Abbreviated Title: mCPT+CRP
Version Date: 07/10/25

PROTOCOL TITLE:
Augmenting Massed Cognitive Processing Therapy (CPT) to Prevent Suicide Risk among Patients with PTSD

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VERSION NUMBER/DATE: V1, 07/10/25

REVISION HISTORY

Revision #	Version Date	Summary of Changes	Consent Change?

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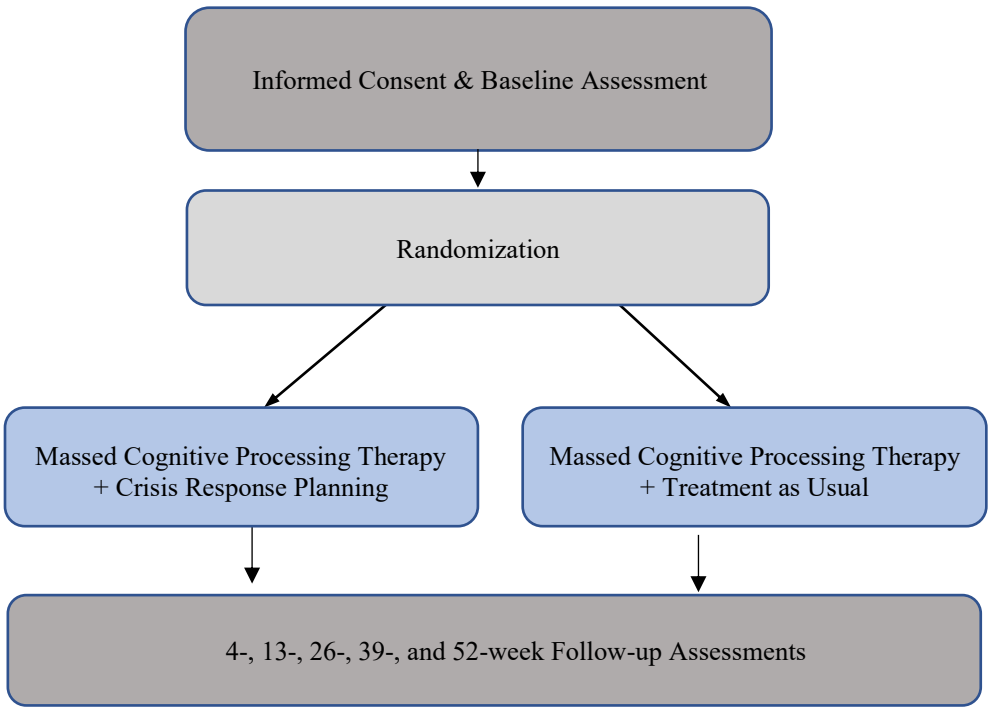
1. STUDY SYNOPSIS

Protocol Information	Description
Study Title	Augmenting Massed Cognitive Processing Therapy (CPT) to Prevent Suicide Risk among Patients with PTSD
Study Design	Randomized Clinical Trial
Objectives/ Specific Aims	The objective of this research is to determine if suicidal behaviors can be significantly reduced when massed Cognitive Processing Therapy (mCPT) is enhanced with Crisis Response Planning (CRP). 150 military personnel meeting diagnostic criteria for PTSD or subthreshold PTSD who also report active suicidal ideation within the past week and/or suicidal behavior within the preceding month will be enrolled. **Specific Aims** **Aim 1:** Determine if the addition of CRP to CPT reduces suicide attempts. **Aim 2:** Identify early markers of treatment response and relapse of suicide risk. **Aim 3:** Identify treatment content and design features that influence treatment effectiveness and acceptability.
Research Intervention(s)	**Massed Cognitive Processing Therapy (mCPT):** Cognitive processing therapy (CPT) is a trauma-focused treatment that involves learning to recognize and challenge thoughts related to the traumatic experience. During this treatment, patients are asked to think about past traumatic experience and beliefs about the meaning of the traumatic event, as well as current beliefs about themselves and others. Topics such as problematic thinking, beliefs, safety, trust, power and control, esteem, and intimacy are discussed. CPT sessions will be scheduled daily for 10 consecutive business days (i.e., "massed" CPT). **Crisis Response Planning (CRP)**: CRP is a collaborative process wherein a suicidal person provides a narrative description of a recent suicidal crisis or acute period of emotional arousal then creates a plan that lists indicators of acute affective arousal and strategies the person could use to regulate this arousal (e.g., self- management strategies, reasons for living, sources of social support, professional support).
Setting/Approach	Treatment will be provided and data collected at the Carl R. Darnall Army Medical Center (CRDAMC) located on Fort Hood.
Study Population	Active duty service members and veterans at least 18 years of age seeking care for PTSD symptoms who have experienced active suicidal ideation within the past week and/or suicidal behavior within the preceding month.
Sample Size	Number of participants to be consented to determine eligibility: 190 (anticipating 20% of participants may screen out Target number of randomized (or enrolled) participants: 150
Participant Duration	Approximately 13 months to complete treatment and follow-up.
Study Duration	48 months from when the study opens to enrollment until completion of data analyses.

1.1 Study Schema

Figure 1. Research Design and Overview



1.2 Schedule of Events (SOE)

Study Procedures & Assessments		Visit Schedule							
		Week							
	BL	Intake	1	2	4	13	26	39	52
Consent	R								
Randomization (when determined eligible)		R							
Interventions (mCPT with or without CRP)									
Massed Cognitive Processing Therapy (mCPT)			1x/day						
Crisis Response Planning (CRP) or Treatment as Usual (TAU)			R						
Booster Sessions					up to 3 over the follow-up year				
Adverse Event Reporting		R	R	R	R	R	R	R	R
Assessments:	R	R	R	R	R	R	R	R	R
1. Demographic and Military Service Characteristics	x								
2. History of Head Injuries Questionnaire + Addendum (HHI+HHI-A)	x								
3. Self-Injurious Thoughts and Behaviors Interview-Revised (SITBI-R)	x I	x* SR	x* SR	x* SR	x* I	x* I	x* I	x* I	x* I
4. Scale for Suicide Ideation (SSI)	x	x	x	x	x	x	x	x	x
5. Interpersonal Needs Questionnaire (INQ)	x					x	x	x	x
6. Beck Hopelessness Scale (BHS)	x					x	x	x	x
7. Suicide Cognitions Scale-Revised (SCS-R)	x	x	x	x	x	x	x	x	x
8. Difficulties with Emotion Regulation Scale-Short Form (DERS-SF)	x					x	x	x	x

9. Monetary Choice Questionnaire (MCQ)	x					x	x	x	x
10. Behavioral Inhibition System and the Behavioral Activation System (BIS/BAS)	x					x	x	x	x
11. Clinician Administered PTSD Scale for DSM-5 (CAPS-5) with Selection of Index Events (SOIE)	x								
12. Life Events Checklist (LEC)	x								
13. PTSD Checklist for DSM-5 (PCL-5)**		x	x	x	x	x	x	x	x
14. Posttraumatic Cognitions Inventory (PTCI-9)		x	x	x	x	x	x	x	x
15. Satisfaction with Therapy and Therapist Scale – Revised (STTS-R)				x					
16. Cornell Services Index-Short Form (CSI-SF)	x					x	x	x	x
17. PROMIS Computer Adaptive Tests (PROMIS- CATs)		x	x	x	x	x	x	x	x
18. Clinical Global Impression (CGI)			x	x					
19. Ecological Momentary Assessment (EMA)		6x/day for 28 days							
20. Fitbit		for 28 days							
21. Qualitative Interview					x				
All activities are for research. * "Since your last assessment" version ** "In the past week" version for all assessments. I = Interview; SR =Self-report									

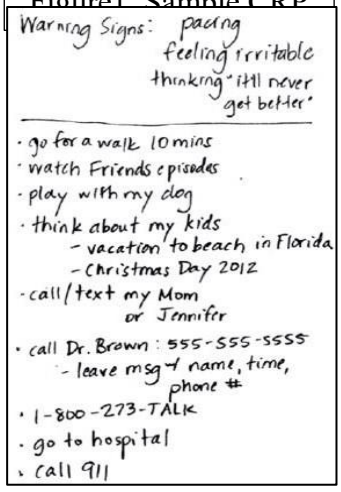
2. INTRODUCTION

2.1 BACKGROUND

Suicide is a significant threat to military readiness. Suicide prevention in military personnel is one of the highest priorities of the Department of Defense (DoD). Despite the DoD's considerable investment in suicide prevention over the past 15 years, military suicide rates remain elevated (Ovis, 2021; Suicide Prevention and Response Independent Review Committee, 2023). Concerns about rising suicide rates are not limited to military personnel, however; suicide rates have also increased over the past two decades in both veteran (Department of Veterans Affairs, 2019) and civilian populations (Xu et al., 2021). The suicide rate in veterans is now 1.5 times the rate of non-veterans, with approximately 20 U.S. military personnel and veterans dying by suicide each day (Department of Veterans Affairs, 2019).

Rapid reductions in suicidal ideation decrease risk for suicidal behavior. Research shows that trajectories of suicidal ideation are heterogeneous (e.g., some patients take longer to recover than others) and are differentially associated with risk of suicidal behavior. PI Bryan has shown, for instance, that faster reductions in suicidal ideation among military personnel are associated with significantly reduced risk of suicidal behavior (Lee et al., 2020). Similar patterns have been observed in non-military settings (Czyz et al, 2012, 2015; Prinstein et al., 2008; Sicotte et al., 2023), suggesting rapid (and early) reductions in suicidal ideation may underlie the effectiveness of evidence-based suicide-focused interventions like crisis response planning (CRP). CRP is a collaborative, patient-centered intervention that focuses on several key components: (1) warning signs, (2) self-regulatory strategies, (3) reasons for living, (4) sources of social support, and (5) professional and crisis services. An example CRP is displayed in Figure 1. In a DoD-funded RCT previously conducted by PI Bryan

Figure1. Sample CRP



(W81XWH1020181), acutely suicidal military personnel who received CRP showed significantly faster reductions in suicide ideation during the following month and were 76% less likely to attempt suicide as compared to military personnel receiving treatment as usual (Bryan et al., 2017). Subsequent research by PI Bryan shows that CRP's effects on suicidal ideation can be observed within hours of the intervention (Bryan et al., 2017), confirming the intervention's rapid effects. Although promising, to date this is the only RCT of CRP that has been conducted with military, veteran, or civilian participants. As noted by the Defense Centers of Excellence for Psychological Health and Traumatic Brain Injury (PHCoE), the quality of evidence supporting CRP's effectiveness therefore remains low (Workman et al., 2021). For this reason, the PHCoE identified additional CRP-focused efficacy research as one of the DoD's most important suicide prevention research gaps in their 2020 research gaps report; only lethal means safety strategies ranked higher (Workman et al., 2021). Informed by these identified research gaps, we propose to evaluate the CRP's effectiveness for rapidly reducing suicidal ideation and suicidal behavior when used in conjunction with outpatient mental health treatment.

