HUMAN SUBJECTS RESEARCH PROTOCOL

1. PROTOCOL TITLE: Decreasing Suicide Risk among Service Members with Posttraumatic Stress Using Written Exposure Therapy

2. ABSTRACT

Studies of active duty service members have shown that posttraumatic stress disorder (PTSD) is a prevalent condition and that service members who screen positive for PTSD are more than twice as likely to make a suicide attempt (Hoge et al., 2004; Nock et al., 2014). Research has shown that evidence-based PTSD treatments can reduce suicidal ideation (Gradus, Suvak, Wisco, Marx, & Resick, 2013; Bryan et al., 2016); however, it is challenging to provide these treatments to high-risk service members on an acute inpatient unit because they require more time and resources than are typically afforded during inpatients stays. Written Exposure Therapy (WET) is an evidence-based, 5-session treatment for managing PTSD (Sloan et al., 2018). WET, adapted for treatment of co-morbid PTSD and suicidality, may overcome many implementation challenges in an inpatient acute care treatment setting (e.g., minimal therapist-patient contact, nominal time needed to train therapists, treatment brevity, and low attrition). Additionally, pilot data indicate that WET reduces suicidal ideation. To directly target suicidal risk and PTSD this study will use a new formulation of WET referred to as WET-for suicide, or WET-S, that includes crisis response planning (CRP) for suicide prevention to the WET condition. WET-S will be delivered in a condensed or "massed' treatment format, consisting of at least one WET-S session each day.

The purpose of this randomized controlled trial (RCT) is to determine if five 60-minute sessions of Written Exposure Therapy for Suicide (WET-S) reduces the presence, frequency, and severity of suicidal ideation, suicide plans, suicide gestures, suicide attempts, non-suicidal self-injurious behaviors, and re-hospitalization for suicidality and if WET-S reduces posttraumatic stress (PTS) symptom severity among 124 service members and veterans admitted to an acute psychiatric inpatient unit for co-morbid suicide ideation (SI) or attempt and PTSD or posttraumatic stress (PTS) compared with Treatment as Usual (TAU). Treatment will be administered during the acute inpatient stay and, if necessary,after discharge into outpatient behavioral health, to complete the five sessions. Participants will be assessed at pre-treatment, post-treatment, and then 1- and 4-months after treatment completion.

3. OBJECTIVES/SPECIFIC AIMS/RESEARCH QUESTIONS

Purpose: The purpose of this randomized controlled trial (RCT) is to evaluate the efficacy of five 60-minute sessions of Written Exposure Therapy for Suicide (WET-S) + Treatment as Usual (TAU) compared with TAU in high-risk, suicidal service members, veterans, and DEERS eligible beneficiaries with posttraumatic stress disorder (PTSD) or posttraumatic stress symptoms (PTSS).

Research Aims and Hypotheses:

Aim 1: Determine if Written Exposure Therapy for Suicide (WET-S) reduces the presence, frequency, and severity of suicidal ideation, suicide plans, suicide gestures, suicide attempts, non-suicidal self-injurious behaviors, and re-hospitalization for suicidality measured by the Self-Injurious Thoughts and Behaviors Interview (SITBI; Nock et al., 2007) among service members,veterans, and DEERS eligible beneficiaries admitted to an acute psychiatric inpatient unit for suicidal ideation (SI) and/or attempt with posttraumatic stress disorder (PTSD) or posttraumatic stress symptoms (PTSS) compared with Treatment as Usual (TAU).

Hypothesis 1. Compared with TAU alone, WET-S + TAU will result in significantly greater reductions in suicide-related outcomes pre-treatment to 1- and 4-months follow-up.

Aim 2: Determine if Written Exposure Therapy for Suicide (WET-S) reduces posttraumatic stress symptoms (PTSS) severity measured by the Clinician Administered PTSD Scale for DSM-5 (CAPS-5; Weathers, Blake, Schnurr, Kaloupek, Marx & Keane, 2013) among service members, veterans, and DEERS eligible beneficiaries admitted to an acute psychiatric inpatient unit for suicidal ideation (SI) or attempt and posttraumatic stress disorder (PTSD) or PTSS compared with Treatment as Usual (TAU.)

Hypothesis 2. Compared with TAU alone, WET-S + TAU will result in significantly greater reductions in PTSS severity from pre- to post-treatment, 1- month, and 4-month follow-up.

Aim 3: Determine if reductions in posttraumatic stress symptoms (PTSS) severity mediate the association between treatment condition and suicide-related outcomes (suicidal ideation, plans, gestures, attempts, non-suicidal self-injurious behaviors, and re-hospitalizations) measured by the Clinician Administered PTSD Scale for DSM-5 (CAPS-5) and the Self-Injurious Thoughts and Behaviors Interview (SITBI).

Hypothesis 3. WET-S + TAU will demonstrate an indirect effect on suicide-related outcomes through greater reductions in PTS symptoms as compared with TAU.

4. MILITARY RELEVANCE

Currently, service members and veterans have unacceptably high rates of suicidal behavior and PTSD. The military's immediate and long-term mission readiness would benefit from a brief, easily implemented, evidence-based intervention that meaningfully reduces the future risk of suicide among service members with PTSD and improves morale. Active duty work and schedule demands require efficient treatment delivery models (e.g., treatment delivered in a condensed format of consecutive daily sessions) and psychiatric inpatient treatment focused on suicide risk stabilization is typically a short time period. Because WET-S is brief, easy to administer, and requires fewer resources and training to administer, it could very easily be scaled up and disseminated. This advantage would allow service members to engage in this therapeutic technique in a variety of settings (e.g., home, barracks, in theatre) with a high degree of privacy and a significantly reduced effort by already overburdened military mental health providers. This privacy and flexibility may help reduce stigma concerns. This project targets active duty military personnel at varying stages of psychiatric care: the inpatient stay, the high-risk post-discharge period, and the return to living within their military communities. WET-S can be disseminated easily across DoD to reduce suicidal behavior among service members and veterans. Overall, although we expect that WET-S will prove useful to the general population, we believe this time-efficient, cost-effective, and easily implemented intervention holds special promise for improving the prevention of suicidal behavior among service members and veterans.

