Assessing the Effectiveness of Self- and Clinician-administered Crisis Response Planning for Suicide Risk

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1. **Objectives**

The aim of the current project is to compare the use and preliminary effectiveness of a self-administered version of the Crisis Response Plan (CRP) in decreasing suicidal/death ideation and distress and increasing positive affect when compared to a clinician-administered version of the protocol in a sample of 150 military Veterans experiencing current death or suicidal ideation. As the aim of examining the effectiveness self- and clinician-administered versions of the CRP is exploratory, no hypotheses are proposed. However, the results of this research will inform best practices for administration of the CRP in future research and clinical contexts.

2. **Background and Rationale**

In response to enhanced detection of suicide risk, there is a need to identify psychotherapeutic interventions targeting suicide risk among military veterans who may be unable or unwilling to seek follow-up mental health services. Indeed, reasons for refusal to seek mental health services among veterans include public and self-stigma (Held & Owens, 2013), adherence to masculine norms (Burns & Mahalik, 2011). However, Wilson et al. (2008) observed that the majority of Army soliders who were unwilling to speak to a clinician about mental health care have were willing to utilize technology-based approaches to mental health care.

2.1 Crisis Response Planning for Suicide Risk. Crisis Response Planning (CRP) is a brief, psychotherapeutic intervention with demonstrated efficacy in increasing positive affect, decreasing negative affect and psychiatric hospitalizations, and reducing suicide attempts by 76% in military personnel when compared to contracts to safety (Bryan et al., 2017, 2018). Give the efficacy and flexibility of the intervention, CRP has been successfully implemented as part of interventions targeting PTSD and suicide risk (Bryan and Rudd, 2018; Rozek & Bryan, 2020). **This proposed research is aimed at examining the efficacy of the intervention in reducing suicidal ideation, distress, and negative affect and increasing positive affect when compared to a self-administered version.**

CRP is focused on creating personalized set of steps for individuals to follow in case of a crisis and includes individuals' personal warning signs of distress, behavioral coping strategies, reasons for living, social supports to contact, and contact information for professional services, including emergency services. Personalization of the CRP is encouraged, and individuals are instructed to handwrite each step of the CRP on an index card. Additionally, clinicians instruct patients to review the CRP periodically in order to mentally rehearse each step and change the contact of the CRP as needed (e.g., after using the CRP, a behavioral coping strategy was found to be unhelpful or iatrogenic).

3. **Procedures**

3.1. Research Design. A two-arm randomized controlled simulation design will be employed in both parts of this proposed research. Participants will be randomized using stratified blocks of 6 or 8 participants, per recommendations by Krenan et al. (1999), based on gender and suicide attempt history (no history of suicide attempts, history of one suicide attempt, or history of multiple suicide attempts).

3.2. Sample. A sample of 150 Veterans will be included in the study and randomized to study conditions (75 in the clinician-administered CRP condition and 75 in the self-administered CRP condition). Results of a priori power analyses conducted using G*Power software (Faul et al., 2007)

indicate that a total sample of 150 will results in a highly-powered study (β =.98-.99) to detect medium-sized effects in all regression-based analyses, assuming moderate correlations amongst the seven daily measurements for this proposed study. Therefore, although we anticipate low attrition from this study, the proposed sample size is sufficiently powered for the proposed analyses, even when conservatively assuming a 20% attrition rate observed in longitudinal efficacy trials of the CRP (Bryan et al., 2017). Online recruitment methods for the study are include wed-based survey and research recruitment systems (e.g., SurveyMonkey), listservs and forums, and social media sites (e.g., Facebook, Twitter, Reddit). Additionally, we are requesting use of ResearchMatch (RM), which is an NIH sponsored national registry for research volunteers. ResearchMatch (RM) and OSU have had a fully executed agreement since August 2009. The IRB of record for ResearchMatch is Vanderbilt University. The Principal Investigator will be authorized to recruit study participants.

