Study Protocol

Study Title: Narrative Exposure Therapy for Justice-Involved Veterans

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Background, Significance, and Specific Aims

Data from the National Vietnam Veterans Readjustment Study found that nearly half of all Vietnam combat Veterans with posttraumatic stress disorder (PTSD) had been arrested one or more times (Center, 2008), and several more recent studies have identified combat exposure, PTSD, and combat-related moral injury as predictors of criminal justice involvement and violence in Veterans of the wars in Iraq and Afghanistan (Angkaw et al., 2013; Dennis et al., 2017; Elbogen et al., 2012; Elbogen et al., 2014; Jakupcak et al., 2007; MacManus et al., 2015; Van Voorhees et al., 2016). Finally, childhood maltreatment has been identified as risk factor for violent crime in both Veterans and non-Veteran samples (Flanagan, Teer, Beylotte, Killeen, & Back, 2014; WIDOM, 1989), and research has found higher rates of childhood abuse and other adverse childhood experiences in Veterans compared to their civilian counterparts (Blosnich, Dichter, Cerulli, Batten, & Bossarte, 2014; Zinzow, Grubaugh, Monnier, Suffoletta-Maierle, & Frueh, 2007).

A body of research has evolved outside of the U.S. for a type of trauma focused therapy, Narrative Exposure Therapy (NET), which was specifically developed for survivors of organized violence (Alghamdi, Hunt, & Thomas, 2015; Bichescu, Neuner, Schauer, & Elbert, 2007; Crombach & Elbert, 2015; Ertl et al., 2011; Hermenau et al., 2013; Orang et al.; Robjant & Fazel, 2010; Schauer, Nuener, & Elber, 2011). NET also has a specialized adaptation, Narrative Exposure Therapy for Forensic Offender Rehabilitation (FORNET), designed to address the treatment needs of those who have committed acts of violence and struggle with community reintegration after wartime and/or incarceration. FORNET, in particular, explicitly calls into question the victim/perpetrator duality in its approach to interrupting the cycle of violence in traumatized offenders (Hecker, Hermenau, Crombach, & Elbert, 2015). This approach has been found to be effective in reducing PTSD symptoms and aggression in several contexts (Crombach & Elbert, 2015; Ertl, Pfeiffer, Schauer, Elbert, & Neuner, 2011; Hecker et al., 2015; Hermenau, Hecker, Schaal, Maedl, & Elbert, 2013; Hinsberger et al., 2017). The flexibility of having the option to use either NET or FORNET with U.S. military Veterans may be particularly powerful, given that this population is likely to have varying incidence of perpetration experiences.

Rationale for the Therapeutic Approach

Trauma focused therapy for PTSD: The fear network.

The majority of therapies currently employed to treat PTSD are based upon the *fear network* model which holds that traumatic experiences create a unique form of memory. In a traumatic memory, trauma-related cues become powerfully associated with a fear network comprised of sensory (sight of blood, smell of perpetrator), cognitive ("I will die", "I am helpless"), emotional (fear, anger), and physiological (heart racing, sweating) elements. Many of these elements of memory are stored pre-verbally, and trauma survivor's efforts to avoid thinking about traumatic material keeps these memories walled off from verbal processing. PTSD develops when the trauma memory remains walled off and is not integrated into autobiographical memory. Because the trauma memory remains unintegrated and thus unmoored from time, place, and context, triggers related to one element of the trauma memory (i.e. a smell reminiscent of the perpetrator, feeling the heart racing) can activate the entire fear network, even

in situations where there is no actual threat (Foa, Huppert, & Cahill, 2006; Schauer, Neuner, & Elbert, 2011).

The existence of the fear network forms the theoretical basis for one of the therapies for PTSD treatment that has received the most support, Prolonged Exposure Therapy (PE). PE seeks to recontextualize the trauma in time and place, with the therapeutic goal of reducing avoidance symptoms and preventing the maladaptive reactivation of the trauma-related fear network in the absence of threat (Foa et al., 2006; Schauer et al., 2011).

Some forms of PTSD-related aggression can also be accommodated by the fear network model. Reactive aggression, for example, is a form of aggression that occurs in the context of perceived threat, and is typically associated with impulsive lashing out in response to fear and negative affect. Cognitive biases associated with perceiving threat in ambiguous or neutral situations have been associated with both PTSD and with aggression (Taft, Creech, & Murphy, 2017; Taft et al., 2015), and in fact addressing these biases is a fundamental element of the Strength at Home Program for Veterans who have used violence in intimate relationships (Taft, Macdonald, Creech, Monson, & Murphy, 2016).

Narrative Exposure Therapy (NET): The fear network and chronic trauma

NET is an empirically supported therapy for PTSD that, like PE, is based upon the construct of the fear network as being fundamental to the development and maintenance of PTSD. NET differs from PE, however, in that it does not focus on a single index trauma, but rather takes a "lifeline" perspective that allows for the identification and processing of multiple traumatic events within a broader developmental context. This therapy was developed specifically to treat individuals with complex, cumulative trauma who live in low resource situations of ongoing instability or threat (Schauer et al., 2011). Several RCTs have demonstrated NET to be effective in treating PTSD and improving functioning in refugees, asylum seekers, former child soldiers, and demobilized combatants in war-torn areas, including those who have experienced high levels of cumulative trauma such as child maltreatment, war, genocide, and/or torture (Alghamdi, Hunt, & Thomas, 2015; Bichescu, Neuner, Schauer, & Elbert, 2007; Crombach & Elbert, 2015; Ertl et al., 2011; Hermenau et al., 2013; Orang et al.; Robjant & Fazel, 2010).

Brief description of NET. NET begins with a session of psychoeducation that reviews the symptoms of PTSD and how they develop, and provides the rationale for the therapy. In the second session patients create a "lifeline" using a rope or string to symbolize the flow of their lives from birth to the present, placing flowers along the rope to symbolize positive events or people in their lives, and stones to symbolize losses or traumatic events. Over the following 6 to 8 sessions, patients narrate the most important events of their lives as the therapist takes notes and asks questions to facilitate processing. When traumatic events are reached, the pace of narration is slowed, and the therapist encourages the patient to describe the event slowly and in great detail. The detailed narration of each trauma allows for processing of traumatic material so that it can be integrated into the broader life story, and so that it can be contextualized as an event that happened at a specific time and place in the past. In the context of social injustice or oppression, NET also offers the possibility of integrating other factors known to contribute to criminal behavior and/or violence into the broader personal narrative, including poverty (Markowitz, 2003), injustice (Beugré, 2005), and racial discrimination (Brody et al, 2006;

McCord & Ensminger, 2003; Simons, Chen, Stewart, & Brody, 2003).

As in other forms of exposure therapy, the session does not end until the patient's emotional response has peaked in intensity and the level of distress has begun to diminish. During each session, the therapist takes notes on the narration and the account is read back to the patient at the beginning of the next session. After corrections are made, the narration process continues until the entire lifeline is complete. The final session involves reconstruction of the lifeline, and discussion of hopes for the future. The patient is offered a copy of the written narration (Schauer et al., 2011).

FORNET: Trauma and aggression in the context of organized violence

FORNET was developed as an extension of NET for use with individuals who have both experienced and used violence. It is not uncommon for ex-combatants and traumatized violent offenders to report that their worst trauma involved harm to others (Hinsberger et al., 2017), and the commission of violent acts in war has been found to be associated with distress and impairment over and above the effects of PTSD (Dennis et al., 2017). Within the past decade the unique psychological sequelae that are associated with harming others in the context of war has begun to be studied under the construct of "moral injury" (Litz et al., 2009; Maguen et al., 2017). Pointing to the complexity of the relationship between trauma and aggression, there is evidence that combat Veterans can come to regard violence as appealing, even as they are traumatized by their own violent acts (Weierstall, Castellanos, Neuner, & Elbert, 2013).

