Date: 10-23-2023

IRB #: UNLV-2022-263
Title: Task Sharing to Expand Access to Mental Health Services: Pilot Clinical Trial
Creation Date: 5-13-2022
End Date:
Status: Approved
Principal Investigator: Brenna Renn
Review Board: Social/Behavioral
Sponsor: National Institute of General Medical Sciences

Study History

Submission Type Initial	Review Type Expedited	Decision Approved

Key Study Contacts

Member Brenna Renn	Role Principal Investigator	Contact brenna.renn@unlv.edu
Member Brenna Renn	Role Primary Contact	Contact brenna.renn@unlv.edu
Member Ting Tong	Role Primary Contact	Contact tongt2@unlv.nevada.edu

Initial Submission

Getting Started

About Cayuse Submission System

The Cayuse submission system is an interactive web application. As you answer questions, new sections relevant to the type of research being conducted will appear on the left-hand side. Therefore not all sections may appear.

Additional information has been added throughout the form for guidance and clarity. That additional information can be found by clicking the question mark "?"at the top-right corner of each section.

You do not have to finish the application in one sitting. **Be sure to click the "Save" button periodically.**

UNLV IRB

- You must have a formal approval letter from the IRB before beginning data collection.
- The Social/Behavioral IRB meets on the first Thursday of each month and the Biomedical/School of Medicine IRB meets on the third Tuesday of each month. Applications that need review by the Board should be submitted at least four weeks prior to the meeting.
- Protocols are reviewed in the order they are received.

Information to have available

- Study Recruitment Material(s)
- Detailed Study Information
- Consent Form(s)
- Questionnaires, Interview Guides, and other Data Collection Instruments
- Facility Authorization/Acknowledgement Letters
- Agreements (IRB Authorization Agreements, Volunteer Agreements, Data Use Agreements, etc.)
- Funding and/or Sponsor Information

*required

I have read the information above and I am ready to begin my submission.

✓ Yes

Is this human subjects research?

*required

Does your proposed project fit the definition of "research" defined as a "systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge"?

- ✓ Yes
- No

*required

Does your proposed project include activities using "human subjects" defined as a "living individual about whom an investigator (whether professional or student) is conducting research"?

- ✓ Yes
- No

Collaborative Research

*required

Is this a multi-institutional/collaborative study?

Multi-institutional/collaborative studies are research conducted in conjunction with an institution or with personnel not affiliated with UNLV.

- Yes
- ✓ No

Funding

*required

Do you have funding for this research study?

- ✓ Yes
- No
- Pending

Funding Source

Please search for your funding source. If the sponsor is not found, enter the information in the text field below.

National Institute of General Medical Sciences

Provide the sponsor if it is not found above.

*required

What is the funder type?

- ✓ Federal
- State Government
- Sponsor
- Foundation
- Department/College
- Other

Optional: Please attach your grant application.

PLEASE NOTE: Once you obtain additional funding, a modification will need to be submitted.

Key Personnel Information

Key Personnel

***NOTE**: If you cannot find a person in the people finder, please contact the ORI-HS Office.*

ORI-HS has moved to a "key personnel" model, in which protocols only need to list the PI, Student Researcher (if a student is conducting the research as part of their own capstone/thesis/dissertation), and at least one Primary Contact (this defaults to the individual completing the form, but this can be any individual(s) who need edit/direct access to the protocol application). The PI will be responsible for keeping a record of all research team members and ensuring that all have completed the required CITI training and any other study requirements in a Research Team Member Log or documented elsewhere in their own study records, which does not need to be submitted to the IRB for review.

Ultimately, it is the PI's decision to decide who constitutes key personnel. However, ANY persons working on the protocol listed must complete CITI training. In addition, it is the PI's responsibility to verify that the training has been completed.

*required

Principal Investigator

One individual must be designated as the principal investigator(PI). The PI must be UNLV faculty. Students are not eligible to fill this role.

Click on the people finder below to search a name. You must provide the name of the PI here in order to complete submission.

Name: Brenna Renn
Organization: Psychology Department
Address: 4505 S. Maryland Pkwy. , Las Vegas, NV 89154-5030
Phone: +1 (702) 8950569
Email: brenna.renn@unlv.edu

*required

What is your role in the study?

Select all that apply

✓ Recruiting

✓ Consenting

✓ Administering study procedures

✓ Handling Identifiable data/specimens

✓ Other

*required

Please specify

training, supervision; all study oversight

*required

Do you qualify for automatic PI eligibility?

UNLV policy is that only full-time academic faculty members (appointments at 50% or more) may serve as PI. Exceptions can be granted and PI status conferred on a case-by-case basis for individual research projects.

✓ Yes

No

PI Eligibility Exception

I applied for and received PI Eligibility Exception approval for this study.
Note: School of Nursing PIs can receive annual PI Eligible approval and do not require the PI Eligibility Exception form to be submitted for each individual study.

I am from School of Dental Medicine.
School of Dental Medicine ONLY: If you do not qualify for automatic PI eligibility, you must add Jeffrey Ebersole (SDM Associate Dean of Research) as a Primary Contact below. Do not complete the PI Eligibility Exception form.

Select your status:

Faculty in Residence

Visiting Professor

Adjunct

Lecturer

Other

*required

Primary Contact

This will auto-populate to the person completing the form. If someone else should be identified, please use the people finder below. ***Add additional persons who may need edit access to the protocol here.***

Name: Brenna Renn
Organization: Psychology Department
Address: 4505 S. Maryland Pkwy. , Las Vegas, NV 89154-5030
Phone: +1 (702) 8950569
Email: brenna.renn@unlv.edu

Name: Ting Tong
Organization: College of Liberal Arts
Address:
Phone:
Email: tongt2@unlv.nevada.edu

*required

Student Researcher

Add students ***ONLY*** *if they are conducting this research to satisfy graduation requirements such as Thesis, Dissertation, Senior Capstone, etc.*

Yes

✓ No

*required

Volunteer Researchers

UNLV researchers may conduct research with community members who are not otherwise affiliated with any institution. These are considered volunteers and as such would need to complete the Volunteer Agreement for Researchers form. This form needs to be completed in its entirety and a copy should be submitted to the appropriate Human Resources Office. Volunteer researchers must also satisfy CITI education requirements as required by the ORI-HS. It is the PI's responsibility to submit the form

to Human Resources (as instructed), to keep a copy for your study records, and ensure that CITI training has been completed and kept current. ***You do not need to attach the Volunteer Agreement to this submission****.*

Does your research team include volunteer researchers?

Yes

✓ No

Note: All study personnel will need to complete the following:

*The human subject training course: "*Social/Behavioral Research" or "Biomedical Research" *course offered through CITI. Must be taken within the last five years.*

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*required

Conflict of Interest

Do you or any investigator(s) participating in this study have a financial interest related to this research project?

Yes

✓ No

Does the PI or any member of the research team have an authoritative role over the research subjects (e.g., PI is the instructor of the course being recruited to participate).

If recruiting in classrooms, it is preferred to recruit before the start of a class or after a class. In addition, if the researcher is an instructor or teacher of the class, it is best to have another research team member recruit and conduct the consent/assent process so that potential participants do not feel coerced to participate.

Yes

✓ No

Subject Enrollment

*required

Select the age range of participants that will be enrolled in this study.

Check all that apply

- [ ] fetus
- [ ] birth to less than 18 years old
- [x] ✓ 18 years and older

*required

Describe the different populations that will be recruited and enrolled

Provide the inclusion/exclusion criteria for each population.

This study will recruit and enroll two groups of participants: (1) coach participants, who will be trained and supervised to deliver the investigative treatment protocol; and (2) patient participants, who will receive the investigative treatment from the coach participants.

