CPHS Approval #_____ Exp. Date_____

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Date

RESEARCH PROTOCOL

TITLE: Assessing the Efficacy of Returning Home: A Somatic Experiencing® Trauma Healing Retreat for Veterans.

INVESTIGATORS: Alexandra Whitney, Ph.D., SEP - Principal Investigator, Michael Changaris, PsyD. Consultant,

Abstract:

Somatic Experiencing® (SETM) is a resiliency-based treatment for autonomic nervous system (ANS**) dysregulation syndromes such as PTSD, anxiety, depression, and physical syndromes like chronic pain, migraines, IBS, fibromyalgia, and chronic fatigue (Briggs, Hayes, & Changaris, 2018; Brom et. al., 2018; Levine, Blakeslee, & Sylvae, 2018). SETM focuses on re-establishing an individual's innate capacity for ANS, physical, and emotional regulation. Veterans returning home from military service often face significant readjustment to civilian life, research demonstrates this population faces disproportionately high mental health challenges, such as PTSD, depression, and anxiety compared to their civilian counterparts (Morin, 2011).

Returning Home is an intensive short-term Somatic Experiencing® treatment protocol designed to address the life altering and debilitating symptoms of PTSD, shock trauma and related stress conditions in men and women due to combat and military service. The retreat curriculum has been specially designed to integrate the Somatic Experiencing® trauma healing model with Equine and Yoga therapies, and other wellness practices that unify the body and the mind (Cushing, Braun, & Alden, 2018; Vasher, Delano, Herlache-Pretzer, Meyer, & Stawowy, 2017).

During the retreat each participant will develop self-regulating skills to decrease trauma symptoms while managing physical discomfort. In order for the participants to experience consistent strategies and trauma healing techniques from a Somatic Experiencing perspective a 'toolbox' of simple and repeatable SETM interventions has been designed. These interventions address basic SETM concepts of grounding, tracking sensation, pendulation, presence, resourcing, and sensing. The SETM 'toolbox' will be used with all aspects of the retreat program including individual SETM sessions, equine therapy, yoga, meditation, forest bathing, boating and during meals.

This mixed methods approach between groups waitlist controlled will use both qualitative and quantitative methods to assess the impact of the SETM informed five-day retreat. This study will be the first to evaluate an SETM based multi-day integrated approach to trauma treatment. This study could add to the literature of SETM based trials and to be a proof of concept for a multi-day integrated treatment context intensive for addressing symptoms of trauma in returning veterans. This study will evaluate symptom reduction in returning veterans with military service-related trauma, depression, anxiety, and moral injury, and the extent to which SE increases veteran's quality of life, interpersonal relationships, religious and or spiritual commitment.

Key Words Index: Post-Traumatic Stress Disorder, Somatic Experiencing, Equine Therapy, Yoga, Dissociation.

A. <u>Specific Aims</u>

Quantitative Aims: The aims of this study include identifying: (1) The extent to which the SE retreat protocol reduces the symptoms of PTSD in veterans, (2) The extent the SE retreat protocol increases veteran's quality of life, interpersonal relationships, and religious/spiritual commitment, (3) the overall efficacy of the six-day intensive SE protocol.

Quantitative Hypotheses:

- Participants in the SE-based Returning Home retreat will have reduced symptoms of Post-traumatic stress disorder as measured by Post-Traumatic Stress Disorder Check List for DSM 5 (PCL-5), The Dissociation Subscale (DSPS), Dimensions of Anger Reactions (DAR-5)
- 2. Participants in the SE-based Returning Home retreat will have reduced symptoms of depression as measured by Patient Health Questionnaire 9 (PHQ-9)
- Participants in the SE-based Returning Home retreat will have reduced symptoms related to moral injury as measured by the Expressions of Moral Injury Scale – Military (EMIS-M).
- 4. Participants in the SE-based Returning Home retreat will have reduced anxiety symptoms as measured by Beck Anxiety Inventory (BAI).
- 5. Participants in the SE-based Returning Home retreat will have increased quality of life as measured by the Quality of life Questionnaire (QOLS) and the Satisfaction with Life Scale (SWLS).
- 6. Participants will return home with a better ability for self-care of symptoms due using skills from workshop as measured by self-report of subjective units of distress (1-10 Likert scale), self-efficacy for self-regulation tools (SE Toolkit) as measured by 1-10 Likert scale and awareness of skills as measured by a 1-10 Likert scale (SE Toolkit).

Qualitative Aims: The purpose of the qualitative component of this research is to 1). Understand the subjective experience of each retreat participant, 2) To illustrate the personal interaction with the SE model and the various SE components of the curriculum, 3). To understand how this interaction is relevant and applicable to relieving the adverse effects of trauma and PTSD, and 4). To determine how the curriculum could be improved for future programs.

Qualitative Research Questions: The primary questions that will be used to determine each participant's experience are:

1. Participant Experience of Self

- a. How does the participant experience themselves (physically, mentally, emotionally, spiritually, and in relationship to others) prior to the retreat?
- b. How does the participant experience themselves (physically, mentally, emotionally, spiritually, and in relationship to others) post retreat?

- 2. *Experience of Retreat:* How does the participant experience each component of the retreat's curriculum; equine, yoga, individual SE sessions, psycho-education, walking meditation?
- 3. *Impact of Retreat:* How did Returning Home inform the participant's experience of who they are and how they feel physically, emotionally, spiritually? Does the participant identify any ways in which they have changed since the retreat?
- 4. *Therapeutic Value:* What, if at all, is the therapeutic experience and value of the five-day Somatic Experiencing retreat, Returning Home? What are the drawbacks of the experience?

B. <u>Background and Significance</u>

Combat deployments impact the physical, psychological, and social health of veterans. Of a sample of combat veterans returning from Iraq and Afghanistan, 40% suffered from mental health issues. (Seal, Metzler, Gima, Bertenthal, Maguen, Marmar, 2009). The population which comprises less than 2% of the population makes up 20% of the suicides each year (National Center for Veterans Analysis and Statistics). Overall, veterans experience lower life-satisfaction than civilians (Tsai, Harpaz-Rotem, Pietrzak, & Southwick, 2012). Over fifty percent of returning veterans who served in combat describe the readjustment to civilian life as a "real struggle" (Morin, 2011a).

There are now more casualties attributable to suicide than to combat among the military's activeduty population. Many of those who take their lives have been diagnosed with Post Traumatic Stress Disorder. The demand to address the needs of military veterans with PTSD is so high that in 2018 the VA Mission Act became law. It directs the Department of Veterans Affairs to expand access to VA-funded care in the private sector, highlighting the need for treatment services beyond those currently practiced in the VA healthcare system. The need for increased effective alternative therapies that provide trauma-informed treatment to women and men dealing with PTSD as a result of their military service will be addressed in this study. To date, the literature on the effectiveness of Somatic Experiencing for the treatment of combat related PTSD in the veteran population is scarce.

Currently, there are limited research studies that examine the effectiveness of Somatic Experiencing implemented as an intensive short-term treatment protocol to address military service-related trauma. The first randomized controlled trial evaluating the effect of Somatic Experiencing (SE) was done in Denmark in a population with co-morbid PTSD and lower back pain. This study found SETM to be associated with a significant change from symptoms at baseline to post treatment (Mean Difference=2.53, p=.003, Cohen's d=0.45) (Anderson, Lahav, Ellegaardc & Manniche, 2017).

In 2017, a randomized controlled outcome study evaluated the effectiveness of Somatic Experiencing treatment for symptoms that meet the *DSM-IV TR* criteria for post-traumatic stress disorder (PTSD) in the Israeli civilian and military communities. Researchers found a large effect size (Cohen's d > 0.8) on PTSD and depression symptoms. The results also indicated that 44.1% of the participants no longer qualified for the diagnosis of PTSD. The study revealed positive results, indicating that SE has shown to be an effective way to treat trauma (Brom et al., 2017).

Another study evaluated the effectiveness of SETM in a sample of Hurricane Katrina survivors, and found that among participants in the SETM treatment group, follow-up symptoms increased at a lower rate than those in the control group and PTSD symptoms improved significantly better than those in the control group (Leitch, Vanslyke & Alle, 2017).

There is a demonstrated need for intensive short-term programs like Returning Home. As of yet, there is no research on the effectiveness that an intensive SE protocol has on the treatment of US military and combat related injury. In light of the positive results in the limited research SETM has in controlled trials, it seems advantageous to examine the effectiveness of an intensive SE treatment protocol on the veteran population.

In light of current research, we expect that Returning Home's intensive SE-based treatment protocol will reduce symptoms of PTSD, depression, anxiety and moral injury and also increase life satisfaction, social support and religious/spiritual commitment.

C. <u>Research Design and Methods</u>

Overview: Veterans with a diagnosis of post-traumatic stress disorder will be recruited from a cohort of individuals attending a five-day trauma retreat. The retreat supports participants to develop self-regulation skills, address symptoms of trauma and develop understanding of how to develop and increase resilience. This study will use a mixed methods pre-test post-test between subject's design-controlled and Heuristic Inquiry approach design. Participants will be recruited for the workshop. When the initial workshop has filled (N = 30) a wait list of individuals will be assigned to the control group. The second workshop will occur within 6 months of the initial workshop and will follow the same format as the initial workshop.

Retreat/Workshop Daily Activities: Veterans will engage in 6 daily sessions each having these components

- 1) Individual Somatic Experiencing Sessions with an SEP for 60 min
- 2) Group psycho-educational session (120-min sessions)
- 3) SE Equine therapy (variable duration no greater than 120 min)
- 4) SE Yoga therapy (30 minutes)
- 5) SE mindfulness-based forest bathing (30-60 minutes)
- 6) Evening campfire group with a chaplain present to address the spiritual dimension of war-related injury.