Developed for situations where the victim/perpetrator duality is not clear cut, FORNET integrates social learning theory with a theoretical foundation that proposes a *hunting network* that operates in parallel to the *fear network* (Hecker et al., 2015). Human history is replete with examples where hunting behaviors or aggression against other humans has resulted in social and evolutionary advantages, and this has resulted in the developed of a reward-driven network where violence cues can elicit an approach or attack response (Hecker et al., 2015; Weierstall & Elbert, 2011). While the hunting network can include many of these same elements as the fear network, the associated affective valence is positive and can be associated with feelings of power, control, and self-efficacy. For example, the sight of blood and the feeling of the heart racing can be paired with cognitions of "I defeated the enemy" and "I am strong", and with emotions such as exhilaration, fascination, and excitement (Hecker et al., 2015; Weierstall & Elbert, 2011). Aggression associated with positive feelings is known in the literature as "appetitive aggression" (Weierstall & Elbert, 2011), an experience that in some military circles has been referred to as a "combat high" (Grossman, 1995).

The overlap between the fear and hunting networks in violence-related PTSD can give rise to some of the confusion and enduring psychological distress experienced by combat Veterans who have used violence in the context of war. Failure to integrate both the fear and the hunting network into processing of traumatic events involving harm to others may contribute to the higher rate of non-responders to trauma-focused therapy for PTSD among traumatized individuals with a history of violence (Stenmark, Guzey, Elbert, & Holen, 2014).

While over time the hunting network can become dominant as a mechanism of adapting to situations of ongoing violence, there appears to be a spectrum of appetitive violence even among those who have participated in situations of chronic violence and combat. Consistent with the construct of a "cycle of violence", high levels of appetitive aggression are most common in situations of the most severe and unrelenting violence, where ceasing to feel distress at others'

suffering may be self-protective (Weierstall & Elbert, 2011). In many cases, however, tension is likely to remain between fear and hunting networks, and the cultural prohibitions against harming others are likely to continue to be a part of an individual's identity. In such cases, PTSD symptoms, moral injury, and other trauma sequelae may be particularly severe. For example, in our own research with U.S. Veterans who had been deployed to Iraq or Afghanistan, we found that 14% of participants endorsed the item, "I came to realize during the war that I enjoyed violence" at a level of "sometimes" or "often", and that endorsement of this item was significantly positively associated with PTSD symptoms, moral injury, suicidality, aggression, depression, and trauma-related guilt.

Brief description of FORNET.

FORNET builds upon NET by nonjudgmentally acknowledging all emotions and experiences associated with experiencing and using violence, and by anchoring both the negative and positive aspects of these events firmly in the past. It seeks to "deconstruct" the hunting network by linking the positive elements of violence to a specific time and context, and by reinforcing the association of positive, appetitive emotions to more prosocial or socially acceptable activities in the present. FORNET also devotes specific attention to focusing on building an identity as a citizen, rather than a "criminal" or an "offender" (Hecker et al., 2015).

Much of the process of FORNET is similar to NET. FORNET begins with psychoeducation and building the rationale for the therapy, and patients build a "lifeline" of the flow of their lives from birth to the present. In addition to flowers symbolizing positive events and stones symbolizing loss or trauma, patients have the option to use sticks to represent situations in which they harmed another person. Sticks can be combined with flowers or stones to reflect the complexity of these situations. During the narration of events, the therapist helps patients to identify their feelings at the time, and to juxtapose those with their current feelings, firmly anchoring the events and all associated cognitions and affect in the past. After narration of such an event, the therapist can help patients identify the meaning of the events from their current point of view (Hecker et al., 2015).

In situations where someone has harmed another person more than once, the first event is often critical because it is most likely 1) to have required particular effort to overcome neurobiological and cultural aversion to harming others; and 2) to involve particularly salient awareness of personal vulnerability that contributed to the ability to overcome those inhibitions (Hecker et al., 2015; Weierstall & Elbert, 2011). Attention to these elements of the first event can be particularly important in helping individuals make meaning of this experience. At the end of each session, the patient and therapist focus on how their understanding of their history can inform what they want to make of their future (Hecker et al., 2015).

The final session focuses specifically on developing perspectives for the future, strengthening self-efficacy for engaging in a positive, values-driven life, and identifying positive people in patients' lives who care about their future. The final session also includes asking patients to recall a recent prosocial event where they experienced feelings of excitement, power, enjoyment, pride, or control, and to recount this in detail. Rather than continuing the story until the intensity of the emotion diminishes, however, the therapist stops the narration at the most exciting part. This experience is intended to prime the creation of a positive associative network with prosocial experiences, and to reinforce the sense that the patient can create positive experiences in the future that are aligned with an identity consistent with their values (Hecker et

al., 2015).

A New Approach to Trauma Treatment for U.S. Military Veterans: VETNET

Though there is limited research on factors that moderate the success of NET or FORNET with traumatized individuals who have used violence against others, the studies that do exist suggest that increased political or social stability, and perceptions of personal role change from "offender" or "combatant" to a more positive, pro-social community identity, may reduce the risk of recidivism (Kobach, Schaal, Hecker, & Elbert, 2017). The idea of integrating reparations with self-forgiveness and fostering reconnection with the community is also part of treatments for moral injury (i.e. adaptive disclosure; Litz et al, 2009) and is consistent with the principles of restorative justice (Latimer, Dowden, & Muise, 2005; Morrison & Ahmed, 2006).

Building upon the foundation of NET and FORNET, we propose to adapt these therapies for use with US military Veterans. Specifically, during the lifeline exercise the therapist will elicit discussion of what are often life-altering military-related events including military training, deployments, and separation from the military. Participants will be offered the option to use sticks to symbolize events where they harmed another person. If participants do not indicate that they have ever harmed another person, then the NET protocol will be used, though the possibility of using FORNET will be kept open if disclosure of harm is made later on in therapy. If participants do choose to use sticks in their lifeline, then the therapist will be alert to the possibility of needing to address moral injury or appetitive aggression by using adaptations specific to the FORNET protocol.

For all Veterans, whether the NET or FORNET protocol is used, therapists will include in the final session a component that will be unique to VETNET and that draws upon elements of Acceptance and Commitment Therapy (Hayes, 2004) and Adaptive Disclosure Therapy (Litz et al, 2009). This session will include an invitation to Veterans to consider how they will reconnect with their communities in ways that will build upon their strengths. The therapist will work with Veterans to identify their values, and how they would best act upon these values to contribute in meaningful ways to their communities. Examples could be working at an animal shelter, volunteering at a church, joining a Veterans' service organization, or volunteering for a community garden, homeless shelter, or Habitat for Humanity. The therapist will help Veterans identify clear behavioral goals for following through on these ideas. The end of the final session will also include an evaluation and referral to services the Veteran is eligible for, either within the VA or in the community, such as housing assistance, educational assistance, or employment training, to continue to support successful reintegration.

Specific Aims

The overall objective of this application is to gather data on the feasibility and acceptability of Narrative Exposure Therapy (NET) in a pilot sample of Veterans with PTSD and history of anger and aggression. We are also interested in evaluating whether the intervention has the potential to have an effect on key clinical outcomes, including PTSD symptoms, suicidality, substance abuse, and aggression.

The following **Specific Aims** have been developed for this project:

Aim 1: Evaluate study feasibility and treatment delivery procedures of Narrative Exposure Therapy (NET) in Veterans with PTSD and history of anger and aggression. Data gathered will include recruitment rates, drop-out rates, adverse event frequency and severity, participant engagement in treatment, and therapist fidelity.

Aim 2: Collect data on appropriateness of assessment measures of key clinical constructs in the Veteran population. Clinical outcomes evaluated will include PTSD symptoms, suicidality, substance abuse, and aggression.

