

## Using Emotion Regulation to Decrease Aggression in Veterans With PTSD

**Short Name: Manage Emotions to Reduce Aggression (MERA)**

**Protocol v.4 Dated 1/08/2018**

**IRB ID: Pro00023884**

**PI: Shannon Miles, PhD**

AUDIT	..... Alcohol Use Disorders Identification Test
CAP	..... Consortium to Alleviate PTSD
CAPS	..... Clinician-Administered PTSD Scale
CPT	..... Cognitive Processing Therapy
DERS	..... Difficulties in Emotion Regulation Scale
DSM	..... Diagnostic and Statistical Manual of Mental Disorders
DUDIT	..... Drug Use Disorder Test
EBP	..... Evidence-Based Psychotherapy
ERQ	..... Emotion Regulation Questionnaire
ERQ-cog	..... Emotion Regulation Questionnaire - cognitive reappraisal subscale
ERQ-es	..... Emotion Regulation Questionnaire - expressive suppression subscale
IPAS	..... Impulsive Premeditated Aggression Scale
MERA	..... Manage Emotions to Reduce Aggression
JAHVA	..... James A. Haley Veterans Hospital
OEF	..... Operation Enduring Freedom
OIF	..... Operation Iraqi Freedom
OND	..... Operation New Dawn
OAS	..... Overt Aggression Scale
PCL	..... Posttraumatic Stress Disorder Checklist
PC-PTSD	..... Primary Care PTSD Screen
PCT	..... PTSD Clinical Team
PE	..... Prolonged Exposure
PTSD	..... Posttraumatic Stress Disorder
VA	..... Veterans Affairs

### Funding Source:

Organization: Department of Veteran Affairs: Consortium to Alleviate PTSD (CAP)

### Institutions where work will be performed:

James A Haley Veterans Affairs Hospital

**1. Rationale:** Veterans with posttraumatic stress disorder (PTSD) have higher rates of impulsive aggression, aggression that is emotionally charged, reactive, and uncontrolled, than Veterans without PTSD. Emotion

regulation difficulties mediated the relationship between PTSD symptoms and impulsive aggression. Additionally, Veterans who feared their emotions at pretreatment were less likely to complete PTSD evidence-based psychotherapy, such as cognitive processing therapy (CPT) or prolonged exposure (PE). These results indicate a potential treatment avenue to reduce impulsive aggression and improve evidence-based psychotherapy outcomes, namely, to increase emotion regulation skills. This pilot project will test the feasibility of implementing a 3-session emotion regulation training and generate pilot data on its effectiveness at reducing impulsive aggression and increasing PTSD treatment initiation, engagement, and completion.

**2. Background: Aggression in returning Veterans.** Aggression is common among Veterans with PTSD.<sup>1</sup> Forty-eight percent of returning Veterans with PTSD reported engaging in physical aggression, and 20% reported engaging in severe violence in the first year after deployment.<sup>2</sup> Veterans with PTSD have more anger, hostility<sup>3</sup> and certain forms of violence, such as intimate partner aggression,<sup>3,4</sup> than civilians. The association between PTSD and aggression is concerning, considering 7-20% of Afghanistan and Iraq War Veterans have PTSD.<sup>5,6</sup> Aggression can have devastating interpersonal and societal consequences for victims and perpetrators, including incarceration,<sup>7,8</sup> family violence, and disruption of treatment-facilitating factors, such as social support.<sup>9,10</sup>

Aggression research has identified two primary aggression subtypes—impulsive and premeditated<sup>11</sup>—and each has been associated with different clinical correlates<sup>12</sup> and treatment outcomes.<sup>11,13</sup> Impulsive aggression has been characterized as emotionally charged, reactive, and uncontrolled. Episodes of impulsive aggression frequently result in regret for the act. Premeditated aggression is considered deliberate, instrumental, and planned.<sup>11</sup> Seventy percent of Veterans presenting to a Veterans' Affairs (VA) hospital with PTSD and aggression primarily engaged in the impulsive type of aggression.<sup>18</sup> The preponderance of impulsive aggression in this population indicates a potential opportunity for intervention, and we are therefore focusing our efforts on this subtype.

**Emotion dysregulation mediates the relationship between PTSD and impulsive aggression.** One factor related to impulsive aggression is emotion regulation.<sup>16</sup> Lacking or underdeveloped skills in emotion awareness, emotion acceptance, behavioral control, and/or content-appropriate regulation strategies is considered emotion dysregulation.<sup>17</sup> A diminished capacity for emotion regulation is evident in PTSD samples,<sup>25</sup> in both cross-sectional<sup>25-26</sup> and longitudinal studies.<sup>27</sup> Importantly emotion dysregulation fully mediated the relationship between PTSD severity and impulsive aggression in a Veteran PTSD sample.<sup>16</sup> Emotion dysregulation as the mediator, or underlying mechanism, of the relationship between PTSD and impulsive aggression allows for the potential of addressing impulsive aggression through building emotion regulation skills. In civilian samples, emotion regulation treatments have already augmented PTSD treatments and led to better emotion regulation abilities and reductions in PTSD symptoms.<sup>34-36</sup> While emotion regulation treatments are commonly provided in the VA, only 1 published study tested an emotion regulation treatment *in conjunction with* cognitive-behavioral skills training for trauma-exposed Veterans.<sup>37</sup> This study found that reductions in fear of losing control of one's affect (an aspect of emotion regulation) predicted reductions in PTSD symptoms ( $\beta = .56$ ). The proposed study addresses the need for research on how emotion regulation training can augment PTSD treatments in Veteran samples, and to determine whether emotion regulation can be taught in a condensed time frame, to better accommodate busy Veterans' schedules.