Cognitive processing therapy for PTSD rapidly reduces suicidal ideation. Another research gap identified by the PHCoE is the need for additional research focused on how diagnosis-specific therapies and interventions may—or may not—reduce suicidal thoughts and behaviors. Research by our team and others suggests PTSD treatments are associated with significant reductions in suicidal ideation (Brown et al., 2019, 2020; Bryan et al., 2016, 2018, 2022; Gradus et al., 2013). PTSD is a common mental health condition among U.S. military personnel (Tanielian et al., 2008) and significant risk factor for suicide. PTSD is not just a consequence of military service, however; sexual assault, domestic abuse, accidents, and child abuse are other common contributors to PTSD. PTSD significantly increases the risk of suicidal thoughts, behaviors, and death (May & Klonsky, 2016; Nock et al., 2009; 2018) and is one of the few psychiatric conditions that distinguishes people who have attempted suicide from those who only thought about suicide, suggesting PTSD facilitates the transition from suicidal thought to action (Nock et al., 2009; May & Klonsky, 2016). Early treatment of PTSD could therefore reduce suicide risk in the military. Cognitive processing therapy (CPT) is a trauma-focused therapy that produces very large reductions in PTSD symptoms (Forbes et al., 2010; Watts et al., 2013) and suicidal ideation (Bryan et al., 2016; Gradus et al., 2013; Resick et al., 2017). PI Bryan has further shown that CPT's effects on reducing suicidal ideation are accelerated when CPT sessions are scheduled daily over 2 weeks (called "massed" CPT) versus the more typical pace of scheduling sessions weekly over several months (Bryan et al., 2018; Sciarrino et al., 2020). Massed CPT therefore achieves similar reductions in suicidal ideation and PTSD symptoms within a much shorter timeframe. Conclusions about CPT's effects on suicidal *behavior* remain unknown, however, because studies to date have excluded higher risk patients and/or did not enroll a large enough number of high-risk patients to examine suicidal behavior as an outcome. To address this critical knowledge gap, the proposed study will: (a) enroll only high-risk patients who report active suicidal ideation or a recent suicide attempt and (b) examine suicidal behavior as our primary outcome.

2.2 RISK/BENEFIT ASSESSMENT

2.2.1 Known Potential Risks

- Emotional distress including experiencing an initial increase of PTSD symptoms and suicidal ideation due to the discussion of traumatic events.
- Assessment and treatments may be associated with a temporary or occasional increase in symptoms of depression, anxiety, or other pre-existing psychiatric symptoms.
- Participants may experience skin irritation from wearing the Fitbit.
- Risk of breach of confidentiality while handling research data.

- One of the risks of PTSD, both in and out of treatment, is attempted suicide, which can result in death.

2.2.2 Known Potential Benefits

The main benefit to participating in this research is the receipt of high-quality, closely supervised, trauma-focused therapy (i.e., massed CPT) and suicide risk monitoring at no cost to the participant. In addition, the knowledge gained from this study will serve to inform the most effective interventions for the treatment of elevated suicide risk among active duty service members and veterans diagnosed with PTSD.

2.2.3 Assessment of Potential Risks and Benefits, none of which are expected to negatively affect an active duty participant's fitness for duty.

Research procedures	Risks
Assessments (questionnaires, interviews, computer testing, EMA, wearing the Fitbit)	• Serious and likely; none • Serious and less likely; none • Serious and rare; breach of confidentiality with the use of online conferencing systems, handling medical and research records, EMA, and by the Fitabase service • Not serious and likely; discomfort, emotional distress, and a temporary increase in PTSD symptoms and suicidal ideation thinking about and completing assessments • Not serious and less likely; skin irritation from wearing the Fitbit
Massed CPT Crisis Response Planning	• May be Serious and likely; treatment can cause some discomfort or emotional distress and can even produce a temporary increase in symptoms • Serious and less likely; none • Serious and rare; breach of confidentiality with the use of online conferencing systems, handling medical and research records, and by the Fitabase service • Not serious and likely; none • Not serious and less likely; none

3. OBJECTIVES AND ENDPOINTS

The primary objective of this project is to determine if suicidal behaviors can be significantly reduced when massed CPT is enhanced with CRP. CPT is an empirically supported psychotherapy for PTSD and CRP is an empirically supported intervention for suicidal thoughts and behaviors. To accomplish this objective, we will enroll military personnel meeting diagnostic criteria for PTSD or subthreshold PTSD (i.e., meeting threshold levels for 3 of 4 symptom criteria) who also report active suicidal ideation within the past week and/or suicidal behavior within the preceding month.

Specific Aims and Hypotheses

Aim 1: Determine if the addition of CRP to CPT reduces suicide attempts.

Hypothesis 1 (H1): The rate of follow-up suicidal behavior will be significantly reduced among military personnel receiving CRP versus usual care risk management in addition to massed CPT.

Hypothesis 2 (H2): Reductions in the severity of suicidal ideation will be significantly larger among military personnel receiving CRP versus usual care risk management.

Aim 2: Identify early markers of treatment response and relapse of suicide risk.

Hypothesis 3 (H3): Less severe suicide risk features during treatment will predict treatment response (i.e., change in severity of suicidal ideation) and treatment relapse (i.e., follow-up suicidal behavior). Exploratory Research Question 1 (RQ1): Which subjective, objective, and treatment-related factors are most useful for predicting treatment response (i.e., change in severity of suicidal ideation) and treatment relapse (i.e., follow-up suicidal behavior)?

Aim 3: Identify treatment content and design features that influence treatment effectiveness and acceptability.

Hypothesis 4 (H4): More frequent CRP use will be correlated with reductions in suicide attempts and suicidal ideation. Exploratory RQ2: Which treatment components and design features do participants find most helpful for reducing suicidal ideation and attempts?

4. STUDY DESIGN

4.1 Overall Design

This is a two-arm parallel randomized clinical trial comparing CRP versus CPT to usual care suicide risk management procedures among military personnel and veterans receiving massed CPT for PTSD.

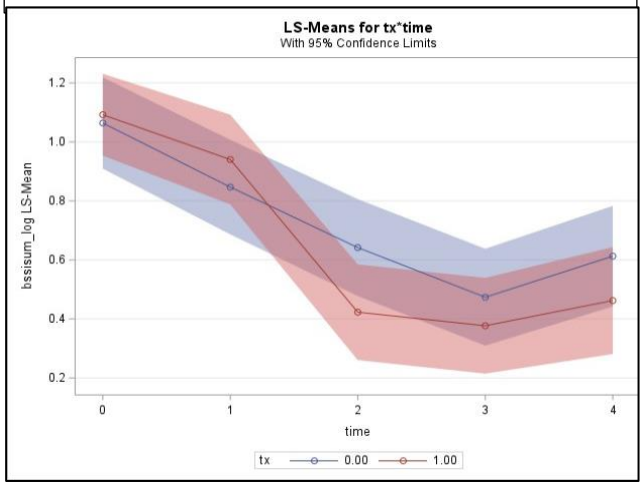
4.2 Scientific Rationale for Study Design

Treatments that rapidly reduce suicidal *ideation* also reduce suicidal *behaviors*. Results of a previous RCT indicates CRP rapidly reduces suicidal ideation and suicide attempts among military personnel, but additional studies of CRP are needed to evaluate the intervention's effectiveness in a broader range of clinical settings and populations. Pilot data collected by our team indicate that, as compared to usual care suicide risk management, CRP accelerates reductions in suicidal ideation and reduces suicidal behavior among military personnel and veterans receiving treatment for PTSD. This study will build on these promising findings to further test the effectiveness of CRP on suicidal ideation and suicidal behaviors when combined with massed CPT for PTSD. This study will also investigate early indicators of treatment response (i.e., reductions in suicidal ideation) and treatment relapse (i.e., suicidal behavior), thereby providing critical information for developing novel decision-making tools for clinicians working with high-risk patients.

4.3 Justification for Intervention

CRP accelerates reductions in suicidal ideation and prevents suicidal behaviors when used in conjunction with CPT. Preliminary data from a pilot RCT conducted by PI Bryan suggests the addition of CRP to massed CPT leads to (a) faster and larger reductions in suicidal ideation among military personnel and veterans diagnosed with PTSD or subthreshold PTSD (i.e., meeting 3 of 4 diagnostic criteria) and (b) reduces suicide attempts during follow-up. In that study, 74 military personnel and veterans reporting active suicidal ideation within the past week were randomly assigned to receive massed CPT in conjunction with either CRP or usual care suicide risk management procedures (e.g., suicide risk screening, safety planning). As compared to usual care (n = 33), participants

Figure 2. Mean suicidal ideation (log-transformed) among military personnel and veterans randomized to CRP (red) or safety planning (blue) during massed CPT for PTSD



receiving CRP (n = 41) reported significantly larger reductions in suicidal ideation within 1 week (t(281) = 2.1, p = .041; see Figure 2), which corresponds to the midpoint of massed CPT. By 6 months, there were 73.2% fewer suicide attempts in the CRP group (7 attempts) versus usual care (21 attempts), suggesting CRP also reduced suicidal behaviors. These pilot results support the feasibility of our proposed study and suggest CRP may be more effective than usual care suicide risk management strategies for rapidly reducing suicide risk among military personnel with PTSD. Though promising, these findings require further examination in a larger clinical trial with suicidal behavior as the primary outcome.

Early reductions in suicidal ideation promote recovery from PTSD. Recent findings by our team further suggest that rapid reductions in suicidal ideation may also be critical for recovery from PTSD. Using aggregated data from multiple DoD-sponsored clinical trials testing treatments for PTSD (Brown et al., 2021), PI Bryan and Co-Is Peterson and Young-McCaughan found that change in suicidal ideation during trauma-focused therapy preceded and influenced subsequent change in PTSD symptoms among treatment-seeking military personnel diagnosed with PTSD. Early change in PTSD symptoms did not influence subsequent change in suicidal ideation, however, suggesting early reductions in suicidal ideation may be critical not only for preventing suicidal behavior but also for recovery from PTSD. These findings are currently under review for publication. Additional research focused on early markers of treatment response are needed, though, to confirm these promising findings.

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4.4 End-Of-Study Definition

A participant is considered to have completed the study if he or she has completed the baseline assessment, all treatment sessions, 28 days of EMA assessments and wearing the Fitbit, and all follow-up assessments.

A treatment completer is considered to have completed 7 of the 10 (70%) of the treatment sessions.

5. STUDY SETTING

Participants will be seen and treated at the STRONG STAR offices, part of the Carl R. Darnall Army Medical Center (CRDAMC), located on Fort Hood.

6. STUDY POPULATION

Active duty service members and veterans at least 18 years of age seeking care for PTSD symptoms who have experienced active suicidal ideation within the past week and/or suicidal behavior within the preceding month.

6.1 Inclusion Criteria

1. Active duty service member or veteran aged 18 or older eligible for military medical care.
2. Able to read, write, and speak English.

3. Meeting diagnostic criteria for PTSD or subthreshold PTSD (i.e., meeting diagnostic threshold for 3 of 4 symptom criteria within the past month) on the Clinician Administered PTSD Scale for DSM-5 (CAPS-5).
4. Active suicidal ideation within the past week as assessed by scoring ≥ 1 on Scale for Suicidal Ideation (SSI) item 4 (i.e., active suicidal ideation within the past month) or report an interrupted, aborted, or actual suicide attempt within the preceding month on the Self-Injurious Thoughts and Behaviors Interview-Revised (SITBI-R).
5. Regular use of an iPhone or Android smartphone.