Sampling: This study will comprise a convenience sample of self-selected male and female military veterans who report a diagnosis of post-traumatic stress disorder and who are participating in the Returning Home Somatic Experiencing Workshop (N = 30 in waitlist control and N = 60 in experimental group). Two workshops will be conducted six months apart and

clinical outcomes between the two groups will be compared with-in subjects and to a wait list control group of participants who are not able to attend the initial workshop.

Study Recruitment: Participants for the workshop and study will be recruited using an email to an existing mailing list, fliers posted at mental health clinics providing services to veterans in the area of the study, therapist referrals, Facebook advertisements. Advertisements that announce both the research study and the workshop will include language that indicates participating in the workshop is not contingent upon participation in the research study. See the Appendix A for sample advertisement and announcements.

Participant Selection: Subjects participating in the SE[™] informed retreat will be offered an opportunity to participate in the study. They will be informed that their participation in the study in no way will impact their participation in the retreat. This will be listed in all recruitment emails, Facebook posts and written recruitment fliers. Participants will be offered minor inducements for completion of surveys these will include gift cards not to exceed \$20.

In screening call for the study participants will be given verbal informed consent with a brief overview of study procedures, risks and benefits. Participants will be informed that they can withdraw from the study at any time with no consequences to their participation in the workshop. See appendices B, C, & D for initial screening informed consent script.

Somatic Experiencing® (SETM) is a resiliency-based treatment for autonomic nervous system (ANS**) dysregulation syndromes. The treatment is therapeutically experienced during a methodical, metered, slow application process. More than eight studies have been published to date and no adverse events were noted in the publications.

Participants of this study will be veterans of the US military, from all eras and all branches of service. Participants will primarily be between the ages of 20 and 75-year old males and females. Screening tools will be implemented to rule out active suicidal ideation using Columbia Suicide Severity Rating Scale (C-SSRS), active substance use disorder (assessed in initial clinical interview and if risk is identified followed up with Alcohol Use Disorders Identification Test (AUDIT) and Drug Abuse Screening Test (DAST) and those with untreated psychosis. Applicants for the study who meet the exclusion criteria will be referred to appropriate treatment in their local area.

The ongoing safety and support for participants at all times is an utmost priority in this study. For this reason, this precautionary measure is implemented in the participant selection process. A sample of Screening Interview Questions is located in Appendix B.

Informed Consent Procedures: At the beginning of the workshop those who are participating in the study will have an in person informational meeting that will include completion of informed consent forms, review of the study processes and completion of initial measures. Participants will be told that they will need to complete measures on four occasions. The first is before the workshop on the day of the informational meeting, the second is at the end of the

workshop, the third is at one month after the workshop and the fourth is at six months after the workshop.

Individuals will be informed prior to signing the forms that they can drop out of the study at any time with no consequences for their completion of the workshop. They will be informed that they are under no obligation to complete the informed consent form or participate in the study. Care will be taken to make sure group members know that they can participate in the workshop sessions without participating in the study. Participants will be informed that they can be sent a copy of the completed study if they wish and they can simply indicate this by writing yes at the bottom of their forms. See Appendix B, C, & D for informed consent script. Once initial individuals will be given verbal informed consent and offered the opportunity to sign an informed consent form. A sample of Informed Consent Acknowledgement is located in Appendix D.

Data Collection:

Quantitative Data Collection: Individuals who are interested in participating in the study, at the end of the in person informational meeting, will be handed a packet with a patient number on it, and an envelope with the same number written on the outside. Individuals who have signed informed consent will be asked to seal the envelope with the name inside and the number on the outside of the envelope. They will give the envelope back to the researcher or research assistant. Each participant will be given a \$20 gift card upon completion of the first measurement packet.

The research assistant will create a master list of participant number and name that will be stored separately from the measures in a HIPPA compliant double locked container. This list will only be consulted if a participant does not remember their number upon end of workshop follow up and for contacting. This will ensure that there is a limited ability to connect the name of the individual on the informed consent with the collected data. The patient list will be destroyed after the last data collection. All raw data will be held in a HIPPA compliant double locked container for three years after the end of the study and then destroyed.

The packet of measures given to participants at each of the four measurement points will include: A brief demographic survey, Post-Traumatic Stress Disorder Check List for DSM 5 (PCL-5), Patient Health Questionnaire – 9 (PHQ-9), Beck Anxiety Inventory (BAI), Expressions of Moral Injury Scale – Military (EMIS-M), The Dissociation Subscale (DSPS), Dimensions of Anger Reactions (DAR-5), Quality of life Questionnaire (QOLS) and Satisfaction with Life Scale (SWLS). The forms are expected to require 45 minutes to complete with average reading level of 6th grade or above.

The signed informed consent forms will be stored in a separate HIPAA compliant locked filing cabinet from the data and the envelopes. The informed consent forms will be destroyed one year after publication date. The data will be held in a HIPAA compliant locked file cabinet. In a separate double locked HIPPA compliant file the master list of participant names and participant numbers will be kept until the completion of the fourth measure and then they will be destroyed. At that point there will only be a list of participant numbers. The raw data will be saved for 3

years in a HIPAA compliant locked file cabinet and destroyed thereafter. There will be no participant identifiers on the raw data.

At the end of the workshop participants will be offered a private place to complete their follow up measures. They will be handed an envelope with their participant number on envelope back. They will then be able to select the packet associated with their number from a file folder. If they do not remember or are not able to find their number their number will be retrieved. Once completed the forms will be sealed in an envelope with the participant number on the outside and returned to the research assistant. Each participant will be given a \$20 gift card upon completion of the second measurement packet.

At one-month post completion of the workshop each participant will be mailed a packet with the forms and instructions inside, along with a return addressed envelope. One week after the forms are mailed a research assistant will contact participants to assess if they need assistance completing the forms. In this call the research assistant may help the patient complete the form and they will ask before ending call about suicide risk. If risk is identified the patient will be referred to appropriate services or a wellness check with local police will be initiated if risk is high. The participant will be informed in the call that they will be mailed a \$20 gift card once the forms are received.

At six-months post completion of the workshop each participant will be mailed a packet with the forms and instructions inside, along with a return addressed envelope. One week after the forms are mailed a research assistant will contact participants to assess if they need assistance completing the forms. In this call the research assistant may help the patient complete the form and they will ask before ending call about suicide risk. If risk is identified the patient will be referred to appropriate services or a wellness check with local police will be initiated if risk is high. The participant will be informed in the call that they will be mailed a \$20 gift card once the forms are received.

Qualitative Data Collection: Participants will participate in a post-study Heuristic Inquiry. Heuristic inquiry, developed by Clark Moustakas (1990), was selected in order to illuminate the lived experience of Returning Home and how does each participant experience themselves and others as a result of the retreat?

The meaning of the word heuristic stems from the Greek heuriskein, which means "to discover" or "to find" and refers to a process of internal search through which one discovers the nature and meaning of experience (Moustakas, 1990, p. 9). Heuristic inquiry will help facilitate an understanding of the benefits of the retreat process through self-reflection of personal experience of Re-turning Home.

One-on one recorded interviews will be used to identify what experiences were gained from the retreat. In addition, as part of the retreat curriculum, a collage art project will be analyzed to garner the subjective meaning that each participant will take home from the retreat process.

The purpose of the qualitative component of this research is to 1). Understand the subjective experience of each retreat participant, 2) To illustrate the personal interaction with the SE model and the various SE components of the curriculum, 3). To understand how this interaction is relevant and applicable to relieving the adverse effects of trauma and PTSD, and 4). To determine how the curriculum could be improved for future programs.

Rationale for Measures:

Post-traumatic Stress Disorder. The PTSD Checklist for DSM-5 (PCL-5) Is a 20-item measure to assess Post-traumatic Stress Disorder in accordance with the DSM 5. It offers a Criterion A event option. These items (e.g., "In the past month how much were you bothered by: Suddenly feeling or acting as if the stressful experience were actually happening again (as if you were actually back there reliving it)?") are rated on five-point Likert scale (e.g., 0 = not at all, 4 =extremely). The PCL-5 had good test-retest reliability (r =.82). (Weathers, Litz, Keane, Palmieri, Marx, & Schnurr, 2013).

Dissociation Subtype. The Dissociation Subscale (DSPS) assess the degree to which an individual meets criterion for the dissociative subtype of PTSD. The scale measures factors reflecting derealization/depersonalization, loss of awareness, and psychogenic amnesia. The DSPS is a 15item scale and assesses a Criterion A event by inquiring into what event occurred and if it occurred in the past month by asking respondents for a (yes/no) response. Items (Have you felt "checked out," that is, as if you were not really present and aware of what was going on around you?) rate frequency on a Likert scale where $\theta = never$ and 4 = daily. Intensity is also rated on a Likert scale where $\theta = N/A$ and 5 = Very Strong. Alphas and citation

Moral Injury. The Expressions of Moral Injury Scale-Military Version (EMIS-M) assesses the presence of Moral Injury in Military personnel. It is a -item measure that with two sub-scales. One scale measure moral injurious expression directed towards self (9 items) (e.g. I am ashamed of myself because of things that I did/saw during my military service.) and the second scale measures morally injurious expressions towards the other (8 items) (eg. My military experiences have taught me that it is only a matter of time before people will betray my trust.) Items are rated on a Likert scale where l = strongly disagree and 5- strongly agree.

Anger. Dimensions of Anger Reactions (DAR-5) is a 5-item scale that assesses veterans' anger frequency, intensity, duration, aggression, and interference with social functioning (e.g. My anger prevents me from getting along with people as well as I'd like to.) Responses utilize a 5-point Likert scale from 1 = None of the time to 5 = All of the time. Cronbach α was 0.88 (SE=0.02) (Hawthorne, Mouthaan, Forbes, and Novacos, 2006).