5. BACKGROUND AND SIGNIFICANCE

Studies of active duty service members have shown that PTSD is a prevalent condition and that service members who screen positive for the disorder are more than twice as likely to make a suicide attempt (Hoge et al., 2004; Nock et al., 2014). Research has shown that evidence-based PTSD treatments can reduce suicidal ideation (Gradus, Suvak, Wisco, Marx, & Resick, 2013; Bryan et al., 2016); however, it is challenging to provide most of these treatments to high-risk service members on an acute inpatient unit because they require more time and resources than are typically afforded during inpatients stays. This means that those with PTSD who are at highest suicide risk are not receiving treatment for PTSD until they are discharged from the hospital and there is no available evidence to suggest that treatment as usual in inpatient psychiatric settings reduces the likelihood of suicide after discharge.

WET is a 5-session treatment that is included in the 2017 VA/DoD Clinical Practice Guidelines for managing PTSD (2017). WET is associated with large within- and between-group effect sizes that are comparable with other evidence-based PTSD treatments (Sloan, Marx, et al., 2018). Sloan and colleagues (2012) examined the efficacy of WET relative to wait list (WL) comparison condition delivered to men and women who had a diagnosis of PTSD related to a motor vehicle accident. Intent to treat findings indicated a very large between group differences (Cohen's d = 2.49 and 2.19 at post-treatment and 3-month follow-up, respectively), with 91% of participants no longer meeting diagnostic criteria for PTSD 6 months following treatment (Sloan et al., 2012). Moreover, WET was associated with low attrition (n = 2; 9%) and high treatment satisfaction ratings. Next, WET was compared with Cognitive Processing Therapy for PTSD, a first- line PTSD treatment that is much more time intensive than WET, in a non-inferiority trial. Participants in both treatments displayed a significant reduction in PTSD symptom severity (large within group effect sizes). However, a significant treatment condition difference in dropout was also observed, with 39% dropout in CPT compared with 6% in WET (Sloan et al. (2018). Thus, WET may overcome many implementation challenges in an inpatient acute care treatment setting (e.g., minimal therapist-patient contact, nominal time needed to train therapists, treatment brevity, and low attrition). Preliminary data suggest that WET also reduces suicidal ideation. Specifically, secondary analysis of data from the WET vs. CPT study sample demonstrated that among those who received WET and who endorsed SI at baseline (n = 18 of 63; 28.57%), a significant effect of linear time was observed (B = 0.338, SE = 0.07, p<.001), indicating that participants were significantly less likely to endorse SI over time. Roughly half of those who endorsed SI at baseline no longer endorsed SI 60 weeks later.

To directly target suicidal risk and PTSD among service members admitted to an acute psychiatric inpatient unit the study will use a new formulation of WET referred to as WET-for suicide or WET-S that includes crisis response planning (CRP) for suicide prevention to the WET condition. CRP is a brief strategy that reduces suicide attempts among military personnel by 76% compared with typical suicide risk management strategies (Bryan et al., 2017a). CRP also contributes to significantly faster reductions in suicide ideation (Bryan et al., 2017a), as well as immediate reductions in emotional distress and suicidal intent (Bryan et al., 2017b). WET-S aims to work synergistically by addressing trauma-related symptoms or cognitive-affective states (e.g., intrusive thoughts, self-blame, hyperarousal) that are both PTSD treatment targets and warning signs for suicidal thoughts and behaviors (Bryan, 2016; Bryan, Grove, & Kimbrel, 2017). The development and review of CRP aims to support the regulation of these trauma-focused cognitive-affective states (among other patient warning signs) while the patient engages in trauma-focused treatment through the WET protocol.

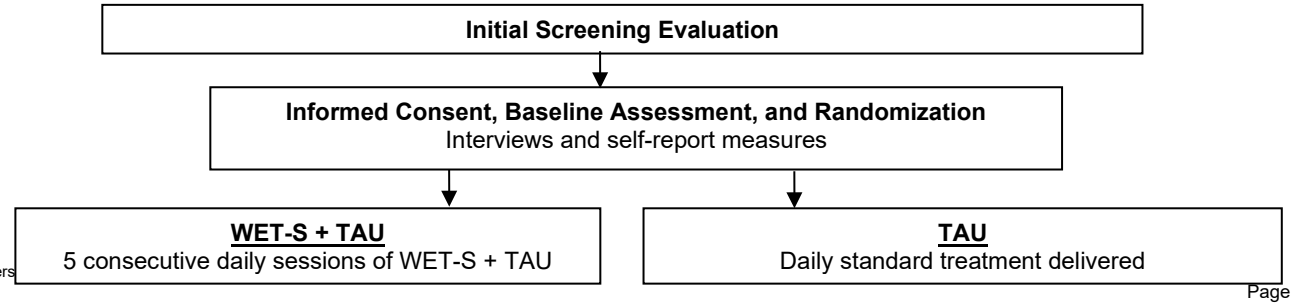
WET-S will be delivered in a condensed or "massed' treatment format, consisting of at least one WET-S session each day. For some patients, two WET-S sessions per day may be considered with the objective that the protocol is completed prior to discharge. Recent data support condensed formats version of evidenced-based cognitive behavioral therapies for PTSD work equally well as the spaced (weekly) version with significantly less dropout (Foa et al., 2018; Fredman et al., 2018; Peterson et al., 2018). Although primary data exist to support reductions in suicide risk with WET, it has yet to be tested with patients at high risk for suicide requiring inpatient hospitalization management. Therefore, as a part of risk management strategies for the experimental treatment of WET with this population we are including increased suicide risk monitoring and management by the inclusion of CRP in the WET condition (WET-S). WET-S will be delivered in five sessions, with the allowance of an additional two WET-S sessions, based on therapist judgment to support good end state functioning and treatment goals to reduce PTS symptoms.