**Condensing the duration of emotion regulation treatments for Returning Veterans.** Often, efficacious treatments need to be adapted to be successfully implemented within existing clinics and cultures.<sup>43</sup> For example, current emotion regulation treatments improve emotion regulation abilities; yet their format may need to be altered to fit the needs of busy Operation Enduring Freedom (OEF) / Operation Iraqi Freedom (OIF) and / Operation New Dawn (OND) Veterans. Emotion regulation treatments in previous studies were delivered

in residential/inpatient settings<sup>37</sup> or in outpatient settings over 8 to 12 weeks.<sup>34-36</sup> This duration of treatment, particularly when offered in combination with CPT or PE, is an unfeasible time commitment for OEF/OIF/OND Veterans, who are already difficult to engage in mental health care due to family and work obligations.<sup>44</sup> Additionally, the majority of drop outs from PTSD evidence-based psychotherapies occur prior to session 3,<sup>45</sup> thus, the initial therapy sessions with these Veterans are a critical time for skill development and treatment “buy in.” A provider may only have up to 3 sessions to assist Veterans with impulsive aggression.

A secondary consequence of teaching Veterans how to manage their emotions may be increasing evidence-based psychotherapy initiation, engagement, and completion. PTSD severity is a predictor of dropout from evidence-based psychotherapy.<sup>46-48</sup> Providing initial relief of negative affect through better emotion regulation skills may help Veterans manage their everyday distress and be able to focus on PTSD evidence-based psychotherapies.

**In summary, the primary goal of this pilot project is to test the feasibility and preliminary outcomes of a brief course of emotion regulation training in Veterans with PTSD and impulsive aggression. An exploratory goal is to gather information on the subsequent PTSD evidence-based psychotherapy initiation, engagement, and completion rates.**

### 3. Research Questions

**Research objectives.** This is a 2-year pilot study designed to test the feasibility and preliminary effectiveness of Manage Emotions to Reduce Aggression (MERA), delivered in three (3) 90-minute sessions.

#### Research Aims

Aim 1: To examine the feasibility and acceptability of MERA training in a sample of 20 OEF/OIF/OND male Veterans who have not initiated a PTSD evidence-based psychotherapy.

Aim 2: To gather data on the effectiveness of MERA by measuring pre- to posttraining changes in impulsive aggression and emotion regulation skills.

Exploratory aim: To obtain data on whether MERA increases PTSD evidence-based psychotherapy initiation, engagement, and completion.

### 4. Design/Procedure

Select one category that most adequately describes your research:

Pilot study that will be an open trial without a control group. There will be no random assignment; all subjects will get the active treatment.

Recruitment. Veterans will be identified in 3 ways: 1.) At JAHVH, Veterans who are diagnosed with PTSD are offered evidence-based psychotherapy; providers who give a Veteran a PTSD diagnosis will offer MERA to Veterans who endorse aggression. If the Veteran agrees, providers can co-sign the research staff on the Veteran’s note in the electronic medical records or call the study staff. 2.) Research staff will examine up to 1000 new referrals for PTSD evidence-based psychotherapy and with the Waivers of HIPPA Authorization and Informed Consent examine their electronic medical

records to see if they may be eligible for the study. If veterans appear to meet study criteria, study staff will send the Veteran a letter and if no opt-out call is received within two weeks, call Veteran and explain the study. 3.) Veterans can self-refer if they see study flyers or hear about the study from other Veterans.

Research staff will conduct a phone screen to estimate if the Veteran will meet inclusion criteria, and if the Veteran appears appropriate for the study, a full assessment will be conducted.

Screening Procedures. Research staff will call referred Veterans two weeks after the initial study letter is sent to Veterans (or after a provider refers them to the study), explain the study, and receive verbal consent to continue the telephone call. Research staff will then conduct a phone screen to assess for PTSD (PC PTSD-5), aggression frequency in the past month (self-reported number of aggressive acts); active suicidal intent; active homicidal intent; history of PE/CPT initiation; and, if the Veteran has an independent aggression rater, s/he will allow the study staff to contact in order to verify aggressive acts. No screening data will be used as study data. For their convenience, Veterans may be seen in person for the screening. Veterans who meet study criteria will be invited to schedule a time to learn about the study and review informed consent forms. Veterans must then meet eligibility criteria based on the pre-training assessment, before being included in the study.

Measures and assessment schedule. All assessments are routinely used within the VA and DoD.