Depression. The Patient Health Questionnaire (PHQ-9) is a 9-item instrument used for screening, monitoring and measuring the severity of depression. Respondent self-report how bothered they have been by problems over the past two weeks (e.g. Little interest or pleasure in doing

things). Items are self-reported on a Likert scale where 0 = Not at all and 3 = Nearly every day. The measure has sensitivity and specificity of 88% for major depression (Kroenke, Spitzer & Williams, 2001)

Quality of Life. The Quality of life Questionnaire (QOLS) assesses quality of life. This measure is related to overall enjoyment, ease, comfort, health and quality of living (Burckhardt, & Anderson, 2003). Post-traumatic stress disorder relates to lower quality of life (Olatunji, Cisler, & Tolin, 2007; Schnurr, Lunney, Bovin, & Marx, 2009). Reduced symptoms could related to increase quality of life. This scale was originally developed in the 1970's by John Flanagan, PhD. The 15 item measure was found to be internally consistent in a sample of 240 patients with chronic illness (alpha = .82 to .92). One more question was added after initial assessment for total of 16 questions with similar alpha to 15 question measure. The measure has solid convergent validity with Life Satisfaction Index (r = .67 to .75) (Burckhardt, & Anderson, 2003). Some data indicates the measure is responsive to clinical change. This measure is available in multiple languages and has been assessed multiple times since initial norms were developed. It remains in use and a robust measure (Burckhardt, & Anderson, 2003).

Life Satisfaction. Life Satisfaction will be measured with the Satisfaction with Life Scale (SWLS) This instrument measures the participant's over-all subjective well-being. This measure's 5-items (e.g. In most ways my life is close to my ideal.) are rated on a 7-point Likert scale (1 = strongly disagree, 7 = strongly agree) In a previous study, reliability was reported at (α =.87) (Diener, Emmons, Larsen, & Griffin, 1985).

Rational for Heuristic Inquiry: Moustakas (1990) identifies seven core principles that shape heuristic inquiry. These principles rely on an interior and self-referential process of discovery and inquiry, which permeate the re-search and that aim to develop and nurture a fundamental ability to listen and discern. As Moustakas describes them, the seven core principles are in summary:

- 1. **Identify with the focus of the inquiry**. The heuristic process is an open-ended inquiry, a self-directed search and absorption in the research subject. The researcher must "get inside" the question and become one with what one is seeking to know as a means to fully and wholeheartedly understand it. Jonas Salk, who developed the polio vaccine, referred to this process as "the inverted perspective" (p. 16).
- 2. **Self-dialogue.** Heuristic inquiry encourages the researchers to be "open, receptive, and at-tuned to all facets of one's experience of a phenomenon, allowing comprehension, and compassion to mingle and recognizing the place and unity of intellect, emotion, and spir-it" (p. 16).
- 3. Tacit knowing. In addition to knowledge that we can make explicit, there is knowledge that is implicit in our actions and experiences that "allows one to sense the unity or wholeness of something from an understanding of the individual qualities or parts" (pp. 20–21). This tacit knowledge precedes intuition, and, according to Moustakas, underlies all other concepts of heuristic research.

- 4. **Intuition.** "Intuition makes immediate knowledge possible without the intervening steps of logic and reasoning" (p. 23).
- 5. **Indwelling.** This refers to the conscious effort to turn inward, to obtain a more thorough, deeper understanding of the essence or meaning of a particular human experience. It requires "a willingness to gaze with unwavering attention and concentration into some facet of human experience in order to understand its constituent qualities and its wholeness" (p. 24).
- 6. **Focusing.** Eugene Gendlin developed the process of focusing, which is used in heuristic inquiry. Focusing is an internal process of awareness that allows one to contact the more central meanings of an experience, allowing one to identify qualities of an experience that were previously unconscious. "Focusing facilitates a relaxed, and receptive state, enables perceptions and sensing to achieve more definitive clarification, taps into the essence of what matters, and sets aside peripheral qualities or feelings" (p. 25).
- 7. **Internal frame of reference.** "To know and understand the nature, meanings, and essences of any human experience, one depends on the internal frame of reference of the person who has had, is having, or will have the experience" (p. 26).

These seven principles of heuristic inquiry form a compatible and natural offspring of the Returning Home's curriculum. They create a context that will facilitate self-inquiry and that serve to expose the essence of the participants' experience.

<u>Time Line</u>

A timeline of milestones of the study can be found in Appendix G.

Statistical Analysis

This is a pre-test, post-test between groups design. Main effects will be assessed using paired one-way T-Tests for each variable. Pearson's r will be used to assess correlational data. Post hoc analysis will be used to identify impact of any mitigating demographic variables or treatment factors. Statistical analysis will be conducted using SPSS, or Microsoft Excel.

Risk to Participants and Ethical Considerations

Subjects who participate in this study may experience discomfort while answering some pre- and post- test questions. But there is no clear data indicating iatrogenic effects of answering the mentioned measures.

While all therapeutic treatments can lead to discomfort in having to face difficult feelings and address emotional challenges, the interventions assessed here are based on a well-established treatment. This treatment has been assessed in three other studies. No adverse events were reported. Subjects participating in SETM informed group process may experience some discomfort during the emergence of material relative to their therapeutic process while engaged in group experience. Somatic Experiencing® (SETM) is a resiliency-based treatment. The treatment is therapeutically experienced during a methodical, metered, slow application process. However, some emotional discomfort can occur as the person begins to experience the felt senses

of stored traumatic material in the body as it completes a natural process of release; a process that was thwarted during an interrupted defense response.

Participants will engage in Equine and Yoga therapies designed for those who suffer from chronic pain, or injury such as amputation. Canoeing, kayaking and non-strenuous hiking and possibly other physical activities will be offered over the course of the retreat. It is possible, though not likely that a participant may fall and become injured. Participants will sign a site waiver for the retreat venue (see attached waiver) and researchers will obtain current health insurance information. Nearest medical care facility has been located at (and in the event of an injury there are identified staff members authorized to transport participants. In the event of an emergency, 911 will be called and participants will be transferred via ambulance in the event a participant is injured or needs medical attention.

Due to these factors the risks and ethical concerns associated with this study are deemed to be low. Individuals will be informed at multiple points of their ability to terminate their participation in the study at any time without jeopardizing their treatment. Individuals will be informed that if they are experiencing distress due to participation in the study, they can request a referral to treatment. Individuals who make this request will be given a short list of appropriate referrals in the local area.

Veterans will travel to attend this retreat. As such veterans who are employed will need to take time off. This may result in some voluntary impact to wages for that period of time. The program will offer support for written time off if it is deemed helpful by the veteran. Housing and other food costs will be offered at no expense. The free attendance and housing will not be impacted if a veteran opts out of the study. This will be made clear during informed consent procedures.

Veteran Participants will be debriefed at the end of the retreat and any questions or concerns will be addressed at that time. All participants will be provided resources for follow up care and an eight-week post retreat SE support group will be established. First contact will be made during the retreat with Veterans and an individual trained in the SE model and approved to be an assistant in trainings.

Risks to participants are expected to be low. The There is no risk of private records being compromised because this study will not incorporate them. There is no use of deception or manipulated, created or otherwise manufactures social environments. There are not images, videos or other media that contain materials that may be offensive, threatening or degrading to participants.

D. <u>Study Population</u>

Participants of this study will be veterans of the US military, from all eras and all branches of service. Participants will primarily be between the ages of 20 and 50, though there may be additional participants outside of those age specifications depending on physical health and agility. This retreat will serve male veterans. All ethnic backgrounds will be invited to participate. Screening tools will be implemented to rule out active suicidal ideation, active substance addiction (where abstinence would cause withdrawal symptoms) and those with untreated psychosis. These applicants will instead be referred with local treatment resources.

E. <u>Potential Benefits of Study:</u>

This study will offer insight into whether participation in a SE[™] informed six-day workshop can significantly reduce negative symptoms of trauma and improve quality of life for Veterans with PTSD. Often therapeutic contexts require weekly one to one therapy or group interventions. Rarely, has an intensive workshop setting been assessed for impact to long-term symptoms of trauma. Along with increased knowledge of the impacts of SE based therapies this will increase possible ways to address traumatic symptoms. This maybe the first of its kind study to assess the impact of integrated yoga, equine therapy and somatic skills in a multi-day workshop setting.

F. <u>Setting of the Research</u>

Returning Home will be held at Fair Haven Camps in Brooks, Maine. Fair Haven, founded in 1950 as a Christian camp for children, is located on a large lake surrounded by over 300 acres of pasture and woods. This natural environment is ideal as a safe, nurturing place for the retreat. Fair Haven is a rustic setting complete with a camp lodge, cabins, a chapel, campfire site, horse stables, hiking trails and an indoor basketball court. All meals will be home cooked.

G. <u>Costs to Subjects</u>

Participants in this study will receive no monetary compensation. However, veterans who participate in the 5-day retreat will do so at no cost to them. They will receive 5 hours of individual Somatic Experiencing Sessions, five 120-min group Somatic Experiencing sessions, 5-hours of yoga instruction, and all meals and lodging for 5 days. If a participant should choose to drop out of the retreat or otherwise be unable to continue, there will be no expectation of payment for received services.

H. <u>Subject Compensation</u>

There is no compensation for this retreat or to participant in the study. The individual sessions stay at the retreat center, access to equine therapy, food during the retreat will be offered at no cost to research participants. Participants will not be required to participate in the study to receive these services and those who would like to drop out of the study will still be supported to participate fully in all workshop and post workshop events. However, there will be compensation of \$20 for completion of each packet of measure. This will be given in the form of a gift card. Participants who don't complete packets will not receive the gift card. Due to the nominal amount of each gift card this is not expected to be an undue inducement to remain in the study.

