# Enhancing the effectiveness of cognitive processing therapy among suicidal military veterans with PTSD

## 1. Objectives

Our **long-term goal** is to prevent suicides among individuals diagnosed with PTSD by integrating trauma-focused therapies with suicide-focused interventions. Consequently, the **primary objective** of this project is to test the efficacy of cognitive processing therapy (CPT), an empirically-supported psychotherapy for PTSD, when enhanced with the crisis response plan (CRP), an empirically-supported intervention for suicidal thoughts and behaviors. To accomplish these objectives, we will enroll military personnel and veterans meeting diagnostic criteria for PTSD or subthreshold PTSD (i.e., meeting threshold levels for 3 of 4 symptom criteria). We will use self-report, psychophysiological, behavioral, and ecological assessment methods to compare treatment effects. To achieve our primary objective, we specifically propose to:

**Aim 1: Determine if the effects of cognitive processing therapy (CPT) on suicide ideation can be enhanced by integrating the crisis response plan (CRP) into treatment**

H1: Severity of suicide ideation will be significantly reduced over time among veterans receiving CPT+CRP as compared to veterans receiving standard CPT.

H2: Among participants reporting suicide ideation at baseline, severity of suicide ideation will be significantly reduced over time in CPT+CRP as compared to standard CPT.

**Exploratory Aim: Determine if CPT+CRP reduces the risk of new-onset suicide ideation as compared to CPT.**

Exploratory Hypothesis: Among veterans denying active suicide ideation at baseline, rates of new-onset suicide ideation will be lower in CPT+CRP as compared to standard CPT.

## 2. Background and Rationale

Posttraumatic stress disorder (PTSD) is considered one of the “signature injuries” of the U.S. military operations in Iraq and Afghanistan (Institute of Medicine [IOM], 2012), and is the most frequently diagnosed mental health condition among veterans of these conflicts (Tanielian & Jaycox, 2008). Estimated rates of probable PTSD among veterans of Iraq and Afghanistan ranging from 5-20% (Hoge, Castro, Messer, McGurk, Cotting, & Koffman, 2004; Hoge, Terhakopian, Castro, Messer, & Engel, 2007; Milliken, Auchterlonie, & Hoge, 2007; Tanielian & Jaycox, 2008). PTSD is not just a consequence of combat, however; many military personnel and veterans experience noncombatrelated traumas such as sexual assault and domestic abuse, or have histories of early life trauma such as child abuse that can also contribute to PTSD. Regardless of the associated event, PTSD is associated with a host of functional problems and negative outcomes among military personnel including occupational and marital dissatisfaction, violence, alcohol and substance abuse, and suicide (Hoge et al., 2004; Jakupcak et al., 2007; Panagioti, Gooding, & Tarrier, 2009).

Cognitive behavioral treatments tend to be the most highly efficacious treatments for PTSD. Cognitive Processing Therapy (CPT) is one such treatment that has garnered a significant amount of empirical support, with a recent metaanalysis showing it was the most effective treatment for PTSD (Watts et al., 2013), typically yielding a 50% or larger reduction in PTSD symptoms from pre- to posttreatment (e.g., Chard, Schumm, Owens, & Cottingham; Forbes et al., 2012; Monson et al., 2006; Morland et al., 2014; Resick et al 2015; Resick et al., 2017). Recutions in PTSD symptoms are similar in magnitude when CPT is delivered in a virtual or telehealth format as compared to face-to-face delivery (Morland et al., 2011, 2014). Long-term follow-up studies conducted in nonmilitary samples also suggest the beneficial effects of CPT endure for up to 10 years posttreatment (Resick et al, 2012). However, among military samples, most studies to date have not assessed long-term effects of CPT, with the longest follow-up period among

military or veteran samples being 6 months for individual treatment (Morland et al., 2014; Resick et al., 2017) and 1 year for group treatment (Resick et al., 2015). Clinical improvement and recovery rates tend to be higher among patients who complete CPT compared to those that drop out of treatment early (Resick et al, 2008). Data also suggest that PTSD outcomes are moderated by session frequency, such that CPT sessions spaced closer together yield better effects than CPT sessions that are spaced further apart (Gutner, Suvak, Sloan, & Resick, 2016).