We will enroll any prospective Veteran meeting inclusion criteria (18 years of age or older, US military veteran, death or suicidal ideation/suicide attempt within the past month) in the proposed study. Exclusion criteria include: non-Veteran status, acute intoxication or active psychosis precluding provision of informed consent, an inability to communicate and comprehend English, residence outside the United States, and lack of past-month death/suicide ideation or attempt. Participants recruited through web-based survey and research and recruitment systems will provide consent for study personnel to initiate contact through email or phone call, while those recruited through other online methods (e.g., listservs, forums) will be provided contact information for study personnel in order to inquire about the study or schedule participation.

3.3 Measurement/Instrumentation. The following self-report measures will be administered through Qualtrics online survey software during baseline procedures as part of the proposed research:

Visual Analog Scale - Participants will be instructed to reflect on their urges for suicide using the Suicide Visual Analog Scale (S-VAS; Bryan, 2019) The S-VAS assesses “urge to kill myself” using a horizontal line with anchors on the left reflecting “none” (score: 0) and on the right reflecting “extreme” (score: 100). The S-VAS is initially presented with the indicator on the “none” position, and non-movement of the indicator is followed by a prompt to remind the participant to move the indicator, if relevant, to ensure response accuracy

The Patient Health Questionnaire Depression Scale (PHQ-2; Arrol et al., 2010). The PHQ-2 is a 2-item measure of depression symptom severity adapted from the 9-item version of the PHQ (Kroenke & Spitzer, 2002). Item responses are scores on a Likert scale ranging from 0 to 3, with higher scores indicating greater symptom severity. This version of the PHQ was chosen in lieu of the PHQ-9 in order to omit an item about suicide risk contained on the PHQ-9 and decrease participant burden.

Positive and Negative Affect Schedule – Short Form (PANAS-SF; Mackinnon et al.,1999) is a 20-item validated self-report measure of state positive and negative affect. In the current study, the PANAS-SF will assess past-day positive and negative affective states.

3.3.1 Daily surveys. Prior to completing the CRP and once daily for seven days following completion of the CRP, participants in both conditions will be emailed a secure link to a Qualtrics survey including the following questionnaires:

Visual Analog Scale – See above.
Patient Health Questionnaire – 2. See above
Positive and Negative Affect Schedule – Short Form. See above.
Crisis Response Plan Use – In order to assess whether CRP use after completion impacts suicide urges and affect, participants will be instructed to “Please list all dates and times that you used part or

all of the Crisis Response Plan that you completed since you last completed this survey. (or since you completed your Crisis Response Plan if this is the first survey you will complete)" You may provide us with your best estimates of dates and times."

3.4. Informed Consent and Confirmation of Eligibility

Informed consent will be obtained through Qualtrics survey software from each participant prior to initiation of study tasks. Study personnel will obtain informed consent from participants and answer questions about the study or informed consent process prior to beginning study activities. Following informed consent, participants will complete a demographics questionnaire through Qualtrics that also includes items assessing history of suicide attempts from the Self-Injurious Thoughts and behaviors Interview (Nock, Holmberg, Photos, & Michel, 2007) for study eligibility determination and randomization purposes as well as the Suicide Visual Analog Scale (Bryan, 2019). Regardless of eligibility, all participants will be provided with contact information for crisis resources including the National Suicide Prevention Lifeline and Veterans Crisis Line.

3.5. Randomization to Study Conditions.

REDCap, a secure online survey and data management system maintained by The Ohio State University, will be utilized to randomize participants to study conditions in both components of the study immediately after obtaining demographic information (man, woman, other) and information about suicide attempt history (no suicide attempts, one suicide attempt, more than one suicide attempt) obtained from the SITBI). Participants will be randomized using stratified blocks of 6 or 8 participants, per recommendations by Krenan et al. (1999). After randomization, each participant will complete the remainder of the research study, but will be presented with one of the following pages containing instructions for completing the CRP:

Self-Administered CRP: In this condition, participants will be presented with instructions for completing and printing off the CRP. They will be directed to type in their responses onto the Qualtrics page and upload a picture of their CRP.