Veterans will be assessed on the following areas:

- 1) Demographics and Military Service Characteristics Form - The form measures standard demographics (race, gender, age) and military service information (e.g., rank). Veteran will be asked to list all medications they are taking.
- 2) Alcohol Use Disorders Identification Test (AUDIT) self-report version. The AUDIT<sup>59</sup> will be used to identify people with hazardous or harmful patterns of alcohol consumption, which is an exclusion criterion. Items are scored on a 4-point scale for a highest possible total score of 40. The AUDIT has good internal consistency ( $\alpha = .80-.93$ ) as well as sensitivity and specificity.<sup>60</sup> The first three items identify current alcohol use. Only the first three items will be scored. Veterans with scores of 5 or above will be excluded from the study.
- 3) Drug Use Disorder Identification test (DUDIT) self-report version.<sup>86</sup> DUDIT will be used to identify people with hazardous patterns of substance use (all drugs besides alcohol). Items are scored on a 4-point scale for a total of 44 points. A scores of 25 suggests a person is highly dependent on drugs and any Veteran with this score will be excluded from the study.
- 4) Mini International Neuropsychiatric Interview (MINI 7.0): The MINI 7.0 is a short, structured clinical diagnostic interview designed to cover the major psychiatric disorders in DSM-5 and ICD-10. It is widely used in epidemiological studies and multi-site clinical trials. Responses to the interviewer's questions are rated as either "yes" or "no." The MINI cannot be used to index the severity of a given psychiatric problem, only caseness. When there are many skip-outs, the MINI takes ~15 minutes to administer. The MINI will be used to assess for bipolar and psychotic disorders, which are exclusion criteria.
- 5) PTSD Criteria
  - a) Primary Care PTSD Screen (PC-PTSD-5<sup>61,62</sup>). The PC-PTSD-5 contains 5 items (PC PTSD-5) that are scored dichotomously as either 0 (no) or 1 (yes). Items map onto re-experiencing,

emotional numbness, avoidance, hyperarousal, and changes in cognition/affect symptoms experienced in the past month. A score of 3 or more is considered a positive screen. The PC-PTSD-5 will be given during a screening phone call to assess whether the Veteran will likely meet the eligibility requirement of having a current PTSD diagnosis.

b) Life Events Checklist for DSM-5 (LEC-5): The LEC-5 (Weathers, Blake, Schnurr, Kaloupek, Marx, & Keane, 2013) includes the same list of 16 different potentially traumatic life events from the original LEC that are commonly associated with PTSD symptoms and designed to facilitate PTSD diagnosis (Gray, Litz, Hsu, & Lombardo, 2004). There is also a blank for specifying an additional stressful event not encompassed in the 16 events. For each potentially traumatic life event, respondents rate their experience of that event on a 6-point nominal scale (1 = happened to me, 2 = witnessed it, 3 = learned about it, 4 = part of my job, 5 = not sure, and 6 = doesn't apply). The primary addition to the LEC-5 is a category involving occupational exposure ("for example, paramedic, police, military, or other first responder"). There has not been a publication on the psychometric properties of the LEC-5, but the measure is nearly identical to the original LEC. In a group of 108 undergraduate psychology students the LEC demonstrated good convergence with the Traumatic Life Events Questionnaire (average kappa = 0.55) and correlated with the Posttraumatic Stress Disorder Checklist – Civilian version (reliability coefficients 0.34 to 0.48). The LEC demonstrated good test-retest reliability over 7 days. In 131 combat veterans the LEC was related in the predicted directions with other measures of psychopathology known to be associated with potentially traumatic life events as assessed by the Posttraumatic Stress Disorder Checklist – Military version, Clinician-Administered PTSD Scale, and the Mississippi Scale for Combat-Related PTSD.

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

d) Clinician-Administered PTSD Scale (CAPS) is a structured diagnostic interview for assessing PTSD. It has excellent psychometric properties and diagnostic efficiency.<sup>63</sup> The CAPS-5 uses a single 5-point ordinal rating scale to measure symptom severity. CAPS-5 scores range from 0 to 80, with higher scores indicating greater PTSD severity. The CAPS-5 will be administered by the study staff. To meet PTSD diagnostic criteria and be included in the study, a Veteran must endorse a score of 2 or higher on at least 1 Criterion B, 1 Criterion C, 2 Criterion D, and 2 Criterion E symptoms. The Veteran must have the symptoms for at least 1 month with clinically significant distress and/or functional impairment. The dimensional CAPS-5 score will be used to assess symptom change pre- to posttraining (exploratory outcome). To identify the index trauma(the worst and most currently distressing event), participants will first complete the DRRI-2 Combat Experiences Scale, the DRRI-2 Postbattle Experiences Scale, and the Life Events Checklist for DSM-5 (described above).

e) PTSD Checklist-5<sup>64</sup> (PCL-5) is similar in form to the PTSD Checklist (PCL) based on the *DSM-IV*.<sup>65,66</sup> The PCL-5 is a 20-item self-report measure, selected for its dimensional sensitivity, with higher scores reflecting greater PTSD severity. Scoring is based on how much the patient has been bothered by the symptoms in the past month on a scale from 0 (not at all) to 4 (extremely). A cutoff of 38 represents a likely PTSD diagnosis. +

6) Emotion regulation.

a) The Difficulties in Emotion Regulation Scale (DERS)<sup>17</sup> is a 36- item self-report measure with 6 different emotion-dysregulation factors: nonacceptance of emotional responses, difficulties engaging in goal-directed behaviors, impulse-control difficulties, lack of emotional awareness,

limited access to emotion regulation strategies, and lack of emotional clarity. The factor structure has been replicated in college-student samples<sup>17</sup> and psychiatric inpatients with good psychometric properties.<sup>67</sup> Scoring is based on how well the item describes the individual, from 1 (almost never) to 5 (almost always); higher scores represent more emotion dysregulation. The total score will be used in this study.