In addition to reducing PTSD symptoms, recent studies indicate CPT is also associated with significant short-term reduction in suicide ideation (Bryan et al., 2016; Gradus, Suvak, Wisco, Marx, & Resick, 2013; Resick et al., 2017), potentially due to its effects on PTSD and depression symptom severity (Bryan et al., 2016; Gradus et al., 2016). In several of these studies, suicide ideation increased in severity again several months after the conclusion of therapy, however, suggesting a period of increased vulnerability for suicide. Enhancing CPT with procedures that have been shown to significantly reduce suicidal thoughts and behaviors could serve to further reduce suicide risk during and after treatment completion.

One such procedure is the crisis response plan (CRP), a collaborative, patient-centered intervention that is typically handwritten on an index cards and 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 the figure to the right. In a randomized clinical trial previously conducted by our team, acutely suicidal patients who received a CRP showed significantly faster declines in suicide ideation and were 76% less likely to attempt suicide during the 6-month follow-up as compared to treatment as usual (Bryan et al., 2017a). Subsequent research has found that the inclusion of reasons for living section within the CRP is also associated with significant increases in positive psychological states like optimism and hope (Bryan et al., 2017b), suggesting this component may be acting upon unique mechanisms that are not influenced by other interventions.


## 3. Procedures

### 3.1. Research Design

The study includes a two-arm, single blind parallel randomized clinical trial.

### 3.2. Sample

We will enroll 750 military personnel and veterans who meet full diagnostic criteria for PTSD (i.e., having 4 of 4 symptom criteria at or above threshold levels) or subthreshold PTSD (i.e., having 3 of 4 symptom criteria at or above threshold levels), as established by the Clinician Administered PTSD Scale for DSM-5 (CAPS-5).

### 3.3. Recruitment

Potential participants will be identified via a combination of strategies including Qualtrics Panels, video and static advertisements placed on social media pages and websites, television commercials run in select markets, and referrals from veteran support organizations and veteran-focused non-profits.

**3.3.1. Qualtrics Panels.** Qualtrics Panels is an online survey platform that maintains a database of several million U.S. residents who have volunteered to participate in periodic survey-based research. Because of their efficiency, online survey panels have been used with increased frequency to obtain general population samples for health-related and social research. Qualtrics Panels uses quota sampling methods to identify participants meeting each study's eligibility criteria. Panel members will receive an email invitation with an embedded hyperlink to webpage that includes basic information

about the study purpose, procedures, and risks and benefits, and a web-based survey that includes our screening tools. Participants who complete the screener will be financially compensated in the amount that was agreed upon with Qualtrics when they initially agreed to join a panel.

**3.3.2. Online and television advertising.** Static and video advertisements will be developed in collaboration with CBS Community Partnerships, a component of the CBS Entertainment Group, whose mission is to give back to communities across the country by capitalizing on CBS's extensive resources and long history of successful advertising and marketing initiatives, and RallyPoint, a social media platform designed by and for military personnel and veterans. Our previous collaborations with CBS Community Partnerships and RallyPoint has resulted in significantly increased enrollment across multiple research studies and clinical trials. Sample advertisements are included in this protocol, and will be updated to reflect our current affiliation with The Ohio State University. Updates and changes to these advertisements will be submitted to the IRB for review prior to fielding.

**3.3.3. Referrals from veteran support organizations and mental health professionals.** Potentially eligible military personnel and veterans will be referred to our team for screening and assessment to determine eligibility by veteran support organizations (e.g., Honor365, Project Unbreakable, the PJ Foundation, the Navy SEAL Foundation) and mental health professionals at the Department of Veterans Affairs, Department of Defense, and broader community.

**3.3.4. ResearchMatch.org.** ResearchMatch is a secure NIH sponsored volunteer registry that is available to all research team members at OSU. ResearchMatch is a free participant recruitment and feasibility analysis tool for researchers at participating institutions. The tool is offered to researchers who are conducting research which is health related.

### 3.4. Eligibility Criteria

Our **inclusion criteria** will include the following: (1) 18 years of age or older; (2) current or prior service in the U.S. military; (3) current diagnosis of PTSD or subthreshold PTSD; (4) ability to speak and understand the English language; and (5) ability to complete the informed consent process. Our **exclusion criteria** will include the following: (1) substance use disorder requiring medical management; (2) imminent suicide risk warranting inpatient hospitalization or suicide-focused treatment; and (3) impaired mental status that precludes the ability to provide informed consent (e.g., intoxication, psychosis, mania).