Coach Participants: Inclusion criteria are: 1) age ≥ 18 years; 2) advanced UNLV undergraduate student (Junior or Senior standing, or recent UNLV graduate since 2020); 3) major in psychology or similar field (e.g., social work, human services, pre-med); 4) completion of coursework in abnormal psychology or equivalent, with a grade of B+ or higher; 5) overall GPA > 3.0; 6) ability and willingness to complete training program and plan to deliver intervention with up to three patient participants; 7) agree to the TREATment lab confidentiality practices to protect patient and coach participant information; and 8) pass training activities and role plays with fidelity to intervention manual. In order to be invited to continue in they study as a coach delivering the intervention with patient participants, coaches need to complete all training and pass the fidelity review of their final, submitted roleplay demonstration with a global score of "3" (satisfactory).

Patient Participants: Inclusion criteria are: 1) age ≥ 18 years, 2) score on the Generalized Anxiety Disorder [GAD-7] scale equal to or greater than 8, and 3) ability to speak English. Exclusion criteria are: 1) other psychological conditions rendering the person unlikely to benefit from a brief treatment, including psychosis, bipolar disorder, cognitive impairment, and active substance abuse or dependence (comorbid depression permitted); 2) current suicidal ideation or intent; 3) past suicide attempt or psychiatric hospitalization; 4) concurrent receipt of regular individual psychotherapy; 5) use of anxiolytic medication (including benzodiazepine and tranquilizers ; antidepressants okay).

*required

Maximum number of subjects

Enter the total maximum number of subjects to be recruited and enrolled

30-32

*required

Provide the enrollment breakdown number for each participant population

For example: n = 5 teachers, n = 30 students

Coaches: 5-7; Patient participants: up to 25

*required

What are the selection criteria for research participants?

Include sample size calculations, if applicable.

This exploratory pilot study will rely on convenience sampling. Coach participants (n = 5-7, to allow for attrition) will be recruited from the UNLV department of psychology and related departments. Patient participants (up to n = 25) will be recruited from the UNLV PRACTICE, UNLV campus, and the general community (see below).

This is a single-arm trial focused on feasibility and acceptability as well as preliminary clinical response (e.g., improvement in anxiety symptoms, engagement of purported psychological mechanism of avoidance) for a future R-series application to NIMH. There is no power analysis for such exploratory work; the sample sizes are not powered to detect treatment effects or statistical significance. Rather, these sample size estimates are determined by prior literature to demonstrate proof-of-concept and identify preliminary feasibility, acceptability, and appropriateness alongside initial demonstration of clinical impact.

See inclusion/exclusion criteria above for further details.

*required

Vulnerable Populations

Please check the population(s) that will be enrolled. Check all that apply.

Pregnant Women/Fetuses/Neonates

Minors with Parental Permission

Minors who can consent themselves

Prisoners

Other

✓ None of the Above

*required

Are you excluding your populations based on gender, race or ethnic origins?

Yes

✓ No

*required

Would your population be considered decisional/cognitively impaired?

Yes

✓ No

*required

Recruitment

Describe when, how, and by whom potential participants will be informed about the opportunity to participate in the research.

Note:

- *If you will be posting to a website, list serv, etc., ensure that you obtain permission from the website/list serv owners and/or administrators to disseminate your recruitment materials*
- *If you will be receiving contact information from another source, explain how you will obtain this information and ensure that they have permission to access/share the contact information for the purpose of research recruitment*
- *If recruiting in classrooms, it is preferred to recruit before the start of a class or after a class. In addition, if the researcher is an instructor or teacher of the class, it is best to have another research team member recruit and conduct the consent/assent process so that potential participants do not feel coerced to participate*

Describe how subjects will be recruited.

Coach Participants: Coaches will first be recruited by approaching undergraduate/post-baccalaureate students affiliated or interested in working with the PI/TREATment Lab. Dr. Renn gets an average of 10 -15 inquiries per academic year from psychology majors and minors interested in serving as undergraduate/post-bacc research assistants. These students will be given a brief description of the study in a 15-min introductory Zoom meeting with the PI, which includes an overview of the lab, basic description of the study, and overview of basic time commitment. If they are interested and, they will undergo informed consent procedures. (The brief description of the study will map onto the email uploaded for subsequent recruitment.)

If recruitment as described above yields an insufficient number of coaches, they will be additionally recruited through email distribution via the PI to colleagues across the UNLV psychology department (including referrals from labs in the Department of Psychology), the UNLV Mental and Behavioral Health Coalition (comprised of faculty across UNLV mental and behavioral health disciplines), and the UNLV PRACTICE (interdisciplinary training clinic). See attached email. The email will ask faculty to forward the email information to students they recommend who may be eligible and interested. Students are asked to contact the PI directly.

Patient Participants: They will be recruited from a variety of clinical or community partners, or directly from the community via bulletin postings/ads and distribution of flyers to primary care clinics, UNLV PRACTICE (training clinic), other mental health organizations/clinics, community organizations (e.g., libraries), mental health organizations (e.g., National Alliance on Mental Illness), low-income housing, and social service settings (including senior centers, community centers). We also request permission to post a recruitment ad on UNLV Today (e-newsletter) if other community recruitment sources do not yield the desired sample size.

The study will also be posted on the PI's lab website (http://brennarenn.faculty.unlv.edu/) and on clinical trials.gov.

Describe the type of documents used (e.g., flyers, email, verbal announcements, online post, etc.).

Patient participants: flyers, verbal announcement during community presentations, online post (e.g., UNLV Today or community-based newsletters), emails to community/clinical partners in Las Vegas, Henderson, and surrounding areas. Students ("coach participants): emails sent directly to UNLV faculty; faculty will be asked to distribute to recommended students.

Attach recruitment materials here

At minimum, recruitment materials should include the following criteria: UNLV, that the activity is research (specifically use the term research), purpose of the research, inclusion/exclusion criteria, brief description of the study procedures (including any audio/video recording), location of the study, time commitment involved, compensation (if applicable), the PI's name, and contact information for the PI/researcher.

Note: Attachments are required because links can be changed or removed.
IRB_Aim 2 patient flyer_v2.0.docx

IRB_Aim 2_student recruitment email_v2.0.docx

*required

Purpose

State the purpose of the study in lay terms.

Note: DO NOT copy and paste directly from your grant proposal, dissertation prospectus, clinical protocol, etc.

Access to treatment for common mental health conditions (namely, depression and anxiety) is limited across the U.S., due in part to shortage of available providers. According to a 2022 report from the UNLV Lincy Institute, all of Nevada's counties are federally designated mental health provider shortage areas, and the state ranks last in the nation for mental health metrics like access to care and high prevalence of mental illness (https://digitalscholarship.unlv.edu/cgi/viewcontent.cgi?article=1011&context=bmw_lincy_health)Global mental health initiatives are bridging this gap with provider task sharing, in which tasks are redistributed in a stepped care model. With this model, low-intensity behavioral health services are delivered by nonspecialist providers (NSPs) under appropriate supervision, thereby expanding access and freeing up limited expert resources . The need for such services is great in low- to middle-income countries, and such strategies are readily translatable to high-income countries. Notably, in England, task sharing is the linchpin of the National Health Service's Improving Access to Psychological Therapies program (IAPT; recently renamed The NHS Talking Therapies, for anxiety and depression programme), in which psychological well-being practitioners deliver structured, low-intensity behavioral interventions for depression and anxiety disorders within a stepped care model. These practitioners have the U.S. equivalent of college coursework and no prior specialized training in mental health. Such a model has served as the inspiration for the development of the current study; however, development and deployment of such models in the U.S. are rare. There have been a few demonstrations of nonspecialist providers delivering brief structured treatments for depression; to date, only one published study (Stanley et al.) has investigated this model for anxiety treatment. While Stanley and colleagues' findings were promising, the intervention they delivered was akin to traditional cognitive behavioral therapy (CBT), consisting of 12 sessions. Pressing is the need for briefer, streamlined interventions (e.g., 6-8 sessions) appropriate for non-speciality settings such as primary care, where the majority of people receive diagnosis and treatment for common mental health conditions.In response to the large numbers of individuals with untreated anxiety and the lack of mental health specialists, the PI has developed a brief structured intervention program for anxiety, designed to be delivered by non-specialists ("coaches"). The focus of this intervention is to provide individuals with education about anxiety, guide them to track their symptoms, teach different ways of thinking about situations, assist them with re-engaging with activities. The treatment is based on evidence-based principles of strategies of cognitive behavioral therapy (CBT), a gold standard treatment for anxiety disorders. The goal of this intervention is to reduce symptoms of anxiety and accompanying distress in individuals with mild-to-moderate anxiety conditions. This pilot study will test the feasibility and preliminary effectiveness of this intervention delivered by coaches. The findings are expected to create a foundation to inform acceptable, effective, and sustainable mental health care within various non-specialty community and clinical infrastructures.Select references:Hoeft, T. J., Fortney, J. C., Patel, V., & Unützer, J. (2018). Task-sharing approaches to improve mental health care in rural and other low-resource settings: a systematic review. The Journal of rural health, 34(1), 48-62.Patel, V. (2022). Scale up