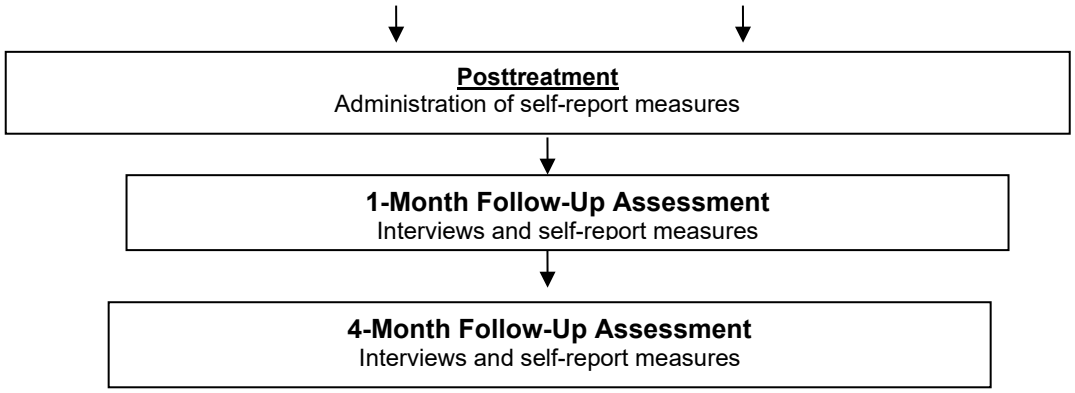
Telehealth is an essential and safe mode of delivering mental health services, to include the delivery of exposure-based PTSD treatment17, 18. Telehealth is broadly defined as behavioral health services that are delivered via communication technologies including telephone and clinical video teleconferencing. Because of the physical distancing recommendations in place with the COVID-19 pandemic, all assessment and treatment sessions for this study will occur using a computer or tablet talking over a secure line in real-time with the research staff using a computer in his or her office. The video telehealth platform used for these communications is HIPAA-compliant. While participants are in care at the CRDAMC inpatient unit, the computer or tablet will be provided by the staff to use for study procedures only. For sessions or assessment that occur after participants are discharged from inpatient care, participants will need to use a computer with high speed internet access (e.g., broad-band internet connection of at least 384kbps at 720 pixels) to support the telehealth platform. The computer must be equipped with speakers or a standard headphone jack to be able to hear and speak with the research staff. Participants will also need to have access to a private location with the ability to control access during assessment and treatment sessions to ensure your privacy and confidentiality. If participant does not have access to a computer in a private location, they can come to the STRONG STAR offices located at the Shoemaker Center on Fort Hood and use a computer in one of our offices

6. RESEARCH DESIGN

The proposed randomized controlled trial will examine the efficacy of the WET-S + TAU compared with TAU alone among high-risk, suicidal service members and veterans with PTSD or PTSS admitted to the CRDAMC acute inpatient psychiatry unit for suicide risk. Assessment and treatment session will be delivered via a HIPAA compliant video telehealth platform. The design overview of the study is summarized in Figure 1.

Figure1. Study Design Overview.





7. RESEARCH PLAN

7.1 Selection of Subjects

- Target enrollment (number consented): 140
- Target number randomized: 124

7.1.1. Subject Population. Active duty military service members and veterans admitted to the CRDAMC inpatient psychiatry unit for treatment for suicidal thoughts or behaviors and PTS. The study will use a continuous enrollment process to allow for maximum flexibility in meeting individual patient/participant scheduling needs. Active duty service members will have priority for being enrolled in the study.

7.1.2. Source of Research Material. Interviews, self-report questionnaires, medical record review.

7.1.3. Inclusion and Exclusion Criteria.

Inclusion Criteria

1. Active duty military service member, veteran, or and DEERS eligible beneficiary (age 18- 65 years) hospitalized at Carl R Darnall Army Medical Center (CRDAMC) for non-suicidal self-injury, suicide thoughts, suicide plan or attempt confirmed by CRDAMC inpatient admission documentation.
2. PTSS of at least moderate severity (total scores > 20) confirmed by the CAPS-5.
3. Speak, read, and write English.

Exclusion Criteria

1. Active psychosis.
2. The presence of moderate to severe cognitive impairment (as determined by the inability to comprehend the baseline screening questionnaires).
3. The presence of any clinically significant factor that may impair an individual's ability to comprehend and effectively participate in the study, e. g., the presence of extreme agitation or violent behavior.

7.1.4. Description of the Recruitment and Prescreening Process. Under a waiver HIPAA Authorization for screening, study staff will collaborate with CRDAMC staff to identify potential participants who have been admitted for suicide thoughts and/or suicidal behaviors and that have symptoms of PTS as documented as part of the admission assessments.