I. <u>Confidentiality/ Data Management:</u>

Attempts will be made to assure that data is anonymized at each step in the procedures to ensure optimal data safety. Participant identifiers will be kept separately from all surveys and electronic data systems. Participant's data will be maintained in a HIPPA compliant double locked file cabinet. Individual survey's will be stored under participant number. Excel and SPSSS spreadsheets will list only participant number. The electronic data will be kept on an encrypted password protected smart drive in the HIPPA compliant file system. The master list of names and participant numbers will be stored in a separate double locked filing system. Participant number and names master list will be destroyed using shredding system after the final six month follow

up assessment. Participant data will be held using HIPPA compliant locked cabinets for three years after final data collection and then destroyed using a shredder.

J. <u>References & Literature Cited</u>

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K. <u>Appendices</u>

- A. Sample of Promotional Material Content
- B. Pre-screening Interview Questions
- C. Informational Meeting Discussion Points (printed format layout may differ)
- D. Informed Consent Acknowledgement
- E. Demographic Questions
- F. SELECTED MEASURE INSTRUMENTS
- G. Timeline

Appendix A – Outreach and Recruitment (Facebook, Email, Flier Examples)

Language and images of outreach below will be used in multiple contexts and adapted but not substantively changed in content.

RETURNING HOME

A Trauma Healing Retreat for Veterans

October 10th thru 15th, 2019

Why is Returning Home Important?

According to recent data from the Department of Veterans Affairs, the number of suicides among military veterans is 20 per day.... nearly one suicide every hour.



There is an acute need for programs like Returning Home. There are now more casualties attributable to suicide than to combat among the military's active-duty population. Many of those who take their lives have been diagnosed with Post Traumatic Stress Disorder (PTSD).

Peer reviewed research has established that Somatic Experiencing® is an effective treatment for post traumatic stress disorder (PTSD).

Community Health SE™



Returning Home is the first Somatic Experiencing® trauma healing retreat for veterans presented by Dr. Peter A. Levine.

Returning Home is an intensive five-day Somatic Experiencing® treatment protocol designed to address the life altering and debilitating symptoms of PTSD, shock trauma, and related stress conditions due to combat and military service. This retreat is free to all participants, lodging, food, program services, and a travel stipend.

The retreat curriculum has been specially designed to integrate the Somatic Experiencing® trauma healing model with Equine therapy and other wellness practices that unify the body, heart, and mind.

Each participant will develop skills to decrease trauma symptoms while managing physical discomfort. An eight-week online SE™ support group will be offered after the retreat to further assist each participant with

1



What is Somatic Experiencing®?

The Somatic Experiencing (SE) method is a body-oriented approach to the healing of trauma and other stress disorders.

The SE approach releases traumatic shock, which is key to transforming PTSD. SE offers a framework to assess where a person is "stuck" in the fight, flight or freeze responses and provides clinical interventions to resolve these fixated physiological states.

SE facilitates the completion of selfprotective motor responses and the release of thwarted survival energy bound in the body, thus addressing the root cause of trauma symptoms and suppressed emotions.

Who is Dr. Peter A. Levine?

Dr. Levine, Ph.D. (medical biophysics, UC Berkeley) and Ph.D. (psychology, International University), developed the Somatic Experiencing® method and has worked in the field of stress and trauma for more than 40 years. His organization has trained over 12,000 practitioners in 6 different countries. usage and integration of SE™ 'tools' and techniques learned during the retreat.

Returning Home will be held at Fair Haven Camps in Brooks, Maine. Fair Haven is on a beautiful lake surrounded by over 300 acres of pristine pasture, hiking trails, and forest. This natural environment is ideal as a safe, nurturing place for the retreat. This rustic setting is complete with a retreat lodge, chapel, campfire site, horse stables, canoeing, kayaking, and an indoor basketball court. All meals will be home cooked.

Research Study

Participating veterans will have the opportunity to join the research component of the retreat. Participation in the study is strictly voluntary.

Retreat participants will not be required to participate in the study to receive retreat services and those who would like to drop out of the study will still be supported to participate fully in all retreat activities and the post-retreat online support group.

The study will examine the benefits of Returning Home by implementing a series of questionnaires prior to the retreat and post retreat; one, three and six months after the retreat. These questionnaires will help determine if the Somatic Experiencing curriculum helps to decrease identified symptoms of chronic stress, trauma, and PTSD.

Participants of this study will be veterans of the US military, from all eras and all branches of service.

For more information and to attend, please go to:

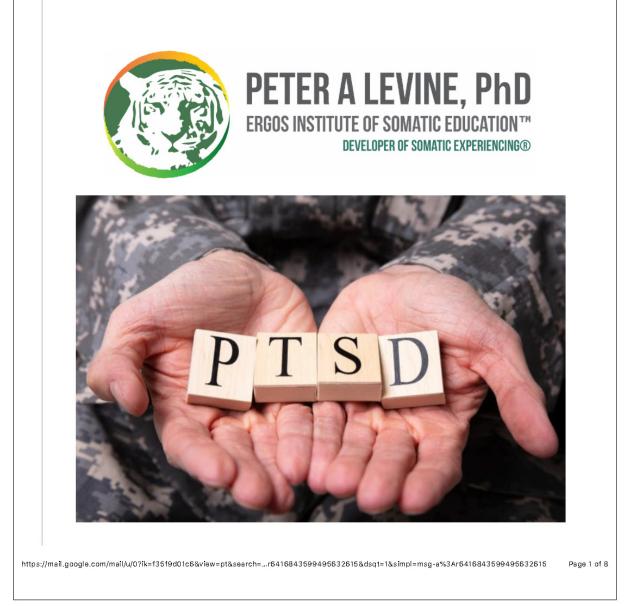
<u>https://returning-home.com</u> Or contact: Alexandra Whitney (303) 588-4939

Community Health SE™

2

Appendix A – Outreach and Recruitment (Facebook, Email, Flier Examples)

Language and images of outreach below will be used in multiple contexts and adapted but not substantively changed in content.



Gmail - Fwd: SE Veterans Retreat in October

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Returning Home

A Trauma Healing Retreat for Military Veterans

October 10th - 15th, 2019

Fair Haven Camps in Brooks, Maine

<u>Support Returning Home on gofundme</u> goal of \$30,000 by September 15th

Returning Home is the first <u>Somatic Experiencing® (SE™)</u> trauma healing retreat for veterans presented by Dr. Peter A. Levine's Community Health SE[™] program. It will take place at <u>Fair Haven</u> <u>Camps</u> in Brooks, Maine.

This retreat...

- is a six-day Somatic Experiencing® trauma healing retreat for 30 veterans displaying PTSD symptoms.
- is free to all participants, including travel, lodging, food, and program services.
- integrates SE with Equine therapy and other wellness practices that unify the body, heart, and mind.
- will help veterans develop skills to decrease trauma symptoms while managing physical discomfort.
- has a research component to ensure the effectiveness of future SE[™] intensive trauma healing retreats for veterans.
- includes a post-retreat eight week online SE™ support group.

Returning Home is important because...

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Gmail - Fwd: SE Veterans Retreat in October

- the number of suicides among military veterans is 20 per day nearly one suicide every hour.
- there are now more casualties attributable to suicide than to combat among the military's active-duty population.
- many of those who take their lives have been diagnosed with Post Traumatic Stress Disorder.
- Dr. Levine believes that this SE retreat will set the gold standard for trauma treatment that will increase the quality of life for veterans.

Support Returning Home on gofundme

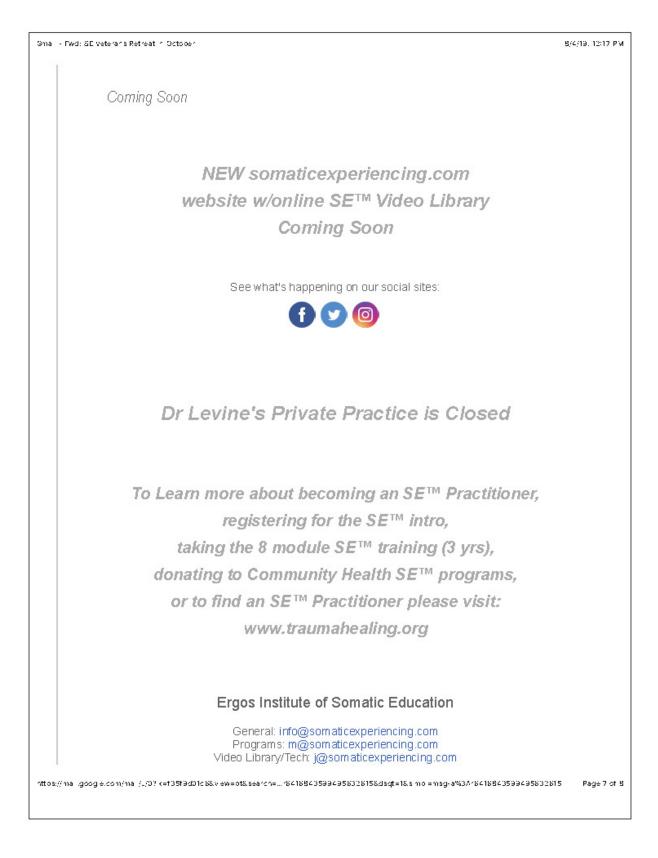
You can support this program by Donating & Fundraising

- All new gifts up to a total of \$20,000 will be matched by a generous donor.
- All donations large or small make a difference.
- To donate by check or PayPal click here for more info.
- To help with fundraising in your community, please <u>contact us</u> to get started.
- We invite you to share this <u>program</u> and our <u>fundraising goals</u> on your Social Media accounts.