task-sharing of psychological therapies. Focus, 20(3), 330-331.Renn, B. N., Casey, C., Raue, P. J., Areán, P. A., & Ratzliff, A. (2023). Task Sharing to Expand Access to Care: Development of a Behavioral Health Support Specialist. Psychiatric Services, 74(1), 76-78.Renn, B. N., Sams, N., Areán, P. A., & Raue, P. J. (2022). A low-intensity behavioral intervention for depression in older adults delivered by lay coaches: proof-of-concept trial. Aging & Mental Health, 1-8.Stanley, M. A., Wilson, N. L., Amspoker, A. B., Kraus-Schuman, C., Wagener, P. D., Calleo, J. S., ... & Kunik, M. E. (2014). Lay providers can deliver effective cognitive behavior therapy for older adults with generalized anxiety disorder: a randomized trial. Depression and Anxiety, 31(5), 391-401.

*required

Objectives

Briefly describe your research questions and the objectives of this study in lay terms. State what you hope to learn from the study and assess the importance of this new knowledge. What do you aim to achieve through this research?

Note: DO NOT copy and paste directly from your grant proposal, dissertation prospectus, clinical protocol, etc.

This study will examine the feasibility, acceptability, appropriateness, and preliminary clinical outcomes in a single-arm pilot/feasibility trial. A sample of up to 25 adult individuals with clinically significant anxiety (“patient participants”) will be recruited from the community. These participants will receive 8 weekly sessions of a brief, structured intervention for anxiety. The intervention will be delivered by a trained and supervised “coach.” Coaches will be UNLV students with advanced standing (juniors or seniors) or recent graduates at the bachelor's level. They will be trained and supervised by the PI. Assessments will measure the acceptability and appropriateness of the intervention and non-specialist delivery, and assess participants' anxiety, avoidance, and disability/functioning. Investigators will also measure the adequacy of recruitment, enrollment, and retention strategies, as well as the retention, attitudes, and compliance of coaches. Differences between pre- and post-intervention patient participant outcomes will be calculated as preliminary evidence of intervention effectiveness, to be tested in a future randomized controlled trial powered to detect treatment effects.

*required

Research Methods

Describe ALL the study procedures that human participants will undergo for purposes of the research.

Keep this in mind - If you are:

- *Observing participants - describe the setting and what you will document*
- *Asking participants to complete a survey - describe how the survey will be distributed*
- *Interviewing participants - describe how you will interview them and what the setting of the interview will be*
- *Audio or video recording - describe how the audio/video tapes will be used and how confidentiality will be maintained*
- *Conducting blood draws - describe how the blood will be collected (e.g. fingerstick, arterial, venipuncture, etc.), the amount of blood that will be drawn (in layman terms, e.g. teaspoons, tablespoons, cups, etc.), and the frequency of blood draws*
- *Collecting specimens - describe what specimens will be obtained and how they will be collected*
- *Conducting secondary analysis - describe the data source and provide a list of the variables that will be obtained and analyzed*

Include:

- *Time commitment for each participant including if there are multiple visits (e.g., 30 minutes per week for 3 weeks for a total time of 1.5 hours)*
- *Explain what will happen if the participant no longer wants to participate and they are no longer interested in being in the study. What will happen to data/biological specimens that have already been collected?*
- *Describe what will happen to the data/biological specimens after they are collected and analyzed. If data is presented publicly, will it be identifiable or de-identified?*

*required

How will you conduct this study?

Clearly describe any procedures used during the conduct of the study for each participant population. A step-by-step description is recommended.

This study largely replicates the methods of a prior trial of nonspecialist-delivered treatment for depression and extends it to a new intervention strategy (STARS program) for anxiety. This prior trial was conducted by the PI at her former institution (the University of Washington, Seattle, WA; IRB approved study #00005877) and published under Renn, Sams, Arean, & Raue (online first), doi: 10.1080/13607863.2022.2084709. It is heavily inspired by a standard of care across England--what was formerly called "Improving Access to Psychological Therapies" (IAPT), and now referred to as "NHS Talking Therapies for depression and anxiety programme"--in which

nonspecialists are trained to deliver brief CBT-informed interventions for depression and anxiety (see more: https://www.england.nhs.uk/mental-health/adults/nh...)

Background on the STARS program. The PI developed the intervention to be delivered by coach participant to patient participants (see UNLV IRB study UNLV-2022-145 for iterative development and stakeholder involvement of this protocol). It is rooted in foundational principles from cognitive behavioral therapy (CBT) and streamlined in such a way that is intended to be delivered by nonspecialists. The STARS (strategies to treat anxiety research study) program consists of eight 30-min sessions (although the first session may last 45-to-60-min) conducted individually between a coach and patient participant. The first session focuses on (a) psychoeducation, (b) explaining the CBT model of anxiety, (c) selecting specific treatment targets from either worry management (for generalized anxiety symptoms; notably, uncontrollable worry) and exposure (for panic, phobia, or other anxiety related to avoidance), and (d) creating an exposure action plan ("homework; planned anxiety treatment activities for the week). Subsequent sessions focus on success or difficulties with the homework/activity plan for the week, including measurement-based care using repeated assessment of anxiety and depression symptoms to track treatment response.

Recruitment and Training of Coaches. The PI will recruit 5 undergraduate students with advanced standing in mental health majors (e.g., psychology, social work) and train them to deliver the low-intensity anxiety intervention. Training will be informed by prior trials of similar work (Renn et al., online first; Raue, Hawrilenko, Corey, et al., 2022) and consist of approximately (a) approx 8 hours of synchronous training conducted by the PI, including didactics related to anxiety psychopathology; general clinical skills; foundations of cognitive behavioral therapy; specific components of the STARS program; demonstrations of techniques; and issues of diversity, inclusiveness, and equity; and (b) between-session homework, including roleplays, readings, and review of materials. Fidelity to the STARS program intervention will be assessed by external review of recorded standardized roleplays conducted during training. After training, the students with "passing" or greater fidelity scores will be selected to participate as Coaches in a pilot trial to evaluate the feasibility, acceptability, and preliminary outcomes of the intervention. Intended sample size for the pilot trial is n = 3 patient participants for each student interventionist, for a minimum of 15 patient participants. We will overrecruit patient participants (up to 25) to allow up to 5 patients per coach.

Patient Participants: Recruitment, Screening, and Enrollment. We will recruit patient participants from the UNLV and greater Las Vegas Valley community and enroll them if they have clinically significant symptoms of anxiety (Generalized Anxiety Disorder [GAD-7] scale scores equal to or greater than 8) and otherwise meet the inclusion and exclusion criteria.

1. Eligibility screening will be conducted via telephone by a trained TREATment lab research assistant. Potential participants will first be told about the general structure and purpose of the eligibility screening.

We will collect name, age (to ensure 18 or older), and contact information (phone, mailing address as well as current location, email). This will be entered into the Master List for the parent study, in part to ensure that we do not screen the same person multiple times. Potential patient participants will first be screened with a 7-item anxiety screener (GAD-7; routinely used in primary care and other routine care settings, with good psychometric properties for research and clinical purposes). Only those with threshold anxiety symptoms (score of ≥8 on GAD-7; cut score selected to maximize

sensitivity) will proceed to further eligibility evaluation. This includes, in order:

- Mood Disorders Questionnaire (MDQ; a screener for bipolar disorder),
- Medication list (name, dose, frequency)
- AUDIT, a screener for alcohol misuse,
- Drug Abuse Screening Test (DAST-10), a screener for other substance misuse,
- psychosis screening questions;
- MacLean Screening Instrument for Borderline Personality Disorder (MSI-BPD; a screener for borderline personality disorder), and
- Columbia Suicide Severity Rating Scale (C-SSRS); a screener for suicide risk

See assessment schedule (attached).