Methods

Overview of Study Visits

This pilot feasibility trial will use a randomized controlled design to 1) evaluate and refine the treatment access and delivery procedures in a Veteran sample; 2) evaluate and develop procedures to ensure therapist fidelity; 3) evaluate the adequacy of outcome measures (i.e. distribution of scores, potential ceiling or floor effects); and 4) identify potential reasons for treatment adherence and treatment dropout.

Participants will be screened over the phone to determine whether basic inclusion criteria are met, after which they will be invited to an in-person screening visit at the laboratory. At the laboratory screening and baseline visit, informed consent will be obtained. Veterans who meet inclusion criteria will be assigned to NET

Study participation will include a baseline visit, participation in 10 weekly therapy sessions if randomized to NET a post-treatment follow-up visit, and completion of 3-month follow-up questionnaires by mail.

Participants

We expect that it will be necessary to complete a total of 29 in-person baseline assessments to enroll a final sample of 20 eligible participants. Based on Dr. Van Voorhees' previous pilot RCT enrollment rates, we anticipate 70% of those screened to be eligible for participation.

Table 2. Inclusion/Exclusion Criteria

Participants must meet **all** inclusion criteria:	Participants who meet **any** one of the exclusion criteria will be excluded:

• Is a Veteran; • Has a history of physical aggression; • Meets current criteria for PTSD.	• Currently incarcerated; • Current, active psychosis; • Is at imminent risk for suicide or homicide warranting immediate intervention; • Substance abuse that is severe enough to prevent full engagement in the study protocol; • Is unable to unwilling to complete study procedures. • Concurrent trauma-focused psychotherapy including Prolonged Exposure Therapy (PE), Cognitive Processing Therapy (CPT), or EMDR

Recruitment

Potential participants will be recruited through referrals by clinicians who work with Veterans with a history of aggressive behaviors, including Lucas Vrbsky, the Incarcerated Veterans Reentry Specialist for VISN 6; Courtney Ma'at, the Durham VAMC's Health Care for Reentry Veterans Specialist & Veteran's Justice Outreach Coordinator; Kathy Williams-Brown, the Interpersonal Violence Program Coordinator for the Durham VAMC; and Jeremy Brogden, the Veterans Justice Outreach Specialist for the Durham VAMC.

Clinicians working with these Veterans will introduce the study to them, using the attached IRB-approved clinician card as a guide. Similar to VA consults, a clinician can refer a participant directly to our clinic by adding the study PI or study coordinator as a co-signer to a note in CPRS in which the clinician has documented that the participant wishes to be contacted about participation. If Veterans are interested in participation, they will also be given a business card and brochure containing contact information for the study coordinator.

We also plan to use several other recruitment strategies. First, we will use VA Data Access Request Tracker (DART) requests to identify Veterans with PTSD who have attended at least one appointment in the Veterans Justice Outreach clinic to be mailed invitational letters informing them of this study. Second, the Durham VAMC is the primary site for the VISN 6 Mental Illness Research, Education, and Clinical Center (MIRECC), which focuses on Post-Deployment Mental Health of OEF/OIF/OND-era Veterans. As of February 2013, over 2,500 Afghanistan/Iraq era Veterans have participated in the VISN 6 MIRECC's study, the Study of Post-Deployment Mental Health (IRB# 00933). A majority of those Veterans have agreed to be re-contacted regarding participation in future research studies regarding post-deployment issues as part of their enrollment in the Re-Contact Database of the VISN 6 MIRECC Post-Deployment Mental Health Data Repository (IRB# 01706). Application to recruit from the Re-Contact Database of the VISN 6 MIRECC Post-Deployment Mental Health Data Repository will be made to the VISN 6 MIRECC Director (Dr. John Fairbank) in accordance with IRB and R&D approved data repository procedures. Third, Peter Tillman, the Chief of the Health

Administration Service the Durham VA Health Care System, has compiled a list of Veterans who were Other Than Honorably (OTH) discharged from service, and has agreed to share these lists with the study team. Veterans with OTH discharge status are at greater risk for suffering from psychiatric conditions, are at higher risk for suicide, and are more likely to have a history of incarceration than Veterans with honorable discharge status (Elbogen, et al, 2018; Reger et al, 2015). Veterans identified as having an OTH discharge status are eligible for participation in this study. Fourth, we plan to recruit from the Traumatic Stress and Health Laboratory's "Contact Database," IRB #1080; this database contains information about previous lab study participants who have agreed to be contacted about other studies for which they may qualify.

Any potential participant who is identified via a DART request, through the VISN 6 MIRECC Repository, via Mr. Tillman's list, or through the Traumatic Stress and Health Laboratory's "Contact Database" will be sent a recruitment letter that provides basic information about the study. The letter will inform Veterans that they will be contacted by phone in the coming days regarding their interest in participating in the study. In the letter, potential participants will be given an "opt-out" number to call in order to decline participation and/or further contact regarding participation. Seven business days after the mailing, Veterans who have not called the toll-free number to decline participation will be called by the study coordinator to request their participation in the research study.

Study staff members will perform random spot-checks of names and addresses on all letters prior to mailing. This will capture any sorting error that may have occurred during the preparatory procedures. Any person who contacts the study coordinator for more information about the study (whether it be through brochures, word of mouth, etc.) will be informed about the study using the IRB-approved telephone screen script.

Additionally, Jeremy Brogden, the Veterans Justice Outreach Specialist for the Durham VA Health Care System, receives notifications from the Durham and Pitt County jail staff and from mental health providers about Veterans who are in custody in these county jails. He also reviews weekly arrest records for Wake County and cross-references these with CPRS to identify Veterans in custody in Wake County. Mr. Brogden has agreed to share these lists with the study team. *We note that VA policy prohibits recruitment of Veterans while they are incarcerated*. Our study exclusion criteria also indicates that incarceration is an exclusion criterion. However, Mr. Brogden has noted that individuals in county custody are often quickly released, frequently within 24-hours of his becoming aware of their arrest.

Upon receiving these lists each week from Mr. Brogden, the study coordinator will use the VINE system (a publicly available network providing information regarding custody status) to ensure Veterans from Mr. Brogden's lists are no longer incarcerated prior to mailing IRB-approved recruitment letters to the Veterans' home addresses to invite them to participate. *Consistent with VA policy and with study inclusion/exclusion criteria, Veterans will only be eligible to participate after they have been released from custody*.

Seed recruitment is suitable for sampling "hidden populations" of participants who are best known by their own peers (Heckathorn, 1997). It includes providing incentives to participants

for referral of other eligible participants. In our model, each participant, or seed, will receive three coupons to recruit other Veterans in his/her social networks. The recruitment coupons will provide a brief description of the survey and a phone number for contacting the study coordinator. The coupon will be marked with a unique identification number (not the study identification number) so that when the coupons are returned to us, the ID number can be used to provide a small payment ($15) to the participant who made the referral. The key connecting the participant's study ID number with the seed ID number will be kept in a database separate from other PHI, creating two layers of separation between the seed ID and the already-participating Veterans' identifying information. Any Veteran who does not wish to recruit in this manner will not be required to do so.

Informed Consent, Screening and Baseline
Participants will be pre-screened over the phone to determine whether basic inclusion criteria are met. If the participant passes the phone screen, an in-person assessment/baseline visit will be scheduled.

At the in-person screening/baseline visit, informed consent with HIPAA authorization will be obtained prior to initiation of study procedures.

Screening.
The following measures will be used to determine eligibility criteria, and to gather baseline characteristics of the sample

Demographics Questionnaire – A demographics questionnaire will collect demographic information including age, race, education, military history, and history of justice-involvement.

The Traumatic Life Events Questionnaire [TLEQ; (E.S. Kubany et al., 2000)] is a brief self-report inventory that asks about exposure to 21 kinds of potentially traumatic events from natural disasters to sexual abuse. The TLEQ provides a 7-point response format to indicate frequency of occurrence. This instrument allows for detailed assessment of trauma exposure prior to military service, during military service, and following military service. TLEQ results in trauma exposure summary categories of combat, childhood sexual assault, childhood violence, adult sexual assault, attack, illness and accident. This measure will be administered at baseline to provide an index of the range of trauma exposure in the sample.