If you know a Veteran in need of treatment, *who has not received SE in the past*, please contact:

Retreat Director Dr. Alexandra Whitney (303) 588-4939 info@returning-home.com

https://mail.google.com/mail/u/0?ik=13519d01c6&view=pt&search=...r6416843599495632615&dsqt=1&simpl=msg-a%3Ar6416843599495632615 Page 3 of 8



Gmail - Fwd: SE Veterans Retreat in October

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Pacific Time Zone unless on travels for courses

www.somaticexperiencing.com

Ergos Institute | 788 Apple Valley Road, Lyons, CO 80540

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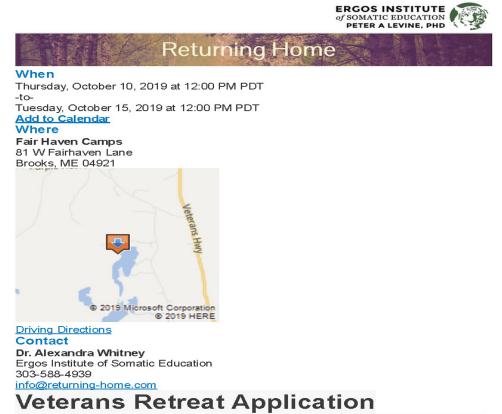
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Appendix B – Recruitment and Registration



Welcome to the Returning Home Veterans' Registration page. In order to apply for this retreat or to be considered for next year's retreat, please fill out this form. We will contact you after you submit your registration. If you have any questions or need help filling out the application, contact Alexandra: info@returning-home.com / 303.588.4939

* Required information

	*
	First Name:
•	*
	Last Name:
•	*
	Email Address:
•	*
	Confirm Email Address:
•	*
	Address 1:
•	Address 2:
•	*
	City:
•	*
	State:
•	Choose
•	
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•	Phone:
	*
·	Date of Birth:
	Date of Difti.

- *If you had trouble entering your birthday, try entering the year first and then the month and date a glitch in the system.
- Please fill out the registration questionnaire to the best of your ability. Every question has to be answered, you can write n/a for anything not applicable to you. Do not worry if you've left anything off or forgotten something. There will be a call to review your form when it's received. If you'd prefer not to fill this out online, we can send you a form in the mail, or schedule a call to take your info by phone. If so, please contact Alexandra at info@returning-home.com / 303.588.4939.
 - Gender:
- *
- Race:
- Ethnicity:
- .
 - Are you employed?
 - --Choose--

Yes No **Company:** Job Title: City: State: Have you ever been treated with Somatic Experiencing®, if so, list provider and duration? 500 characters remaining What are your goals for attending this retreat? 500 characters remaining Branch of military, rank, dates, and region served: 500 characters remaining Have you ever been diagnosed with PTSD and/or experienced PTSD like symptoms, such as anxiety, depression, rage, etc? 500 characters remaining Have you ever been diagnosed with the following; schizophrenia, bipolar, borderline personality disorder, and if so, are you receiving treatment? 500 characters remaining Are you concerned with any physical or mental health symptoms, treated or untreated? If yes, please list: 500 characters remaining What is your mental health and/or trauma treatment history (Psychotherapy, EMDR, CBT, Exposure Therapy, etc)? Please list the type and the duration of treatment: 500 characters remaining

What is your medical and therapeutic treatment history (surgeries, physical therapy, pain management, massage, acupuncture, reiki, equine therapy, daily exercise program, retreats, yoga, meditation, walking, etc)? Please list the types and the duration of treatments: 500 characters remaining If you have received treatment, what has been helpful and what has not worked for you? 500 characters remaining Significant medical history (seizures, amputation, TBI, concussion, spinal cord injury, etc): 500 characters remaining List of medications and supplements (prescribed, sleep aids, allergy meds, vitamins, etc.): 500 characters remaining Medical doctor contact info: Mental health practitioner contact info: Do you have insurance, if so, please list insurer information: 500 characters remaining Emergency contact info: 500 characters remaining Do you have any special needs (wheelchair, caregiver, medical equipment)? 500 characters remaining *Fair Haven Camps is wheelchair accessible. Do you have any dietary needs or restrictions? 500 characters remaining *The kitchen staff is capable of catering to specific dietary needs. Is there anyone you'd like to refer to this retreat? Name, relation, email, and/or phone number:

Yes, I would like to receive your email newsletters

500 characters remaining

By checking this box, you're consenting to receive marketing emails from: Ergos Institute of Somatic Education, 788 Apple Valley Road, Lyons, CO 80540, United States http://www.somaticexperiencing.com You can revoke your consent to receive emails at any time by using the SafeUnsubscribe[™] link, found at the bottom of every email. Emails are serviced by Constant Contact.



Mobile View

Appendix C – Informational Meeting Discussion Points Script

Research Assistant Note: Read outload to group with informed consent document in front of participants. Ask at the end if there are any questions.

Research Assistant Reads: Thank you for choosing to learn more about participation in this study entitled: Assessing the Efficacy of Returning Home: A Somatic Experiencing® Trauma Healing Retreat for Veterans.

This study aims to add to the body of scientific evidence on the effects of SETM by studying a sixday model for reducing symptoms of trauma in veterans who have combat exposure and PTSD symptoms. This workshop and retreat will include five SE individual sessions, daily yoga skills for individuals with PTSD, equine assisted therapy, education on SE skills group training for self-regulation and trauma, a somatic based mindfulness practice and a daily evening fire circle.

SE treatment has been found in initial work to reduce symptoms of trauma significantly and the educational skills from the SE training has shown reduced symptoms and increased resilience in clinicians. This will be the first multi-part SE based workshop that has been assessed for its impact on trauma symptoms. Because of this the study we are conducting could have an impact in developing other intensive retreat base treatment models.

If you choose to sign up for the study, you will need to sign and return the informed consent form in front of you and then you will be given a packet of questionnaires. These questionnaires are expected to take 45 minutes. If you remain in the study, you will be asked to complete the questioners on a total of four occasions 1. Today, 2. At the end of the workshop retreat, 3. At one month follow up and 4. At six months follow-up. There will be no compensation for participating in the study how-ever all workshop events will be given free of charge. All those who complete a packet fully will be given a \$20 gift card at the completion of the packet for a total possible of 4 \$20 gift cards by the end of the study.

Any questions?

Research Assistant Note: Read outload to group with informed consent document in front of participants. Ask at the end if there are any questions.

Research Assistant Reads: You could receive several positive gains from participation

- 1. A 6-day workshop with no cost to you and an 8 week follow up support group after the initial workshop.
- 2. Learn about the theory behind SETM- the body's instinctual fight, flight, freeze and collapse responses.
- 3. Learn and practice skills to recognize, adjust, re-establish and build capacity for Autonomic Nervous System (ANS), physical, and emotional regulation.

- 4. Learn the importance of social engagement and the sharing of common experiences, and how building healthy relations and working together can benefit your own health and well-being.
- 5. Yoga and other movement skills to manage symptoms of trauma and increase health and wellbeing.
- 6. Equine assisted therapy and skills gained from being in contact with horses.
- 7. If you are locked in frequent anxiety or rage, you can learn to relax into a growing sense of peace and safety.
- 8. If you find yourself stuck in depression, you can gradually find your feelings of hopelessness and numbness transformed into empowerment, triumph, and mastery.
- 9. You can develop skills to help restore inner balance, enhance resilience to stress, and increase your capacity to actively engage in life.
- 10. You will not be paid for participating in this study. However, you can receive a gift card for completion of each round of surveys.

Any questions?

Research Assistant Note: Read outload to group with informed consent document in front of participants. Ask at the end if there are any questions.

Research Assistant Reads: You are being asked to take part voluntarily in the research project described below. Please take your time making a decision and feel free to discuss it with your friends and family. Before agreeing to take part in this research study, it is important that you read the consent form that describes the study. Please ask the study researcher or the study staff to explain any words or information that you do not clearly understand.

Any questions?

Research Assistant Note: Read outload to group with informed consent document in front of participants. Ask at the end if there are any questions.

Research Assistant Reads: Risks and Benefits – Individuals participating in this study will be given the opportunity to contribute to the body of scientific knowledge and receive a treatment that has the possibility of positively impacting their life. While SETM treatment has not been studied extensively, SETM has been used in several research studies. No adverse reactions were reported. Several studies found significant positive results.

Completing surveys and questionnaires can at times bring up uncomfortable information and feelings. However, the measures used in this study have been widely used in many clinical settings. There have been no adverse reactions reported. If you discover any mental health or health challenges through completing these surveys, you can request a referral to treatment at any time from the principal investigator.

Any questions?

Research Assistant Note: Read outload to group with informed consent document in front of participants. Ask at the end if there are any questions.

Research Assistant Reads: Participation is Voluntary – Participation in this study is completely voluntary, and other than the opportunity for additional individual support if necessary, participants will participate completely anonymously. Choosing to withdraw from the study will in no way impact your ability to engage in the workshop of post workshop groups.

However, individuals who do not complete a specific packet of forms will not receive the gift card for that packet of forms. Your data will be held in confidential HIPPA compliant containers. Specific identifiers of you as an individual will be kept in a locked HIPPA compliant container separate from measures.

All specific identifiers of you as an individual will be destroyed after final 6-month measurement. The completed documents used for your written responses to the demographic questions and self-assessment questions will be stored in a locked file cabinet.

You may refuse to take part or withdraw from this study at any time and for any reason without prejudice. Please inform study if you choose leave, so that we can be sure that you are safe or if you have any additional concerns that we might assist you with.

Any questions?

Research Assistant Note: Read outload to group with informed consent document in front of participants. Ask at the end if there are any questions.

Research Assistant Reads: Adverse Reactions – If any questions on the self-assessment tests disturb you beyond your comfort level, or if you become unable to emotionally manage any group experiences outside of the group after processing within the group, you may obtain a referral to a qualified therapist by speaking with the principal investigator Alexandra Whitney at: alexandra@whitney.net

Any Questions?

Research Assistant Note: Read outload to group with informed consent document in front of participants. Ask at the end if there are any questions.