7.1.5. Pre-Screening and Consent Process. A CRDAMC staff member will identify potential participants as part of their admission assessment of new patients. UTHSCSA STRONG STAR staff will attend the unit morning meeting via telephone. Following the morning meeting, a CRDAMC inpatient staff member will introduce the UTHSCSA STRONG STAR staff to the patient via a HIPAA compliant video telehealth platform. Potential participants will be approached to consider participation in this study as soon as is practically and clinically feasible after their initial evaluation and stabilization. An authorized and trained member of the research team will engage the potential participant in an interactive explanation of the study guided by the informed consent document (ICD). During the consent appointment, potential participants will have the study explained to them in a private location on the inpatient

psychiatry unit. The potential participant will be given a copy of the informed consent document (ICD) to read. After the potential participant has read the ICD, they will be given the opportunity to discuss the research with family and friends. Once the potential participant has reached a decision, a member of the study team will again review with the participant the purpose of study, duration of study, study procedures, the experimental components of the study, the potential risks and discomforts, the potential benefits, any alternatives to participation, protection of participant's confidentiality, and the contact information for both the researchers and the regulatory bodies overseeing the conduct of the study to ensure the participant has an understanding of the study. If the individual is agreeable to participation, the informed consent document will be signed electronically or on paper form by the participant. A clean copy of the informed consent form will be given to the patient. During the course of the study, the research team will be available to answer any questions about the research, and ongoing discussions will occur to ensure the participant's questions and concerns are addressed. Baseline assessment for screening will occur after consent.

7.1.6. Subject Screening Procedures. Once the informed consent is completed, participants will complete the baseline questionnaires and study interviews with the Independent Evaluator (IE) to ensure inclusion and exclusion criteria are met. The first choice will be for the participant to complete all measures online through a secured electronic link. Interview assessments will be conducted using a HIPAA-compliant video telehealth platform. In the event there are technical difficulties, consent and self-report assessment measures may be completed on paper.

7.1.7. Compensation for participation. Participants will not be compensated for participation.

7.1.8. <u>Treatment Procedures.</u>

<u>Written Exposure Therapy-for Suicide (WET-S)</u>. Typically, WET-S consists of 5 treatment sessions, each lasting approximately 60 minutes, with the exception of the first session which will last 90 minutes. Each session includes a written exposure exercise for participants randomized to the WET+TAU arm. The first session will consist of the therapist educating the participant about common reactions to trauma and providing information regarding the rationale of WET-S as a treatment for PTSD. The participant will then be given general instructions for completing the trauma narratives, specific instructions for completing the first session, and will then complete the first narrative writing session. Participants will be instructed to write about the same trauma experience during each session. This event will be the same event identified as the index trauma during the baseline assessment session. The importance of delving into their deepest emotions surrounding the trauma event is emphasized, as well as the importance of providing detailed information about the event. All WET-S sessions will take place via a HIPAA-compliant video telehealth platform in a private room on the inpatient ward while being monitored by inpatient staff. The participant will be provided with the writing instructions and the provider will remain virtually connected with the patient while the writing session is completed. Writing instructions begin with a focus on describing the details of the trauma and emotions and thoughts that occurred during the traumatic event and then change to a focus on the meaning of the trauma event (e.g., what the event has meant to the person, how it has changed the way they view his or her life). Based on regular consultation between the treating therapist and supervising investigators, 1 to 2 additional WET-S sessions will be provided to ensure the rationale of WET-S as a treatment for PTSD is understood by the participant and to allow for a full course of WET-S sessions. WET-S will be delivered in a condensed or "massed' treatment format, consisting of at least one WET-S session each day until the treatment is complete. For some participants, two WET-S sessions per day may be considered to complete the protocol prior to discharge if possible. However, if participants are discharged from inpatient care prior to completing the WET-S protocol, WET-S will continue using a secure HIPAA-compliant video telehealth platform.

WET-S treatment also includes the development and monitoring of a Crisis Response Plan (CRP) for suicide risk. Participants assigned to WET-S will complete the CRP prior to beginning their writing in session 1. Patient use of the CRP since the previous session will be briefly reviewed at the start of each WET-S session to manage safety and problem solve fluctuations in risk during treatment.

<u>Treatment As Usual (TAU).</u> The TAU condition consists of daily contact and patient centered care by the acute psychiatric inpatient unit provider team (e.g., psychiatrists, therapists, case managers, behavioral health techs). TAU includes initial psychiatric stabilization, nurse case management, medication management, psychoeducation groups, and discharge planning. Patients engage with the provider team daily and have structured times for psychoeducation groups, case management, medication management, hygiene, and meals.

7.2 Drugs, Dietary Supplements, Biologics, or Devices. N/A

7.3. Study Procedures/Research Interventions.

Study Procedures	Baseline	Post-BL (w/in 48 hrs of baseline)	Post-Treatment session	1-Mo FU+/- 1 week	4-Mo FU +/- 3 weeks
Informed Consent	X				
Randomization		X			
1. Supplemental Demographics Form	X				
2. Military Suicide Research Consortium (MSRC) Demographics	X				
3. MSRC Common Data Elements	X			X	X
4. Health Questionnaire	X			X	X
5. Self-Injurious Thoughts and Behaviors Interview (SITBI)	X			X	X
6. Depression Symptom Index-Suicidality Subscale (DSI-SS)	X		X	X	X
7. Clinician Administered PTSD Scale (CAPS-5)	X			X	X
8. Life Events Checklist for DSM-5 (LEC-5)	X				
9. PTSD CheckList-5 (PCL-5)	X		X	X	X
10. Risk and Resilience Inventory (DRRI-2) Subscales: - Combat Experience - Post-battle Experiences	X				
11. Monetary Choice Questionnaire	X		X	X	X
12. Suicide Cognitions Scale – Short Form (SCS-S)	X		X	X	X
13. Posttraumatic Cognitions Inventory (PTCI)	X		X	X	X

7.3.1 Collection of Human Biological Specimens. N/A

7.3.2 Data Collection.

7.3.2.1 <u>Instrumentation</u>. See the table in Section 7.3 for a summary of the assessments and timing of administration. A description of each of the assessments can be found at the end of this protocol. Assessments will be administered via a secure HIPAA-compliant video telehealth platform, phone, in person, 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 follow up assessment.