All assessment measures for Eligibility Screening will be conducted over the telephone by a trained research assistant. The RA will ask the participant each question and will record the response in the study database. Screening data will not be used for research purposes other than determining participant recruitment and enrollment per CONSORT guidelines and future study feasibility planning (e.g., proportion of sample ineligible for particular reasons). It may also be reference during the study in case an individual calls again to attempt to re-enroll after initial screening (e.g., told they're ineligible, and then they call back). Once the Master List is destroyed at the end of the study, all screening data will be retained as part of the parent dataset but will be deidentified.

No portion of the screening assessment administration will be recorded. Any endorsement of an exclusion criteria will cease participation in the screener as soon as the assessment measure is complete (e.g., once the entire MDQ is completed, not just a single item on the MDQ). Ineligible participants will be informed of the following: "We have completed our screening questions and I appreciate your time. I'm sorry, but our criteria for you to continue in the study have not been met." They will be offered a list of community resources for mental health services (see attached).

All identifying information collected as part of the eligibility screener will be stored in an electronic database on a secure server and will be password protected. Eligibility screening data will be labeled with a unique study identification number. The link between the personal identifiers and the related eligibility screening data will be kept until the end of the study. Deidentified information will be kept indefinitely.

Patient Participants: Baseline and Subsequent Assessments; STARS Program

1. Baseline assessment:
Participants who are eligible upon screening will be asked to schedule a baseline assessment and first STARS session. This will be in-person at UNLV TREATment lab space on main campus. Informed consent for the intervention study will occur at this visit.

First, the patient participant will meet with a research assistant for approximately 1 hour - 1.25 hours. They will be sent the informed consent document ahead of time to review. During the meting, the RA will first describe the study, answer any questions, and obtain informed consent. At that point, patient participants will be considered "enrolled." They will then complete a clinical interview (HAM-A) administered by the RA, provide demographic information, and complete six additional self-report study measures (ASI-3, OASIS, MEAQ, CAQ, WHODAS, ISI):

- Hamilton Anxiety Rating Scale (HAM-A), an interviewer-rated measure consisting of 14 items, each defined by a series of symptoms, to measure both psychic anxiety (mental agitation and psychological distress) and somatic anxiety (physical complaints related to anxiety). A corresponding interview guide will be used to increase the reliability. This measure has demonstrated sensitivity to change in clinical trials.
- Anxiety Sensitivity Index (ASI-3), an 18- item self-report scale containing items specifying different concerns someone could have regarding their anxiety.
- Overall Anxiety Severity and Impairment Scale (OASIS), a 5-item self-report scale quantifying anxiety-related distress and impairment
- Multidimensional Experiential Avoidance Questionnaire (MEAQ), a 62-item self report assessment of avoidance. To be used to measure activation of target mechanism of avoidance.
- Cognitive Avoidance Questionnaire (CAQ); a 25-item self-report measure of the tendency to employ cognitive avoidance strategies when dealing with threatening intrusive thoughts. To be used to measure activation of target mechanism of avoidance.
- World Health Organization's Disability Assessment Schedule 2.0 (WHODAS 2.0); this 12-item generic health-status measure assesses functioning across six domains: communication, mobility, self-care, interpersonal, life activities, and participation. Item scores (0 = no difficulty to 4 = extreme difficulty or cannot do) are summed, with higher scores representing greater disability.
- Insomnia Severity Index (ISI); 7-item self-report questionnaire to assess cooccurring sleep difficulties (prevalent in anxiety)

2. First STARS Session:
After completing the Baseline Assessment, the patient ppt will meet with their study "coach" for approximately 45 min for the first session of the STARS program. Patient participants will complete a brief self-report inventories of anxiety (7-item Generalized Anxiety Disorder [GAD-7]) and co-occurring depressive symptoms (9-item Patient Health Questionnaire [PHQ-9]) at the beginning of every STARS session. These assessments are used in routine mental health care and primary care settings. These will be reviewed in session by the coach to monitor treatment response, identify session needs, and reinforce patient attempts at change. These scores will also be used by the PI to monitor treatment response and adverse events across participants.

The patient ppt will also complete the Credibility/Expectancy Questionnaire (CEQ) and the Working Alliance Inventory-short form (WAI-SF) at the end of Session 1, after treatment rationale has been explained. These will be paper forms that will be entered into the study database by the RA.

Both the baseline assessment and STARS session will be audio recorded for training and fidelity review.

3. Subsequent STARS sessions:

The patient ppt will meet with their assigned Coach for 8 weekly sessions. Sessions 2-8 are expected to last 30 min. These sessions will be audio recorded and uploaded to the study database alongside the patient ppt's responses to GAD-7 and PHQ-9 for ongoing supervision and monitoring by Dr. Renn.

4. Subsequent assessments

See the Assessment Schedule for details of follow-up assessments.

Patient Participants: Patient participants will complete post-intervention assessments at Week 8, including brief exit interview questions of their experiences. They will also complete follow-up assessments to assess maintenance of treatment effects at 6 and 12 weeks after completion of treatment. These assessments can be conducted by Zoom, in-person at UNLV, or over the telephone. Patient participants will receive $40 incentive payment for completion of each assessment (baseline, post-treatment, 6- and 12-week follow-up) for a total possible incentive of $160.

Assessments and STARS sessions will be audio recorded for training and fidelity review.

BL, Wk 8, FU 1, FU2:
For all study-related assessment timepoints once enrolled, an RA will conduct the HAM-A clinical interview. The remaining instruments will be completed as self-report forms either using paper forms, for RA entry into the study database, or entered directly into the study database as survey responses by the participant.

For BL and Wk 8 assessments, this assessment visit will occur in person in the TREATment Lab space prior to their scheduled STARS coaching visit. After completion of the HAM-A interview, the participant will have time to complete the remaining self-report inventories.

For follow-up assessments (FU 1 and FU 2), the HAM-A will be conducted over the telephone and/or Zoom. The self-report forms will be completed either over the telephone (by verbal self-report from the patient participant) or possibly by emailing a survey link via REDCap. (Note: UNLV REDCap is still pending as of 7/11/2023 per Maureen Shaw, ORI Data Privacy Officer, so exact functions have not yet been trialed to see if we can build this function into our database.)

STARS Visits:
At each STARS visit, the participant will complete a GAD-7 (anxiety screen) and PHQ-9 (depression screen) at the start of session. This will be a paper self-report form that is then used in session for review between the coach and patient participant as is often the case in routine clinical care. This data will be entered by the coach into the STARS visit note at the end of the visit.

All assessments will be labeled only with the Study ID number, visit number (e.g., BL for baseline), and date of visit. The electronic study database will be the ultimate record for data capture; any responses on paper forms will be immediately transferred to the study database (same day) by the RA or Coach and all or any paper forms will be shredded as soon as possible.

Risk of Harm Protocol (Patient Participants).

During screening, potential patient participants will be asked explicitly and specifically about suicidality to ensure appropriateness and eligibility for this study. It is possible that responses may "trigger" the risk of harm protocol, including any positive responses to CSSRS items 1 ("Have you wished you were dead or wished you could go to sleep and not wake up?") or 2 ("have you actually had any thoughts of killing yourself?"). The CSSRS administration will be followed, such that any positive response to Item 2 will result in additional questions being asked. At the end of the CSSRS, the rater makes a risk determination of low, moderate, or high. Instructions for low, moderate, and

high risk assessments are detailed in the attached Risk of Harm Protocol, which we use across lab studies. All assessors have immediate access to the PI (Dr. Renn) for questions or for Dr. Renn to contact the patient participant in any instances of moderate or high risk disclosure to conduct further assessment and take any necessary action (e.g., calling emergency services to conduct a wellness check).