6.2 Exclusion Criteria

1. Inability to comprehend and complete the consent and baseline screening questionnaires.
2. Current suicide or homicide risk meriting crisis intervention.
3. Serious mental health symptoms, such as mania, psychosis, alcohol or substance use disorders warranting immediate clinical attention based on interviewer assessment and clinical judgement.
4. Currently engaged in evidence-based psychotherapy for PTSD (e.g., Cognitive Processing Therapy, Prolonged Exposure Therapy, Written Exposure Therapy).

6.3 Inclusion of Vulnerable or Special Populations.....N/A ☒

6.4 Lifestyle Considerations.....N/A ☒

6.5 Screen Failures

Participants who do not meet one or more criteria required for participating in the study will be offered other options for care.

6.6 Strategies for Recruitment and Retention

The target sample size is reported in Section 1 (Study Synopsis) as well as Section 10.12 (Sample Size Determination). The recruitment of women and minorities is presented in Section 6 (Study Population).

Planned Recruitment Strategies: Participants will be recruited from the Carl R. Darnall Army Medical Center (CRDAMC) and the Fort Hood and Killeen communities through provider referrals, recruitment events, flyers, study information posted on the STRONG STAR website, and social media. Interested individuals will be provided a consent to contact at recruitment events that allows the study staff to contact the potential participant. No commanders are or will be present for their service members' medical care at CRDAMC. Providers can give their patients contact information for the study staff so that interested individuals may contact STRONG STAR directly. Alternatively, providers can provide referral information (e.g., patient's name, contact information, reason for referral) to STRONG STAR study staff via encrypted DoD email.

6.6.1 Costs

There are no anticipated costs to the participants in this study other than transportation to and from the clinic for assessment and treatment.

6.6.2 Compensation N/A ☐

- Participants can be compensated for completing follow-up assessments using the following schedule:
    - $50 for the posttreatment qualitative interview
    - $25 at 1 month
    - $25 at 3 months
    - $25 at 6 months
    - $25 at 9 months

- $50 at 12 months

Participants will also be compensated for completing EMA surveys and wearing their Fitbits. Participants will be compensated based on the number of EMA surveys completed per week:

- $20 per week for completing at least 75% of EMA surveys (32 of 42 surveys) and wearing their Fitbit at least 75% of days (5 of 7 days) per week (total $80 for the four weeks) or
- $30 per week for completing at least 90% of EMA surveys (38 of 42 surveys) and wearing their Fitbit at least 90% of days (6 of 7 days) per week (total of $120 for the four weeks).

This yields a maximum possible compensation of $120 for EMA completion and Fitbit wear, totaling $320 of possible compensation for all study activities. Participants will be allowed to keep the Fitbit.

- As required by UTHSCSA, these funds will be distributed using the university ClinCard system.
- Payment will be provided via a rechargeable MasterCard® ClinCard. The MasterCard® ClinCard is a debit card issued to the study participant. Funds are loaded onto the card through the ClinCard website at www.clincard.com. Only authorized users are able to access the ClinCard website with a username and password to add funds. The ClinCard funds will typically be available to recipients within one business day but payment could take up to 2 weeks. ClinCard funds can be used as the participant chooses. The participant will be notified that their name, social security number, address and date of birth will be shared with a third-party (ClinCard) for the purposes of payment processing. This information will be used for the administration of the payment and will be kept strictly confidential.
- The money paid may be taxable. When the total payments from the institution accumulate to $600 or more in one calendar year, the institution must report the amount to the IRS. The IRS considers it earned income and treats it like any other income. In addition to notifying the IRS, the institution will also send participants a tax form that can be used when filing their personal taxes. If a participant chooses not to provide their SSN, ClinCard is required to withhold 24% of the payment for taxes. The withheld amounts may be reclaimed from the IRS when the participant files their personal taxes depending upon their tax situation.
- In accordance with DoDI 3216.02 active duty participants will be compensated if study participation does not adversely impact their ability to perform their assigned duties.

7. STUDY INTERVENTION(S) OR EXPERIMENTAL MANIPULATION(S)

7.1 ADMINISTRATION OF STUDY INTERVENTION(S) OR EXPERIMENTAL MANIPULATION(S)

7.1.1 Study Intervention or Experimental Manipulation Description

Participants will be randomized to receive either Massed Cognitive Processing Therapy (mCPT) + Crisis Response Planning (CPT) or mCPT + Treatment as Usual (TAU).

7.1.2 Administration

Massed Cognitive Processing Therapy (mCPT)

All participants will meet with their assigned research therapist for an initial 1½ -hour "intake" session during which the research therapist will provide information about the massed therapy protocol, schedule dates and times for massed CPT sessions, conduct a suicide risk assessment, and administer the randomly assigned suicide risk intervention. CPT sessions will be scheduled daily for 10 consecutive business days (i.e., "massed" CPT), with the first appointment being 1-2 weeks post-intake. The CPT session content is summarized in Table 1. Participants will be allowed to schedule up to 3 optional "booster sessions" during the follow-up year to review skills learned in therapy and receive additional support and/or coaching after the acute treatment phase.

Table 1. Massed CPT Session Content

Session No.	Session Focus
1	Education about PTSD
2	Impact Statement #1, ABC
3	Challenging Quest.
4	Patterns of Prob. Thinking
5	Challenging Beliefs, Safety
6	Trust
7	Power & Control
8	Esteem
9	Intimacy
10	Impact Statement #2

Crisis Response Planning (CRP).
CRP entails a collaborative process wherein a suicidal person provides a narrative description of a recent suicidal crisis or acute period of emotional arousal then creates a plan that lists indicators of acute affective arousal (i.e., "warning signs") and strategies the person could use to regulate this arousal (e.g., self- management strategies, reasons for living, sources of social support, professional support. With assistance from their research therapist, participants will handwrite a crisis response plan on an index card. Consistent with the intervention's design, participants will be asked about CRP use during each massed CPT session as part of homework review.

Usual Care.

Usual care entails safety planning, a procedure that includes warning signs for a suicidal crisis; self-management strategies; list of people, places, or events to distract from or decrease distress, contact information for social support; and contact information for professional resources, crisis services within the participant's local community, and the Military Crisis Line. These components are handwritten on a pre-printed form. Safety planning is routinely administered to suicidal patients at Fort Hood as part of existing behavioral health services. Participants will review their safety plan with the research clinician during the intake session and will be directed to use it as prescribed by their military behavioral health clinician.

7.1.3 Access to and Documenting Care in the Electronic Health Record

MHS GENESIS will be accessed by a member of the research team to document the participant's care delivered per the study protocol and communicate with the participant's medical care team.

7.2 FIDELITY

7.2.1 Interventionist Training and Tracking

Faculty and staff providing the intervention will be required to be credentialed and privileged by CRDAMC or supervised by a credentialed and privileged provider prior to providing therapy at CRDAMC. Collaborating party staff requiring privileges will follow the Federal Laboratory's requirements for requesting clinical privileges.

Research therapists will complete standardized competency-based training in the delivery of CPT and CRP. The CPT curriculum includes the completion of CPTweb 2.0 online training modules available through the Medical University of South Carolina and a 2-day live training workshop conducted by Co-I Losavio and PI Bryan, two certified CPT instructors and consultants. Research therapists will also complete a 1-day CRP live training workshop conducted by PI Bryan, a co-developer of CRP. The

training includes didactics, case examples, demonstration videos, and opportunities for skills practice via role play. Research therapists will initially participate in daily clinical supervision with approved CPT and CRP consultants until they demonstrate protocol fidelity for a minimum of two consecutive cases. Once fidelity has been established, clinical supervision will be scheduled 1-2 times per week to monitor fidelity.

7.3 Measures to Minimize Bias: Randomization and Blinding N/A ☐

Participants meeting study inclusion and exclusion criteria will be randomized to mCPT+TAU or mCPT+TAU using a permuted block randomization algorithm with randomly selected block sizes. This algorithm increases the probability that each arm will contain an equal number of participants while avoiding selection bias by using random block sizes. Randomization will be supervised by the study biostatistician.

Because participants, interventionalists, and study staff cannot be blind to the behavioral therapies being delivered, only the independent evaluators will be blind to the treatment condition.

7.4 Study Intervention/Experimental Manipulation Adherence N/A ☐

Protocol fidelity will be monitored via review of audio recorded sessions using published CPT and CRP fidelity checklists. At the outset of the study, 100% of intake sessions and therapy sessions will be reviewed for fidelity. Research therapists will be required to obtain a minimum fidelity score of 85% for a minimum of two consecutive cases. Once fidelity has been established, 10% of intake and therapy sessions will be randomly selected for fidelity review to monitor fidelity throughout the study. Because protocol fidelity will serve as a predictor of treatment outcomes (Hypothesis 4) in this study, we will continue to assign cases to therapists even if they do not maintain high protocol fidelity. Therapists will continue to receive supervision and corrective feedback to improve fidelity, however. This approach will be adopted to enhance generalizability to usual care conditions.

7.5 Concomitant Therapy N/A ☐

Participants meeting the study inclusion/exclusion criteria and randomized to the active arm will be encouraged to take their prescribed medications regularly and to not start, stop, or change medications or medication doses if possible.

8. DISCONTINUATION AND WITHDRAWAL

8.1 Discontinuation of Study Intervention or Experimental Manipulation

When a participant discontinues from follow-ups, the study team will attempt to collect the following:

- The reason(s) for discontinuing.
- Planned follow-up assessments.

As with all adverse event reporting, if a clinically significant finding is identified the research team member will bring the event to a study teleconference for adjudication and to determine if any action by the research team is warranted.

8.2 Participant Discontinuation/Withdrawal from the Study

Participants are free to withdraw from participation in the study at any time upon request.

An investigator may discontinue a participant from the study for the following reasons:

- Participant does not meet inclusion/exclusion criteria.

- An event or medical condition or situation occurs such that continued participation would not be in the best interest of the participant or might require an additional treatment that would confound the interpretation of the study.
- The participant does not follow the study procedures resulting in significant non-compliance.
- Lost-to-follow up; unable to contact participant.
- Participant has completed the study follow-up period.

The reason(s) for participant discontinuation or withdrawal from the study will be recorded in the study database. Participants who sign the informed consent form and are randomized but who never begin the study intervention may be replaced. Participants who sign the informed consent form, are randomized and receive the study intervention but who subsequently withdraw or are discontinued from the study will not be replaced.

8.3 LOST TO FOLLOW-UP N/A ☐

A participant will be considered lost to follow-up if he or she fails to return for scheduled visits and is unable to be contacted by the study site staff. The following actions will be taken if a participant fails to return to the clinic for a required study visit:

- The site will attempt to contact the participant and reschedule the missed visit as soon as possible and attempt to re-schedule the visit.
- Before a participant is deemed lost to follow-up, the investigator or designee will make every effort to regain contact with the participant through a combination of up to 3 telephone calls or text messages. These contact attempts will be documented in the participant's study file.

9. STUDY ASSESSMENTS AND PROCEDURES

9.1 SCREENING PROCEDURES

See Table in Section 1.2 (Visit Schedule Study Procedures and Assessments).