7.3.2.2 <u>Data Storage, Access and Protection</u>

Interviews and treatment sessions will occur using a secure HIPAA-compliant video telehealth platform. Data will be stored by an assigned participant code number so the data records can be viewed only by password-authenticated, authorized investigators and study personnel. Recordings will be labeled with 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 Biostatistics and Data Management Core staff will have access to either the raw data or electronic study data. Any hard copies of data collected during treatment will be placed into a lock box which will be transported by car to the UTHSCSA STRONG STAR offices by a STRONG STAR staff member who will place it into the locked cabinets at the STRONG STAR offices.

Data will be entered into the STRONG STAR password protected database housed on a secure UTHSCSA server (physically located at the Centralized Computing Facility) by member of the research team. Electronic data will be stored, managed, and analyzed by the STRONG STAR – CAP Data and Statistics Core staff of the STRONG STAR consortium. The overall PI and named collaborators will have access to identifiable data 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. STRONG STAR data server is physically located at the Advanced Data Center (ADC) has 24x7 onsite security, card key, biometric access controls and video surveillance. University of Texas Health Science Center at San Antonio (UTHSCSA) ADC facility also maintains Gen 2 firewall devices to protect and prohibit any unauthorized 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.

Only select 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 Core staff.

This is a single-site study; all study procedures with human subjects will be conducted at the Carl R. Darnall Army Medical Center (CRDAMC) on Ft Hood in Texas by UTHSCSA employees in collaboration with the active duty or GS On-Site collaborator.

Every member of the Research Team will be trained and monitored about how to handle and protect both medical and research record in the context of video telehealth appointments. Furthermore, the Research Team strictly controls access to study data.

Additionally, as a requirement of the funding of this study by the Military Suicide Research Consortium (MSRC), the research team is required to administer the MSRC Common Demographics (CDem) and Data Elements (CDE) and upload a limited data set (with dates but without other identifiers) as a SPSS file to the MSRC website housed at Florida State University (FSU) under protocol number FSU HSC#2018.23936. Participants are notified of this as part of the consent and HIPAA authorization.

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.

7.3.3. Human Biological Specimen (Biomarker) Processing. N/A

7.4 Statistical Consideration

7.4.1 Sample Size Estimation. Based on our prior work, we expected WET-S to have a very large effect on both PTSD symptoms and suicide-related outcomes over and above TAU. However, to be conservative given tempered expectations in this yet unstudied population, we powered the study to detect small to medium sized effects for the group by time interaction. Power was estimated using Repeated Measures and Sample Size computer software, accessible at https://rmass.org. Assuming subject level randomization, a quadratic design matrix for the time effect, a 1-tailed alpha level of .05, desired power of .80, equal sized treatment groups at baseline, an overall expected 15% attrition rate, a stationary AR1 error correlation matrix starting at a modest r = .30, and desire to be able to detect at least a conventional small to medium sized effect (d = .35) at the final assessment, the desired total sample size we intend to recruit is N = 124 (n = 62/group), a feasible recruitment goal given the targeted population.

7.4.2 Primary (i.e., primary outcome variables) and secondary endpoints. The primary dependent variables for suicidality are the Self-Injurious Thoughts and Behaviors Interview (SITBI) interview and the Depression Symptom Index-Suicidality Subscale (DSI-SS) self-report. The primary dependent variables for PTS symptoms and PTSD are the Clinician Administered PTSD Scale (CAPS-5) interview and the PTSD CheckList-5 (PCL-5) self-report. Secondary endpoints include associated psychopathology (severity scores on measures of depression, general anxiety, anger, and PTSD-related cognitions)

7.4.3 Data Analyses. To examine hypothesis 1 (determine if WET-S + TAU reduces presence (past month), frequency, and severity of suicidal ideation, suicide plans, suicide gestures, suicide attempts, and non-suicidal self-injurious behaviors and re-hospitalizations related to suicidality relative to TAU only and hypothesis 2 (determine if WET-S + TAU

reduces PTS symptom severity relative to TAU only) , we will conduct intent-to-treatment (ITT) analyses including all randomized participants who attend at least the first therapy session. General or Generalized Linear Mixed Effects models, depending on the nature of the specific outcome, will be implemented for the primary ITT randomized comparison of total CAPS-5 scores as well as SITBI variables of interest and number of subsequent inpatient hospitalizations for suicidal behavior. The planned statistical design includes fixed effects for treatment (between-groups), time (within-subjects), and the group by time interaction. This latter effect captures differences in changes over time between the groups; as such it is the effect of substantive interest in each of the models that will be examined. Advantages of the general(ized) linear mixed effects model include the ability to include cases with missing data (assumed missing at random), flexible specification of the covariance structure among the repeated measures, the ability to model nonlinear trajectories of change over time, and the ability to perform between- and within-groups contrasts both at and across assessments to examine significant group by time interactions. Prior to performing statistical analyses, the data will be inspected to determine the advisability of scale transformation to normalize distributions (where applicable) or reduce variance heterogeneity and to identify missing data, outliers, or other unusual features that may be influential. To test hypothesis 3, growth curve modeling will be used to examine mediation. Specifically, treatment condition will be entered as a predictor of change in both PTS symptom severity and suicide related outcomes. To achieve mediation, WET-S +TAU would achieve superior reductions in suicide related outcomes and PTS symptom severity relative to TAU only. Finally, we will examine the indirect effect of treatment condition on suicide related outcome change via PTSD symptom change. Identification of an indirect effect would allow us to conclude that WET-S + TAU's superior effect on suicide risk relative to TAU only is mediated by changes in PTS symptoms.