Throughout the study, suicidal thoughts or behaviors may be identified such as on the PHQ-9 (item #9, “Thoughts that you would be better off dead, or thoughts of hurting yourself in some way?”) or in conversation (e.g., self-report of a patient participant during STARS session). If a participant endorses a score of ≥ 1 on item #9 of the PHQ-9 or self-reports any suicidal ideation, the C-SSRS will be administered to determine risk and the Risk of Harm protocol will be followed.

TREATment Lab staff, research assistants, and graduate students are trained and supervised by the PI, a licensed clinical psychologist, to conduct these screenings. They also receive supplemental training such as video tutorials in proper admiration of the Columbia Suicide Severity Rating Scale (e.g., https://www.youtube.com/watch?v=sWX3lk2AoxU)

Coach Participant Assessment. Primary assessment of coach participants will occur through observation of their performance in role plays and STARS sessions. Coach participants will be paid $10 per session completed with a patient participant (x 8 sessions = up to $80 per patient). They will also be invited to participate in a post-study qualitative interview. We request flexibility in this exit interview, per the standards of qualitative methodology (see attached coach interview guide). The interview will last no longer than 60 min and will be audio recorded for transcription by a third party. The transcripts will be deidentified and audio files will be deleted after transcription. The interview will be conducted by a TREATment lab research assistant(s). The interview will focus on the coach participant’s experience (1) learning the intervention, (2) delivering the intervention, and (3) other comments about the intervention or implementation. Coaches will receive $50 for participation in the exit interview.

*required

What is the anticipated time commitment involved for each study procedure (e.g. 30 minutes for the survey, 1 hour for the interview, etc.)? What is the total time that each participant will spend in the entire study?

Describe the duration of study participation (i.e. the anticipated amount of time commitment required for each subject), the length and number of study visits, and the timetable for study completion.

Describe, in timeline sequence, the activities participants will be asked to perform specifically for the research, and how much time each activity will take. Attach your schedule of assessment, if applicable.

Event	Time
Eligibility Screening	Half-hour
Baseline Assessment	1.25 hours
STARS Session 1	Up to 1 hour
STARS Sessions 2-8	30 min each = 3.5 hours
Post-Treatment Assessment	Up to 1 hour (expected 45-60 min)
Follow-up 1 (6 weeks after completion of STARS)	Up to 1 hour (expected 45-60 min)
Follow-up 2 (12 weeks after completion of STARS)	Up to 1 hour (expected 45-60 min)
Total	9-10 hours over 20 weeks

Schedule of assessment (if applicable)

Assessment Schedule_STARS_v2.0.docx

*required

What is the anticipated completion date for the study?

08-30-2024

*required

Study Procedures

Check all that apply

✓ Survey/Questionnaires

Attach survey(s)/questionnaire(s)

MSI-BPD Screener.pdf

OASIS_overall anxiety severity and impairment scale.pdf

Patient Health Questionnaire (PHQ-9).pdf

Psychosis screener.docx

WHODAS_2.0_Form.pdf

Working Alliance Inventory_short (WAI-SR) client version.pdf

ASI3.pdf

Audit-C.pdf

CEQ.docx

Cognitive Avoidance Questionnaire (CAQ).pdf

C-SSRS-Screener-lifetime-recent-with-triage-colors-2021 (3).docx

Drug Abuse Screening Test (DAST-10).pdf

Generalized Anxiety Disorder scale (GAD-7).pdf

Insomnia Severity Index (ISI).pdf

Mood Disorder Questionnaire (MDQ).pdf

Multidimensional Experiential Avoidance Questionnaire (MEAQ).pdf

Demographics_STARS.docx

STARS_CBT-A Fidelity Form Session 1.doc

STARS_CBT-A Fidelity Form Follow-Up Sessions .doc

STARS Program_Coach training outline_July 2023.docx

How will these be administered?

- ✓ Online
- ✓ Hard copy
- ✓ Telephone
- Other

✓ Interviews

*required

Attach script

STARS Program_coach exit interview guide.docx

Eligibility screener_STARS.docx

HAMILTON-ANXIETY (HAM-A).pdf

Community Referrals and Resources_TREATment Lab (1).pdf

Risk of Harm Protocol_TREATment lab 2023.docx

✓ Audio Recording

*required

Provide details of activities to be recorded and who will be recorded.

Training (led by PI) will be conducted and both audio and video recorded via Zoom for later training purposes. These recordings will include the PI and coach participants.Assessments and STARS sessions will be audio recorded for training and fidelity review. Assessments will feature both TREATment lab RAs and patient participants; these will be randomly selected for interrater reliability and training specific to the HAM-A (Hamilton) clinical interview. STARS sessions will feature both the coach and patient participant. These will be reviewed by the PI for supervision, training, any any potential safety or ethical concerns. They will also be randomly reviewed for fidelity monitoring.The exit interview with coaches will be audio recorded only and will feature the coach participant(s) and a member of the TREATment lab research team serving as facilitator. These recordings will be sent for third-party transcription and returned deidentified (coach and interviewer names removed).

✓ Video Recording

*required

Provide details of activities to be recorded and who will be recorded.

Training (led by PI) will be conducted and both audio and video recorded via Zoom for later training purposes. These recordings will include the PI and coach participants.

Diaries or Journals

Still Photography

Focus Group

Observation

Secondary Analysis

Blood/Specimens

✓ Other

*required

Please describe

(1) Risk of Harm protocol and (2) community resources attached above with interviews.

*required

Project Site(s):

Where will you conduct this study?

NOTE: If the project site is other than UNLV or online, a Facility Authorization Letter must be submitted for each site. You can find a template letter here.

✓ UNLV campus

*required

Specify which campus:

✓ Maryland Campus

Shadow Lane/Medical Campus

Other

External Collaborating Site(s) (e.g. collaborating site where study procedures are being conducted)

External Public Site(s) (e.g. coffee shop, library, etc.)

CCSD School(s)

International Site(s)

Online

Other (e.g., Non-CCSD schools)

*required

Is this study a clinical trial?

NIH defines a clinical trial as a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes.

For help in determining if your study is a clinical trial, please use the NIH decision tool.

✓ Yes

*required

ClinicalTrials.gov registration is required for studies that meet the definition of an "applicable clinical trial" (ACT).

For help in determining if your study is an ACT, please use the ClinicalTrials.gov checklist and flowchart. ***Note: If your study is an ACT, the IRB protocol cannot be approved until the NCT ID number is received.***

If your study is an ACT, provide the ClinicalTrials.gov number (NCT ID) below.

Note "pending" if you have submitted to ClinicalTrials.gov but have not yet received your NCT ID.

NCT05398016

Attach a study protocol.

Study Record PHS Human Subjects and Clinical Trials Information_Renn.pdf

No

*required

Describe the consent process.

Include:

- Who is obtaining consent?
- When and where will consent be obtained?
- How will the consent form be distributed to the participant?
- If obtaining signed consent, how will you collect the signed consent form?
- Will you be obtaining consent in a non-English language? If so, include who will be consenting, and explain your ability to speak, read, and write the language of the potential participants. Explain provisions for translators if needed.
- Who will be providing consent? (e.g., the subject, the parent, etc.)
- If minors are subjects, include how parent permission and assent will be obtained.

NOTE: If identifiable information will be published, shared or disseminated, the consent form must describe this for the subject.

Patient Participants.

All consenting and assessment activities conducted with patient ppts will be conducted by trained research assistants in the PI's TREATment Lab.

Prior to study enrolment, potential patient participants will complete an eligibility screening assessment that will ask demographic questions, basic contact information (e.g., name, date of birth, phone number, current physical location/address in the event of an emergency, and email), and inclusion/exclusion criteria that include questions about anxiety, mood, alcohol use, other mental health factors, and a brief suicidality assessment. Participants will be verbally provided with study information that outlines the purpose of the screening assessment. Stated agreement to proceed with procedures will be obtained prior to continuing the screening portion of the study.