Research Assistant Reads: Participants Rights – If you have questions or concerns about your rights as a research participant, or to offer your input, you may contact principal investigator Paul C. Briggs at alexandra@whitney.net or IRB at Wright Institute in Berkeley, California.

You have the right to obtain a copy of the results of this study within one year of the end of data collection and can receive a copy by emailing a request to the principal investigator Alexandra Whitney at: <u>alexandra@whitney.net</u>

Any questions?

Research Assistant Note: Read outload to group with informed consent document in front of participants. Ask at the end if there are any questions.

Research Assistant Reads: Participants Agreements – You must be over 18 years of age and legally able to provide consent to participate in this study, and you must agree with the following statement: "To the best of my knowledge or belief, I do not have any physical or mental health challenges that would likely be negatively impacted by this project."

You must agree to not be under the influence of alcohol or other substances during participation in groups. Mind altering substance use will impede and diminish your ability to be able to fully experience the transformational benefits of SETM informed work.

Any questions?

Research Assistant Note: Read outload to group with informed consent document in front of participants. Ask at the end if there are any questions.

Research Assistant Reads: – Please sign the informed consent forms and place them in the envelope marked informed consent with you participant ID number on the outside.

Please write your full name, address and phone number and place it in envelop with your participant ID number on it that is titled "contact information."

Once complete come to the front of the room turn in the signed informed consent forms and you will be given an envelope with your participant ID on the outside with a packet of screeners to complete. We thank you in advance for completing them.

Once you are finished with the screeners bring them in the envelope to the research assistant to confirm they are fully complete. Once they are confirmed you will be given a gift card and you can return to the workshop.

Any questions?

Thank you!

Appendix D.

Somatic Experiencing Returning Home Workshop Research Informed Consent Form

Principle Investigator: Alexandra Whitney, PsyD.

You are being asked to take part voluntarily in the research project described below. Please take your time making a decision and feel free to discuss it with your friends and family. Before agreeing to take part in this research study, it is important that you read the consent form that describes the study. Please ask the study researcher or the study staff to explain any words or information that you do not clearly understand.

Study Rationale

This study aims to add to the body of scientific evidence on the effects of SETM by studying SETM informed work combined with complimentary healing modalities for an intensive trauma treatment and symptom reduction period. SE helps to assist with the completion of the release of self-protective survival fight/flight and freeze states that can be bound in the body after a sudden interruption during the experience of a traumatic event. Workshop participants are guided in a natural, gentle way to develop increasing tolerance for difficult bodily sensations and suppressed emotions as these self-protective motor responses are completed. Workshop participants will be offered daily yoga, equine assisted therapy and other supportive workshop events. SETM does not require that a person re-tell or re-live a traumatic event and is a resiliency-based model in which participants learn to listen to their own bodily needs and gain skills to regulate difficult emotions.

<u>Risks and Benefits</u>

Individuals participating in this study will be given the opportunity to contribute to the body of scientific knowledge and receive a treatment that has the possibility of positively impacting their life. While SETM treatment has not been studied extensively, SETM has been used in several research studies. No adverse reactions were reported. Several studies found significant positive results.

Completing surveys and questionnaires can at times bring up uncomfortable information and feelings. However, the measures used in this study have been widely used in many clinical settings. There have been no adverse reactions reported. If you discover any mental health or health challenges through completing these surveys you can request a referral to treatment at any time from the principal investigator Alexandra Whitney, PsyD. at alexandra@whitney.net.

Participation in this Study

Participation in this study will require a completion of the Returning Home Somatic Experiencing informed workshop. This is a six-day retreat, during this time frame, you will be part of a Somatic Experiencing® informed psychotherapeutic and psychoeducational workshop experience. Following the six-day workshop session, there will be an 8 week follow up support group. You will complete measurements on four occasions immediately prior to starting the study, one completion of the workshop, one-month post completion of the workshop and at six months after completion of the workshop.

You will be given a series of demographic questions. You will also complete several questionnaires. At the end of the study, statistical results will be analyzed and published in a scientific journal. You will not be identified in any publications. The total time required to answer all question sets and self-report questionnaires will be approximately 45 minutes.

Participation is Voluntary

Participation in this study is completely voluntary, and other than the opportunity for additional individual support if necessary, participants will data will be held in a confidential protected environment. The anonymously completed documents used for your written responses to the demographic questions and self-assessment questions will be stored in a locked file cabinet and separate from your name or other identifier. You may refuse to take part or withdraw from this study at any time and for any reason without prejudice.

Adverse Reactions

If any questions on the self-assessment tests disturb you beyond your comfort level, or if you become unable to emotionally manage any group experiences outside of the workshop or after processing within the workshop, you may obtain a referral to a qualified therapist by speaking with by emailing the principal investigator Alexandra Whitney at alexandra@whitney.net or contacting workshop leaders.

Inducements

Participants in this study will be offered \$20 gift card for completion of each survey packet. Participants in the study also know that they are supporting research that will explore the benefits of SETM informed work that would be made available for other Veterans with PTSD.

Participants Rights

If you have questions or concerns about your rights as a research participant, or to offer your input, you may contact principal investigator Alexandra Whitney, PsyD at alexandra@whitney.net or IRB at Wright Institute in Berkeley, California.

You have the right to obtain a copy of the results of this study within one year of the end of data collection and can receive a copy by emailing a request to the principal investigator Alexandra Whitney at alexandra@whitney.net or from the Wright Institute IRB.

<u>Participants Agreements</u>

You must be over 18 years of age and legally able to provide consent to participate in this study, and you must agree with the following statement: "To the best of my knowledge or belief, I do not have any physical or mental health challenges that would likely be negatively impacted by this project."

You must agree to not be under the influence of alcohol or other substances during participation in groups. Mind altering substance use will impede and diminish your ability to be able to fully experience the transformational benefits of SETM informed work.

Please keep this information handy for future reference when necessary.

Participant Name: (Please Print)	
Participant Signature:	 Date:
Witness Signature:	Date:

Appendix E – Demographic Questions for Survey

- 1. Age: What is your age?
 - a. 18-30
 - b. 30-40
 - c. 40-50
 - d. 50-60
 - e. 60-70 or older
- 2. Ethnicity (or Race): Please specify your ethnicity:
 - a. Nonresident Alien
 - b. Hispanics of any race
 - c. American Indian or Alaska Native
 - d. Asian
 - e. Black or African American
 - f. Native Hawaiian or Other Pacific Islander
 - g. White
 - h. Two or more races
 - i. Race and Ethnicity Unknown
 - j. Other(please specify)
 - k. Prefer not to respond
- 3. Gender: What is your gender?

- a. Male
- b. Female
- c. Gender Non-Conforming
- d. Transgender
- e. Gender Fluid
- f. Other
- g. Prefer not to respond

- 4. Sexual Orientation
 - a. Bisexual
 - b. Gay
 - c. Lesbian
 - d. Straight/Heterosexual
 - e. Queer
 - f. Questioning
 - g. Prefer not to respond
- 5. What region of the United States were you born?
- (Returning Home) Research Protocol (IRB) (Approval Status IRB Committee only)

- a. Northeast
- b. Northwest
- c. Southeast
- d. Southwest
- e. Midwest
- f. Far West
- g. Far East
- h. Outside the United States
- 6. Marital Status: What is your marital status?
 - a. Single
 - b. In a relationship
 - c. Married
 - d. Separated
 - e. Divorced
 - f. Widowed
- 7. Income: What is your total annual income before taxes?
 - a. Less than \$20,000
 - b. \$20,000-\$40,000
 - c. \$40,000-\$60,000
 - d. \$60,000+

Appendix F Study Timeline

- 1. August 16th, 2019 Submission of Protocol to IRB for review, consideration and approval.
- 2. August 30th, 2019 Recruitment of participants
- 3. September 1st, 2019 First study initial screening calls
- September 15th, 2019 Anticipated start of waitlist group for second workshop in April 2020
- 5. October 20th, 2019– First workshop conducted. In person informational meeting, informed consent and measure completion.
- 6. October 26th, 2019 In person post-measure packet completed
- 7. November 10th, 2019 One-month follow up measures sent. Compensation gift care sent via mail upon receipt of forms packet.
- 8. November 25th, 2019 Research assistant to call any participant who has not returned forms to support form completion.
- 9. January 20th, 2020 Recruitment for second workshop will be explored and will be accomplished if needed using the same procedures as listed above
- 10. April 10th, 2020 Initial Participant Group six month follow up measures sent. Compensation gift care sent via mail upon receipt of forms packet.
- 11. April 25th, 2020 Research assistant to all call initial group who have not returned forms.
- 12. April 30th, 2020 Second in person workshop conducted. In person informational meeting, informed consent and measure completion.
- 13. May 5th, 2020 In person post-measure packet completed
- 14. May 31st, 2020 One month follow up measures sent. Compensation gift care sent via mail upon receipt of forms packet.
- 15. June 5th, 2020 Research assistant to call any participant who has not returned forms to support form completion.
- 16. October 30th, 2020 Initial Participant Group six month follow up measures sent. Compensation gift care sent via mail upon receipt of forms packet.
- 17. November 5th, 2020 Research assistant to all call initial group who have not returned forms.
- 18. November 30th, 2020 Prepare for publication.
- 19. February 28th, 2021 Paper submitted for publication

20. Appendix G – Measures and Screeners

PCL-5 with Criterion A ID #: Date:

Instructions: This questionnaire asks about problems you may have had after a very stressful experience involving actual or threatened death, serious injury, or sexual violence. It could be something that happened to you directly, something you witnessed, or something you learned happened to a close family member or close friend. Some examples are a serious accident; fire; disaster such as a hurricane, tornado, or earthquake; physical or sexual attack or abuse; war; homicide; or suicide.