9.1.1 Screening activities performed prior to obtaining informed consent

Under an IRB-approved HIPAA Partial Waiver of Authorization, study personnel will conduct a brief discussion by in person or telephone in a private setting where the basic study inclusion and exclusion criteria will be reviewed to help the individual determine if he or she meets the study criteria or has obvious exclusions from the study protocol to prevent individuals from making unnecessary travel for consent and more in-depth screening. This information will be entered into a secure database as a phone call to a potential participant or a phone call from a potential participant: name, phone number, name of study the caller is interested in, referral date, referral source, potential eligibility status, reason if not eligible, and verbal permission to contact the caller in the future for other studies. We will also record the date and time of the call, outcome of the call, and any notes. Individuals who agree to study participation will sign a consent document before any further screening takes place. Any individually identifiable information and Protected Health Information (PHI) collected from individuals who do not consent to participation will not become part of the research data. This data will be stored in a locked file cabinet in the research offices (only accessible to study staff) and will be destroyed at the end of the study. If participants agree to participate in the research, the identifiable data collected will become part of the participants' research records and will be stored according to the research confidentiality plan.

Active duty or retired military service members who are not eligible or interested in other IRB-approved STRONG STAR protocols will also be told about this study. If interested, a member of the research team will review eligibility with these potential participants over the phone. If the person believes they may qualify for the study, the participant will be scheduled for an appointment in which consent will be obtained.

9.1.2 Screening activities performed after a consent for screening has been signed

See Table in Section 1.2 (Visit Schedule Study Procedures and Assessments).

9.2 STUDY EVALUATIONS & PROCEDURES

9.2.1 Visits and Procedures

Visits: See Table in Section 1.2 (Visit Schedule Study Procedures and Assessments) for Study Visits.

Procedures:

- Individuals referred by their provider for consideration of the study or who self-refer in response to study advertisements will have a brief discussion with a member of the study team where the basic study inclusion and exclusion criteria will be reviewed to help the individual determine if he or she meets the study criteria or has obvious exclusions from the study protocol so as to prevent individuals from taking unnecessary time for consent and more in-depth screening.
- Following consent, participants will complete the baseline assessment. The baseline assessment will include questionnaires and interviews and will last 2-3 hours in total.
- Once confirmed eligible, the participant will be randomly assigned into one of the two study arms, Crisis Response Planning (CRP) or Treatment as Usual (TAU). Regardless of which study arm the participant is randomized to, all participants will receive Massed Cognitive Processing Therapy (mCPT). This information will be conveyed to the participant during a 1½ -hour Intake Appointment. During this appointment additional questionnaires will be completed either on paper or on the computer. Also at this time, the participant will sync their Fitbit or a Fitbit provided by the study staff with Fitabase and load the EMA app onto the participant's phone. The data collection through Fitabase and EMA prompts will start at this time and continue for 28 days.
- CPT sessions will be scheduled daily for 10 consecutive business days (i.e., "massed" CPT), with the first appointment being 1-2 weeks post-intake. Participants will be allowed to schedule up to 3 optional "booster sessions" during the follow-up year to review skills learned in therapy and receive additional support and/or coaching after the acute treatment. Each of the 10 treatment sessions and up to 3 optional booster sessions will last 1-hour.
- Within 1 month of ending therapy, participants will complete one 45–60-minute semi-structured interview with study staff.
- Follow-up assessments will be completed 4-, 13-, 26-, 39-, and 52-weeks following treatment. Each follow-up will last 30-45 minutes.

Description of the Assessment Measures Administered throughout the Study. See Table in Section 1.2 (Visit Schedule Study Procedures and Assessments) for when specific measures will be administered.

1. ***Demographic and Military Service Characteristics.*** Participants will provide demographic information at their baseline assessment to include age, marital status, education, sex, and military service. This information will be used to compare and evaluate outcomes across participants.
2. ***History of Head Injuries Questionnaire + Addendum (HHI+HHI-A).*** The HHI is a modified version of the Defense and Veterans Brain Injury Center (DVBIC) 3-Item Screening Tool (Schwab et al., 2007). This instrument was used as the gold standard for the diagnosis of TBI in a sample of soldiers returning from duty in Iraq and/or Afghanistan (Schwab et al. 2007). The HHI has been modified to gather information on the number of head injuries and to inquiry about any head injury sustained outside of deployment.

3. ***Self-Injurious Thoughts and Behaviors Interview-Revised (SITBI-R_Bryan 84-CRP_TBI; Fox et al., 2020).*** The SITBI-R is a semi-structured interview assessing the presence, frequency, and characteristics of self-injurious and suicidal thoughts and behaviors. The SITBI-R has high interrater reliability, strong test-retest reliability (Fox et al., 2020; Gratch et al., 2021). The SITBI-R was developed from the SITBI which also demonstrated strong psychometric properties (Nock et al., 2007). The SITBI-R consists of multiple modules assessing suicide related outcomes. Each module includes an initial question assessing the lifetime occurrence of the target construct (e.g., the suicidal ideation module asks respondents, "Have you ever had thoughts of killing yourself?"). Respondents who answer "Yes" to the initial question are then asked a series of quantitative and qualitative follow-up questions. Respondents who answer No" to the gate question skip to the end of the module. The SITBI-R does not generate a total score. The administration takes approximately 5 to 45 minutes to complete, depending on the number of modules administered. This study will use selected questions from the SITBI-R to measure the incidence of non-suicidal self-injury, suicidal ideation, aborted and interrupted attempts, and suicide attempts. The interview version of the SITBI will be administered at baseline and at all follow-up appointments; however only 4 selected items from the interview version will be administered by self-report at intake, and weeks 1 and 2 assessments.
4. ***Scale for Suicide Ideation (SSI; Beck et al., 1979).*** The Scale for Suicide Ideation (SSI) is a 19-item semi-structured interview that assesses the severity of suicide-related thoughts, urges, and behaviors (e.g., writing suicide notes) within the past week using 3-point ordinal scales. Items are summed to obtain an overall metric of suicide risk severity. To be eligible for this study, participants will be required to score ≥1 on SSI item 4, which assesses the severity of active suicidal ideation.
5. ***Interpersonal Needs Questionnaire* (*INQ*; Van Orden et al, 2012).** The INQ is a self-report measure that assesses perceived burdensomeness and thwarted belongingness. This study will use a 5-item version of the INQ developed by the Military Suicide Research Consortium that showed an excellent internal consistency (Stanley et al., 2019).
6. ***Beck Hopelessness Scale* (*BHS*; Beck, 1974).** The BHS is a self-report measure that assess hopelessness using a dichotomist scoring system (0 or 1). Higher scores indicated higher levels of hopelessness. The BHS has strong reliability and construct validity (Beck, 1974), high test-retest reliability (Fernandez, 1994), and good convergent validity (Steed, 2001). This study will use a 5-item version of the BHS developed by the Military Suicide Research Consortium that (Stanley et al., 2019)
7. ***Suicide Cognition Scale-Revised (SCS-R;* Bryan et al., 2022*).*** The SCS-R is a 16-item, self-report measure that assesses suicide-specific thoughts and belief. The scale has demonstrated good internal consistency, convergent validity, and divergent validity (Bryan et al., 2014). The SCS-R evaluates how much an individual agrees with the suicide-related cognition.
8. ***Difficulties with Emotion Regulation Scale-Short Form (DERS-SF; Kaufman et al., 2016).*** The DERS-SF is an 18-item measure created to identify emotional regulation problems. The measure assesses for aspects of emotional regulation and includes six subscales: nonacceptance of emotional responses, difficulty in goal-directed behavior, impulse control challenges, lack of emotional awareness, limited access to regulation strategies, and lack of emotional clarity.
9. ***Monetary Choice Questionnaire* (*MCQ;* Kirby & Maraković, 1996).** The MCQ is a 27-item, self-administered questionnaire. For each item, the participant chooses between a smaller, immediate monetary reward and a larger, delayed monetary reward (e.g., "Would you prefer $54 today or $80 in 30 days?"). The protocol is scored by calculating where the respondent's answers place them amid reference discounting curves, with steeper curves indicating higher levels of impulsivity. The MCQ has good external validity (Kirby & Maraković, 1996), as well as good internal consistency, test-retest reliability (Duckworth & Seligman, 2005). PI Bryan has used the MCQ in multiple studies and

found that MCQ scores are elevated (indicating a preference for immediately available rewards) among adults who have recently attempted suicide.

10. ***Behavioral Inhibition System / Behavioral Activation System Scale* (*BIS/BAS Scale; Carver & White, 1994).*** The BAS/BIS Scale is 24-item self-report assessment that measures individual differences in motivation. PI Bryan has used the BIS/BAS Scale in several ongoing research studies and has found that suicide attempts are significantly elevated among adults who score high on both subscales. The BIS/BAS Scale has demonstrated good convergent and discriminant validity, reliability, and test-retest reliability (Carver & White, 1994).

11. ***Clinician Administered PTSD Scale for DSM-5 (CAPS-5) with the Selection of Index Events (SOIE).*** The CAPS-5 is structured interview that assesses the DSM-5 criteria for PTSD (Weathers et al., 2013). Each item is rated on a severity scale ranging from 0 (Absent) to 4 (Extreme/incapacitating) and combines information about frequency and intensity for each of the 20 symptoms. Additional items that are not included in the total score evaluate overall symptom duration, distress, impairment, dissociative symptoms, and global ratings by the interviewer. Validation studies are nearly complete to establish the psychometric properties of the CAPS-5 and findings will be reported in peer-reviewed publications. Subscale scores are calculated by summing severity scores for items in the following PTSD symptom clusters: re-experiencing, avoidance, negative alterations in cognitions and mood, and hyperarousal. The Selection of Index Event is a semi-structured questionnaire was developed by the STRONG STAR Consortium. It is designed to assist participants in identifying their most distressing traumatic experience, for the focus of further assessment and treatment. It will be used in this study, in conjunction with the CAPS-5, to assist in the assessment of PTSD symptoms.

12. ***Life Events Checklist (LEC).*** Life Events Checklist for DSM-5 (LEC-5; Weathers, Blake, et al., 2013) includes a list of 16 potentially traumatic life events commonly associated with PTSD symptoms, along with an additional item (17) that allows respondents to describe any other stressful events or experience. The STRONG STAR Consortium included two additional items that screen for military sexual trauma, which are also used by the VA to assess for uninvited and unwanted sexual attention as well as sexual assault. A final item asks the participant to consider what they consider their "worst event." For each potentially traumatic life event, respondents rate their experience of that event on a 6-point nominal scale (1 = happened to me, 2 = witnessed it, 3 = learned about it, 4 = part of my job, 5 = not sure, and 6 = doesn't apply). The LEC-5 has demonstrated desirable levels of test-retest reliability when utilized as a cumulative trauma measure to assess for varying types of traumatic experiences (e.g., direct experience of trauma, witnessing trauma, etc.; Pugach et al., 2021).

13. ***Posttraumatic Stress Disorder Checklist for DSM-5 (PCL-5; Weathers, Litz, et al., 2013)***. The PCL-5 is a 20-item self-report measure designed to assess PTSD symptoms as defined by the DSM-5. The PCL-5 evaluates how much participants have been bothered by PTSD symptoms as a result of a specific life event. Each item of the PCL-5 is scored on a 5-point scale ranging from 0 (*not at all*) to 4 (*extremely*). The PCL has excellent psychometric characteristics for screening and as a secondary indicator of PTSD symptom severity (see McDonald & Calhoun, 2010). The PCL-5 has also demonstrated excellent internal consistency ($\alpha = .96$), as well as convergent and discriminant validity (Bovin et al., 2016). The PCL-5 also has strong test-retest reliability (Blevins et al, 2015).