Patient participants eligible for the full study based on the screening assessment will be scheduled for an in-person meeting to be consented for the main study, sign a hardcopy consent form, completed baseline assessment measures, and meet with their STARS program coach to begin the program. They will be provided with a copy of the consent form for their records and future reference.

Coach Participants.

The study PI (Dr. Renn) will obtain consent from all coaches at the beginning of the first Zoom-based training session. Dr. Renn will send a PDF copy of the informed consent form to each coach individually ahead of the scheduled time, and she will be available for questions or concerns in advance of the group call. On the group call, everyone will have the chance to ask questions in front of one another or request a 1:1 "breakout room" discussion with Dr. Renn via Zoom. If anyone is uncertain, they can participate in the first training prior to providing consent, as no information will be gathered from coach ppts at this point. Then Dr. Renn will meet individually with that person to obtain consent.

*required

Select all that apply for your consent process

Informed consent (with signature)

✓ *Note: Signed consent may be a physical signature on a hard copy consent form, an electronic signature, or a typed name (for non-FDA regulated research).*

Check all that apply

Parent Permission Form(s)

Assent Form(s)

✓ Informed Consent Form(s)

Informed Consent Form(s) with HIPAA authorization.

Attach informed consent forms here.

ConfidentialityAgreement_TREATment Lab.pdf

STARS_Main Study Consent_patients_v3.0.docx

STARS_Main Study Consent_coaches_v3.0.doc

Waiver of Documentation of informed consent (i.e. waiving the requirement to obtain signed consent)

Note: A Waiver of Documentation of Informed Consent is when you are still conducting a consent process, but you are not obtaining signed consent.
Examples: verbal consent, clicking a radio button to indicate consent, providing an information sheet, etc.

Waiver of informed consent

Note: A Waiver of Informed Consent is when you are not conducting a consent process at all.

Alteration of informed consent (use for deception/incomplete disclosure of purpose).

Research involving non-English speakers

If study documents (e.g. recruitment materials, surveys, interview questions, consent forms, etc.) will be given to participants in a non-English language, the Translator's Statement should be completed by the person(s) translating the documents. All translated documents should be attached in the corresponding protocol section along with the English versions.

Attach here.

*required

Compensation

Will subjects be paid or otherwise compensated for research participation?

NOTE: UNLV has implemented the Forte Research Payments System as the central system to electronically manage incentives for UNLV research participants. The system will pay research participants via VISA credit card, check, or direct account deposit. Please contact hscomp@unlv.edu if you have questions about the use of Forte, to begin the process, or want to receive a waiver in order to use an alternative payment method.

✓ Yes

State the amount of compensation and describe the nature of any compensation to subjects (e.g. gift card, research credit, extra credit, gift, etc.).

Coach Participants: Coach participants will be paid $10 per session completed with a patient participant (x 8 sessions = up to $80 per patient). Coaches will receive $50 for participation in the exit interview.Patient Participants: Patient participants will receive $40 incentive payment for each completed assessment (baseline, post-treatment, follow-up 1, follow-up 2). These will be issued in the form of a Forte payment card and reloaded as indicated. Total for completion of all assessments: $160. Attendance in STARS interventions are not incentivized.

No

*required

Indicate the method of payment.

✓ Forte System Gift Card

The Forte Research Payment System asks for participant identifiers (name, gender, email, mailing address, and date of birth). In the consent form, please include that participants may be asked to provide their name, gender, email, mailing address, and date of birth for compensation purposes. Specify if these identifiers will or will not be linked to their study data.

Research Credit/Extra Credit

Other

*required

When and how is the compensation provided to the subject?

Most studies require partial compensation be given for partial participation. Please address if payment will be prorated.

Coach Participants: Coaches will earn incentives per session completed (or, if the patient participant ends the session prematurely, the coach will still earn payment). Although recruitment and training will emphasize the desire for coaches to see approximately 3 patient participants each to learn and improve on their intervention delivery, there is no consequence if they do not see that many patient participant; payment will still be based per session. All coaches who enroll will be invited to complete the exit interview to ensure variety of viewpoints; for this, they are eligible to receive $50 payment.Patient Participants: Study participation entails several assessments along the time course of study completion. Participating in assessments is incentivized; there is no monetary incentive for participating in the investigational psychotherapy. Participants may elect to discontinue treatment and still complete assessments, for which they will receive compensation.

Study Procedures

*required

Will the study involve administering and/or collecting data from any of the following?

Check all that apply.

- Drugs
- Devices (includes software and mobile applications)
- Biologics
- Medical Records
- ✓ None of the above

Participant Protection

*required

Do you consider this research study to be:

✓ Minimal Risk (something that a normal person would expect to encounter in their daily life).

More than Minimal Risk (this level of risk could place participants at risk of civil or criminal liability; damage their financial standing, employability or reputation; or place them at risk of emotional or physical damage).

*required

Potential Risks

Examples of risk include physical risks, psychological risks (such as stress, discomfort, or invasion of privacy) and social risks (such as jeopardy to insurability or employability).

Describe immediate risks, long-term risks, the rationale for the necessity of such risks, alternatives that were or will be considered, and why alternatives may not be feasible. Describe any potential legal, financial, social, or personal effects on subjects of accidental data disclosure.

Coach participants: Coach participant risk consists of possible personal distress while speaking with anxious patient participants about their psychological symptoms; medical or psychiatric emergencies that may arise during interactions with patient participants; and inadvertent breach of confidentiality related to information about their performance and fidelity.

The nature of working in such "therapeutic" or interventional contexts with individuals with mental health symptoms means there are no viable alternative to the risks of potential distress or unanticipated emergencies; see below as to how we seek to prevent and minimize these risks to both coaches and patient participants.

Patient participants: Patient participating in this study may be exposed to the following risks:

(a) Risks of worsening mental or emotional state: It is not believed that the risk of these depressive, anxious, suicidal, or other adverse outcomes are increased as a function of being enrolled in this study. It is well known that merely asking about mood or suicidal ideation does not increase the risk of adverse mental health outcomes. We will screen for active/acute suicidality,

history of suicide attempt(s), and other mental health conditions that are inappropriate for this intervention (i.e., psychosis, mania/hypomania, active substance abuse) as an exclusion criterion. However, we detail the procedures to mitigate potential risk of emergent suicidality during the course of the study below ("What procedures will be utilized to prevent/minimize any potential risks?").

(b) Risks associated with the intervention: Evidence-based mental health intervention programs are not expected to cause any harm. The intervention under evaluation is based on principles of evidence-based practice from cognitive behavioral therapy (CBT), a first-line treatment for anxiety, depression, and other common mental health interventions. However, patient participants may experience temporarily exacerbated symptoms of anxiety (typically to moderate levels) while they are engaging in therapeutic activities to target avoidance of worry/anxiety/fear. They are told that this is expected and indicates the treatment is working.

(c) Risks associated with study assessments: Study assessments include questions about depression, anxiety, and other mental and emotional problems that may make study participants experience discomfort or stress. Participants can choose to take a break; assessors are also trained in how to empathically and sensitivity deliver such assessments. The instruments used throughout the study are well tested, frequently used in clinical practice and clinical research, and are not known to directly cause problems or distress in participants.

(d) Risks associated with potential loss of confidentiality: Social or personal effects of accidental data disclosure could result in shame or embarrassment, particularly if data related to their mental health is breached. There is also the remote possibility that research records could be subpoenaed by a court of law. All of these potential losses of confidentiality and measures to protect security will be disclosed in the consent documents.

Study data will be collected and stored using REDCap, a secure web application for building and managing online surveys and databases. REDCap is used by over 4,700 institutions for over 1 million research projects. At the time of this writing, conversations with the AVP for IT have indicated that a HIPAA compliant server for REDCap at UNLV is expected to be approved and accessible to faculty by late April/early May. **update: As of 7/13/2023, UNLV ORI and OIT have begun implementing REDCap for faculty research use with identifiable information.*

The only identifiable information collected as part of this study are participant name, date of birth, email address, mailing address, audio recordings, and phone number. These are stored in a separate master list in a separate REDCap database, linked using participant Study ID number. The Forte/Advarra Research Payment System asks for participant identifiers (name, gender, email, mailing address, and date of birth). These will be obtained by the RA from the master list and input into the Advarra/Forte system.