### 3.5. Treatment Conditions

Participants will be randomized to receive cognitive processing therapy (CPT) for PTSD with or without a crisis response plan (CRP). Both treatments will be scheduled on a daily basis during a 14-day window, and will be provided either in-person or via telehealth format, depending on the geographic location and preference of the participant.

In the **standard CPT** condition, participants will complete a self-guided safety plan, a procedure that includes personal warning signs for a suicidal crisis, self-management strategies, sources of social support, and contact information for professional resources and crisis services within the participant's local community, as well as the National Suicide Prevention Lifeline phone number. As a recommended standard care practice with suicidal patients, the combination of CPT and safety plan represents treatment as usual. The safety plan will be administered during the first therapy session.

In the **enhanced CPT** condition, participants will complete a CRP instead of a safety plan. The CRP is another recommended standard care practice with suicidal patients that includes many of the same elements as the safety plan (i.e., warning signs, self-management strategies, sources of social support, crisis services), but is created collaboratively by the patient with active input of their clinician rather than being self-guided. The CRP also includes a section focused on the participant's reasons for living, an

addition that has been shown to increase positive emotional states (e.g., hope, optimism) and lead to faster reductions in suicidal intent. The CRP will be administered during the first therapy.

The present study is therefore designed to examine if treatment effects on suicide ideation are improved with the addition of (a) active collaboration between a patient and clinician and (b) components that increase positive emotional states.

### 3.6. Clinician Training and Supervision

Research therapists will be required to have completed the two-day CPT training workshop with follow-up consultation and supervision, as well as the one-day CRP training workshop with follow-up consultation and supervision.

### 3.7. Randomization

Stratified block randomization with a computerized randomization algorithm will be used to assign participants to each condition. Three strata will be used: (1) suicide ideation within the past week (defined as a positive endorsement of either item 4 or item 5 on the SSI), (2) biological sex (male or female), and (3) therapy format (in-person or telehealth). Participants will be randomized in blocks of 6 and 8 to reduce the possibility of research staff being able to ascertain the randomization sequence.

### 3.8. Sample Size Estimation

The primary outcome, suicide ideation, will be assessed up to 4 times: baseline, 2 weeks, 26 weeks, and 52 weeks). We will analyze data from the full sample and also conduct separate analyses for two subgroups of interest: those with suicide ideation at baseline and those without suicide ideation at baseline. Our primary planned analyses entail slope comparisons for suicide ideation scores.

Our assumptions for sample size estimation were based on previous research conducted by our team. In two separate pilot studies of our two-week treatment program, 50-70% of participants reported suicide ideation at baseline. We used this range to estimate the percentage of participants expected to report suicide ideation at baseline. We also based estimates on the results of a published RCT comparing the CRP to treatment as usual (Bryan et al., 2017a), which found small to moderate differences in suicide ideation between treatment groups over time ($0.3 < d < 0.7$). We used this range to estimate a lower bound for the anticipated effect size (i.e., $d=0.3$).

Assuming a two-tailed $\alpha<.05$, a within-between interaction (i.e., treatment x time), a small correlation ($r=0.1$) among repeated measures, a sample size of 112 ($n=66$ per group) provides 80% power to detect an effect size equivalent to $d=0.3$. To account for expected attrition (~25%) and missing data (participants completing only 3 of 4 scheduled assessments), we will aim to enroll a total of $N=150$ ($n=75$ per arm) eligible participants, which provides 86% power to detect an effect size equivalent to $d=0.3$. Assuming two-thirds of the sample report suicide ideation at baseline—a rate comparable to our pilot studies—we will have 80% power to detect a minimum effect size of $d=0.38$ among participants endorsing suicide ideation at baseline. Because we expect to consent and screen approximately 5 veterans to identify each eligible participant who consents to treatment, we will therefore enroll a total of 750.

## 4. Measurement / Instrumentation

The measures and instruments to be used in the study, along with the planned assessment schedule, are summarized in the table below.

### 4.1. Primary Outcomes

**4.1.1. Suicide ideation** will be measured using the Scale for Suicide Ideation (SSI), an empirically-supported self-report scale that assesses the intensity of suicide-related thoughts, urges, intentions, and behaviors. All subjects complete the first 5 items. If a subject positively endorses either item 4 (active ideation) or item 5 (passive ideation), they are directed to complete an additional 14 items.