14. ***Posttraumatic Cognitions Inventory-9 (PTCI-9; Wells et al., 2019).*** Trauma-related beliefs will be assessed using the shortened version of the Posttraumatic Cognitions Inventory (PTCI), which is a self-report scale that assesses negative beliefs about the self, others, and the world stemming from one's trauma.

15. ***Satisfaction with Therapy and Therapist Scale – Revised (STTS-R; Oei & Green, 2008).*** The STTS-R (Oei & Green, 2008) is a 12-item self-report measure with strong psychometric properties used to assess the patient's satisfaction with the therapy provided and the therapist. Even number items assess satisfaction with therapy and odd number items assess satisfaction with therapist. Higher scores are reflective of greater satisfaction. Items are on a 5-point Likert scale that ranges from 1 = "Strong disagree" to 5 = "Strongly Agree'. Additionally, a 13th item provides an independent assessment of the patient's global improvement.
16. The Cornell Services Index – Short Form (CSI-SF; Sirey et al., 2005) is a brief assessment tool that measures service utilization across medical, mental health, social support domains. It helps identify care patterns, service gaps, and overall service impact, making it useful for research, clinical assessments, and program evaluations.
17. ***PROMIS Computer Adaptive Tests (PROMIS-CATs; Segawa et al., 2020).*** Mental health symptoms (e.g., depression, anxiety, insomnia) and quality of life will be assessed using PROMIS Computer Adaptive Tests (PROMIS- CATs) in REDCap. Please note that while all of the possible PROMIS-CATs questions are being submitted for regulatory reviews, the actual number of questions participants respond to will be less based on the PROMIS-CATs adaptive testing algorithm.
18. ***Clinical Global Impression (CGI; Busner & Targum, 2007).*** The Clinical Global Impression (CGI) scale is a measure developed for clinical trials to provide a brief assessment of the clinician's view of a patient's functioning prior to and after initiating a study treatment. The CGI provides an overall summary measure that considers knowledge of the patient's history, psychosocial circumstances, symptoms, behaviors, and life functioning. The CGI involves two 7-point items that evaluate (a) the severity of a participant's psychopathology and (a) change from the start of treatment. This study will only use the improvement scale.
19. ***Ecological Momentary Assessment* (*EMA*).** This study will utilize EMA to assess participants' behaviors, mood, and social context in real time in participants' natural environments. Positive and negative mood state will be assessed using 15 items to assess affect, some drawn from the Positive and Negative Affects Scale (PANAS; Watson et al., 1988). Social context will include researcher-developed items to assess who participants are with and perceived closeness to other people. Suicidal ideation will be assessed using a sum score of items assessing various facets of ideation including wish to live, wish to die, suicidal intent, feeling that life is not worth living, and thoughts about suicide. Consistent with best-practice recommendations (Conner & Lehman, 2012), we will employ a mixture of fixed time-based sampling and experience sampling. A fixed time-based survey will be administered every morning to assess the occurrence of variables during the preceding night or prior day, and experience sampling will be used to deliver five standardized surveys, distributed quasi-randomly during each day (<5 minutes to complete). The protocol for these prompts draws from items from a battery that measures: 1) select items assessing current positive and negative affect and rumination; 2) items measuring suicidal ideation and behavior; 3) items measuring substance use; 4) behavioral and contextual factors that can impact risk/resilience for our outcomes of interest (i.e., stressful situations, social engagement), 5) sleep characteristics, and 6) crisis response plan use.

    Please note that while all of the possible 96 questions are being submitted for regulatory reviews, a selection of questions 1-50 will be administered each morning during EMA and a selection of questions 1-46 (starting on page 7) will be administered the other times throughout the day.

    Participants will respond to EMA prompts through their smartphone. Participants will be trained to complete the EMA procedures by study staff who will lead participants through a training demo to ensure that participants understand how and when to answer questions through EMA. EMA prompts will be randomly delivered throughout the day, with no scheduled differences between weekend and weekday prompts. To offset participant reactivity, question sets will be administered in a random

order each day. These procedures are in line with those currently of DoD-funded EMA research of CRP (W81XWH-22-2-0072; PI Bryan, Co-I Khazem).

EMA is administered through the HIPAA certified MetricWire system, which provides a cross-platform (iOS and Android) application for the delivery of EMA surveys and collection of phone sensor data. EMA data will be collected for approximately a 4-week EMA period. The MetricWire system has been enhanced to comprehensively collect and analyze participant interaction data through various phone sensors, ensuring privacy and battery conservation. As part of the Intake Interview, participants will be instructed how to set up, log into, and manage their MetricWire account on their smart phone. The participant will enter their email address to activate their account. No PHI is maintained by the MetricWire. Question prompts are sent out by MetricWire and the participant's responses are linked to the participant via their study ID number which The OSU collaborators will download for analysis. All EMA prompts contain an integrated safety protocol to direct participants to their treatment team and/or emergency services should we identify suicide risk during momentary assessments. See Section 9.3 (Safety Assessments) below for details.

20. ***Fitbit.*** Fitbit Inspire HR will measure heart rate, physical activity, and nighttime wakefulness. Fitbit has psychometric validation for assessing each of these constructs (Wallen et al., 2016). Fitbit data will be collected through Fitabase, HIPAA-compliant software. This product collects Fitbit data (connected to an identification number) in real-time and makes it accessible to the research team for continual monitoring. Fitabase provides more fine-grained detail about the data than is typically provided through Fitbit.

21. ***Qualitative Interviews.*** Within 1 month of ending therapy, participants will complete one 45–60-minute semi-structured interview with study staff, which will be recorded and later transcribed for data analysis. Sample interview questions are listed below and will focus on participants' treatment experiences, strategies for coping with suicidal thoughts, and treatment acceptability.

Sample qualitative interview questions	
Treatment Experiences	What part of the treatment do you think helped you the most? How so?
	Was there a time during treatment where it "clicked" or you felt more comfortable with the materials and understanding?
Coping with Suicidal Thoughts	What skills, if any, have you learned from your treatment to cope with suicidal thoughts?
	Was there a time when you considered discussing your suicidal ideation, plans, or attempts, during CPT treatment and decided not to? If yes, what stopped you from discussing them? If no, what made you comfortable enough to discuss them?
Treatment Acceptability	What parts of treatment do you think you will retain in your day-to-day life after ending? Are there parts that you will not continue?
	Would you recommend this treatment to other service members experiencing similar difficulties? Why or why not?

Interviews will be conducted virtually using a HIPAA-compliant video-based communication platform and will be recorded using the system's automated transcription feature. Interview recordings and associated transcripts will be saved on the encrypted study database server at UTHSCSA that is only accessible to IRB-approved members of the study team. A member of the study team will review the transcriptions for accuracy and to remove any identifying information so that the transcriptions are de-identified.

Content Coding of the Transcribed Interviews: We will use interpretative phenomenological analysis,[63,64] a qualitative, thematic approach which fundamentally acknowledges phenomenological, hermeneutic, and idiographic principles in the development and interpretation of one's subjective, lived experience and has been extensively used in healthcare and in the examination of chronic illness and pain.[65,66] NVivo, a qualitative analysis software platform that allows researchers to organize, and assign attributes to data for comparative purposes will be used to assist the researchers code and categorize the text into personal experiential themes and then into group experiential themes across participants using interpretative phenomenological analysis. No data are stored in NVivo, rather it is a tool to facilitate the qualitative analysis of research interview data.

9.2.1 BIOSPECIMEN EVALUATIONS **N/A ☒**

9.2.2 SAMPLES FOR GENETIC/GENOMIC ANALYSIS **N/A ☒**

9.3 SAFETY ASSESSMENTS **N/A ☐**

Study assessments that will be done to ensure inclusion and exclusion criteria are outlined as part of the inclusion and exclusion criteria in Section 6 (Study Population) and Section 9 (Study Assessments and Procedures).

Baseline suicide-specific measures are reviewed by a member of the study staff to determine if any additional assessment or intervention is warranted.

***Safety Assessment Specific to EMA*:** Participants will be instructed to complete the EMA surveys in a safe place and during a time when they can briefly (< 5 minutes) stop what they are doing to answer the EMA questions. Participants will have up to an hour to respond to the questions to allow them time to respond to the EMA prompts in a safe place.

Risk of suicide might be a concern for some participants. Although suicidal ideation is a risk factor for suicidal behavior, most people who think about suicide do not act on these thoughts. Additionally, studies have demonstrated that repeated assessment does not cause or lead to suicidal thoughts/behaviors. As such, the current protocol itself is not likely to increase participant's risk for suicide. Nonetheless, suicide risk might naturally change throughout the course of the study, and we have developed a detailed protocol to address safety concerns that might arise. For suicidality reported during EMA prompts, our research team has successfully conducted a number of studies assessing suicidality via EMA among high-risk patients, including both adolescents and adults.

The following procedures were developed in collaboration with the National Institute of Mental Health (NIMH) and have been successfully used by our team and collaborators to manage suicide risk identified via EMA. We will not actively monitor EMA data for suicide content for several reasons: 1) Any one instance of elevated suicidal ideation or behavior is unlikely to predict a future death by suicide. Intervention in this context might result in unnecessary psychiatric hospitalization, loss of freedom or employment due to unexcused work absence for our participants, or violation of privacy. In the most extreme of cases, unnecessary intervention can result in physical harm or death to the patient (i.e., combative interactions with first responders). 2) For a small subset of our sample, the presence of suicidal ideation may be frequent and chronic, and reacting to each instance would be clinically counterproductive. 3) As this study is designed in part to identify novel risk factors for suicide, intervention in the presence an instance of elevated suicidal ideation or behavior will alter the nature of the study, making it much more difficult to achieve our study goals.

The need to protect participant safety must be balanced against the statistically unlikely event of a death by suicide, the inherent risk of overreacting and unnecessarily harming or inconveniencing our participants, and the effect of increased contact with participants on study aims. Consequently, all participants will be explicitly instructed during the app training that no one will be monitoring data

collected from the mobile app in real-time and will be provided instead with resources if they indicate suicide risk (threshold criteria described below): National Suicide Prevention Lifeline (Call or Text): 9-8-8); For emergencies, call 9-1-1 and ask for a CIT (Crisis Intervention Team)] Officer. All participants are provided with an EMA survey that can be accessed 'on demand' that contains a list of mental health resources, including the suicide prevention hotline, should they experience a crisis or desire assistance during periods when they are not responding to EMA prompts.

If, during the course of an EMA survey, a participant "flags" as being at current high risk for suicide, they are directed within the survey to a "we are concerned about you" message. This message will contain information expressing concern about the participant's wellbeing, remind the participant that EMA responses are not actively monitored by the research team, and provide resources for the participant to reach out to for help (including the suicide prevention hotline and information about nearby emergency resources). The following criteria will be used to flag the "we care are concerned about you" message: Suicidal intent: defined as a score of 3 or higher (range 0-4) on the suicidal intent item, "how sure are you that you want to kill yourself?"; Suicidal Behavior: defined as a positive endorsement of the item, "have you done anything to hurt yourself with at least some intent or desire to die?" or selected any suicide-related behavior from the item, "In the past 2 hours, have you done any of the following." See Appendices for the EMA MetricWire "we are concerned about you" Message.

All interview measures as well as indicated safety assessments will be performed by qualified personnel.

For this study, all Adverse Events Documents collected on patients for this protocol will be reviewed by the PIs at least monthly to determine if a serious safety problem has emerged that result in a change or early termination of the protocol such as:

- suspending enrollment due to safety or efficacy, or
- termination of the study due to a significant change in risks or benefits.