Removal of the master list at study completion will render the final dataset deidentified and help protect participant privacy and confidentiality of study records.

What procedure(s) will be utilized to prevent/minimize any potential risks?

We have developed procedures to minimize risk to our participants and to create conditions that make study participation as comfortable as possible.

Coach participants: To mitigate and address distress among our non-mental health specialist coach participants, we have incorporated such issues into our training protocols. This is similar to our standard training for Research Assistants in interacting with patient participants across studies related to mental health. For example, we will discuss and role play how to sensitively inquire about mood and symptoms of anxiety; how to respond to patient distress, including reassuring the patient or facilitating contact with PI if necessary; and how to manage one's own emotions such as concern, worry, anxiety, and possible distress over patients' conditions.

Coaches are asked to read, acknowledge and sign a TREATment lab confidentiality agreement as a condition of participation in order to protect patient participant and other coach participant information, as well as to safeguard research documents in the lab space where sessions will be conducted.

The PI and research team will maintain regular contact with all coach participants. Coaches will be supervised by the PI (a licensed psychologist) on a weekly basis while carrying an active caseload and will be able to contact their supervisor outside of that time whenever necessary. Weekly supervision will involve discussion of ways in which coach participants can cope effectively with patient distress. Supervision will include group supervision, in which coaches will present cases identified only by Study ID number. Such desire for group supervision was expressed by similar student coaches in the PI's former trial of a similar nature (conducted at the University of Washington; these experiences from student coaches were published in Woodard, Mraz, & Renn, 2023, BMC Psychiatry).

Research staff will always be present on campus and the PI will be available by phone when coaches meet with patient participants. In addition, as part of standard protocol the PI will be reachable at all times during the week, evening, and weekend if necessary via cell phone.

The PI will train research assistants and coaches in an emergency protocol (attached risk of harm protocol). The existing protocol the PI has used in related work with lay volunteers and other nonspecialists/coaches is as follows: If patients report any thoughts of committing suicide or harming themselves, worsening of mental health symptoms, emergent manic or psychotic symptoms, thoughts of homicide or harming others, or elder or child abuse/neglect during or outside of STAR sessions, coaches immediately contact the PI. The PI will conduct a risk assessment with the patient participant and will arrange emergency psychiatric services, contact police, or place a report to child or elder abuse services if indicated. Coaches only see patient participants during hours when our research group in on campus; the PI is always aware of these meetings and will be available during these times and are reachable via phone.

The research team has agreed to abide by the confidentiality and data protection rules of the study outlined above. Investigators will not share information regarding intervention fidelity with other coaches or study staff.

Patient participants: The following safeguards will be implemented to increase the safety of patient participants:

(a) Clinical deterioration and suicide risk: We will attend to clinical deterioration for both participant protection purposes, and in order to document the safety of the intervention. We define “clinical deterioration” as 1) the development of passive or active suicidal ideation (as confirmed by investigators) at any point during the study; 2) the development of manic or psychotic symptoms; or 3) ≥30% increase in PHQ-9 or GAD-7 scores at follow-up assessment. Rating scales may not adequately capture clinical deterioration in all patients. For this reason, we will encourage coaches to report when they notice a worsening of clinical state that is not identified by the above criteria.

Any patient participant exhibiting ≥30% increase in GAD-7 scores for two consecutive sessions will trigger specific case-focused individual supervision with Dr. Renn, which may include specific guidance on following sessions, outside recommendations, and/or direct contact of Dr. Renn with the patient.

Despite excluding individuals with active suicidality at screening, a patient participant may later (at sessions 2-8) endorse item 9 on the PHQ (reporting having “Thoughts that you would be better off dead, or thoughts of hurting yourself in some way?”). This is unlikely to happen but is possible. This will be handled on a case-by-case basis and a positive answer endorsement to item 9 is not necessarily indicative of active suicidality (e.g., there may be thoughts of death but not actually wanting to die/kill oneself). Any patient participant who endorses PHQ-9 item 9 (suicidal ideation) will trigger the coach to conduct the C-SSRS (Columbia Suicide Severity Rating Scale). Any indication of moderate or high risk will trigger the PI to immediately telephone and evaluate the patient participant to determine presence of suicidal ideation and level of risk. Also, any client exhibiting ≥30% increase in PHQ-9 scores for two consecutive sessions will trigger specific case-focused individual supervision with Dr. Renn, which may include specific guidance on following sessions, outside recommendations, and/or direct contact of Dr. Renn with the patient.

Patients with current suicidal ideation or a history of suicidal behavior will be ineligible to participate in this study. Individuals who develop active suicidal ideation will be removed from the study and referred to the crisis line, their PCP, and other relevant clinical services by the PI. Patients who develop passive suicidal ideation or who evidence ≥30% increase in PHQ-9 or GAD-7 may be permitted to remain in the study and receive the intervention; they will also meet with the PI to discuss appropriate treatment recommendations (e.g., PCP, the UNLV PRACTICE, other resources). Investigators will follow up to ensure this connection takes place. This may include obtaining permission from the patient ppt for the PI to contact the PCP to discuss the clinical concerns and assist the PCP in management recommendations. Study research coordinators are trained to assess manic and psychotic symptoms and will conduct follow up assessments.

In non-emergent cases of active ideation (e.g., nonspecific thoughts of wanting to kill oneself), the patient participant will be allowed to continue with the day’s planned coaching session and any scheduled assessments, as more information (e.g., from a clinical interview) may assist with better understanding and documenting the worsening. If the patient participant does not continue with a scheduled assessment because of PI discretion, they will still receive payment for their next scheduled assessment (either same-day or otherwise close in time; e.g., scheduled Week 8 assessment and PI withdraws patient participant after week 6 or 7 session).

b) Risk associated with intervention: The STARS program is a brief, structured behaviorally-based mental health intervention that is based on and informed principles from cognitive behavioral therapy (CBT), a well-known and extensively researched treatment paradigm for depression and

anxiety. The PI is a licensed clinical psychologist, clinical supervisor, and graduate faculty instructor with specialty in CBT and clinical trials conduct. To limit distress, research personnel and coaches will be trained and supervised by the PI in procedures for helping patients cope with protocol-generated concerns, stress, and anxiety.

(c) Risk associated with assessment: To minimize assessment-related burden, we will not use redundant inquiries. The option to administer assessments over multiple meetings if needed will be based on patient tolerance. The burden associated with research assessments will be described in the informed consent, so that a patient may refuse to enroll in the protocol if he/she considers its time commitments onerous. To limit distress, research personnel and coaches will be trained and supervised by the PI in procedures for helping patients cope with protocol-generated concerns, stress, and anxiety.

(d) Risk associated with breach of confidentiality: To limit the possibility of such a breach of confidentiality, coaches and research personnel will be trained in confidentiality and privacy. We will instruct coaches that they must not reveal personal patient participant information to family or friends, but only to the PI (clinical supervisor) and research staff as appropriate. We will counsel coaches against having any type of “dual relationship” with study participants with whom they are paired, such as a friendship. We will track dual relationships, breaches of confidentiality, and adverse responses by the coaches as Adverse Events.

*required

Potential Benefit to Participants

Do not include compensation here.

None (it is acceptable to have no benefit)

✓ Direct benefit to participant

*required

Describe

Coach participants will learn evidence-informed approaches for adults with elevated anxiety symptoms.Potential benefits to patient participants include the following:1. A structured evaluation of psychopathology and an assessment of functional limitations for which interventions are needed.2. Ongoing monitoring of clinical status and appropriate referral for clinical care in the event of deterioration.3. Assignment to and receipt of a potentially active intervention.

✓ Benefit to society

*required

Describe

Research findings may progress a novel pathway to expanding access to mental health care services for anxiety, a common mental health condition.

Other

*required

Privacy and Confidentiality

How will you protect the subjects privacy during research activities?