**4.1.2. Suicidal behaviors** will be measured using the Self-Injurious Thoughts and Behaviors Interview-Revised (SITBI-R), an empirically-supported self-report scale that assesses a range of self-injurious behaviors including suicide attempts, interrupted suicide attempts, preparatory behaviors, and non-suicidal self-injury.

### 4.2. Secondary Outcomes

**4.2.1. PTSD symptom severity** will be measured using the National Stressful Events Survey PTSD Short Scale (NSESS), a 9-item self-report scale of PTSD symptom severity. Respondents are directed to rate the intensity of each symptom within the past 7 days on a 5-point scale ranging from 0 (not at all) to 4 (extremely). Items are summed to provide an overall metric of PTSD symptom severity.

**4.2.2. Psychiatric symptom severity** will be measured using the DSM-5 Self-Rated Level 1 Cross-Cutting Symptom Measure, a 23-item self-report scale of symptoms that cut across 13 diagnostic domains (e.g., depression, anger, mania, anxiety, psychosis, etc.). Respondents are directed to rate the intensity of each symptom within the past 7 days on a 5-point scale ranging from 0 (none/not at all) to 4 (severe/nearly every day).

**4.2.3. Psychological well-being** will be measured using the Ryff Scales of Psychological Well-Being (SPWB), an 18-item self-report scale that assesses 6 domains of well-being: autonomy, environmental mastery, personal growth, positive relations with others, purpose in life, and self-acceptance. Respondents are directed to rate their agreement level with each item on a 7-point scale ranging from 1 (strongly agree) to 7 (strongly disagree).

### 4.3. Ecological Momentary Assessment

EMA assessments will be programmed and collected using MetricWire, a HIPAA-compliant EMA program that can coordinate sending mass text and email queries within a predetermined time-window. MetricWire collects de-identified responses using subject ID numbers. The program pushes assessment notifications to each subject's smartphone. Subject responses are then submitted to an encrypted server. MetricWire can automatically respond to invalid responses (e.g., numeric values outside the range of possible responses), filter multiple responses, and send standardized information to subjects based on predetermined response criteria (e.g., sending crisis hotline information for subjects indicating severe suicide ideation). Subjects will receive 4 EMA prompts per day on the 14 consecutive days coinciding with active treatment. EMA prompts will be sent at randomly selected times between 8 AM and 11 PM. EMA prompts will assess mood state, suicide ideation, PTSD symptom severity, emotion regulation strategies, location, and social context.

**4.3.1. Mood state** will be measured using a short form of the Positive and Negative Affect Scale (PANAS), a self-report scale that assesses positive and negative emotional states. Respondents are directed to rate the extent to which they are currently experiencing positive emotions and negative emotions.

**4.3.2. Suicide ideation** will be assessed using the first 5 items of the Scale for Suicide Ideation (SSI), described above in Section 4.1.1. The first 5 items assess intensity of the wish to live, wish to die, balance of the wish to live and wish to die, active suicide ideation, and passive suicide ideation.

**4.3.3. PTSD symptom severity** will be assessed using the NSESS, described above in Section 4.2.1.

**4.3.4. Location** will be assessed will be assessed with a checklist that directs subjects to indicate their current location: home, work, school, friend's residence, family member's residence, bar/tavern/pub, indoor public space (e.g., grocery store, shopping center, gym), or outdoor public space (e.g., park, swimming pool). These items were selected to assess subjects' physical location.

**4.3.5. Social context** will be assessed with a checklist that directs subjects to indicate if the following types of people are within their immediate environment: no one (i.e., alone), romantic partners, non-partner family members, friends, coworkers, neighbors, acquaintances, and strangers. These items were selected to assess physical proximity to others.

### 4.4. Covariates

**4.3.1. Psychiatric diagnosis** will be measured using a combination of (a) the Diagnostic Interview for Anxiety, Mood, and OCD and Related Neuropsychiatric Disorders (DIAMOND), (b) the American Psychiatric Association Disorder-Specific Severity Measures, and (c) the Adjustment Disorder New Module 8.

**4.3.1.1. Diagnostic Interview for Anxiety, Mood, and OCD and Related Neuropsychiatric Disorders (DIAMOND).** The DIAMOND is an empirically-supported structured diagnostic interview that assesses the most common mood, anxiety, and trauma-related psychiatric disorders in mental health.