- b) The Emotion Regulation Questionnaire<sup>23</sup> (ERQ) is a 10-item self-report measure with 2 factors that assess specific emotion regulation strategies: cognitive reappraisal (changing the way one thinks about a situation) and expressive suppression (not expressing the emotion outwardly but feeling it internally). More effective emotion regulation is indicated by higher cognitive reappraisal scores and lower expressive suppression scores. Internal-consistency estimates (alpha) were .80 for the reappraisal factor and .73 for the suppression factor in a college-student sample,<sup>23</sup> and both were greater than .75 in a Veteran sample.<sup>69</sup> Scoring is based on how well the items describe the individual in the past week, from 1 (strongly disagree) to 7 (strongly agree).
- 7) Aggression.
  - a) The Impulsive Premeditated Aggression Scale<sup>50</sup> (IPAS) is a 30-item self-report measure that assesses impulsive and premeditated aggression. In psychiatric outpatients, Cronbach's alphas were .82 and .77 for premeditated aggression and impulsive aggression, respectively. Scoring is based on how well each item describes an individual's aggressive acts, from 1 (strongly disagree) to 5 (strongly agree). To determine eligibility for the study, the measure will be scored in a categorical method by calculating the total percentage of positive items ("strongly agree" or "agree") for each aggression subscale and classifying the Veteran as either a primarily impulsive or premeditated aggressor, based on which subscale has the highest percentage of positive items. The summed dimensional score for the impulsive aggression subscale will be used to examine pre to posttraining differences in impulsive aggression.
  - b) The Overt Aggression Scale (OAS<sup>58</sup>) is a 17-item self-report measure that assesses frequency of different aggression acts, including verbal and physical aggression against self, other, and objects. Intraclass correlation coefficients of reliability ranged from .89-.99 in 2 adult psychiatric samples.<sup>58</sup> The measure will be adapted for the current study to indicate frequency of each aggressive act over the past week. Aggressive acts will be summed to create a total score.
  - c) Independent verification of aggressive acts – all Veterans will have an adult (18 years or older) live-in partner, family member, or roommate with whom he has in-person contact most days of the week verify aggression by independently answering the OAS, based on the Veteran's behavior. Independent verification of aggressive acts is an important feature of high quality aggression research,<sup>70,71</sup> improving the quality of data without, in our experience, hindering recruitment. Impulsive aggressors may have impaired memory of the aggressive acts because of the intensity of rage, and they often confuse anger with aggression. Veterans may not think they are improving if they still experience anger, even if they are not acting aggressively.<sup>13,70,71</sup> However, it is the decrease of aggression, not the elimination of anger, that is the goal of the training. The independent aggression rater will complete the OAS before and after their Veteran participants in MERA via a phone call with the study staff.
  - d) The Pre Index Event Aggression survey is an 8-item self report of aggressive acts prior to the PTSD index event. Currently, there is no available instrument to briefly and retrospectively gauge aggression in Veterans across the life span. This is a new instrument that is being piloted with this study. This is not an outcome measure.

- 8) Veterans' acceptability of the training will be measured by an exit interview during the post-training assessment. The 25-item exit interview has 6 open-ended questions that asks about the most and least useful parts of MERA and suggestions for improvement. The 8 skills taught in the training are listed, and Veterans answer whether they learned the skill, are using it, and if it is helpful. The remaining items are either yes/no or Likert-scale questions that ask about therapist characteristics and the overall program experience.

Pretraining assessment procedures. Veterans who are eligible based on the phone screen will be scheduled for an in-person, pretraining assessment. Prior to the assessment, research staff will explain the study to the Veteran and answer any questions. After providing informed consent, the Veteran will complete study measures (described above in Measures and Assessment Schedule).

The CAPS-5 will be administered by a master's level independent evaluator. The assessment session will be audio taped; to estimate interrater agreement, a random 3% of tapes will be evaluated by the study staff. After the pre-training assessment, study staff will review the Veteran's answers to the self-report questionnaires and the structured interviews. If the Veteran meets inclusion criteria and does not meet exclusions criteria, then study staff will call the Veteran within 7 days to notify him that the study appears to be an appropriate fit and alert him of when the next treatment session will be. If the Veteran does not meet criteria, study staff will call the Veteran (within 7 days) and explain that the study does not appear to be a good fit for the Veteran. All Veterans will already be established within the VA and will be reminded of their next mental health appointments. If the Veteran desires additional resources, the PI will complete appropriate requests via the electronic medical records.