Any protocol modifications, problematic safety reports, unanticipated problems, and/or suspension or early termination of a study will be reported to all members of the research team, the UTHSCSA IRB, the CRDAMC Human Protections Director, the STRONG STAR Data Safety Monitoring Board (DSMB), the sponsor, and the funder according to each's policies and guidance. Suspension and early termination of a study will be reported immediately to the STRONG STAR Data Safety Monitoring Board (DSMB), the sponsor, and the funder.

9.4 Adverse Events and Serious Adverse Events.

Adverse Event definition: An adverse event (AE) is defined as any untoward or unfavorable medical occurrence in a human subject, including any abnormal sign (e.g., abnormal physical exam or laboratory finding), symptom, or disease, that is a change from baseline, whether or not considered related to the subject's participation in the research. For this study, all adverse events will be documented at each study visit and be completed with the last study visit. Serious Adverse Event definition: A serious adverse event (SAE) is any adverse event that:

1. results in death;
2. is life-threatening (places the subject at immediate risk of death from the event as it occurred);
3. results in inpatient hospitalization or prolongation of existing hospitalization;
4. results in a persistent or significant disability/incapacity;
5. results in a congenital anomaly/birth defect; or
6. based upon appropriate medical judgment, may jeopardize the subject's health and may require medical or surgical intervention to prevent one of the other outcomes listed in this definition.

9.5 Unanticipated Problems

Unanticipated Problem Involving Risks to Subjects or Others definition: Unanticipated problem involving risk to subjects or others includes any incident, experience or outcome that meets all of the following criteria:

A. unexpected (in terms of nature, severity, or frequency) given (a) the research procedures that are described in the protocol-related documents, such as the IRB-approved research protocol and informed consent document; and (b) the characteristics of the subject population being studied; and
B. definitely related or probably related to participation in the research; and
C. suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.

9.6 Reporting of Pregnancy N/A ☒

10. STATISTICAL CONSIDERATIONS

10.1 Statistical Hypothesis

Aim 1: Determine if the addition of CRP to CPT reduces suicide attempts.

Hypothesis 1 (H1): The rate of follow-up suicidal behavior will be significantly reduced among military personnel receiving CRP versus usual care risk management in addition to massed CPT.

Hypothesis 2 (H2): Reductions in the severity of suicidal ideation will be significantly larger among military personnel receiving CRP versus usual care risk management.

Aim 2: Identify early markers of treatment response and relapse of suicide risk.

Hypothesis 3 (H3): Less severe suicide risk features during treatment will predict treatment response (i.e., change in severity of suicidal ideation) and treatment relapse (i.e., follow-up suicidal behavior). Exploratory Research Question 1 (RQ1): Which subjective, objective, and treatment-related factors are most useful for predicting treatment response (i.e., change in severity of suicidal ideation) and treatment relapse (i.e., follow-up suicidal behavior)?

Aim 3: Identify treatment content and design features that influence treatment effectiveness and acceptability.

Hypothesis 4 (H4): More frequent CRP use will be correlated with reductions in suicide attempts and suicidal ideation. Exploratory RQ2: Which treatment components and design features do participants find most helpful for reducing suicidal ideation and attempts?

10.2 Sample Size Determination

See Power and sample size calculations in Section 10.4.2 (Analysis of the Primary Endpoints) below.

10.3 Populations for Analyses

Data collected from all participants will be included for analysis. Comparisons will be made to determine differences in outcome measures between the intervention groups.

10.4 Statistical Analyses

10.4.1 General Approach

Prior to statistical analyses, data will be screened to assess the need for scale transformations (e.g., log, reciprocal) to normalize distributions or reduce variance heterogeneity. The study design is a two-arm randomized clinical trial with a superiority hypothesis (i.e., CRP superior to usual care). Analyses will use survival analysis and mixed effects regression with repeated measures. Follow-up assessment data will be collected from participants even if they drop out of therapy early. The primary focus will be on

group differences over time. All hypotheses will be two-sided at the α=.05 level. Little's MCAR test will be used to determine if data are missing at random (Li, 2013; Little et al., 2002) and random effects pattern-mixture modeling will be used to determine if missingness influences longitudinal results (Hedeker & Gibbons, 1997; Little, 1993). The principal statistical software to be used is SAS 9.4 supplemented with SPSS, R, and MPlus.

10.4.2 Analysis of the Primary Endpoints

Hypothesis 1: The rate of follow-up suicidal behavior will be significantly reduced among military personnel receiving CRP versus usual care risk management in addition to massed CPT.

Survival analysis with time-to-suicide attempt will be used to test overall differences between the two intervention groups. We will use the hazard ratio derived from the Cox regression supplemented with the log-rank and Wilcoxon statistics derived from the Kaplan-Meier method. Time will be calculated as number of days since the intake appointment. Multiple suicide attempts within participants will be handled using the Andersen-Gill counting process model (Anderson & Gill, 1982), which assumes that the time increments between multiple suicide attempts can be explained by past suicide attempts (e.g., shorter time intervals between suicide attempts are more likely among patients who have previously attempted suicide). **Power Analysis:** Power calculations for H1 were conducted using PROC POWER in the SAS 9.4 software. Anticipated suicide attempt rates were based on previously published clinical trials conducted within and external to the military. In previous studies of cognitive behavioral therapies for suicide prevention, the suicide attempt rate in the usual care conditions often ranges from 40-50% during the first year and active suicide-focused interventions typically have 50% lower suicide attempt rates (Brown et al., 2005; Gysin-Maillart et al., 2016; Linehan et al.., 1991; Rudd et al., 2015). In our previous RCT of CRP versus usual care (Bryan et al., 2017), participants receiving CRP were 76% less likely to attempt suicide. Results of our pilot study of massed CPT yielded a similar 73% reduction in suicide attempts in the CRP group versus usual care. We therefore estimated statistical power for hazard ratios ranging from 0.50-0.75 when suicide attempt rates in usual care ranged from 30-50%, assuming 15% attrition, 1-year follow-up, and a two-tailed $p<.05$. N=150 yielded >80% power under nearly all conditions.

Hypothesis 2: Reductions in the severity of suicidal ideation will be significantly larger among military personnel receiving CRP versus usual care risk management.

Mixed effects regression models with repeated measures will be used to test group differences in suicidal ideation over time. Treatment group, time, and the treatment*time interaction will be entered as independent variables and SSI scores as the outcome. Random intercepts and slopes will be tested, and covariance structures will be selected by comparison of likelihood criteria (e.g., Akaike's Information Criteria). Group differences in mean SSI scores will be probed at 2, 4, 13, 26, 39, and 52 weeks, with the largest differences between groups expected to occur at 2 and 4 weeks. Consistent with these expectations, we will also compare the SSI slopes from baseline to session 5 (treatment midpoint) and session 10 (treatment end) to determine if the rate of change in suicidal ideation differs across groups. **Power Analysis:** We used the General Linear Mixed Model Power and Sample Size (GLIMMPSE) software to calculate power for H2 using data from our pilot study to estimate SSI mean differences between groups at baseline (Mdiff=0), treatment midpoint (Mdiff=4), and treatment end (Mdiff=2) assuming a two-tailed $p<.05$. Results indicated N=150 provided 81% power.

Hypothesis 3: Less severe suicide risk features during treatment will predict treatment response (i.e., change in severity of suicidal ideation) and treatment relapse (i.e., follow-up suicidal behavior).

For H3, we will use suicidal ideation EMA ratings collected during the 2 weeks of massed CPT. We will first calculate the following indices of change in suicidal ideation during the entire 2-week observation

window (up to 42 EMA surveys per participant) for each participant: stability (i.e., the autocorrelation of scores over time), severity (i.e., mean score across all responses), and variability (i.e., the root mean square successive difference [RMSSD] across all responses). Each change index will be entered as an independent variable into a linear regression model predicting pre-post change in SSI score and a binary logistic regression model predicting follow- up suicidal behavior. To evaluate the specificity of these findings to the two weeks of active treatment, we will expand these analyses to include all 5 weeks of planned EMA data collection (i.e., 1 week prior to treatment start, 2 weeks of treatment, 2 weeks after treatment completion). This approach will allow us to distinguish treatment- specific patterns from more general patterns that signal treatment response and treatment relapse. **Power Analysis:** Power calculations for H3 were conducted using G*Power 3.1.9.2 (for suicidal ideation) and PROC POWER in the SAS 9.4 software (for suicide attempts). For the linear regression model, N=150 yielded 80% power to detect a medium effect (R^2=0.06) and for the binary logistic regression, N=150 provided >80% power to detect an odds ratio=1.5, assuming a conservative 20% of participants attempts suicide during follow-up.

Exploratory Research Question 1: Which subjective, objective, and treatment-related factors are most useful for predicting treatment response (i.e., change in severity of suicidal ideation) and treatment relapse (i.e., follow- up suicidal behavior)?

We will use the same analytic approach described for H3 but extend the analyses to all other variables assessed via EMA (i.e., positive and negative affect, negative thinking, and maladaptive behaviors) and Fitbit (i.e., physical activity, sleep quality). We will construct a series of models to determine which variables (and combination of variables) maximize the variance explained in pre-post change in SSI score and follow-up suicidal behavior. **Power Analysis:** Power calculations for RQ1 were conducted using G*Power 3.1.9.2. Assuming our model includes no more than 6 predictor variables, N=150 yielded 80% power to detect R^2 increases of 0.06-0.08 associated with each additional predictor variable.

Hypothesis 4: More frequent CRP use will be correlated with reductions in suicide attempts and suicidal ideation.

We will sum the number of EMA responses during which participants endorsed the use of their CRP (and safety plan), such that higher values indicate more frequent intervention use. This count variable will be entered into a Cox regression model predicting time to suicide attempt and a linear regression model predicting change in SSI score to assess the correlation of intervention use with, respectively, follow-up suicidal behavior and severity of suicidal ideation. We will construct separate models or each treatment group. To test the specificity of our findings to CRP, we will repeat these analyses with CPT homework completion, also assessed during EMA and calculated as the sum of positively endorsed EMA responses, entered as a covariate. **Power Analysis:** The power analysis for H4 mirrors the power analysis for H3 above.

Exploratory Research Question 2: Which treatment components and design features do participants find most helpful for reducing suicidal ideation and attempts?

We will use descriptive statistics of participant characteristics, chi-squared tests, and Pearson correlations (where applicable) to explore relationships among personal experiential themes, group experiential themes , and participant characteristics. **Power Analysis:** Recommendations for minimum sample size in qualitative studies using IPA typically range from 2-25 participants, depending on the homogeneity that exists within participants' lived experience (Alase, 2017; Smith et al., 1999). Because we plan to interview all enrolled participants, our sample size will be more than adequate.

10.4.3 Analysis of the Secondary Endpoint(s)

See Section 10.4.2 (Analysis of the Primary Endpoints) for the analysis plan for each of the study aims.

10.4.4 Safety Analyses

Not applicable.

10.4.5 Baseline Descriptive Statistics

Section Demographic and military service demographics will be presented. Appropriate statistical tests for categorical and continuous data will be calculated.

10.4.6 Sub-Group Analyses

See Section 10.4.2 (Analysis of the Primary Endpoints) for the analysis plan for each of the study aims.