**4.3.1.2. American Psychiatry Association (APA) Disorder-Specific Severity Measures.** The APA Disorder-Specific Severity Measures include a collection of self-report scales that assess the frequency of symptoms associated with commonly occurring psychiatric disorders. In the present study, we will use the Disorder-Specific Severity Measures for depression, specific phobia, social anxiety disorder, panic disorder, agoraphobia, generalized anxiety disorder, dissociative symptoms, and substance use.

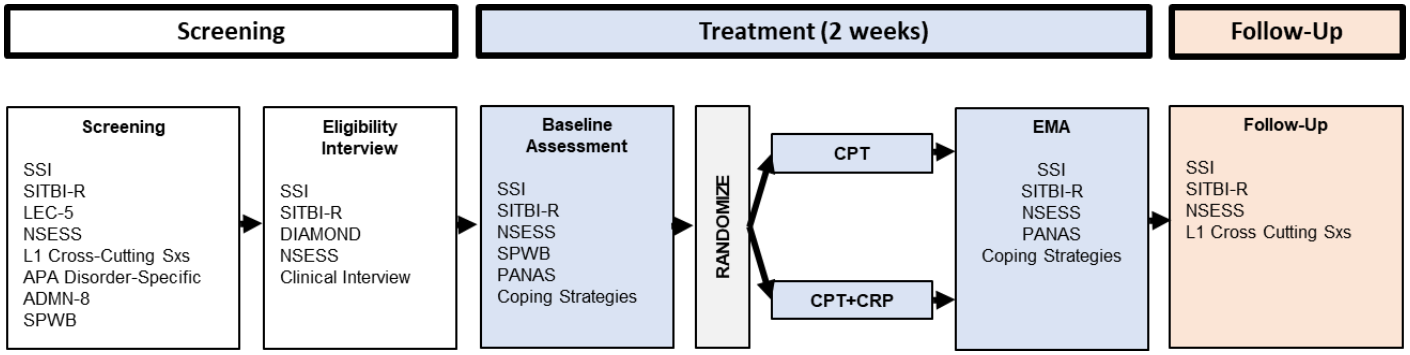
**4.3.1.3. Adjustment Disorder New Module 8 (ADNM-8).** The ADMN-8 is an 8-item self-report scale that assesses recent exposure to a range of non-traumatic life stressors (e.g., divorce/separation, family conflicts) and frequency of symptoms associated with an adjustment disorder.

**4.3.2. Trauma exposure** will be measured using the Life Events Checklist for DSM-5 (LEC-5), an 18-item self-report scale that assesses exposure to a range of potentially traumatic events, and several features of the most stressful or upsetting event (e.g., potential for injury or death, involvement of sexual violence).

| Assessment Measures | Screen | Eligibility | Pre-Tx | Tx | FU1 | FU2 |
|---|---|---|---|---|---|---|
| | | | Week | | | |
| | | | 1 | 1-2 | 26 | 52 |
| **Primary Outcomes** | | | | | | |
| Scale for Suicide Ideation | S | I | E | E | S | S |
| Self-Injurious Thoughts and Behaviors Interview-Revised | S | I | E | E | S | S |
| **Secondary Outcomes** | | | | | | |
| National Stressful Events Survey PTSD Short Scale | S | I | E | E | S | S |
| DSM-5 Self-Rated Level 1 Cross-Cutting Symptom Measure | S | | | | S | S |
| Scales of Psychological Well-Being | S | | | | S | S |
| **Covariates** | | | | | | |
| Severity Measure for Depression | S | | | | | |
| Severity Measure for Social Anxiety Disorder | S | | | | | |
| Severity Measure for Specific Phobia | S | | | | | |
| Severity Measure for Panic Disorder | S | | | | | |
| Severity Measure for Agoraphobia | S | | | | | |
| Severity Measure for Generalized Anxiety Disorder | S | | | | | |
| Severity of Dissociative Symptoms | S | | | | | |
| Level 2 Cross-Cutting Symptom Measures, Substance Use | S | | | | | |
| Adjustment Disorder New Module 8 | S | | | | | |
| Mini International Diagnostic Interview | | I | | | | |
| Life Events Checklist for DSM-5 | S | | | | | |
| Positive and Negative Affect Scale | | | E | E | | |
| Coping Strategies | | | E | E | | |
| | S=Self-Report, I=Interview, E=Ecological Momentary Assessment | | | | | |

## 5. Detailed Study Procedures

The flow of participants through the study procedures are displayed in the figure below:




Potential participants will be recruited via a combination of methods outlined above in Section 3.2.1 and will complete an initial self-report screening to assess for the presence and intensity of psychological symptoms associated with PTSD and other common comorbid conditions (e.g., depression, panic disorder), and presence and intensity of suicide ideation. Potential participants will also be asked about their military service history. The entire screening process is expected to take less than 30 minutes to complete. Based on their responses to survey items, potential participants may be invited to share their contact information, which will be emailed to a member of the research team.