First, please answer a few questions about your worst event, which for this questionnaire means the event that currently bothers you the most. This could be one of the examples above or some other very stressful experience. Also, it could be a single event (for example, a car crash) or multiple similar events (for example, multiple stressful events in a war-zone or repeated sexual abuse).

Briefly identify the worst event (if you feel comfortable doing so):	I don't feel comfortable describing the worst event.
How long ago did it happen? (please	e estimate if you are not sure)
Did it involve actual or threatened death, serious injury, or sexual viole Yes No	nce?
How did you experience it? It happened to me directly I witnessed it I learned about it happening to a close family member or close friend I was repeatedly exposed to details about it as part of my job (for exa first responder) Other, please describe	ample, paramedic, police, military, or other
If the event involved the death of a close family member or close friend violence, or was it due to natural causes? Accident or violence Natural causes Not applicable (the event did not involve the death of a close family r	

PCL-5 with Criterion A (14 August 2013)

National Center for PTSD

Page 1 of 2

Second, below is a list of problems that people sometimes have in response to a very stressful experience. Keeping your worst event in mind, please read each problem carefully and then circle one of the numbers to the right to indicate how much you have been bothered by that problem in the past week.

	In the past week, how much were you bothered by:	Not at all	A little bit	Moderately	Quite a bit	Extremely
1.	Repeated, disturbing, and unwanted memories of the stressful experience?	0	1	2	3	4
2.	Repeated, disturbing dreams of the stressful experience?	0	1	2	3	4
3.	Suddenly feeling or acting as if the stressful experience were actually happening again (as if you were actually back there reliving it)?	0	1	2	3	4
4.	Feeling very upset when something reminded you of the stressful experience?	0	1	2	3	4
5.	Having strong physical reactions when something reminded you of the stressful experience (for example, heart pounding, trouble breathing, sweating)?	0	1	2	3	4
6.	Avoiding memories, thoughts, or feelings related to the stressful experience?	0	1	2	3	4
7.	Avoiding external reminders of the stressful experience (for example, people, places, conversations, activities, objects, or situations)?	0	1	2	3	4
8.	Trouble remembering important parts of the stressful experience?	0	1	2	3	4
9.	Having strong negative beliefs about yourself, other people, or the world (for example, having thoughts such as: I am bad, there is something seriously wrong with me, no one can be trusted, the world is completely dangerous)?	0	1	2	3	4
10	Blaming yourself or someone else for the stressful experience or what happened after it?	0	1	2	3	4
11	Having strong negative feelings such as fear, horror, anger, guilt, or shame?	0	1	2	3	4
12	Loss of interest in activities that you used to enjoy?	0	1	2	3	4
13	Feeling distant or cut off from other people?	0	1	2	3	4
14	Trouble experiencing positive feelings (for example, being unable to feel happiness or have loving feelings for people close to you)?	0	1	2	3	4
15	Irritable behavior, angry outbursts, or acting aggressively?	0	1	2	3	4
16	Taking too many risks or doing things that could cause you harm?	0	1	2	3	4
17	Being "superalert" or watchful or on guard?	0	1	2	3	4
18	Feeling jumpy or easily startled?	0	1	2	3	4
19	Having difficulty concentrating?	0	1	2	3	4
20	. Trouble falling or staying asleep?	0	1	2	3	4

PCL-5 with Criterion A (14 August 2013)

National Center for PTSD

Page 2 of 2

Moral Injury Symptom Scale – Military Version Short Form^{©1}

Instructions: Please circle the number that most accurately indicates how you are feeling now:

1. I feel betra	yed by	leaders who	I once tr	uste	d.			
1	2	3 4	5	6	7	8	9	10
Strongly disagre	e M	lildly disagree	Neutral		Mildly	agree		Strongly agree
2. I feel guilt	over fa	ailing to save t	he life o	f sor	neone in w	var.		
1	2	3 4	5	6	7	8	9	10
Strongly disagre	e M	lildly disagree	Neutral		Mildly	agree		Strongly agree
		out what I die 3 4		not (6	_ 0	this til 8		10
1 Strongly disagre	2 • M	3 4 fildly disagree	5 Neutral	6	7 Mildly	•	9	10 Strongly agree
Subligiy disagre	C 1VI	indry disagree	Ivedual		windry	agree		Subligity agree
4. I am troub	led by	having acted	in ways ¹	that	violated n	ny owr	1 mora	ls or values.
1	2	3 4	5	6	7	8	9	10
Strongly disagre	e M	lildly disagree	Neutral		Mildly	agree		Strongly agree
5 Maat	4							
5. Most peop	le are t 2	3 4	5	6	7	8	9	10
I Strongly disagre		Disagree	5 Neutral	0	/ Agre		9	Strongly agree
Subligiy disagre	C	Disagree	INCULIAI		ngr			Subligity agree
6. I have a go	od sen	se of what ma	kes my l	ife n	neaningfu	l.		
1	2	3 4	5	6	7	8	9	10
Absolutely	Mostly			-	Somewhat	Mostl	у	Absolutely
untrue	untrue	untrue	true or f	alse	true	true		true
7 I have for	iven m	yself for what	t hannen	ed t	o me or of	thers d	urina	combat
1	2	3 4	5	6	7	8	9	10
Strongly disagre	_	Disagree	Neutral	-	Agre		2	Strongly agree
0, 0		0						0, 0
8. All in all, I		clined to feel t		a fa	nilure.			
1	2	3 4	5	6	7	8	9	10
Strongly disagre	e	Disagree	Neutral		Agre	ee		Strongly agree
9 I wondered	l what	I did for God	to nunis	h m	A			
1	2	3 4	5	6 6	7	8	9	10
A great deal	-	Quite a bit	U	-	Somewhat	U	2	Not at all
(very true)								(very untrue)
10 0		<i>c</i> .						
						-	_	us faith since then
1 Weakened a lot	2	3 4 Weakened a litt	5 1e	6 Stre	7 ngthened a li	8 ittle	9	10 Strengthened a lot
weakened a lot		vy cakeneu a nu	.10	Sue	nguieneu a li	1110		Suchguieneu a lot

Scoring: Reverse score items 5, 6, 7, 9, and 10, and then sum all items to produce a total score indicating moral injury severity (possible range 10-100). Scores of 8 or higher on any of the 10 items (after reverse scoring) likely require clinical attention.

¹ Koenig, H.G., Ames D, Youssef N, Oliver JP, Volk F, Teng EJ, Haynes K, Erickson Z, Arnold I, O'Garo K. Pearce MJ (2018). Screening for Moral Injury – The Moral Injury Symptom Scale – Military Version Short Form. <u>Military Medicine</u>, in press. Contact: Harold.Koenig@duke.edu

			In this c.	In this past month: c. How often has this happened?	n has thi	s happene	d?	In the	In the past month:	th: d. How stro	d. How strong is that feeling?	ίĝ,		e. Did this only occur when you
Symptom	a. Has this EVER happened?	b. Has this happened in the PAST MONTH?	Never	Once or Twice	Once or Twice a Week	Three or Four times a week	Daily	N/A	Not very strong	Somewhat Strong	Moderately Strong	Very Strong	Extremely Strong	were tired or on medications or drugs that made you tired?
1 Have there been times	undbenea.			I				I						you men.
where you felt	Yes	Yes												Yes
disconnected from your			0	4	2	ω	4	0	1	2	ω	4	ы	
body, as if your body	No	No												No
were not your own?														
2. Have you felt "checked														
out," that is, as if you	Yes	Yes												Yes
were not really present			0	1	2	ω	4	0	1	2	ω	4	თ	
and aware of what was	No	No												No
going on around you?														
3. Have there been times														
when you felt like you	Yes	Yes												Yes
were outside of your	į	į	o	<u> </u>	2	ω	4	0	_	2	ω	4	л	į
own body, as if you	No	N	c		٢				ŀ	r				N
could look at yourself	ie	č												ā
from the outside f								Ī						
4. Have you "lost time" —														
that is, been unable to	:	:												:
account for large	Yes	Yes												Yes
portions of your day or			0	4	2	ω	4	0	1	2	ω	4	б	
had trouble accounting	No	No												No
for what you did for														
portions of your day?														
5. Have there been times														
when you looked in the	Yes	Yes												Yes
mirror and did not			0	ц	2	ω	4	0	1	2	ω	4	л	
recognize yourself	No	No												No
physically?														

The following questions ask about experiences you may or may not have had. For each question, you will be asked if you have ever experienced this symptom and, if so, if you have experienced it in the past month. You will also be asked about the frequency and severity of the symptom in the past month. There are no right or wrong answers to these questions; just respond with what is true for you.