If Veterans are found to be eligible they will obtain a baseline level of aggression (and reduce retrospective bias), by completing an aggression tracking forms (OAS) during the approximate 2 weeks between the pretraining assessment and the treatment sessions. Because Veterans may inaccurately report aggressive acts, an inclusion criterion is an independent aggression rater who is willing to verify aggressive acts. This is clearly stated in the informed consent and will be explained to the Veteran. Study staff will contact the independent aggression rater by phone and read the OAS to him/her (See Independent Aggression Rater Script). This should take less than 10 minutes. Aggression frequency reported by the independent aggression rater and Veteran will be compared to determine whether the Veteran's report is accurate. This information will be helpful in determining recruitment procedures for the subsequent studies/grant.

Veterans who do not meet the inclusion criteria or meet exclusion criteria will be referred back to the appropriate clinic, either General Mental Health Clinic or PTSD Clinical Team, depending on the Veteran's needs. If a Veteran needs immediate treatment (e.g., suicidal intent, active psychotic symptoms), s/he will be referred for immediate evaluation following standard VA emergency protocols. Veterans will be able to engage in usual care during the study.

<b>Assessment schedule</b>
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Measure	No. items	Screen	Pre-training (2 wk. before MERA)	1 <sup>st</sup> MERA session	2 <sup>nd</sup> MERA session	3 <sup>rd</sup> MERA session	Post-training (1 mo. post MERA)	Chart review (6 mo. post MERA)
<b>Inclusion criteria/Sample Description</b>								
PC-PTSD	4	X						
Demo-graphics	18		X					
MINI-Psychotic Disorders	14		X					
MINI-Bipolar Disorders	8		X					
LEC-5	17		X					
DRRI-Combat experience	18		X					
DRRI-postbattle experiences	15		X					
AUDIT	10		X					
DUDIT	11		X					
CAPS-5	30		X				X	
ERQ	10		X	X	X	X	X	
Independent OAS	17		X				X	
IPAS	30		X				X	
PIEA	5		X					
<b>Primary outcomes</b>								
DERS	36		X				X	
OAS	17		X	X	X	X	X	
Exit interview	25						X	
EBP initiation	0	X						X
EBP engagement	0							X

EBP completion	0	X							X
Note: EBP = evidence-based psychotherapies.									

Training. Approximately 2-3 weeks after the pretraining assessment, Veterans will participate in MERA, delivered in 3 90-minute sessions over the course of 3 weeks at the Tampa VA PTSD Clinic. The PI will lead and audio record all treatment sessions. Treatment fidelity of each treatment session will be rated by a psychologist (TBN). Veterans will receive a training manual that contains session content along with tracking forms to monitor progress between sessions. The training begins with education about the adaptive nature of emotions, how childhood and military experiences can influence emotion regulation, and how combat requires different emotion regulation strategies than most civilian environments. It uses modeling and practice with feedback to teach cognitive-behavioral therapy and acceptance-based emotion regulation skills, such as diaphragmatic breathing, cognitive restructuring, and mindfulness. A goal of this training is to teach a variety of skills that can be used in different situations and for basic emotions (generally adaptive responses triggered by the environment that fade with time) and manufactured emotions (triggered by one's inaccurate interpretations of an event that do not fade with time if thoughts continue). Finally, information is provided about PTSD, PTSD evidence-based psychotherapies,<sup>74</sup> and what the Veteran can expect in terms of emotional experiences during evidence-based psychotherapy.

Content of Manage Emotions to Reduce Aggression (MERA) Training	
Module	Content/description
Session 1 – Introduction to emotions (anger, sadness, and joy). Emotion regulation skills training.	<ul style="list-style-type: none"> <li>Training rationale.</li> <li>Discussion of Veterans' current emotion regulation difficulties.</li> <li>Psychoeducation about 3 basic emotions (anger, sadness, joy).</li> <li>Identify: Triggers, accompanying thoughts, and physiological reactions for anger, sadness, and joy.</li> <li>Demonstrate and practice 2 skills: Progressive muscle relaxation and grounding.</li> </ul>
Session 2 – Life's influence on emotions. Education on remaining emotions (disgust and fear). Emotion regulation skills training.	<ul style="list-style-type: none"> <li>Discussion of how childhood and military influenced emotion regulation strategies.</li> <li>Psychoeducation about remaining basic emotions (disgust and fear).</li> <li>Identify: Triggers, accompanying thoughts, and physiological reactions for disgust and fear.</li> <li>Demonstrate and practice at least 2 skills: Remembering values, diaphragmatic breathing, and cognitive restructuring.</li> </ul>
Session 3 – Using emotion regulation	<ul style="list-style-type: none"> <li>Brief introduction to PTSD treatments.</li> <li>Psychoeducation as to what emotional experiences to expect and how to manage them during PTSD treatment.</li> </ul>

during PTSD treatment.	<ul style="list-style-type: none"> <li>• Demonstrate and practice 3 skills: Ride the wave (mindfulness), increase positive emotions, and visualization.</li> <li>• Writing an action plan for next treatment step.</li> </ul>
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Posttraining assessment. One month after the third MERA session, Veterans will be reassessed by the master's level independent evaluator who conducted the pretraining assessment with a similar assessment battery (see Assessment Schedule for exact measures) to detect any changes in PTSD, emotion regulation, and aggression (Aim 2). Veteran will also complete an exit interview that they can express their opinion of the training and any suggestions for improvement. Veterans' independent aggression raters will be asked to complete the OAS again via a phone call.