The Clinician-Administered PTSD Scale (CAPS) (F. W. Weathers et al., 2013) will be administered to evaluate for current PTSD at baseline and at follow-up. To minimize bias in outcomes evaluation, the clinician who conducts the therapy may administer the baseline CAPS, but will not administer the follow-up CAPS. The CAPS has been extensively used with Veterans, and its strong evidence of reliability and validity have established it as the "gold standard" for PTSD assessment. PTSD symptoms will be considered present based on the CAPS frequency ≥1/intensity ≥2 rule (Weathers, Keane, & Davidson, 2001). For Veterans with multiple traumas, CAPS administration will be modified as recommended by the authors of Narrative Exposure Therapy (Schauer et al., 2011). Specifically, rather that requiring Veterans to choose from among multiple events which is the most traumatizing, we will ask Veterans to identify a "type" of

trauma (sexual assaults), or a life period during which they experienced multiple traumas (i.e. combat deployment), upon which to evaluate their experience of PTSD symptomatology.

The Structured Clinical Interview for DSM-V Disorders Research Version (SCID; (First, Williams, Karg, & Spitzer, 2015)) (selected modules) will be administered to assess for active psychosis and severe substance abuse.

Diagnostic raters will be trained using SCID and CAPS standardized training, which includes review of interview manuals, training videotapes, and co-rating training with an experienced rater. Interrater reliability based on videotapes of patient interviews for Axis I diagnoses across previous studies has been excellent (kappa = .96).

Baseline measures.
If a Veteran is determined to meet inclusion criteria and agrees to participate in the study, the following baseline assessments will be administered. These assessments will also be administered at post-treatment and both mailed follow-ups, unless otherwise indicated.

The Appetitive Aggression Scale (AAS) (Weierstall & Elbert, 2011). This scale has two parts. Part 1 is a 17-item scale that asked participants to mark whether they have engaged in or witness specific violent acts. Fifteen of these items measure acts that could reflect appetitive aggression (e.g. "…made another person scream in pain"), and two are more clearly reactive (e.g. "...defended yourself in a fight"). If a participant endorses having engaged in any of the 15 potentially appetitive aggressive behaviors, then Part 2 will be administered. Part 2 is a 19-item scale that asks participants to rate their perceptions of aggression on a 5-point Likert scale ranging from 0 (disagree) to 4 (agree). Part 2 of the scale has been demonstrated to have acceptable reliability, and has been shown to measure a construct distinct from other conceptualizations of aggression (Weierstall & Elbert, 2011). This scale will only be administered at baseline and post-treatment.

Killing Cognitions Scale (KCS) (Maguen et al., 2017)
The KCS includes 55 items that evaluate several constructs identified as associated with distress in Veterans who have killed in the context of war. It is currently under psychometric evaluation by the authors; we have obtained permission to use it for this study from the primary author, Shira Maguen. This scale will only be used with participants who endorse having killed in the context of war on Part 1 of the Appetitive Aggression Scale (AAS).

PTSD Checklist for the DSM-5 (PCL-5) (Weathers et al., 2013). On the PCL-5, participants first report an autobiographical narrative of a trauma, and subsequently rate how bothered they were by each symptom (0 [not at all] – 4 [extremely]) for all DSM-V PTSD symptoms within the past week. Psychometric testing is currently underway on the newest version of the PCL; previous versions have been found to have high reliability and validity across trauma populations.

The Moral Injury Events Scale (MIES) (Nash et al., 2013). The MIES is an 11-item scale that measures moral injury associated with experiences during military service. Statements related to distress or feelings of betrayal related to potentially morally injurious events are rated on a 6

point scale ranging from 1 (strongly agree) to 6 (strongly disagree). Three factors have been identified: Transgressions-Self, Transgressions-Other, and Betrayal. In two samples of Army and Air Force personnel, Cronbach's alphas for the three scales ranged from .79 to .96, and results provided evidence of construct validity as well (Bryan et al., 2016).

Revised Conflict Tactics Scales (CTS2) (Straus, Hamby, Boney-McCoy, & Sugarman, 1996). The CTS2 includes 78 items measuring the use of psychological and physical attacks by the participant, as well as the experience of such attacks. Participants answer how often these behaviors were perpetrated against them within a specified time period, as well as how often they have perpetrated these aggressive behaviors over that same period: 0 (never); 1 (once); 2 (twice); 3 (3-5 times); 4 (6-10 times); 5 (11-20 times); 6 (more than 20 times). The original CTS2 indexed a time period of one year, and was specific to aggression with an intimate partner. Consistent with previous studies on Veterans and violence (Beckham et al., 1997), the original CTS2 instructions will be modified in 2 ways to more appropriately reflect the goals of this study: 1) the target of the behavior will be expanded from "partner" to "anyone"; and 2) the time frame of the response will be reduced from one year to three months to detect potential changes associated with treatment. The CTS2 includes the following subscales: Negotiation, Psychological Aggression, Physical Assault, Sexual Coercion, and Injury. Coefficient alphas for the CTS2 subscales range from .07 to .95, with good evidence of construct validity (Straus et al., 1996).

Dimensions of Anger Reactions (DAR) (Novaco, Swanson, Gonzalez, Gahm, & Reger, 2012). The DAR is a 7-item scale measuring the frequency, duration, and behavioral response to anger, and anger-related functional impairment on social relationships, health, and work. It was found to have concurrent and discriminant validity, and to correlate highly with measures of functional impairment, in a large sample of treatment-seeking soldiers who had served in Iraq or Afghanistan. The DAR will be administered at baseline, at each study visit, and at follow-up to provide information about the pattern of change in anger- and aggression-related cognitions over the course of the intervention.

Trauma-Related Guilt Index (TRGI) (Edward S. Kubany et al., 1996). Guided by appraisal theories of emotion, the 32-item TRGI is an index of guilt associated with the experience of trauma. Participants rate statements on a 5-point scale ranging from extremely true/extremely guilty (4) to not at all true/not guilty at all (0). Factor analyses has revealed four scales: Hindsight-Bias/Responsibility, Distress, Violation of Personal Standards, and Lack of Justification. Evidence of internal consistency and validity has been found in several samples.

Beck Depression Inventory (BDI-2) (Beck, Steer, & Brown, 1996). The BDI-2 is a 21-item scale that evaluates symptoms of depression. It is widely used both clinically and in research, and has been found to have high internal consistency (coefficient alpha = .91) with good evidence of convergent validity (Dozois, Dobson, & Ahnberg, 1998).

Acquired Capability for Suicide Scale - Fearlessness About Death (ACSS-FAD) (Ribeiro et al., 2014). The Interpersonal Theory of Suicide holds that the capacity to commit suicide requires a sense of fearlessness about death and an elevated pain tolerance, both of which can develop as a

result of repeated exposure to horrifying experiences involving pain or death. Such experiences are not uncommon in soldiers, theoretically increasing their risk for suicidal behavior. The ACSS-FAD is a 7-item scale that evaluates fearlessness about death. Participants rate each item on a scale of 0 (not at all like me) to 4 (very much like me). The scale has been found to have good reliability and validity (Ribeiro et al., 2014).

Depressive Symptom Index: Suicidality Subscale (DSI-SS) (Joiner, Pfaff, & Acres, 2002). The 4-item scale screens for suicidal ideation over the prior two weeks. Participants rate each item on a scale of 0 (e.g. "I do not have thoughts of killing myself") to 3 (e.g. "I always have thoughts of killing myself"). Strong evidence of reliability and validity has been observed for this scale (Joiner et al., 2002).