A researcher will then contact the potential participant to complete an eligibility interview conducted by phone or Zoom. During this interview, clinician-administered interviews will be completed to confirm the potential participant's primary diagnosis, to assess level of suicide risk (i.e., determining if there is imminent risk warranting immediate intervention and assistance), and to confirm prior military service. Individuals meeting eligibility criteria will then be given additional information about the study procedures and will be able to ask any questions about the study's procedures. The eligibility interview is expected to take approximately 1 hour to complete.

Those agreeing to continue their participation will be will be assisted in downloading the EMA data collection app to their smartphone, and will receive instructions on how to use the app. Finally, they will be

randomized to one of the two treatment groups and scheduled for their first therapy session. Participants will participate in one hour of psychological treatment per day for 12 consecutive business days (i.e., excluding weekends), for a total time commitment of 12 hours. They will also complete EMA surveys every day for 14 consecutive days (i.e., including weekends). EMA assessments will require 20 minutes per day, for a total of approximately 4.5 hours.

After completing treatment, participants will be given instructions on how to remove the EMA data collection app from their smartphones. Participants will be contacted 6 and 12 months postbaseline to complete the scheduled follow-up assessments. Each follow-up assessment is expected to take approximately 15 minutes to complete.

### 5.1. Potential Risks

**5.1.1. Emotional discomfort during self-report measures and interviews.** Participants could develop mild to moderate emotional discomfort or frustration associated with filling out questionnaires and/or answering interview questions that ask about traumatic or stressful experiences, psychological symptoms, and thoughts about suicide. This potential risk is expected to be comparable to the discomfort experienced when talking with a friend or acquaintance about these same topics. If discomfort is experienced, it is not expected to be severe or to last for more than a few minutes.

**5.1.2. Emotional discomfort during treatment.** Some participants may experience increased emotional distress (e.g., anxiety, guilt, shame) during the course of treatment, especially when asked to talk about traumatic or stressful experiences. This could lead to an increase in sleep disturbance, nightmares, or intrusive memories. This potential risk typically does not exceed the amount of discomfort experienced when thinking about these same topics, however, and typically does not last for more a few hours. <u>This risk is common among individuals with PTSD who receive CPT and other forms of mental health treatment, however, and is not related to the research itself.</u>

**5.1.3. Breach of confidentiality.** Participants' confidentiality could be breached if their identifiers are inadvertently released or accessed by a third party. Participants could also be identified based on the content of their responses. This risk is expected to be low because the data are not stored or analyzed in ways that are likely to reveal a subject's identity. Breach of confidentiality could also occur if an external party or individual hacks into the Zoom interface during a participant's therapy sessions.

### 5.2. Protections Against Risk

To minimize the risk of emotional discomfort associated with survey questions and interviews, we will fully describe to participants the nature of study procedures and the potential for distress will be fully described to participants before they complete any procedures. Moreover, participants will be reminded that they can choose to discontinue any task at any time if they become severely distressed or stop the task and take a break. Research staff are instructed to closely monitor participants while they are completing the tasks.

Because we will be recruiting participants with a history of suicidal thoughts and behaviors, we expect some subjects to be experiencing elevated emotional distress. To minimize risk associated with this issue, all participants will receive either a safety plan during their first session, consistent with standard of care recommendations for the management of suicide risk. The investigators will also be available to meet with distressed participants for additional crisis interventions, where needed.

To minimize the risk of confidentiality breach, research staff will receive rigorous training in confidentiality and privacy procedures. Participant identifiers will also be stored separate from their data. Participant data will be tracked using a sequential numeric ID system generated for each subject (e.g., 1001, 1002, 1003…), and will be stored in a deidentified manner using participant IDs instead of potential identifiers. Finally, we will use recommended security procedures and strategies for maximizing confidentiality and minimizing the risk of third-party intrusion during Zoom-based research activities.