<u>DSPS</u>

			In the p c. l	In the past month: c. How often h	th: In has thi	he past month: c. How often has this happened?	ά?	In the	In the past month:	th: d. How stro	: d. How strong is that feeling?	Ċ.		e. Did this only occur when you
Symptom	a. Has this EVER happened?	b. Has this happened in the PAST MONTH?	Never	Once or Twice	Once or Twice a Week	Three or Four times a week	Daily	N/A	Not very Strong	Somewhat Strong	Moderately Strong	Very Strong	Extremely Strong	were tired or on medications or drugs that made you tired?
6. Have there been times when you were in a	Yes	Yes												Yes
familiar place, yet it seemed strange and unfamiliar to you?	No	No	0	Ч	2	ω	4	0	1	2	ω	4	м	No
7. Have there been times when your body did not	Yes	Yes	5		ç	ω	4	5	<u> </u>	2	u	4	л	Yes
feel real?	No	No	c	۲	м	U	t	c	F	М	U	t	U	No
 Have there been times when the world around you (other people. 	Yes	Yes	D	<u>_</u>	J	υ	2	5	<u>-</u>	c	υ	2	л	Yes
objects, places) did not seem real?	No	No	c	,	r	(c	,	1	((No
 Have there been times when your body felt very strange and unfamiliar 	Yes	Yes	0	1	2	3	4	0	1	2	ω	4	υ	Yes
to you, as if it were not your own body?	No	No		ŀ	1	,	-		ŀ	1	(,	No
10. Have there been times when you felt lost, disoriented, or	Yes	Yes	0	-	v	ω	4	0	-	د	ω	4	л	Yes
confused in a location that you know well?	No	No		I	I				I					No
11. Have there been times (other than when you were tired, sleepy, or														
on medications or drugs that made you	Yes	Yes	0		2	ω	4	0	1	2	ω	4	м	Yes
drowsy) when you felt as if you were in a	No	No						3						No

No												No	No	this worst traumatic event)?
Yes	u	4	ω	2	1	0	4	ω	2	4	0	Yes	Yes	15. Have you thought that you should be able to remember more about
No												No	No	about your worst traumatic event ()?
Yes	u	4	ω	2	1	0	4	ω	2	Ч	0	Yes	Yes	14. Have you had trouble remembering important details
														without remembering how you traveled there)?
No	U	4	ω	2	1	0	4	ω	2	ц	0	No	No	work, at home, at a store, or elsewhere
Yes												Yes	Yes	got somewnere (I.e., finding yourself at
														13. Have you had trouble remembering how you
No	,	1	u	Γ	Ŀ		1	U	n			No	No	an outsider, as if it were a movie, but the world did not seem real?
Yes	n	\$	υ	J	<u> </u>	>	<u> </u>	υ	J		þ	Yes	Yes	12. Have there been times when you felt like you were watching the world around you as
that made you tired?								a week	week			PAST MONTH?	EVER happened?	Symptom
or on medications or drugs	Extremely Strong	Very Strong	Moderately Strong	Somewhat Strong	Not very strong	N/A	Daily	or Four times	or Twice a	Once or Twice	Never	b. Has this happened in the	a. Has this	
when you were tired								Three	Once					
e. Did this only occur		ing?	ı: d. How strong was this feeling?	th: d. How stror	In the past month:	In the	đ	he past month: c. How often has this happened?	ith: 3n has thi	In the past month: c. How often h	In the c.			

PATIENT HEALTH QUESTIONNAIRE (PHQ-9)

ID #: _____ DATE: _____

Over the last 2 weeks, how often have you been bothered by any of the following problems?

bothered by any of the following problems?				
(use "✓" to indicate your answer)	Not at all	Several days	More than half the days	Nearly every day
1. Little interest or pleasure in doing things	0	1	2	3
2. Feeling down, depressed, or hopeless	0	1	2	3
3. Trouble falling or staying asleep, or sleeping too much	0	4	2	3
4. Feeling tired or having little energy	0	***	2	3
5. Poor apporte or overeating	0	ą.	2	3
 Feeling bad about yourself—or that you are a failure or have let yourself or your family down 	0	Adv	2	3
 Trouble concentrating on things, such as reading the newspaper or watching television 	0	4	2	3
8. Moving or speaking so slowly that other people could have noticed. Or the opposite — being so figety or restless that you have been moving around a lot more than usual	0	Adv	2	3
 Thoughts that you would be better off dead, or of hurting yourself 	0	1	2	3
	add columns		•	P
(Healthcare professional: For interpretation of TOT. please refer to accompanying scoring card).	AL, TOTAL:			
10. If you checked off any problems, how difficult have these problems made it for you to do your work, take care of things at home, or get along with other people?		Somew Very dif	cult at all hat difficult ficult aly difficult	

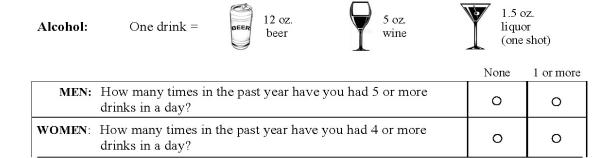
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Appendix G – Addiction Screeners

Brief health screen

We ask all our adult patients about substance use and mood because these factors can affect your health. Please ask your doctor if you have any questions. Your answers on this form will remain confidential.

Patient name:	
Date of birth:	



Drugs: Recreational drugs include methamphetamines (speed, crystal) cannabis (marijuana, pot), inhalants (paint thinner, aerosol, glue), tranquilizers (Valium), barbiturates, cocaine, ecstasy, hallucinogens (LSD, mushrooms), or narcotics (heroin).

	None	1 or more
How many times in the past year have you used a recreational drug or used a prescription medication for non-medical reasons?	0	0

Mood:	No	Yes
During the past two weeks, have you been bothered by little interest or pleasure in doing things?	0	0
During the past two weeks, have you been bothered by feeling down, depressed, or hopeless?	0	0

Alcohol screening questionnaire (AUDIT) Our clinic asks all patients about alcohol use at least once a year. Drinking alcohol can affect your health and some medications you may take. Please help us provide you with the best medical care by answering the questions below.

Patient name:	
Date of birth:	y.

()ne drink equals:	2 oz. eer	5 oz. wine		1.5 oz. liquor (one sh	ot)
1. How often do you have a drink containing alcohol?	Never	Monthly or less	2 - 4 times a month	2 - 3 times a week	4 or more times a week
2. How many drinks containing alcohol do you have on a typical day when you are drinking?	0 - 2	3 or 4	5 or 6	7 - 9	10 or more
3. How often do you have four or more drinks on one occasion?	Never	Less than monthly	Monthly	Weekly	Daily or almost daily
4. How often during the last year have you found that you were not able to stop drinking once you had started?	Never	Less than monthly	Monthly	Weekly	Daily or almost daily
5. How often during the last year have you failed to do what was normally expected of you because of drinking?	Never	Less than monthly	Monthly	Weekly	Daily or almost daily
6. How often during the last year have you needed a first drink in the morning to get yourself going after a heavy drinking session?	Never	Less than monthly	Monthly	Weekly	Daily or almost daily
7. How often during the last year have you had a feeling of guilt or remorse after drinking?	Never	Less than monthly	Monthly	Weekly	Daily or almost daily
8. How often during the last year have you been unable to remember what happened the night before because of your drinking?	Never	Less than monthly	Monthly	Weekly	Daily or almost daily
9. Have you or someone else been injured because of your drinking?	No		Yes, but not in the last year		Yes, in the last year
10. Has a relative, friend, doctor, or other health care worker been concerned about your drinking or suggested you cut down?	No		Yes, but not in the last year		Yes, in the last year
	0	1	2	3	4

Have you ever been in treatment for an alcohol problem? \Box Never \Box Currently \Box In the past

	Ι	II	III	IV
M:	0-4	5-14	15-19	20 +
W:	0-3	4-12	13-19	20 +

Drug Screening Questionnaire (DAST)

Using drugs can affect your health and some medications you may take. Please help us provide you with the best medical care by answering the questions below. Patient name:

Date of birth:

□ methamphetamines (speed, crystal)	\Box cocaine
□ cannabis (marijuana, pot)	□ narcotics (heroin, oxycodone, methadone, etc.)
□ inhalants (paint thinner, aerosol, glue)	□ hallucinogens (LSD, mushrooms)
□ tranquilizers (valium)	□ other

How often have you used these drugs? Monthly or less Weekly Daily or almost daily

1. Have you used drugs other than those required for medical reasons?	No	Yes
2. Do you abuse more than one drug at a time?	No	Yes
3. Are you unable to stop using drugs when you want to?	No	Yes
4. Have you ever had blackouts or flashbacks as a result of drug use?	No	Yes
5. Do you ever feel bad or guilty about your drug use?	No	Yes
6. Does your spouse (or parents) ever complain about your involvement with drugs?	No	Yes
7. Have you neglected your family because of your use of drugs?	No	Yes
8. Have you engaged in illegal activities in order to obtain drugs?	No	Yes
9. Have you ever experienced withdrawal symptoms (felt sick) when you stopped taking drugs?	No	Yes
10. Have you had medical problems as a result of your drug use (e.g. memory loss, hepatitis, convulsions, bleeding)?	No	Yes
	0	1

Have you ever injected drugs? □ Never □ Yes, in the past 90 days □ Yes, more than 90 days ago Have you ever been in treatment for substance abuse? □ Never □ Currently □ In the past

> I II III IV 0 1-2 3-5 6+

Ask questions that are in bold and underlined.		Past month	
Ask Questions 1 and 2		NO	
1) <u>Have you wished you were dead or wished you could go to sleep and not</u> wake up?			
2) <u>Have you had any actual thoughts of killing yourself?</u>			
If YES to 2, ask questions 3, 4, 5, and 6. If NO to 2, go directly to question 6.			
3) <u>Have you been thinking about how you might do this?</u> e.g. "I thought about taking an overdose but I never made a specific plan as to when where or how I would actually do itand I would never go through with it."			
 4) <u>Have you had these thoughts and had some intention of acting on them?</u> as opposed to "I have the thoughts but I definitely will not do anything about them." 			
5) <u>Have you started to work out or worked out the details of how to kill</u> yourself? Do you intend to carry out this plan?			
6) <u>Have you ever done anything, started to do anything, or prepared to do anything to end your life?</u>		Lifetime	
Examples: Collected pills, obtained a gun, gave away valuables, wrote a will or suicide note, took out pills but didn't swallow any, held a gun but changed your mind or it was			
grabbed from your hand, went to the roof but didn't jump; or actually took pills, tried to shoot yourself, cut yourself, tried to hang yourself, etc.		Past 3 Months	
If YES, ask: Was this within the past 3 months?			

Appendix G – Risk Screeners

COLUMBIA-SUICIDE SEVERITY RATING SCALE

Screen with Triage Points

Triage for Risk Levels

Yellow = Safety plan developed and referrals offered.

Orange = Safety plan developed, referrals offered and future check in time set

Red = Safety check or hospitalization initiated