Interpersonal Needs Questionnaire (INQ) (Van Orden, Cukrowicz, Witte, & Joiner Jr, 2012). Based upon the Interpersonal Theory of Suicide (Joiner Jr et al., 2009), the INQ measures two proximal causes of the desire for suicide: Thwarted belongingness and perceived burdensomeness. Participants rate each of the 15 items on a scale of 1 (not at all true for me) to 7 (very true for me). Support for the reliability and validity of these scales has been observed across ages and in samples with varying degrees of psychopathology (Van Orden et al., 2012).

The Alcohol Use Disorder Identification Test (AUDIT) (*Bradley*, Bush, McDonell, Malone, & Fihn, 1998) contains 10 multiple choice questions about behavior and symptoms related to alcohol consumption. *The Drug Abuse Screening Test (DAST) (Skinner, 1982)* contains 20 "yes/no" questions about behavior and symptoms pertaining to substance use. Both the AUDIT and the DAST have shown excellent psychometric properties in studies of Veterans.

Study Visits

Three licensed clinical psychologists who have been trained by some of the original developers in Narrative Exposure Therapy will provide therapy in this study. As needed, consultation will be provided via telephone or video conferencing by national expert on NET, Liz Wieling, Ph.D., and/or by one of the developers of FORNET, Anselm Crombach, Ph.D.

Participants will attend 10 weekly study visits of 90 minutes each. Session one will involve a psychoeducation session wherein the symptoms and etiology of PTSD are explained, and the rationale for treatment is provided. Session two will include development of the lifeline, during which the participant provides an overview of their life using a rope or string as symbol of the passage of time. The participant places flowers along the rope to symbolize positive events or relationships, and stones to symbolize negative events or traumas. A key element of VETNET is that the therapist will elicit discussion of what are often life-altering military-related events including military training, deployments, and separation from the military.

While creating the lifeline, participants will be offered the option to use sticks to symbolize events where they harmed another person. If participants do not indicate that they have ever harmed another person, then the adapted NET protocol will be used, though the possibility of using FORNET adaptations will be kept open if disclosure of harm is made later on in therapy. If participants do choose to use sticks in their lifeline, then the therapist will be alert to the possibility of needing to address moral injury or appetitive aggression by using adaptations specific to the FORNET protocol. In sessions three through nine participants will narrate key

events in their lives, with specific focus on traumatic events as well as events when they harmed another person. During traumatic event narration, therapists will guide participants through slowly explaining the details of the event to allow for exposure and processing of previously avoided emotions, sensations, and thoughts. Therapists will encourage participants to stay in the trauma memory until anxiety, or other strong emotion, has peaked and has begun to subside. During narration of perpetration events, therapists will use a similar protocol, and will focus on contextualizing the perpetration event and contrasting the memory feelings (what was experienced at the time of the event) with the participant's feelings in the here and now while recalling the event. After each session, the therapist will create the written version of the narrative, and this will be read to the participant at the beginning of the following session. After the participant has made corrections or additions to the narrative, the process will proceed to the next critical event.

For all Veterans, whether the NET or FORNET protocol is used, therapists will include in the final session a component that will be unique to VETNET and that draws upon elements of Acceptance and Commitment Therapy (Hayes, 2004) and Adaptive Disclosure Therapy (Litz et al, 2009). This session will include an invitation to Veterans to consider how they will reconnect with their communities in ways that will build upon their strengths. The therapist will work with Veterans to identify their values, and how they would best act upon these to contribute in meaningful ways to their communities. Examples could be working at an animal shelter, volunteering at a church, joining a Veterans' service organization, or volunteering for a community garden, homeless shelter, or Habitat for Humanity. The therapist will help Veterans identify clear behavioral goals for following through on these ideas. The end of the final session will also include an evaluation and referral to services the Veteran is eligible for either within the VA or in the community such as housing assistance, educational assistance, or employment training, to continue to support successful reintegration.

In the final session, the lifeline will also be recreated. The participant will be invited to reflect on the meaning that they attribute to the events, and to develop perspectives for the future. The final session also includes asking the patient to recall a recent prosocial event where they experienced feelings of excitement, power, enjoyment, pride, or control, and to recount this in detail. Rather than continuing the story until the intensity of the emotion diminishes, however, the therapist will stop the narration at the most exciting part. This experience is intended to prime the creation of a positive associative network with prosocial experiences, and to reinforce the sense that the patient can create positive experiences in the future that are aligned with an identity consistent with their values.

To evaluate the change in PTSD symptoms over time, participants will be administered the PCL-5 and DAR at each session.

Participants randomized to TAU will be contacted by phone once each week by the study coordinator for a brief check-in and to complete a PCL-5 and DAR.

Post-treatment Follow-up Visits

In-person follow-up interviews and assessments will be conducted with each Veteran participant. Follow-up will occur 1 to 2 weeks after the final therapy session (for completers) or 11 to 12 weeks after baseline (for those who drop out) to assess changes in PTSD, perceptions of moral injury, anger, aggression, trauma-related guilt, depression, substance use, and suicide-related constructs. For those randomized to TAU, follow-up will occur 11 to 12 weeks after

baseline. The CAPS and all baseline assessments will be re-administered. The CAPS will not be administered by any of the study therapists. To assess the degree to which participants trusted and felt respected and understood by the therapist, the *Helping Alliance Questionnaire (Luborsky et al., 1996)* will also be administered at the follow-up visit.

Qualitative interviews following an interview guide will be administered to all participants. For those completed treatment, questions will evaluate treatment acceptability, as well as participants' impressions of whether and how the therapy was (or was not) helpful to them. For those who dropped out, reasons for dropout at each treatment phase will be explored. The qualitative portion of the post-treatment follow-up visit will be audio recorded using the Olympus DM-720 4GB Digital Voice Recorder or the Olympus DM-620, which are newer models of the approved-for-use Olympus DM-420. Recordings will be transcribed and analyzed using thematic analysis.

Three-month Follow-up

Three months after the final treatment session, packets of questionnaires including the baseline measures will be mailed along with a self-addressed, stamped return envelope, to participants regardless of drop-out status.

Measure	Screening	Baseline	Post-treatment	3 months
Demographics Questionnaire	X			
The Traumatic Life Events Questionnaire	X			
The Clinician-Administered PTSD Scale	X		X	
The Structured Clinical Interview for DSM-V (Psychosis, Substance Misuse Modules)	X			
The Appetitive Aggression Scale		X	X	
The Killing Cognitions Scale*		X	X	
PTSD Checklist for the DSM-5 (PCL-5)**		X	X	X
The Moral Injury Events Scale		X	X	X
Revised Conflict Tactics Scales		X	X	X
Dimensions of Anger Reactions		X	X	X
Trauma-Related Guilt Index		X	X	X
Beck Depression Inventory		X	X	X

Acquired Capability for Suicide Scale - Fearlessness About Death		X	X	X
Depressive Symptom Index: Suicidality Subscale		X	X	X
Interpersonal Needs Questionnaire		X	X	X
The Alcohol Use Disorder Identification Test		X	X	X
The Drug Abuse Screening Test		X	X	X
The Helping Alliance Questionnaire			X	

* The Killing Cognitions Scale will only be administered if participants endorse having killed in the context of war on Part 1 of the Appetitive Aggression Scale.
** To evaluate the change in PTSD symptoms over time, participants will be administered the PCL-5 at each session.