10.4.7 Tabulation of individual Participant Data

Not applicable, individual participant data will not be listed by measure or time point.

11. REGULATORY, ETHICAL, AND STUDY OVERSIGHT CONSIDERATIONS

11.1 Informed Consent Process

11.1.1 Consent/Assent Procedures and Documentation

During the consent appointment, potential participants will have the study explained to them in a private location in-person, by phone, or by video teleconference (using a secure video teleconferencing platform) using a paper form, mailing or emailing electronic consent documents to potential participants, or electronic consent (using online eConsent built in the UTHSCSA REDCap) on Fort Hood at the designated STRONG STAR offices in the Shoemaker Center. The potential participant will be sent a link to the eConsent and/or mailed (electronically or by post) and/or given a copy of the informed consent document (ICD) to read. After the potential participant has read the ICD, and a member of the study team has reviewed the risks and benefits of the study to ensure the participant understands the research, the participant will be given the opportunity to discuss the research with family and friends. The research team will be available to answer any questions about the research on the phone, in-person or using a HIPAA-compliant telehealth platform. Once the potential participant has reached a decision, the participant will sign the consent form either electronically or on a paper form. A copy of the ICD will be given to the participant. Additionally, as noted in the informed consent document, the Fitabase Terms of use (https://www.fitabase.com/terms) and the Fitabase Privacy Policy (https://www.fitabase.com/privacy) will be provided to the potential participant to read and review.

Following consent, participants will have the option of receiving text messages and phone calls using a study cell phone to remind them of upcoming study appointments as is usual practice by CRDAMC.

As described in the consent, participants on active duty will have the option of having their Command or employer notified by the Research Staff to ensure active duty service members and veterans are afforded the time to participate in the study. Command or employer agreement to allow for duty time to participate in this study is not a requirement for study participation.

11.1.2 Consent for minors when they teach the age of majority N/A ☒

11.1.3 Consent of Subjects who are, or become, decisionally impaired N/A ☐

Adults unable to provide consent are excluded from enrolling in the protocol. Adults who become decisionally impaired during study participation will be excluded from the study and the team will coordinate to refer for appropriate care.

11.2 Study Discontinuation and Closure

The study may be discontinued and/or closed based on the PI decision, sponsor/funder decision, regulatory or other oversight bodies' review of serious, unexpected, and/or related AEs, noncompliance, and/or futility.

11.3 CONFIDENTIALITY AND PRIVACY

Confidentiality of Study Data: Data will be stored by an assigned participant code number so that data records can be viewed only by password-authenticated, authorized investigators and study personnel. All assessment and CRP sessions will be audio-recorded. Recordings will be labeled with the participant's study id number and will be stored in the STRONG STAR database until the end of the study. Audio recordings will be stored in the STRONG STAR Repository at the end of the study.

REDCap and/or the STRONG STAR eCAP online data capture system will be used for data collection and monitoring. The REDCap (Research Electronic Data Capture) platform is a HIPAA-secure data management system. REDCap provides audit trails for tracking data changes and maintains a secure environment for data storage, reducing the risk of data breaches. Emails and mobile phone texts will be sent to participants with a survey link, username, and password. Survey data will be transmitted to the REDCap server using an encrypted, secured link and stored at UTHSCSA on password-protected computers and secured cloud storage. The STRONG STAR password protected database is housed on a secure UTHSCSA server (physically located at the Advanced Data Center; ADC) by a member of the research team. Electronic data will be stored and managed by the STRONG STAR Data Management Core staff. If needed, the overall PI and named collaborators will have access to identifiable data as agreed to by participants through the signed HIPAA authorization through the STRONG STAR website and UTHSCSA server. All UTHSCSA STRONG STAR network connectivity is segmented with Access Control Lists and is not accessible to any other UTHSCSA network segments. The ADC has 24x7 onsite security, card key, biometric access controls and video surveillance. UTHSCSA ADC facility also maintains Gen 2 firewall devices to protect and prohibit any unauthorized physical or electronic access to UTHSCSA data. All UTHSCSA network devices are monitored by state of the art monitoring applications that include configuration audit, management, and availability 24x7. The UTHSCSA STRONG STAR data server is currently a VMware Instance running Windows Server 2016 Enterprise Standard with daily backup services and vSphere Business Continuity Advanced Failover.

EMA is administered through the HIPAA compliant MetricWire system, which provides a cross-platform (iOS and Android) application for the delivery of EMA surveys and collection of phone sensor data. EMA data will be collected over a 4-week period. Data will be identified on MetricWire using the participants identification number. Data are stored on the Metricwire cloud servers accessible only to authorized study staff. Data will be downloaded from MetricWire into an Excel or CSV file and uploaded to the study database for analysis.

Access to Study Data: Every member of the Research Team will be trained and monitored about how to handle and protect both medical and research records. Furthermore, the Research Team strictly controls access to study data. Only select STRONG STAR Data Core personnel have direct access to the data on a "need to access basis." Data Core also follows the Principals Of Least Privilege (POLP). For example (but not limited to) detecting and repairing data corruption and producing reports not currently within the STRONG STAR system. All user activity is tracked and recorded within the system so if any records are added, altered or viewed the action is recorded and can be recalled for auditing purposes. Access to this information will require a password-protected login available only to authorized STRONG STAR Data Core staff.

Research staff can enter and view data only through use of the web-based database management software interfaces. These display data only to appropriate personnel with logon privileges for delimited purposes. The database maintains a table of authorized users. Users are individually assigned a role within the application that specifies privileges for that user. Logins to data websites and databases are password

protected. All applications can be independently configured to perform specific tasks and utilize customer-specific security models, database connection schemes, and resources based on such roles.

Every member of the research team will be trained and supervised about how to handle and protect both medical and research records. Furthermore, the research team strictly controls access to study data.

Limits of Confidentiality: Complete confidentiality cannot be promised for military personnel because information regarding the service member's health may be required to be reported to appropriate medical or command authorities to ensure the proper execution of the military mission, including evaluation of fitness for duty. Based on the screening and testing done in the conduct of this research, the team may find out that participants are having unusual mental health symptoms, are consuming dangerous amounts of alcohol, or are feeling like hurting themselves or others. The research team will work with participants to get them the care they need. This care may result in the military revoking participant's clearances, credentials, or other privileged access or duty. Furthermore, suspected or known abuse or neglect of a child, a disabled person, or an elder or threatened violence to themselves or others must and will be reported to appropriate authorities in accordance with state law. There are other local health-reporting requirements that need to be reported.

Data from the Fitbit will be collected using Fitabase, https://www.fitabase.com/, a data management platform designed to support research projects using wearable and internet-connected devices. As described on the Fitabase website, https://www.fitabase.com/resources/knowledge-base/working-with-the-irb/, for collection of the activity data from the Fitbit, a research staff member will create a unique email and password combination in order to create an account on Fitbit.com. The following information will be entered:

- First & Last Name: A de-identified placeholder name.
- Date of Birth: The first day of the month of birth.
- Sex: The participant's biological sex.
- Height: The participant's height.
- Weight: The participant's weight.

These personal demographic details (i.e., date of birth, sex, height, and weight) are required for accurate estimation of data captured by the Fitbit Device. The Fitbit account will be connected to a research device or to the participant's own personal Fitbit if they use a Fitbit Inspire. Once the device is connected to the study-generated and study-controlled Fitbit account it will be manually connected to the Fitabase platform and assigned a unique study ID so that data will be synced and available for viewing and downloading by research staff. All data associated with the Fitbit device will be linked to the study ID in the Fitabase platform. Participants will be given the connected Fitbit device and be provided with the associated email/password so that they may login into the Fitbit.com user account, use the online Fitbit dashboard, and associated mobile applications. They will be informed that research staff will be able to access, view, and download their data through the Fitabase platform.

The research team will set up a study project within the Fitabase system for generating unique identifiers and connecting participants' Fitbit devices to the Fitabase system. When an authorized member of the research team logs into the Fitabase system they will be able to see all currently connected devices and the associated study IDs. Each study identifier has a profile that includes the Fitbit data described in the consent documents. Upon authorization by the PI or participant the Fitabase system will be granted access data gathered by the participant as they use the Fitbit device during the data collection timeframe as described in the consent documents. When the data has been downloaded to Fitabase, a member of the research team will navigate to the participant's profile and download CSV (comma separated value) files that contain sleep data to the secure lab server. No other data will be downloaded. Once the study has been completed and the data has been downloaded and scanned for errors, the participant's profile will be deleted and the authorization will be removed. The Fitabase data security and privacy practices and

policies are described at https://www.fitabase.com/resources/knowledge-base/working-with-the-irb/data-security-privacy/.

Privacy Measures. All study activities will occur in a private room or using secure telecommunication means.

Sensitive Information: UTHSCSA STRONG STAR research staff will be trained to evaluate research participants and assess risk of harm to self, others, and military mission. Sensitive information will be reported according to federal, Department of Defense, and state code regulation. Telephone-based contacts will only occur using secure telehealth platforms or landlines to ensure privacy during telephone-based assessment. Assessors will be trained in privacy practices and calls will only take place with participant consent. Calls will originate from a private room or office at CRDAMC. Procedures for telephone contact with active duty service members and veterans will comply with the provisions set forth in DoD Directive 4640.06 (which prohibits discussion of classified information on non-secure calls). Information safeguards will comply with DoD Directive 5400.11 ("DoD Privacy Program").

This study may involve remote and/or virtual research interactions with participants by the research staff. Privacy and confidentiality are not guaranteed due to the nature of the electronic conferencing platforms that will be used, but precautions are in place to minimize the risks and participants will be informed of actions we and they can take to minimize the risk.

11.3.1 Measures Taken to Ensure Confidentiality of Data Shared per the Data Sharing Policies

The PI will ensure all mechanisms used to share data will include proper plans and safeguards for the protection of privacy, confidentiality, and security for data dissemination and reuse in accordance with the participants' consent and HIPAA authorization. Plans for archiving and long-term preservation of the data will be implemented as appropriate.

11.4 Future use of Stored Specimens and Data N/A ☐

A STRONG STAR Repository has been approved by the UTHSCSA (HSC20100475H) IRB to enable the STRONG STAR Consortium to store specimens and data for future use. The STRONG STAR Repository is a large comprehensive database of information, biological specimens and neuroimages related to the identification, assessment, and treatment of insomnia, posttraumatic stress disorder (PTSD), and other related behavioral health conditions. All information entered into the STRONG STAR Repository will be extracted from primary datasets collected as part of IRB-approved studies, including this study, being conducted and /or supported in collaboration with the UTHSCSA STRONG STAR Consortium. Study databases are established and maintained by the STRONG STAR Data Core Services. A unique, sequential numeric STRONG STAR ID will be assigned to each participant at the time of recruitment into this study. However, all Repository data will be identified with a different code number that can be cross linked to the original study code only through records maintained by the STRONG STAR Data Core Services. At the conclusion of this study, data from participants who signed the consent to have their data placed in the STRONG STAR Repository will be maintained under the UTHSCSA IRB-approved Repository protocol. For participants who decline participation in the STRONG STAR Repository, their data will be de-identified and the data maintained in the Repository without identifiers at the conclusion of the study.

11.5 Safety and Clinical Monitoring

Clinical site safety and data monitoring will be conducted to ensure that the rights and well-being of study participants are protected, that the reported study data are accurate, complete, and verifiable, and that the conduct of the study is in compliance with the currently approved protocol and applicable regulatory requirement(s).