Clinician-Administered CRP: In this condition, study personnel will guide participants through the CRP protocol, outlined by Bryan and Rudd (2018). Participants will be directed to a Qualtrics page instructing them to collaborate with study personnel to develop a personalized CRP. Study personnel will take a screenshot picture of the CRP and upload it to Qualtrics.

3.6. Additional incentives following completion of the first portion of the study.

Following the study session, all participants will receive payment in the form of $50 for participation. Additional incentives will be described to participants at the beginning of the study as part of the informed consent process, and administered no later than two weeks following completion of the study protocol:

3.4. Detailed Study Procedures. One hundred and fifty adult military Veteran participants residing in the United States will complete study components during the baseline study session: consenting, demographics survey and self-reported history of suicide attempts, randomization to study conditions, and the CRP. Consenting procedures will always be completed first, and demographic and suicide attempt history data will always be collected second for randomization to conditions of the study through REDCap online software. We estimate that the total participation time will be approximately 1 hour. Participants will be active in the study for eight days. In order to protect participant confidentiality, password-protected Zoom or phone-based sessions will be conducted during the baseline session and to administer the CRP to individuals in the clinician-administered CRP condition. All data will be collected through the Qualtrics, and non-PHI demographic information will be entered into REDCap system for randomization purposes. ID numbers will be linked to all data collected in the study, including identifying information collected in a separate data set as part of safety procedures, which will be deleted at the conclusion of the study. All deidentified data will be downloaded and deleted from Qualtrics servers at the conclusion of the study and stored on the

password protected OneDrive server hosted by OSU indefinitely for the proposed analyses and secondary analysis. Additionally, in order to protect participant privacy during the study, all study personnel will conduct study procedures from a private location, using a secure Internet connection and instruct all participants to do the same, if possible, and outline the risks of loss of privacy or confidentiality if the participant is unable to so.

3.7. Internal Validity. A number of measures will be implemented to mitigate threats to internal and external validity. Specifically, the randomization procedures employed in the proposed research study (See Section 4.1.2) were selected to account for the potential influences of gender and suicide attempt status on study findings. Further, all study personnel administering the CRP will be trained to administer the protocol to maintain an average fidelity rating of 85%. A random selection of CRP sessions recorded using Zoom teleconferencing software, will be reviewed by the Principal Investigator and other trained members of the research team in order to assess fidelity to administering the protocol. If a personnel's average fidelity rating drops below 85%, they will be temporarily prohibited from administering further CRP sessions until remedial training has been completed and they obtain fidelity ratings of at least 85% for three consecutive practice administrations of the CRP.

3.8 Data Analysis. A linear mixed effects regression analysis with repeated measurements will be conducted to examine differences in suicide risk between Veterans in the clinician-administered and self-administered CRP conditions. Condition will be entered as the independent variable and outcome measures at baseline and each follow-up assessment will be entered as outcomes. These analytic procedures are consistent with previous trials examining the efficacy of the CRP (Bryan et al.,2017; Bryan et al., 2018).

3.9. Safety Procedures. The intervention under study includes two iterations of Crisis Response Planning, an intervention with demonstrated efficacy in reducing suicidal ideation and distress. Therefore, we anticipate that both versions of the CRP will demonstrate similar effects in this proposed study. Additionally, the use of crisis response plans, safety plans, and regular follow-up assessments are widely-used strategies that have been associated with decreased suicide risk and are all included in the proposed research. During enrollment in the study, all participants, regardless of agreement to participate in both portions of the study, will provide their contact information (home address, telephone number, email address) and a telephone number for an alternate person that study personnel may contact in case of imminent suicide risk. Home addresses may be used to contact the participant's local emergency services in case of imminent suicide risk. If a subject reports suicidal 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? Both iterations of the CRP, which is a recommended and empirically-supported strategy for reducing suicide risk, will include contact information for professional resources and crisis services, the National Suicide Prevention Lifeline phone number, and other local behavioral health clinics and emergency departments. These procedures have been used successfully by our research team in dozens of studies with acutely suicidal individuals, to include multiple clinical trials. All participants will be provided with contact information to use in case of crisis (National Suicide Prevention Lifeline, emergency services), regardless of whether individuals choose to participate in developing the CRP.