Chart monitoring. Research staff will examine each Veteran's chart at 6 months posttraining to see whether he initiated, engaged, and completed CPT or PE (Exploratory Aim 3), in addition to any other psychotherapy, during or after MERA (potential confounding variable for Aim 2).

Study Duration/Study Timeline. The study should take approximately 2 years to complete.

#### Data Analysis/Statistics

This pilot study is largely descriptive to determine the feasibility and preliminary effectiveness of MERA. Due to the small sample size, all alpha levels will be set at 0.1 with the goal of maximizing the chance of detecting statistical differences.

Aim 1: Veteran verbal feedback, collected at the end of the third MERA session, will be examined to improve the acceptability of the training. Frequencies will be calculated on the number of Veterans who were referred, completed the screen, completed the pretraining assessment, met eligibility criteria, and attended all 3 emotion regulation training sessions.

Aim 2. Our second aim was to explore changes in aggression and emotion dysregulation from pre- to post-treatment among patients who completed MERA. Given study attrition and our desire to use as much data as possible, the statistical design for the primary analyses was an intent-to-treat, mixed effects regression model examining the main effect of time as the effect of substantive interest. Analyses were conducted using the generalized linear mixed models module in SPSS Version 24 using data from all sessions. Data transformations using appropriate link functions given the nature of the data (e.g., log transformation due to significant skewness in the OAS across all time points), where necessary, were conducted. Results were back translated into the original metric for ease of interpretation. Where appropriate, pairwise comparisons between time points were examined to determine which time points differed from one another. Effect sizes are reported to provide context for statistically significant results. Finally, percentages were provided for the frequency of veterans' engagement in an EBP after MERA (Exploratory Aim).

Exploratory Aim. Frequencies will be used to examine the number of PTSD evidence-based psychotherapy sessions to determine initiation, engagement, and completion rates following MERA.

ADVERTISEMENT: Bulletin Board

Exact language of Advertisement:

Male Veterans Who Served in Afghanistan or Iraq

Manage Emotions to Reduce Aggression

Do you have PTSD and struggle to manage aggression? We are researching a 3-session emotion-regulation training that is designed to help Veterans manage emotions and decrease aggression.

Study Involves:

- 3 treatment training sessions
- 2 assessment sessions

If interested in learning how to decrease your aggression and also want to help other Veterans by evaluating the treatment, please call

Dr. Shannon Miles at 813-972-2000 x6728, Principal Investigator

Offered by James A. Haley

Veterans Affairs Hospital.

Funded by the Department

of Veteran Affairs'

Consortium to Alleviate PTSD.

IRB# 23884

Payment:

Veterans will not be paid for taking part in the 3-session training. However, they will be compensated for the pre and post-training assessments. After completing the pre-training assessment, each Veteran will receive a \$30.00 by direct deposit to his bank account. If he is eligible for the study based on screening questions and complete the training, he will complete a post-treatment assessment and receive a \$30.00 by direct deposit after the assessment. If you do not have a bank account, you can be paid by check. That is a maximum of \$60.00 if both assessments are completed.

Veterans will receive a Form 1099 from the VA, which is required to process their payments. This form requires that study staff to use whole social security number instead of just the last 4 digits.

Costs: There are no costs associated with the study over and above the costs that would be incurred from standard care or services. For VA patients, there may be co-payment costs for some of the non-research procedures for which the VA may not pay even if these occur while you are participating in this research. Some veterans are required to pay co-payments for medical care and services provided by the VA. These co-payment requirements will continue to apply to medical care and services provided by the VA that are not part of this study and that you would receive as part of your regular medical care.

**5. Sample size:** We request to consent up to 60 participants to account for potential dropouts. We aim for a sample of 30 Veterans. The final goal is to have complete pre- and post-treatment data for 20 participants. Up to 25 participants may need to complete the post-treatment assessment in order not to slow recruitment at the end of the study.

**6. Study Population with Inclusion/Exclusion Criteria:** Veterans enrolled at the Tampa VA and who meet the following criteria will be recruited to the study:

Inclusion criteria: 1.) Male Veteran who served in OEF/OIF/OND. 2.) Currently meets criteria for a PTSD diagnosis, determined by the Clinician-Administered PTSD Scale-5.<sup>57</sup> 3.) Engaged in at least 3 self-reported impulsive aggression acts (e.g., yelling, throwing objects, hitting objects/people) in the last month, measured by the Overt Aggression Scale.<sup>58</sup> 4.) Impulsive aggression is his/her primary form of aggression, determined by having a higher Impulsive Aggression subscore than a Premeditated Aggression subscore on the Impulsive Premeditated Aggression Scale.<sup>50</sup> 5.) Because aggressors are poor historians when reporting their aggression frequency,<sup>14-15</sup> each Veteran must agree to allow an independent aggression rater (a person with whom the Veteran has a long-standing, close personal relationship and has in-person interaction most of the days of the week; ) verify the number of aggressive acts, using the Overt Aggression Scale. 6.) No psychotropic medication change for six weeks prior to the assessment and agreement not to ask for a medication change for the duration of the study.