Privacy refers to the environment in which data are collected from participants and the individual's interest in controlling the access of others to themselves (e.g., interviewing participants individually in a place where personal responses will not be seen or overheard, collecting only the minimum necessary PII to carry out the research, etc.).
All study staff have completed CITI training. Data will be collected and stored using a secure online database accessible only to the PI and the study research assistants. The only identifiable information we are requesting from both patient and coach participants is name, date of birth, email address, mailing address, audio recording of sessions, and phone number; and the Forte Research Payment System asks for participant identifiers (name, gender, email, mailing address, and date of birth) for payment purposes. Coach participants will also participate in video-recorded Zoom-based training sessions; however, role play demonstrations and other interactive "breakout room" activities will not be recorded. These videos will focus on the PI-delivered didactic training content. Nonetheless, they may contain identifiable information including coach ppt faces, voices, and first names. These will be labeled simply as "STARS training_Session 1_date" (and so forth for relevant training session numbers and dates) and stored on the UNLV Google Drive lab folder accessible only to the PI and members of her research team. These will be stored indefinitely for training purposes.

In-person assessment and intervention sessions will be conducted in TREATment lab space (private rooms) on UNLV campus, where no other individuals have access to the space. Only the coach and patient participant will be permitted to be in the room when intervention sessions are taking place; likewise, only the assessor and patient ppt will be in the room during assessments. Personal responses will not be seen or overheard by any third party. Any virtual sessions (e.g., assessments) will be conducted from the same private TREATment lab space room on UNLV campus. Coaches or assessors will ensure patient participants are conducting any virtual sessions in a safe and private environment (e.g., bedroom in their residence). In the instance of any

virtual meetings, the researcher or coach will use the lab telephone or HIPAA-compliant Zoom software for healthcare settings. This version of Zoom adds safeguards, including (1) a unique password to safeguard against unintended access from other individuals, and (2) a waiting room, over which the TREATment lab host has control to only let authorized individuals into the meeting room.

The TREATment lab email is a university-sponsored email account (treatment@unlv.edu) and is subject to 2-factor authentication (password entered by user and passcode texted to PI, Dr. Renn, for verification on new devices). Only members of the TREATment lab have access to this email. However, no email system is totally secure; as such, discretion will be handled in all instances of email communication with participants. The lab email signature also includes a standard statement (e.g., used in mental health care treatment settings) that reads, "Please Note: The information transmitted in this email is intended only for the person or entity to which it is addressed and may contain confidential and/or privileged material. Any review, transmission, dissemination or other use of or taking of any action in reliance upon, this information by persons or entities other than the intended recipient is prohibited. If you receive this email in error, please contact the sender and delete the material from any computer."

What precautions will be taken to safeguard *identifiable* information and/or biological specimens?

If identifiable data will be linked to the participant, describe how this will be presented in any written or oral materials related to the study.

If you plan to code the data, describe the method in which it will be coded and indicate who will have access to the key to the code.

If you plan to de-identify the data, describe who will be responsible for the de-identification and how data will be de-identified so identifiers are not linked to the participant data.

Note: Data is considered to be anonymous when identifiable data is not collected at all. If identifiers are obtained, but are replaced with pseudonyms or participant ID numbers which can then be linked back to identifiers, then data is considered to be coded, not anonymous. If the data cannot be linked back to identifiers, then data is considered to be de-identified.

The Forte Research Payment System asks for participant identifiers (name, gender, email, mailing address, and date of birth). Name, gender, email, date of birth, phone numbers, and audio recordings will be collected for assessment and therapy purposes as well. Pending approval, the plan is to use HIPAA-compliant REDCap for study databases. All study materials will be labeled with a participant ID number that is linked back to these identifiers.

Video recordings of coach training will likely contain identifiable information including coach ppt faces, voices, and first names. These will be labeled simply as "STARS training_Session 1_date"

(and so forth for relevant training session numbers and dates) and stored on the UNLV Google Drive lab folder accessible only to the PI and members of her research team. These will be stored indefinitely for training purposes.

*required

Who will have access to *identifiable* information and/or biological specimens?

Check all that apply.

- ✓ Study personnel listed on approved IRB documents
- Funding agency for grant project
- Other

*required

Describe your plans for the storage of *identifiable* and *de-identified* information and/or biological specimens.

- Specify where and how all forms of data (e.g. paper hardcopy, electronic, audio/video files/recordings, etc.) will be stored.
- Describe how data will be destroyed and/or kept at the conclusion of the study.
- If collecting and storing biological specimens, please explain how the specimens will be labelled.

Please note:

- *For review/audit purposes, a copy of all records must be kept in a location accessible to the PI on UNLV property.*
- *A USB Drive cannot be used for storage of the data. No PHI should ever be stored on a USB drive.* A HIPAA compliant storage solution must be utilized, accessible to the PI.
- *UNLV has entered into agreements with Google regarding the way they protect our data. For HIPAA protected data, the core apps that allow storage of Protected Health Information (PHI) are: Gmail, Google Drive (including Docs, Sheets, Slides, and Forms), Google Calendar, Google Sites, and Google Apps Vault. For FERPA protected*

data, the core apps that are compliant are: Gmail, Google Drive (including Docs, Sheets, Slides, and Forms), Google Calendar, Google Sites, Google Classroom, Google Contacts, Google Groups, Google Talk/Hangouts, and Google Vault.

- *UNLV REDCap is HIPAA compliant. Contact the National Supercomputing Institute for additional information.*

All study records, including audio recordings, will be stored in REDCap at UNLV. Video recordings of coach trainings will be stored on the TREATment Lab UNLV Google Drive space.

Signed paper consent forms will be stored in a locked filing cabinet, in a locked room in the designated TREATment lab space in a locked building accessible only to Psychology Dept researchers on UNLV main campus.

Two separate databases will be created in REDCap: (1) a master list, linking participant Study ID numbers with their identifiable information (i.e., name, email address, and phone numbers), and (2) the coded study database, containing all study-related data. Study/lab research staff (including assessors, research assistants) will have access to the master list, particularly for the purpose of scheduling study visits and study-related contact. At the completion of the study (i.e., final participant visits and payments completed), the master list will be deleted, rendering the study database deidentified. Deidentifed data will be kept indefinitely.

Separate from PI study records, the Forte/Advarra Research Payment System asks for participant identifiers (name, gender, email, mailing address, and date of birth) for payment purposes. These will be obtained from the study master list. Compensation records will be included in the coded study database and linkable to the master list until the master list is deleted at study end.

Finally, patient participants will be given the option to be added to our TREATment lab participant registry (UNLV IRB #1767333-EXP; approved 6-14-2021 through 06-13-2024). If they consent to this, their contact informationwill be added to that separate registry for potential outreach for future lab studies. The previously approved consent language has been added as an Addendum to the revised patient ppt consent form (per the approved protocol for the lab registry).

*required

How long will *identifiable* and *de-identified* information and/or biological specimens be kept?

Unless specified otherwise, all signed informed consents and other research related documents (including but not limited to paperwork submitted to and approved by the IRB) should be retained throughout the study and for an additional three years after the study is completed/closed with the IRB. HIPAA requires covered entities to maintain documentation for six years.

Identifiable data obtained for payment will be kept only as long as required by Forte payment system and/or UNLV Office of Human Subjects Compensation. Identifiable data inclusive of name, email address,

date of birth, mailing address, and phone numbers for this study will be destroyed as soon as the study is complete. The exceptions are (1) audio recordings, which will be stored for up to 3 years in REDCap; and (2) identifiable data in training video recordings, which will be kept for up to 5 years for training purposes and stored on the UNLV TREATment Lab Google Drive. Deidentifed study data will be kept indefinitely.All signed informed consents and other research related documents (including but not limited to paperwork submitted to and approved by the IRB) will be retained throughout the study and for an additional three years after the study is completed/closed with the IRB. Patient participants who elect to be added to our TREATment Lab participant registry will be handled in accordance with that protocol (e.g., retention of identifiers for contact purposes, with the option to remove oneself from the registry at any point).