220. Krahn MD, Naglie G, Naimark D, Redelmeier DA, Detsky AS. Primer on medical decision analysis: Part 4—Analyzing the model and interpreting the results. *Med Decis Making.* 1997;17(2):142-151. PMID: 9107609