**High-Risk Management Procedures**

The PI has independently conducted multiple studies with acutely suicidal individuals, and has considerable experience managing suicide risk. If a participant reports suicide ideation, or a research staff member becomes aware that the subject is at imminent risk to harm himself/herself, the following questions will be asked to clarify the nature of risk (and to identify those at imminent risk requiring consideration for hospitalization): (1) Do you have a plan for killing yourself and do you intend to act on the plan?; (2) Do you have a desire to kill yourself that you believe you might act on?; (3) Have you already taken steps to act on your plan? If so, what steps have you taken? It is also possible for subjects to be identified as imminent risk if they indicate a moderate to severe level of suicide intent on the Beck Scale for Suicide Ideation, requiring evaluation for possible hospitalization. Once a participant is identified as having potentially imminent risk, the researcher will conduct a more thorough assessment to include possible evaluation by a member of the research team, all of whom are clinical mental health providers, for possible hospitalization and/or notification of emergency services for the purposes of a rescue.

All participants will complete either a safety plan or a crisis response plan during their first appointment. The safety plan is a recommended strategy for reducing suicide risk that includes contact information for professional resources and crisis services within the participant's local community, as well as the National Suicide Prevention Lifeline phone number.

Finally, if a subject reports severe suicide ideation during an EMA response, an automated email alert will be sent to the research team via email and text message. Severe suicide ideation is defined as a score of 2 on the active suicide ideation item of the SSI, indicating a moderate to strong desire to make a suicide attempt. When an automated alert is received by the research team, a member of the research team will contact the subject to conduct a risk assessment to clarify the nature of risk using the same procedures outlined above, review the subject's safety plan, and determine if the subject is at imminent risk to harm himself/herself, thereby warranting further evaluation for possible hospitalization and/or activation of emergency services (e.g., wellness check by law enforcement). The participant's assigned clinician will also be notified so that suicide risk can be addressed during the next scheduled appointment, which will occur within 24 hours owing to the scheduling of therapy sessions on a daily basis.

## 6. Data Analysis

Prior to statistical analyses, we will visually inspect data to ascertain distributional properties and determine if data meet the assumptions for each of our planned analyses. Based on our previous studies, we expect the primary outcome (suicide ideation) to be positively skewed. If true for this study, we will consider and evaluate the most appropriate method for approaching each analysis (e.g., data transformations, bootstrapped confidence intervals, use of generalized linear modeling). We anticipate having up to 50% missing data from EMA and up to 30% missing data from follow-up. We will first use Little's test to determine if the missing data are ignorable (i.e., missing completely at random or missing at random). If the missing data are not ignorable, we will use multiple imputation. The number of imputed datasets will be determined based on the percent of data that are missing and contemporary recommendations. Our primary outcome for Aim 1 is suicide ideation, measured using the SSI total score.

For H1, we will use generalized linear mixed models with SSI total score as the outcome variable and treatment, time, and treatment x time entered as predictors. We will first assess change in SSI scores across the four primary time points: baseline, posttreatment, 6 months, and 12 months. H1 will be supported if there is a statistically significant treatment x time interaction indicating a faster reduction in suicide ideation among participants receiving CPT+CRP. Sensitivity analyses will then be conducted with SSI total scores from the initial screening and the eligibility interview added to the model, thereby enabling us to determine if reductions in suicide ideation coincided with the start of treatment and ruling out the possibility that observed differences between groups is attributable to pre-treatment temporal trends (e.g., participants in one group showing reductions in suicide ideation that precede the initiation of treatment).

Next, we will use generalized linear mixed models with the sum score of the SSI's first 5 items as the outcome variable and treatment, time, and treatment x time entered as predictors. For this analysis, we will use data obtained from EMA, which will provide up to 56 data points per participant (4 assessments per day over 14 consecutive days). H1 will be supported if there is a statistically significant treatment x time interaction indicating a faster reduction in suicide ideation among participants receiving CPT+CRP.

For H2, we will repeat all of the analyses specified above, but constrain our sample to the subgroup reporting suicide ideation at baseline.

For our exploratory aim, we will compare the percentage of participants within each treatment group who deny suicide ideation at baseline but subsequently endorse either item 4 or 5 at any point during follow-up. We do not expect to have sufficient power to detect statistically significant differences in these rates, but will nonetheless use chi-square tests to estimate effect sizes for the purposes of hypothesis testing that could inform future research.

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