7.7 Confidentiality. All video telehealth therapy sessions and interview assessments will be conducted in private offices in the CRDAMC acute inpatient psychiatry unit and then via video telehealth from a private location of the participant's choosing once the participant is discharged from inpatient care. All assessment interviews and WET-S treatment sessions speaking with the therapist will be recorded using an audio-recorder external to the HIPAA compliant telehealth platform. Recordings will be labeled with the participant's study ID number.
The recordings will be uploaded to a secure password protected server immediately after the session is completed. The recording will then be deleted from the recorder. Study staff will be responsible to upload the audio-recording as soon as possible and then deleting the recording from the audio-recorder.

7.7.1 Certificate of Confidentiality. We are not seeking a Certificate of Confidentiality.

7.7.2 Long Term Data Storage. 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 posttraumatic stress disorder (PTSD), insomnia, pain, and 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 Data Management and Biostatistics Core of the STRONG STAR Consortium. A unique, sequential alpha-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 Management and Biostatistics Core. At the conclusion of this study, 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*, at the conclusion of the study their data will be de-identified and the data maintained in the Repository without identifiers.

8.0 RISKS/BENEFITS ASSESSMENT

8.1 Risks.

Likely but not Serious (expected to occur in more than 1 in 5 participants):

- Participating in mental health treatment and research might increase some symptoms and increase the risk of feeling emotionally uncomfortable in the short term, which might increase the desire for suicide temporarily. This increase is usually not severe, however, and does not last long. Preliminary work with these interventions suggest participants typically experience decreased emotional distress immediately afterwards.

- Possibility of becoming emotionally upset or experiencing an initial increase of PTSD symptoms due to the discussion or journaling of traumatic events.

Rare and Serious (expected to occur in less than 5 out of 100 participants):

- With the handling of medical and research records there is always the possibility of a breach of confidentiality. However, every effort is made to protect the privacy of participants. Every member of the research team is carefully trained and monitored about how to store, handle, and protect participant records.
- Assessment and therapy sessions that are conducted via video telehealth are subject to risks to confidentiality if others in the CRDAMC inpatient ward or home or other location can hear what is being said during the encounter. To minimize this risk, while in the inpatient ward participants will be placed in a private room while monitored by a CRDAMC staff member when doing study activities. When the patient is completing a video telehealth therapy session or assessment following discharge from the inpatient ward, participants will be encouraged to use headphones and to find a quiet area of the home to hold the encounter. Also, although video telehealth sessions are transmitted securely, there is always a risk that others (not affiliated with this research) could breach the network security systems and access the information. Ensuring that the participant has a virus protection on his or her computer will minimize this risk.
- It is possible that technical difficulties will result in missing a scheduled treatment session. The research team will work closely with participants to solve technical problems to minimize missed treatment time and also to re-schedule and conduct missed treatment sessions as soon as possible.

Risks of Suicidality Thoughts and Behaviors or a PTSD Diagnosis regardless of Treatment. One of the risks of suicidality thoughts and behaviors as well as PTSD both in and out of treatment is attempted suicide, which can result in death. Prior research has shown that, following a suicide attempt, up to half of patients in treatment make another suicide attempt. If the suicide attempt occurs within the first year of treatment, on average a patient will attempt suicide 2.5 times. However, safeguards for protecting participants are planned as described below.

Safeguards for Protecting Participants.

Because encounters will be conducted through video telehealth while the participant is on the inpatient ward, a CRDAMC staff member will monitor the visit while also allowing for privacy. Following discharge, when engaged in video telehealth sessions, participants will be asked to provide the name, phone number and address of a participant support person who is at least 18 years of age, able to be contacted by phone and can arrive to the participant's location within 30 minutes in an emergency.

Any indication that the participant is considering suicide will be handled following care facility SOPs and using processes developed by military and civilian consultants to the STRONG STAR Consortium. Trained clinicians and evaluators will assess history of suicide and current suicidal ideation using standardized measures. Treatment that takes place while the participant is on the inpatient unit includes standard procedures within the unit for managing suicide risk and is a treatment milieu focused on managing acute suicide risk. Any treatment sessions or assessments completed in outpatient care via video telehealth will follow standard suicide risk management procedures. CRDAMC acute inpatient psychiatric unit has a standard operating procedure for managing suicide risk after discharge that includes scheduled a written safety plan for patients and behavioral health appointments for follow-up care and medication management within CRDAMC outpatient Department of Behavioral Health. When participants are seen by study staff, severe suicidal ideation could also be addressed through the development of a Crisis Response Plan and/or referral to local resources for additional information. Priority will be given to referring patients to the CRDAMC outpatient Department of Behavioral Health.

Our study will mitigate risk for possible increased emotional distress by obtaining ratings of mood and suicidal intent on a recurrent basis from all study participants and taking action as clinically indicated. Preliminary data further suggest that the procedures used in this study are associated with immediate decreases in emotional distress and/or increases in positive emotions among high-risk military personnel.

To mitigate risk associated with loss of confidentiality, we have ensured that all procedures and data storage methods are secure. Access to data is restricted to research staff on an as-needed basis, research staff are trained regularly in confidentiality and privacy issues, research staff participate in weekly supervision, and quality assurance checks are conducted annually.

Research Monitor.
Vanessa Green, D.O. will serve as the DoD Independent Research Monitor. The duties of the research monitor shall be determined on the basis of specific risks or concerns about the research. The research monitor may perform oversight functions (e.g., observe recruitment, enrollment procedures, and the consent process for individuals, groups or units; oversee study interventions and interactions; review monitoring plans and UPIRTSO reports; and oversee data matching, data collection, and analysis) and report their observations and findings to the IRB or a designated official. The research monitor may discuss the research protocol with the investigators, interview human subjects, and consult with others outside of the study about the research. The research monitor shall have authority to stop a research protocol in progress, remove individual human subjects from a research protocol, and take whatever steps are necessary to protect the safety and well-being of human subjects until the IRB can assess the monitor's report. Research monitors shall have the responsibility to promptly report their observations and findings to the IRB or other designated official.