Exclusion criteria: Veterans who meet the following criteria will be excluded: 1.) Previously began PE or CPT. 2.) Is currently suicidal with intent of self-harm in the last week. 3.) Is currently homicidal with plans to hurt a specific person. 4.) Is unable to complete self-report measures. 5.) Does not have an independent aggression rater. 6.) Has severe alcohol consumption patterns (Alcohol Use Disorders Identification Test<sup>59</sup>), severe drug use consumption patterns (Drug Use Disorders Identification Test), active psychosis, or mania (MINI). 7.) Had a psychotropic medication change within 6 weeks prior to the pretraining assessment. Veterans receiving general mental health services or non- PE or CPT psychotherapy will be allowed to participate in this study.

**7. Expected Results (Publication and Presentation Plans):** The PI plans to publish a manuscript describing the results of the pilot project after the final data are collected in 2019. Data will be presented in aggregate form, or if case studies are written, all information will be disguised with no identifying information.

**8. Name of PI:**

PI: Shannon R. Miles, Ph.D.

**9: Potential Risk:**

Category 1: Research not involving greater than minimum risk.

Potential risks include the 1.) loss of confidentiality including having to report child or elder abuse and 2.) temporary increase in anxiety or worry. 1.) The risk of losing confidentiality is minimal and will be managed by storing personally identifying information in a locked cabinet, using random subject numbers to identify the patient data in paper and electronic form, and not including personally identifiable information in databases. Limitations to confidentiality include situations wherein the patient poses a serious danger to self or others, a medical emergency occurs, or there is cause to believe that a child, older person, or disabled person is being abused, neglected, or exploited. These exceptions to confidentiality are listed on the consent form. The risk will be made explicit to the

patients prior to completing the questionnaires. Additionally, this is consistent with routine clinical practice and state laws. Often Veterans bring in their partners to PTSD treatment sessions and the same reporting laws apply in clinical practice and research.

2.) Veterans will be asked about how they are currently coping with emotional experiences. The assessments and training are already used as routine clinical practice within the VA system, with a difference being the training is delivered in a condensed format rather than the tradition 8-12 sessions. With all psychological treatments and assessments, the procedures may cause a temporary mild increase in worry, anxiety, or other emotions. The goal of the treatment is to teach participants more adaptive ways of coping, and any such increases in emotions are expected to be temporary. All patients will have the opportunity to terminate the assessment or therapy at any time. Further treatment resources will be made available, including the 24-hour Emergency Room, treatment through mental health, and the Veteran suicide hotline number. No physical risk is foreseen.

**10. Any experimental procedures:** Research has shown that emotion regulation skills can help people manage their emotions and daily stress and these skills may also help you manage your aggression. Emotion regulation treatments are already provided in the VA system and are not experimental. However, the condensed treatment format (3 sessions instead of 8-12) has not been tested before and is not currently part of standard VA practice.

#### **11: Potential Benefits:**

Potential benefits to the Veteran.

Emotion dysregulation related to PTSD can lead to aggression and is a huge barrier for OIF/OEF/OND Veterans adjusting back to civilian life. The legal, interpersonal, social, and psychological consequences of emotion dysregulation and aggression are far-reaching and are a constant strain on individuals, families, and society. The intervention teaches Veterans how to better manage emotions and his aggression. The Veteran may feel better in his daily life after learning these skills. Additionally, a goal of the study is to decrease aggression, which has interpersonal, legal, and financial consequences. If the study assists Veterans in being able to control aggression, improved psychosocial functioning may be the result. However, the participant may obtain no benefit from participating.

Potential benefits to society of the planned work.

Expanding the understanding of what treatments work to reduce aggression is imperative and this condensed treatment may offer Veterans some relief from their emotion dysregulation and impulsive aggression in a shorter time frame than traditional anger management treatments. Decreases in aggression not only benefit the Veteran, but also the Veteran's family and community. The treatment may also benefit the VA because of the decrease in provider time required to deliver the training. The VA system is already taxed with serving the increasing number of returning Veterans and this may help reduce that challenge.

Risk-to-benefit ratio.

This proposed work has a favorable risk-to-benefit ratio because there are many potential benefits to the participants and society which include better emotion regulation skills, reducing aggression, and

increasing knowledge about what helps Veterans reduce aggression. Additionally, Veterans may experience improvements in emotion regulation skills after 3 sessions, as compared to traditional emotion regulation treatments, which are 8-12 sessions. The VA may also benefit from the condensed format of the training. The possible risks are minimal and typically transient and are no more than experienced during routine clinical practice.

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## **12. Human Subjects considerations:**

Four forms are being requested as part of this study: A waiver of informed consent, a waiver of HIPPA authorization (for screening), an informed consent, and a HIPPA authorization. In order to screen participants, waivers of informed consent and HIPPA authorization are requested to allow the research staff to open the medical records of veterans who have been referred to the PTSD clinic. This will allow the research staff to see if the Veteran appears appropriate for the study before contacting the Veteran. If the Veteran likely meets study criteria, research staff will send a letter describing the study to the Veteran which will provide a number the Veteran can call for more information or to opt-out of the study. The letter will explain that the research staff will call the Veteran in two weeks if they do not receive an opt-out call. After two weeks, study staff will call the Veteran, explain the study, and receive verbal consent to continue the telephone call. Research staff will then conduct the phone screen.