Evaluation of Specific Aims

Specific Aim 1. *Evaluate study feasibility and treatment delivery procedures of Narrative Exposure Therapy (NET) in with a history of aggression and PTSD. Data gathered will include recruitment rates, drop-out rates, adverse event frequency and severity, participant engagement in treatment, and therapist fidelity.*

To evaluate recruitment rates, we will track the number of Veterans who complete the in-person screening.. To evaluate retention rates, we will consider retention rates > 80% to be successful. Retention will be defined as completing at least 7 of 10 sessions, with the last sessions being a mutually-agreed upon final session. Retention strategies will include: 1) reminder calls, texts, and/or emails 24 hours prior to each study visit; 2) asking each participant at the end of each session about his or her intent to attend the next session; and 3) small appreciation gifts (e.g., pens, magnetized note pads, and thermoses). The second technique has been used successfully in previous clinical trials, and also provides information for assessing the assumption of ignorable attrition required for mixed effects analyses (Leon, Demirtas, & Hedeker, 2007). The third technique has proven extremely helpful in recent longitudinal studies, resulting in high retention rates (Elliott et al., 2015; Cook et al., 2015; Kimbrel, Meyer et al., manuscript in preparation; Kimbrel, Flynn et al., 2015). For those participants who drop out of treatment, we will 1) attempt to contact them to offer compensation for participation in the qualitative interview regarding their reasons for withdrawal and in the post-treatment assessments; and 2) encourage them to complete subsequent study assessments. Qualitative interviews will be audio recorded, and analyses will help identify ways that the intervention can be further tailored to reduce dropout and to meet the needs of justice-involved Veterans.

To facilitate therapist fidelity, consultation will be provided via telephone or video conferencing by national expert on NET, Liz Wieling, Ph.D, and/or by one of the developers of the NET adaptation for traumas involving harm to others, Anselm Crombach, Ph.D. Study therapists will evaluate treatment fidelity after every session using checklists specifically

developed for NET. This checklist will be adapted to maximize effectiveness in future trials over the course of this pilot.

To evaluate participant retention through the 3 month assessment, we will consider the larger RCT feasible if 70% of Veterans complete the 3 month assessment. As recommended by Wisniewski and colleagues (Wisniewski, Leon, Otto, & Trivedi, 2006), we will maintain frequent participant contact throughout the evaluation period. For example, we will make intermittent phone calls to participants to check on their status, and send birthday and holiday cards to encourage a sense of community and ownership of the study.

Adverse event monitoring is discussed in detail in the Human Subjects section of this proposal. Though we do not anticipate adverse events to be frequent or severe, if we observe a problem with adverse events we will build precautions into the structure of the treatment protocol and the study design.

Specific Aim 2. *Collect data on appropriateness of assessment measures for measuring key clinical constructs in Veterans with a history of aggression. Clinical outcomes evaluated will include PTSD symptoms, suicidality, substance abuse, and aggression.*

Change scores from baseline to 3 months post-baseline on the CAPS and on measures of PTSD symptom severity, perceptions of moral injury, anger, aggression, trauma-related guilt, depression, substance use, and suicide-related constructs will be calculated using the measures listed in the baseline section above. Measures will be evaluated for acceptable variability, and for absence of floor or ceiling effects in this sample.

Participant Payment

Veterans will receive $70 at screening baseline, $10 at each study visit for completion of assessment measure (PCL-5), and $80 at end-of-study follow-up. They will receive $35 for completing and returning 3-month follow-up questionnaires. Total possible compensation for full study participation will be $330.

For those study visits that occur in the research laboratory, participants in both arms may be provided with local bus passes in order to facilitate transportation.

Risk/Benefit Analyses

With regards to completing study measures, there is a risk of discomfort or distress in answering questions, especially questions related to traumatic experiences and PTSD symptomatology. There is also a risk of discomfort or distress during narration of traumatic experiences during therapy sessions. However, distress and discomfort related to questionnaire completion are usually temporary and well-tolerated. Distress associated with narrating traumatic events is not uncommon, but it is also usually temporary and well-tolerated, and the therapy protocol requires that the distress level be diminished before the end of each therapy session. There is a potential risk associated with the loss of confidentiality of study data.

Protection Against Risk

Participants are informed clearly during the initial informed consent process that the study is completely voluntary, and that they may refuse to answer any items that they do not wish to answer on the questionnaires and interviews. They are also informed that they are free to decline

participation in any procedure and can withdraw from the study at any time.

Please see "Privacy, Confidentiality, and Information Security" section for more detailed information regarding protections related to storage of electronic and hard data. To ensure confidentiality, all records will be identified by the participant's identification number, not by name. All raw hard copy data will be kept in a locked file cabinet in a locked room. Data files will be stored in a limited access folder on a secure server to which only study staff members have access.

Protections Related to Undue Influence

With regards to participant payments, careful consideration has been given to the risk of undue financial influence. Veteran participants can earn up to $330 for full participation. We believe that the payments proposed are commensurate with the participant burden in this study. Screening, therapy visits, and follow-up procedures are lengthy, and given that the catchment area for our facility is quite large, it is not unlikely that any employed participants will need to take an entire day off in order to travel to the VA and complete the study procedures. It is necessary to provide financial incentive for them to participate because the study does not guarantee personal benefits from participation. We believe that the payments proposed are appropriate given the time and effort being asked of the participants.

Data Safety and Monitoring Plan

The individuals responsible for data safety and monitoring will be Elizabeth Van Voorhees (PI) and the study coordinator. Mechanisms for monitoring and reporting of data safety and adverse events (AEs) will include ongoing participant contact via study personnel, to include check-ins about any adverse events, and weekly meetings between the PI and study personnel.

The PI will meet at least weekly with study personnel to discuss enrollment, participation, and any adverse events or unanticipated problems. Regular meetings between investigators, therapists and the project manager will allow for ongoing progress reports, including the number of participants currently involved in the study, attrition rates, and scheduled data collection from participants, as well as notification and review of any AEs. Safety monitoring for AEs will be conducted in real time by the PI and/or study coordinator. The following information about adverse events will be collected: 1) the onset and resolution of the AE, 2) an assessment of the severity or intensity (use existing grading scales whenever possible), 3) an assessment of the relationship of the event to the study (definitely, probably, possibly or not related), and 4) action taken (e.g., none, referral to physician, start or increase concomitant medication). The PI will determine the severity of the event, will assign attribution to the event, and will monitor the event until its resolution.

Any adverse events will be reported to the IRB in accordance with local guidelines. We will follow established laboratory procedures for reviewing events to determine if they meet criteria for reporting as an AE or SAE. In particular, we will pay close attention to any reports from participants regarding suicidal or homicidal ideation, or increases in aggression or mood dysregulation. Any such reports will be reported as required by our local Human Research Protection Program's research reporting Standards of Practice (SOP).

Based on the study team's long-term clinical and research experience with patients with high risk psychiatric disorders such as PTSD, depression, and anxiety disorders, we have developed IRB-approved standards of practice for psychiatric emergencies. These standards have been used for several years. It is not unexpected that participants will experience increased distress associated with the assessment procedures and diagnostic clinical interviews. Our extensive clinical and research experience suggest that there is no serious risk in these patients associated with assessment and interview procedures as proposed. Over the past several years, several hundred patients with psychiatric diagnoses have participated in our research team's clinical trials at DVAMC, and there have been only rare occurrences of serious adverse events (i.e., hospitalization only) due to temporary psychiatric symptom increases. For more information regarding our standards of practice, please see section "Psychiatric Emergencies" below.

Psychiatric Emergencies
The Traumatic Stress and Health Research Lab has established IRB-approved standards of practice (SOP) for the evaluation of risk of suicide and homicide. All study staff members are trained in use of the psychiatric emergencies SOP by a Ph.D. or Masters' level clinician with years of experience in working with persons with psychiatric disorders. The SOP includes a thorough risk assessment including evaluation of risk factors and protective factors associated with both suicide and homicide. Also included in the policy are differential recommendations for action based on determinations of low, moderate, or high risk. Any staff member conducting an interview in which moderate or high risk is determined will contact a senior staff person with clinical expertise in risk assessment (including the PI, co-investigator(s), and/or DVAMC's Psychiatric Emergency Clinic or the Emergency Department).

At several time points throughout the study, participants are reminded that they are asked to inform the study therapist, study coordinator, or study PI if they experience a psychiatric emergency such as homicidal or suicidal ideation. In addition, participants are provided the telephone number of study staff who they can call in the case of psychiatric emergencies, including an after-hours contact number.