The STRONG STAR Data Safety and Monitoring Plan (DSMP) that has been developed in accordance with the National Institutes of Health Office of Human Research Protection to assure the appropriate clinical safety monitoring of study subjects participating in research will be used to monitor this study.

Representatives of the Department of Defense (DoD), as well as others, as allowed by federal, and university law, regulation, and policy are eligible to review study records.

11.6 Quality Assurance and Quality Control

Each site will perform internal quality management of study conduct, data and biological specimen collection, documentation, and completion. All sites will follow a common quality management plan.

Quality control (QC) procedures will be implemented as follows:

- **Informed consent –** Study staff will review both the documentation of the consenting process as well as a percentage of the completed consent documents. This review will evaluate accuracy and completeness. Feedback will be provided to the study team to ensure proper consenting procedures are followed.
- **Source documents and the electronic data –** Any data initially captured on source documents and will ultimately be entered into the study database. To ensure accuracy, site staff will compare a representative sample of source data against the database, targeting key data points in that review.
- **Intervention Fidelity –** Consistent delivery of the study interventions will be monitored throughout the intervention phase of the study. Procedures for ensuring fidelity of intervention delivery are described in Section 7.2.1 (Interventionist Training and Tracking).
- **Protocol Deviations –** The study team will review protocol deviations on an ongoing basis and will implement corrective actions when the quantity or nature of deviations are deemed to be at a level of concern.

Should independent monitoring become necessary, the PI will provide direct access to all study-related sites, source data/documents, and reports for the purpose of monitoring and auditing by the sponsor/funding agency, and inspection by local and regulatory authorities.

11.7 Data Handling and Record Keeping

11.7.1 Data Collection and Management Responsibilities

Instrumentation. See Sections 1.2 (Schedule of Events; SOE) and 9 (Study Assessments and Procedures) for a summary of the assessments and timing of administration. Assessments will be administered in person whenever possible. However, to accommodate participant schedules and/or instances in which a participant does not reside in the local area at the time of a follow-up assessment, we may collect full or partial assessments in person or via phone, video conferencing, and/or electronic data capture using a secure link to the encrypted STRONG STAR database. Reasonable efforts will be made to collect all data as described in this protocol, but we expect some participants may not be able to complete part or all of any given assessment.

Data Storage, Access, and Protection. Data will be coded using an assigned number. The key linking the participant code number with PII, to include social security number (SSN), will be collected on paper and entered into the STRONG STAR password protected database and an Excel spreadsheet housed on a secure UTHSCSA server or on the DHA Network in a secure study folder accessible only by members of the research team.

In accordance with DoDI 1000.30 (Reduction of Social Security Number (SSN) Use within DoD), the participants' SSNs are being collected and used to:

- accommodate participants who may not possess alternative ID numbers, such as family members, veterans, and civilian research participants and for patient safety by using a feature of the STRONG STAR database intentionally built using SSN to ensure the same individual a) does not attempt to enroll in the study twice and b) is not enrolled in multiple STRONG STAR studies simultaneously without the PIs' awareness and agreement (Exception category #13 Other Cases).
- compensate participants without having income tax withheld (Exemption Category #2.c.7. Federal Taxpayer Identification Number)

SSN will be recorded, used, and destroyed as other personally identifying information (PII) and in accordance with the participant signed consent and HIPAA authorization.

Study files containing any hard copies of data collected during study participation will be kept securely at STRONG STAR offices in locked cabinets.

Interview and treatment sessions will occur primarily in person but may occur via phone or using a secure HIPAA-compliant video telehealth platform. Data will be stored by an assigned participant code number so that data records can be viewed only by password-authenticated, authorized investigators and study personnel. Assessment and treatment sessions will be audio-recorded. Recordings will be labeled with the participant's study id number. Through our secured password protected server there is no option for the reviewers to download or otherwise save the recordings to their computers. Every member of the Research Team will be trained and monitored about how to handle and protect research records. Only authorized study staff, and members of the STRONG STAR Data Core staff will have access to either the raw data or electronic study data. Section 11.3 (Confidentiality and Privacy) above describes measures that will be taken to ensure confidentiality in data storage, access, and protection.

11.7.2 Study Records Retention

Informed consent documents will be stored securely for a minimum of three years following completion of the research in accordance with 45 CFR 46 or in accordance with institutional requirements, whichever is longer. HIPAA authorizations will be stored for a minimum of six years in accordance with HIPAA regulations or in accordance with institutional requirements, whichever is longer. After the study has been inactivated with the IRB, all other hard copy data will be destroyed in accordance with institutional requirements.

11.8 Protocol Deviations and Non-Compliance

A protocol deviation is any changed, divergence, or departure from the IRB-approved research protocol.

- Major deviations: Deviations from the IRB approved protocol that have, or may have the potential to, negatively impact the rights, welfare or safety of the subject, or to substantially negatively impact the scientific integrity or validity of the study.
- Minor deviations: Deviations that do not have the potential to negatively impact the rights, safety or welfare of subjects or others, or the scientific integrity or validity of the study.

The UTHSCSA and STRONG STAR SOPs describing protocol deviations and reports of non-compliance will be used to identify and report deviations and/or non-compliance to the IRB.

11.9 Collaborative Agreements N/A ☐

11.9.1 Agreement Type

A Cooperative Research and Development Agreement (CRADA) Statement of Work (SOW) executed under a Master CRADA #MC-22-0179 between UTHSCSA and CRDAMC was fully executed 6 December 2024 and has been processed in ERMS as CRADA00000023.

A Defense Health Agency (DHA) Data Sharing Agreement (DSA) will be executed following the CRDAMC Human Protections Director's Administrative Review to access MHS GENESIS to document the participant's care delivered per the study protocol and communicate with the participant's medical care team per Section 7.1.3 (Access to and Documentation Care in the Electronic Health Record).

11.10 Conflict of Interest Policy

The independence of this study from any actual or perceived influence is critical. Therefore, any actual conflict of interest of persons who have a role in the design, conduct, analysis, publication, or any aspect of this study will be disclosed and managed. Furthermore, persons who have a perceived conflict of interest will be required to have such conflicts managed in a way that is appropriate to their participation in the design and conduct of this study.

12. PUBLICATION POLICY

As a STRONG STAR study, presentations and publications produced as a result of this work will follow the STRONG STAR Standard Operating Procedure STRONG STAR-ADM-001-5.0: Review and Approval of Publications and Presentation and the International Committee of Medical Journal Editors (ICMJE) "Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Journals" updated January 2024.

13. ABBREVIATIONS

AE	Adverse Event
BIS/BAS	Behavioral Inhibition System/Behavioral Activation System
CAPS-5	Clinician Administered PTSD Scale for DSM-5
CDE	Common Data Element
CFR	Code of Federal Regulations
CGI	Clinical Global Impression Scale
Co-I	Co-Investigator
CPT	Cognitive Processing Therapy
CRADA	Cooperative Research and Development Agreement
CRDAMC	Carl R. Darnall Army Medical Center
CRF	Case Report Form
CRP	Crisis Response Planning
CSSRS	Columbia Suicide Severity Rating Scale
DERS-SF	Difficulties with Emotion Regulation Scale-Short Form
DHA	Defense Health Agency
DoD	Department of Defense
DSMB	Data Safety Monitoring Board
EMA	Ecological Momentary Assessment
GET	Group Experiential Theme
GCP	Good Clinical Practice
HIPAA	Health Insurance Portability and Accountability Act
HPD	Human Protections Director

IE	Independent Evaluator
INQ	Interpersonal Needs Questionnaire
IPA	Interpretative Phenomenological Analysis
IRB	Institutional Review Board
MCAR	Missing Completely At Random
MCQ	Monetary Choice Questionnaire
MSRC	Military Suicide Research Consortium
OHRO	Office of Human Research Oversight
OSU	The Ohio State University
PANAS	Positive and Negative Affect Scale
PCL-5	Posttraumatic Stress Disorder Checklist for DSM-5
PCS	Permanent Change of Station
PET	Personal Experiential Theme
PI	Principal Investigator
PRMRP	Peer Reviewed Medical Research Program
PROMIS-CAT	Patient-Reported Outcomes Measurement Information System Computer Adaptive Tests
PTCI	Posttraumatic Cognitions Inventory
PTHI	Posttreatment Health Interview
PTSD	Posttraumatic Stress Disorder
RCT	Randomized Clinical Trial
SAE	Serious Adverse Event
SCS-R	Suicide Cognitions Scale-Revised
SITBI-R	Self-Injurious Thoughts and Behaviors Interview-Revised
SOE	Schedule of Events
SOP	Standard Operating Procedure
SOW	Statement of Work
SSI	Scale for Suicidal Ideation
STRONG STAR	South Texas Research Organizational Network Guiding Studies on Trauma and Resilience
STTS-R	Satisfaction with Therapy and Therapist Scale-Revised
TDY	Temporary Duty
UPIRSO	Unanticipated Problem Involving Risk to Subjects or Others
UTHSCSA	The University of Texas Health Science Center at San Antonio

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15. APPENDICES

1. Case Report Forms; i.e., Questionnaire(s) and Assessments (See Section 9.2 for a Description)
2. EMA MetricWire "we are concerned about you" Message.

16. PLAN FOR REGULATORY OVERSIGHT

Institution & Site PI	Plan for Regulatory Oversight
University of Vermont (UVM) Principal Investigator: Craig Bryan, PsyD, ABPP **Study Activities:** Dr. Bryan will be responsible for overall coordination and direction of the research team; will lead the development of the study protocols and regulatory reviews; direct the hiring, training, and supervision of study staff; direct fidelity monitoring; oversee participant recruitment, data collection (to include qualitative interviews), data management; direct data analyses; and lead the preparation of reports to the funding agency and manuscripts reporting the study findings.	Personnel associated with UVM will be engaged in research. We will request that UVM defer their review to UTHSCSA as both organizations are SMART IRB members.
The Ohio State University (OSU), Site Principal Investigator: Rosie Bauder, PhD, MPH **Study Activities:** Dr. Bryan will be responsible for overall coordination and direction of the OSU research team; will oversee data collection (to include qualitative interviews), data management; direct data analyses; and lead the preparation of reports to the funding agency and manuscripts reporting the study findings.	Personnel associated with OSU will be engaged in research. We will request that OSU defer their review to UTHSCSA as both organizations are SMART IRB members.
University of Texas Health Science Center at San Antonio (UTHSCSA), Site Principal Investigator and Co-Investigator: Alan Peterson, PhD, ABPP **Study Activities:** As Co-I for the proposed project, Dr. Peterson will facilitate the use of STRONG STAR resources and assist with developing reports, presentations, and manuscripts for the dissemination of the study findings.	Personnel associated with UTHSCSA are engaged in research. The UTHSCSA IRB has agreed to serve as the primary IRB.
Carl R. Darnall Army Medical Center (CRDAMC), Military Site PI: MAJ Jennifer Hein, MD **Study Activities:** MAJ Hein will facilitate the conduct of this study at CRDAMC, consult for behavioral health issues, facilitate	Personnel associated with CRDAMC will be engaged in research. Request that CRDAMC defer their review to UTHSCSA

communication with the hospital command, assist with data interpretation, and assist with dissemination of the research findings.	under the DHA General Reliance Agreement with UTHSCSA.