Veterans who are eligible based on the phone screen will be scheduled for an in-person, pretraining informed consent session which will take place in a private office. Research staff will explain the study to the Veteran including the risks and benefits, that participant is voluntary and will in no way affect his/her treatment, and that s/he can withdraw from the study at any time without explaining why. The research staff will answer all questions. If the Veteran would like to take home the informed consent form and further consider if he would like to participate, another session will be scheduled for the pre-training assessment session.

### **Data Security.**

PHI to be collected and used for this study include name, address (including street, city, and zip code), telephone contact numbers, and date of birth. Real Social Security Numbers (SSN) will be collected in order to compensate Veterans for their time (Form 1099). Past and current diagnoses of alcohol and drug use disorders be gathered from the participant's medical chart. These data are part of Title 38 U.S.C. 7332 protected information (drug abuse, alcohol abuse, HIV infection, and/or sickle cell anemia medical records). The purpose of collecting drug and alcohol abuse (38USC7332) data is to conduct scientific research. No personnel involved, in this study, will identify, directly or indirectly, any individual patient or subject in any report of such research or otherwise disclose patient or subject identities in any manner. Any information about patients obtained from this research will be kept strictly confidential.

The study will generate both paper and electronic data. Access to information obtained for the purposes of this study will be restricted to authorized research personnel who have completed all required research trainings, although just like other hospital records they are subject to subpoena by court order. Paper data will be stored in a locked filing cabinet in the PTSD Clinic, in the PI's locked research space. Consent forms will be stored separately in the locked storage space, apart from all coded study data. Study results will be published without any identifying information reported, and patients' identities will be disguised.

**Data flow:** Data will be collected from the participants, identified with only a code number, stored in a locked filing cabinet in the PI's research office space, and then coded data will be entered into a database on the R drive. Study personnel will work only with de-identified data. The cross-reference file

that links study IDs and PHI will be stored in a separate, secure folder on the James A. Haley VA R drive server with access limited to the study staff. It is understood by the PI and study staff that data will not be used or shared with others outside the scope of the research study as documented in the protocol approved by the IRB and JAHVAMC R&D Committee. Data and research related information will be maintained and destroyed in accordance with VA policy. Access to research study data will be removed from study staff when they are no longer rated to team.

Every member of the research team will be trained and monitored about how to handle and protect both medical and research records. Furthermore, the research team strictly controls access to study data.

#### Serious Adverse Events and Unanticipated Problems

This study does not involve a drug intervention, device intervention, or highly invasive data collection procedure. However, recognizing that unanticipated events can occur in the course of any study, even a minimal risk study, the following reporting protocols will apply:

Unauthorized use, disclosure, transmission, removal, theft, loss, or destruction of VA research-related PHI, individually identifiable private information, or confidential information, as defined by the HIPAA Privacy Rule, the Common Rule, the Privacy Act, or 38 U.S.C. §§5701, 5705, and 7332;

- Report within 1 hour to ACOS for Research, the facility ISO/ PO.

Unanticipated serious adverse events (SAEs) that the Site PI considers to be related, possibly related, or probably related to study participation;

- Site will report within 24 hours of site's awareness to the site IRB and facility ISO/PO.

Serious Adverse Events include deaths, life-threatening physical parameters (laboratory values, blood pressure), hospitalization, disability or permanent damage, congenital anomalies or birth defects, an event that requires intervention to prevent permanent impairment, other serious medical events (bronchospasm, seizures).

For all events, the site PI will assess the event to evaluate whether it is unanticipated, related to the study, or if it places the participant or others at an increased risk for harm in order to determine whether it should be reported to the local and sponsor IRBs.

- As covered in section participants expressing suicidal ideation either in person or on the phone will be managed according to local VAMC protocols, which includes: Stay with the Veteran until s/he can be 'handed off' to appropriate medical staff, including the Emergency Room for evaluation.
- All study personnel who work directly with research participants will be given the names and phone numbers of the patient's medical care team. After the Veteran has been 'handed off' to the appropriate staff, the PI will be alerted.

An Accounting of Disclosure (AOD) will be created and maintained for any disclosure of individually identifiable information (III) outside the VA. The electronic spreadsheet will include the participant's name, date of the disclosure, nature or description of the III disclosed, purpose of each disclosure and the name and address of person or agency to which the disclosure was made.

Who, besides the PI, the study staff, the IRB and the sponsor, will have access to identifiable research data?

Access to identifiable research data from JAMVAH will be restricted to JAHVAH research staff and IRB. People who ensure quality from the institutions where the research is being done, federal and other regulatory agencies will have access to all of the research data. It is understood by the PI that data will not be used or shared with others outside the scope of the research study as documented in the protocol approved by the IRB and R&D Committee. Removal of access to research study data will be accomplished for all study personnel when they are no longer part of the research team.

### **13. Data safety monitoring plan:**

The study is minimal risk.

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