COVID-19 Temporary Study Procedures
Participants who are ongoing at the time of the COVID-19 crisis will complete therapy and follow-up visits via phone and/or other approved telehealth platforms. Questionnaires will be completed by mail, orally, and/or MyHealthyVet. If enrollment continues during the COVID-19 crisis, study procedures will be completed in the same manner. The consent process will take place by mail and phone.

Safety Concerns. Study therapists will be informed that prior to beginning therapy by telephone or telehealth platform, participants will need to identify an emergency contact for the participant to be used only in true emergencies (e.g., medical crisis, high risk suicidal ideation). Second, therapists will be asked to confirm the participant's location at the start of every appointment (the exact address is ideal) in case they need to contact local emergency personnel in the case of a psychiatric or medical emergency. If any participant expresses suicidal or homicidal ideation (SI and HI, respectively), study staff will respond using a standard of practice that has been used

successfully in our lab's past telehealth-based trials. The study staff member responsible for the call will be instructed to gather more information from the participant, including information about plan, means, intent, intended victim (in the case of HI) and history of suicidal and homicidal behavior. Any participant who expressed SI will be provided with the suicide hotline number. The participant will be informed that the PI may contact him/her to talk more about his/her SI or HI. The study coordinator will obtain current contact information for the participant and inform the PI, who will contact the participant as necessary to ensure participant safety. In cases of imminent homicidality or suicidality, which are not anticipated, we will seek guidance from the Psychiatric Emergency Clinic on best strategies for follow-up, which could include, but is not limited to, self-presentation at the VA's emergency room with the help of an emergency contact, calling 911, or calling local police for a wellness check.

Post-Study Referrals for Participants
At completion of the post-treatment assessment, the study therapist will discuss referrals for further treatment or services with the participant. TSHRL has developed patient educational materials regarding available resources, including portable resource cards for Veteran participants. Veteran resources include peer support, local Vet Centers, and information about treatments available at various clinics at the DVAMC and local VA community-based outpatient clinics, including the PTSD Clinic, Mental Health Clinic, Mental Health Access Clinic, Psychiatric Emergency Clinic, and Women's Health Clinic. In addition, we provide information about non-Veteran specific resources such as local community mental health centers, local private mental health providers, and the treatment clinics at nearby Duke University Medical Clinic. Where applicable and convenient to the participant, direct referral will be made in addition to providing resource cards.

Privacy, Confidentiality and Information Security

1. Lists of Data Reviewed and/or Collected for Screening/Recruitment and Conduction of Study:

The Personal Health Information that will be obtained, used, and/or shared for this study includes:

Identifier(s)	Source(s) of Health Information
☒ Names	☒ Medical history & physical exam information
☒ All geographic subdivisions smaller than a State, including street address, city, county, precinct, and zip code. Describe: For the purposes of recruitment, potential participants' mailing address will be used to mail introductory letters. Participants' address will be used to request payment from VA Financial Services.	☒ Photographs, videotapes, audiotapes, or digital or other images
☒ All elements of dates (except year) for dates directly related to an individual, including birth	☐ Biologic specimens (e.g., blood, tissue, urine, saliva). Describe:

Identifier(s)	Source(s) of Health Information
date, admission date, discharge date, visit or treatment dates, etc.; and all ages over 89, Describe: Dates of study visits, dates of mental health treatment, & date of study consent will be obtained and stored. Date of study visits will be shared with VA Financial Services in order to pay participants for study participation.	
☒ Telephone numbers	☒ Progress notes
☐ Fax numbers	☐ Diagnostic / Laboratory test results
☐ Electronic mail addresses	☐ Operative reports
☒ Social Security Numbers	☐ Imaging (x-ray, CT, MRI, etc.)
☒ Medical record numbers	☐ Discharge summaries
☐ Health plan beneficiary numbers	☒ Survey / Questionnaire responses
☒ Account numbers	☐ Billing records
☐ Certificate and/or license numbers	☐ HIV testing or infection records
☐ Vehicle identifiers and serial numbers, including license plate numbers	☐ Sickle cell anemia information
☒ Device identifiers and serial numbers	☒ Alcoholism or alcohol use information
☐ Web Universal Resource Locators (URLs)	☒ Drug abuse information
☐ Internet Protocol (IP) address numbers	☒ Mental health (not psychotherapy) notes
☐ Biometric identifiers, including finger & voice prints	☒ Psychological test results
☐ Full-face photographic images and any comparable images	☐ Genetic testing
☒ Any other unique identifying number, linked study ID, characteristic, or code, describe: Study ID numbers	☐ Other, describe:

2. Data and/or Specimen Acquisition:
Data for this study will be collected through (*check all that apply*):

☒ Prospective data and/or specimen collection obtained from participants. Provide description of processes: Data will be obtained through standardized interviews regarding psychiatric symptoms, self-report questionnaires, and through qualitative interviews. Data are acquired at 14 time points (baseline, each treatment session (10 time points), post-treatment, 3 months, and 6 months).

☐ Retrospective data collection and/or specimens obtained from medical chart review/data access. Describe how data will be obtained (e.g., fileman, CDW, etc.): n/a.

☐ Retrospective data collection and/or specimens obtained from an IRB-approved data and/or specimen repository. Indicate the repository source including name, VA location, and IRB number: n/a.

Note: for data and/or specimens obtained from a VA approved data repository, a Data Use Agreement (DUA) must be executed prior to obtaining data and/or specimens. See VHA Handbook 1200.12 for further information.

3. Level of Data:
The following level(s) of data will be acquired/maintained for this study (*check all that apply*):

☒ Identified (e.g., names, addresses or other identifiers included)
☒ Coded (direct and/or all identifiers removed, but study code/ID included)
☐ De-Identified (all HIPAA 18 and study ID/code removed):
  ☐ Verified Statistically
  OR
  ☐ Verified by Absence or Removal of HIPAA 18 and study ID
☐ Limited Data Set
☐ Other: Describe:

4. Location of Data and/or Specimens, and Data Retention Plan:
Data and/or Specimen Location: Data will be stored electronically in \\v06.med.va.gov\dur\Research \Nicotine Research\Study Information\Study Logbooks\JIV_NET; \\v06.med.va.gov\dur\Research \Nicotine Research\Study Information\Study Databases\ JIV_NET; and \\v06.med.va.gov\dur\Research Nicotine Research\Study Information\Study Logbooks\JIV_NET\Qualitative Recordings. Data that will be stored electronically include name, address, phone number, social security number, amount of study payment earned, and dates of visits (in Study Logbooks location). The study logbook will contain the key connecting PHI and the study identification number. The qualitative recordings will include audio recordings of qualitative interviews with Veterans about their experience with the VETNET therapy. Questionnaire data and interview results will be coded and stored in the "Study Databases" location listed above. Paper records of data include study consent form and HIPAA authorization (identified) and self-report questionnaires and interview results (coded).

☒ Data will be also be placed at the VA Informatics and Computing Interface (VINCI; http://vaww.vinci.med.va.gov/vincicentral/VINCIWorkspace.aspx). The VA Informatics and Computing Infrastructure is a partnership between the VA Office of Information Technology and the Veterans' Health Administration Office of Research and Development. Researchers and operations staff can use VINCI to access data and statistical analysis tools in a virtual working environment through a certified VHA network computer using the VA Intranet or Virtual Private Network (VPN).

B. Data Retention Plan
☒ Research records will be maintained and destroyed according to the National Archives and Records Administration, Records Schedule Number: DAA-0015-2015-0004. Records destruction, when authorized, will be accomplished using the then current requirements for the secure disposal of paper and electronic records. Currently, destruction of research records (see DAA-0015-2015-0004, section 7.6 "Research Investigator Files" for materials included in research records) is scheduled for 6 years after the cut-off (the cut-off is the completion of the

research project) and may be retained longer if required by other federal agencies. Records will not be destroyed without pre-notification to the facility records manager.