8.2 Potential Benefits. Potential benefits of participation in this study may include a reduction in self-injurious thoughts and behaviors and PTSD symptoms over the course of therapy. Our primary goals are to treat participants to reduce long term suicide risk and to the point of symptoms reduction below the level of diagnostic criteria for PTSD. In addition, the knowledge gained from this study will serve to inform the most effective early interventions for the prevention and treatment of suicide risk and PTSD.

8.3 Alternatives. Mental health treatment for both suicidality and PTSD is available via video telehealth at CRDAMC through the Department of Behavioral Health (DBH) including various forms of psychotherapy and drug treatments. Service members and veterans can access treatment for suicide risk and PTSD from the DBH as well as through Army One-Source and may be eligible for care at one of the Veterans Healthcare System facilities or clinics. Not participating in the study is also an alternative.

9.0 ADVERSE EVENTS, UNANTICIPATED PROBLEMS, AND DEVIATIONS

9.1 Adverse Events will be assessed and monitored according to the established STRONG STAR SOP and the IRB of record's policies and procedures.

9.2 Reporting Adverse Events, Unanticipated Problems Involving Risks to Subjects or Others (UPIRSOs), and Deviations to the Office of the IRB. All adverse events, unanticipated problems involving risk to subjects or others, and deviations will be reported to the Institutional Review Board (IRB) in accordance with current IRB policy. UPIRSOs and recurrent non-compliance with study procedures will be reported promptly to the IRB. All adverse events that do not meet the UPIRSO criteria and deviations that are not non-compliance will be summarized at Continuing Review per the IRB of record's policy.

10.0 WITHDRAWAL FROM STUDY PARTICIPATION

Participants may withdraw themselves from this study at any time and for any reason. Withdrawal from this study does not affect the participant's eligibility for care or any other benefits to which entitled. Participants who request to discontinue treatment, but who do not choose to withdraw from the study completely, will be asked to return for the post-treatment assessments. If a participant stops attending treatment sessions without notifying research staff, the therapist or project coordinator will make diligent attempts to contact the person to evaluate their status, attempt to re-engage them in the treatment, and encourage them to complete follow up assessments. Research staff will also refer to appropriate outside resources if necessary. Investigator may choose to withdraw a participant after consultation with the treating therapist and other consultants as appropriate in instances not limited to:

- Patient is noncompliant with treatment requirements
- Patient is in need of more intensive treatment
- Patient's symptoms worsen significantly
- Patient experiences a serious adverse event that is clearly related to the treatment
- Unexpected unavailability of a treating therapist

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12.0 TIME REQUIRED TO COMPLETE THE RESEARCH (including data analysis). Approximately 3 years from the time participant recruitment starts.

13.0 STUDY CLOSURE PROCEDURES

At the completion of the study a protocol closure report will be submitted for review. At the time of study closure, all links between PHI and the study data will be destroyed unless the participant has also agreed to participation in the STRONG STAR Repository approved by the UTHSCSA IRB (HSC20100475H). Informed consent documents and the HIPAA authorizations will be kept for 6 years past the closure of the study IAW 32CFR219 and IAW 45 CFR160-164, before being destroyed.

14.0 Funding.

- The DoD to the Military Suicide Research Consortium at Florida State University managed by the Congressionally Directed Medical Research Program is funding this project.
- Florida State University then awarded a subcontract for this specific project to the Boston VA Research Institute (BVARI), PI: Brian Marx PhD.

- BVARI in turn awarded a subcontract to UTHSCSA for this specific project, PI: Alan Peterson.

15.0 Description of Assessments:

1. Supplemental Demographic Form_v1.0 : The Demographics Form queries eight standard demographics and military service information not part of the Military Suicide Research Consortium (MSRC) Common Demographics (e. g., height, weight, military grade, type of military service, etc).

2. Military Suicide Research Consortium (MSRC) Common Demographics: The MSRC Common Demographics (CDem) were developed by the MSRC. As a requirement of funding, the research team is required to administer these questionnaire and upload a limited data set (with dates but without other patient identifiers) as a SPSS file to the MSRC website. The MSRC Common Demographics is a 32 item self-report questionnaire compromised of questions related to standard demographics (race, gender, age) and military service information (e.g., rank).

3. Military Suicide Research Consortium (MSRC) Common Data Elements: The MSRC Data Elements (CDEs) were developed by the MSRC. As a requirement of funding, the research team is required to administer these questionnaire and upload a limited data set (with dates but without other patient identifiers) as a SPSS file to the MSRC website. The MSRC CDEs is a 91 item self-report questionnaire compromised of questions related to self-injurious thoughts, behaviors and related psychopathology.

4. Health Interview: The original Health Care Utilization (HCU) is a 16-item questionnaire developed in 2000 for Dr. Patricia A. Resick's NIH grant, "Cognitive Processes in PTSD: Treatment II." The questionnaire was based on the 1999 Behavioral Risk Factor Surveillance System. The version that will be administered as part of the STRONG STAR Consortium has been modified to be of increased relevance to active duty service personnel. The measure includes items regarding use of mental health services, current psychiatric medication, past psychiatric medication, hospitalization, and outpatient medical services, as well as items intended to assess changes in participants' military status. Tobacco/nicotine use will also be queried.

5. Self-Injurious Thoughts and Behaviors Interview (SITBI): The SITBI (Nock, Holmberg, Photos, & Michel, 2007) is a structured interview assessing the presence, frequency, and characteristics of self-injurious and suicidal thoughts and behaviors. The SITBI will be administered by an Independent Evaluator, who will instruct the participants to answer the questions based on their entire lifetime of experience. The SITBI has shown high interrater reliability, test-retest reliability, and concurrent validity (Nock et al., 2007).