☐ Other data retention plan, describe:

5. Data Access and Data Recipients:
Only members of our DVAMC research team will have access to identifiers and coded data. In order for data analysis to occur using SAS software (see "Data Analyses" below), a coded dataset will be sent to VINCI for analysis using VA-owned data analysis software (SAS). In the event that appropriate SAS modules for analysis are not available through VINCI, coded data will be moved to Duke University Medical Center for analysis. Any data movement outside the protected VA environment will be accomplished using a VA-issued and owned FIPS-140-2 encrypted thumb drive loaned to a VA study staff member or via FIPS-140-2 encrypted DVD. Data will be stored at Duke on a protected server to which only Dr. Van Voorhees and her study staff have access; data are encrypted at rest.

All VA research personnel who have access to VHA records are instructed, in accordance with VA policy, on the requirements of Federal privacy and information laws and regulations, VA regulations and policies, and VHA policy. All study personnel who are VA employees working within the VA system have fulfilled all required HIPAA and other VA security and privacy policy training requirements and have agreed to follow guidelines pertaining to the protection of patient data. All research staff sign VA Rules of Behavior, and all study staff are up-to-date with VHA Privacy Policy Training and the VA Office of Cyber and Information Security Awareness Training Course. The data security and privacy procedures summarized in that course include logging off or locking the computer when walking away from it; no sharing of access codes, verify codes or passwords; not allowing anyone else to use the computer under one's password; and disposing of sensitive information using VA-approved methods (e.g., shredder bins). Access to study data will be removed for all study personnel when they are no longer part of the research team.

6. Data and/or Specimen Transportation and/or Transmission for all data and/or specimens involved in the study:

I. ☐ Data and/or specimens will <u>not</u> be transported or transmitted outside of Durham VAMC environment. **n/a**

II. ☐ Data and/or specimens will be transported BETWEEN sites that are under the auspices of the Durham VA Medical Center. **n/a**

III. ☐ Data and/or specimens will be transmitted to <u>other VA sites</u> using the following method(s): **n/a**

A. Data

☐ Data are de-identified and thus will be sent via unencrypted e-mail or unencrypted disk (encryption is optional).

☐ Data are coded or contain identifiers and thus will be sent ☐ Other, describe:

B. Specimens

☐ Specimens are de-identified and thus will be sent via standard carrier (tracking is optional).

☐ Specimens are coded or contain identifiers and thus will be sent via VA-authorized carrier with tracking.

☐ Other, describe:

IV. ☒ Data and/or specimens will be transported to non-VA/VHA sites (e.g., academic affiliates, laboratories, etc.) using the following method(s):

A. Data

☐ Data are de-identified and thus will be sent via unencrypted e-mail or unencrypted CD.

☒ Data are coded or contain identifiers and thus will be sent via a VA-issued and owned FIPS-140-2 encrypted flash drive loaned to a VA study staff member or via FIPS-140-2 encrypted DVD. If any carrier is used to transfer data, we will use a VA-approved carrier with tracking.

☐ Data are coded or identified and will be sent via the Safe Access File Exchange (SAFE) at https://safe.amrdec.army.mil/safe/. SAFE is a secure method of exchanging files <2GB to and from individuals with a valid .gov, .mil, .com, or .edu email address. <insert information including collaborator name.

☐ Data are coded or identified and will be uploaded to sponsor website using electronic case report form (eCRF)

☐ Other, describe:

B. Specimens

☐ Specimens are de-identified and thus will be sent via standard carrier (tracking is optional) or will be hand-delivered by research study personnel. Specify method of delivery:

☐ Specimens are coded and thus will be sent via VA-approved carrier with tracking or will be hand-delivered by research study personnel. Specify method of delivery:

In accordance with the HIPAA and the Privacy Act, for any coded or identifiable data released from the Durham VAMC (with the exception of Limited Data Sets), an Accounting of Disclosure (AOD) will be maintained (e.g., in a database or spreadsheet) that includes the participant's name, date of the disclosure, description of the nature of the Individually Identifiable Information (III) disclosed, purpose of each disclosure, and the name and address of the person/agency to whom the disclosure was made.

C. ☐ Local DVAMC memorandum "Authorization to Use, Process, Store, or Transmit VA Sensitive Information Outside VA Owned or Managed Facilities" has been pre-filled out for each study team member who may transport the data and/or specimens off-site. This (these) forms are included with the IRB materials.

D. ☐ Containers (e.g., briefcase, bin) are labeled with the following notice (label placed on the outside of container) in accordance with VHA Directive 6609:

NOTICE!!!

Access to these records is limited to: AUTHORIZED PERSONS ONLY. Information may not be disclosed from this file unless permitted by all applicable legal authorities, which may include the Privacy Act; 38 U.S.C. §§ 5701, 5705, 7332; the Health Insurance Portability and Accountability Act; and regulations implementing those provisions, at 38 C.F.R. §§ 1.460 – 1.599 and 45 C.F.R. Parts 160 and 164. Anyone who discloses information in violation of the above provisions may subject to civil and criminal penalties.

V. ☐ We will communicate with Veterans enrolled as participants in this research study through MyHealtheVet.

7. Risk Mitigation Strategies:

☐ Data are fully de-identified (stripped of HIPAA 18 and study ID/code) before being shared outside of Durham VAMC.

☐ Specimens are fully de-identified (stripped of HIPAA 18 and study ID/code before being shared outside of Durham VAMC.

☒ Direct identifiers will be maintained separately from data and or specimens by using a code to "identify" subjects. In a separate database (i.e., a "linking" or "cross-walk" database) this code will be linked to identifying subject information. Persons responsible for overseeing the privacy and security of the study data are the PI, regulatory coordinator, study coordinator, and statistician. See "Protections Against Risk" herein for additional data protections.

☐ Other, specify:

8. Suspected Loss of VA Information:

Should any incident such as theft or loss of data, unauthorized access of sensitive data or non-compliance with security controls occur it will be immediately reported according to VA policy. All incidents regarding information security/privacy incidents will be reported to the ISO and PO within 1 hour of acknowledgement of issue and done so using the VHADUR Research Events Report e-mail group (VHADURResearchEventReport@va.gov).

9. Reporting of Results:

☒ Reporting of results, such as in scientific papers and presentations, will never identify individual subjects. Data will be presented in aggregate and individual-level data will not be published.

☐ Other results reporting plan, describe:

10. Future Use of Data:

☒ Data will be retained for future use. This is described elsewhere in the protocol and is noted in the HIPAA authorization.

- ☒ Future Use of data is optional (i.e., not required by the research subject).
- ☐ Future Use of data is required for participation in the study.

☐ No future use of data is currently planned.

11. Use of Mail Merge Technology

☒ Mail merge programs will be used to generate letters and/or address labels for mailings to potential or already enrolled research subjects. The study team is aware that to reduce risk of mail merge related privacy incidents, use of mail merge programs requires a 25% accuracy check to verify that (potential) research subject name and mailing address are properly "matched". If discrepancies are found, a 100% accuracy check is required before letters may be mailed.

12. Use of Non-Standard Software

☒ I do NOT intend to use any new specialized software (i.e. Software that's not already approved OR installed) in this study.

☐ I intend to use specialized software that has not already been installed and it has been approved for use by the VA Technical Reference Model (TRM) Group.
(Note: All new software must be approved by TRM before it can be installed on VA systems.)

☐ I intend to use previously installed software on my VA computer.

13. Use of Cloud Computing Services

☒ Cloud computing services will NOT be used in this study.

☐ Cloud computing services WILL be used in this study as described below and have been approved nationally by the VA Chief Information Officer (CIO). (Note: ONLY cloud computing services that have been approved nationally may be used.)

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