6. Depressive Symptoms Index-Suicidality Subscale (DSI-SS): The DSI-SS (Metalsky & Joiner, 1997) will be used to assess current suicidal ideation. The DSI-SS is a 4-item self-report measure of suicidal ideation that focuses on ideation, plans, perceived control over ideation, and impulses for suicide. It is being used as a core measure in the Military Suicide Research Consortium. Scores on each item range from 0 to 3, with higher scores reflecting greater severity of suicidal ideation. Instructions will instruct the participants to respond based on the past two weeks (for baseline and follow up visits) or the past week (for interim assessment visits). A systematic review of measures of suicidal ideation and behaviors found that the DSI-SS had evidence of excellent internal consistency and concurrent validity (Batterham et al., 2014).

7. The Clinician Administered PTSD Scale for DSM-5 (CAPS-5; Weathers, Blake, Schnurr, Kaloupek, Marx, & Keane, 2012): 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. This interview is very similar to its predecessor, the CAPS for DSM-IV, which has been considered the gold standard for evaluating PTSD and demonstrated good reliability and validity (Weathers, Keane, & Davidson, 2001). In addition to reflecting diagnostic changes for PTSD in DSM-5, the CAPS-5 differs from the CAPS in that frequency and intensity ratings for each symptom are no longer scored separately, so the severity rating for each item determines whether a symptom is present or not. 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. Scores ≥ 25 indicate a probable diagnosis of PTSD.

8. Life Events Checklist-5 (LEC-5): The LEC includes a list of 24 potentially traumatic life events commonly associated with PTSD symptoms. The instrument was designed to facilitate the diagnosis of PTSD (Weathers, Blake, Schnurr, Kaloupek, Marx, & Keane, 2013a).). In this study, the LEC-5 will also be used to identify the index event and focus of the PTSD treatment. For each potentially traumatic life event, respondents rate their experience of that event on a 5-point nominal scale (1 = happened to me, 2 = witnessed it, 3 = learned about it, 4 =part of my job, 5= not sure, and 6 = does not apply). Each nominal point will be scored separately, as either 0 (=not endorsed by participant) or 1 (=endorsed by participant).

9. PTSD CheckList-5 (PCL-5): The PCL-5 (Weathers, et al., 2010) is a 20-item self-report measure update of the PCL designed to assess PTSD symptoms as defined by the DSM-5. The PCL-5 is currently available and has been shown to have good psychometric properties. The PCL-5 evaluates how much participants have been bothered by PTSD symptoms in the past month (for baseline and follow up assessments) or the past week (all interim assessments) as a result of a specific life event. Each item of the PCL-5 is scored on a five point scale ranging from 0 “not at all”) to 4 (“extremely).

10. Deployment Risk and Resiliency Inventory-2 (DRRI-2) Combat Experiences subscale and DRRI-2 Postbattle Experiences subscales:: The DRRI-2 (Vogt, et al., 2013) is a suite of 17 individual scales that assess key deployment-related risk and resilience factors with demonstrated implications for veterans’ long-term health. The Combat Experiences and Postbattle Experiences subscales will be used to assess stressful deployment experiences.

11. Monetary-Choice Questionnaire (MCQ): The MCQ (Kirby et al., 1999) 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. The measure is scored by calculating where the respondent’s answers place him/her amid reference discounting curves, where placement amid steeper curves indicates higher levels of impulsivity.

12. Suicide Cognition Scale Short Form (SCS-S): The SCS-S is a 9-item self-report measure designed to assess suicide-specific thoughts and belief, with demonstrated reliability and validity with chronic pain patients (Bryan et al., 2016). The SCS-S evaluates how much an individual agrees with the suicide-related cognition. Scores on each item range from 1-5, with higher scores reflecting greater severity.

13. Posttraumatic Cognitions Inventory (PTCI): The PTCI is a 36-item questionnaire that was developed to determine how an individual views the trauma and its sequelae in an attempt to understand both how PTSD develops and is maintained (Foa, Elhers, Clark, Tolin, & Orsillo, 1999). Using an emotional processing theory, Foa and her colleagues (1999) have suggested that PTSD is a consequence of disruptions in the normal processes of recovery when an individual has excessively rigid concepts about self and world rendering the person vulnerable if a traumatic event occurs. Thus the PTCI was developed as a measure of trauma-related thoughts and beliefs. It is comprised of three subscales (Negative Cognitions about the Self, Negative Cognitions about the World, and Self-Blame). The measure was tested in almost 600 adult volunteers recruited from two university PTSD treatment clinics as well as a university community. Approximately 65% (n=392) of individuals reported having experienced a trauma in which their own life or that of another person was perceived to be in danger and their response at the time included intense terror, horror, or helplessness (Criterion A event). The remaining 35% (n=162) denied such a traumatic experience. Of those who had experienced a trauma, 170 had PTSD symptoms of at least moderate severity while the remaining 185 reported a low symptom severity. The three subscales of the PTCI demonstrated internal consistency with alpha coefficients ranging from 0.86 to 0.97. Convergent validity was demonstrated comparing the PTCI to appropriate subscales of the World Assumptions Scale and Personal Beliefs and Reactions Scale. Significant correlations between the appropriate subscales ranged from 0.20 to 0.85. The PTCI was able to differentiate individuals with and without PTSD demonstrating discriminate validity (sensitivity = 0.78, specificity = 0.93). Test–retest reliability for each of the three subscales at a 1-week interval ranged from 0.75 to 0.89 and for a 3-week interval ranged from 0.80 to 0.86.