Title: Thriving in the Midst of Moral Pain: The Acceptability and Feasibility of Acceptance and Commitment Therapy for Moral Injury (ACT-MI) Among Warzone Veterans

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COMIRB Protocol

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I. Objectives and Specific Aims

The proposed pilot study is designed to support ACT and moral injury content experts in their continued refinement and evaluation of ACT-MI for warzone Veterans. The proposed pilot study would solidify the treatment approach and study design for a future efficacy trial.[17] The specific aims focus on evaluating the acceptability of ACT-MI and determining the feasibility of the efficacy study design. Given these aims, this pilot study is intentionally not powered to test the efficacy of ACT-MI. The proposed pilot study is a critical step in preparing for a future efficacy trial of ACT-MI relative to Present Centered Therapy for Moral Injury (PCT-MI-MI)[82] for the treatment of moral injury among warzone Veterans. We define moral injury as social, psychological, and spiritual suffering stemming from costly or unworkable attempts to control moral pain (e.g., unworkable attempts to control painful moral emotions [guilt, shame, anger, contempt, disgust] and cognitions [thoughts related to blaming the self and others]).[15] Criteria for feasibility outcomes have been specified.[18] A two arm, randomized controlled design (ACT-MI vs. PCT-MI-MI) will be used to:

Aim 1: Evaluate the acceptability of the ACT-MI intervention for Veterans experiencing impairment in functioning associated with moral injury. Acceptability refers to the appropriateness of the intervention from the perspective of the clinical population of interest. We will assess the proportion of participants who find ACT-MI acceptable, defined as ≥ 70% of participants scoring ≥ 24 on the Client Satisfaction Questionnaire (CSQ).[19] The Narrative Evaluation of Intervention Interview (NEII)[20] will be used to inform any necessary revisions to the intervention and refinement of the treatment manual.

Aim 2: Determine the feasibility of the efficacy study design. Feasibility will be assessed by examining the following outcomes related to recruitment, retention, and provider adherence: (1) number of participants approached for the study who are eligible and of those, the number who enroll in the study (i.e., agree to participate). Feasibility is defined as ≥ 50% eligible and of these ≥ 30% willing to participate in the proposed time frame. (2) participant completion of ACT-MI will be measured by the percentage of participants who complete treatment and receive an adequate dose (complete a minimum of 70% of the intervention). (3) percentage of participants lost to follow up (LTFU). The percentage of participants who fail to complete one- month and three-month follow-up visits will be measured, with ≤ 30% LTFU considered feasible, informing

the necessary sample size and treatment retention strategies for future studies. (4) treatment fidelity checklists will examine provider adherence to treatment, with ≤ 15% of deviations to be considered acceptable fidelity.

Aim 3: Select measures and calculate the necessary sample size for a future efficacy study. Evaluate candidate measures based on the following factors: (1) Amount and distribution of missing data, (2) means and standard deviations, and (3) correlations with a measure of self-reported clinically significant change. Estimates of variability in outcome measures will inform power analysis and target sample size for a future efficacy study.

With the onset of the COVID-19 pandemic, it has become clear that the feasibility of delivering interventions through telehealth may be critical to their utility and that research methods must also be feasible for use through telehealth. Two aims related to conducting ACT-MI using telehealth are being evaluated:

Aim 4: Evaluate the acceptability of the ACT-MI intervention delivered over telehealth. ACT-MI will be delivered over telehealth as needed due to the COVID-19 pandemic. Acceptability of in person and telehealth data will be analyzed separately.

Aim 5: Evaluate the feasibility of the efficacy study design with all assessment sessions delivered over telehealth. ACT-MI and all assessment sessions will be delivered over telehealth as needed due to the COVID-19 pandemic. Feasibility of in person and telehealth data will be analyzed separately.

II. Background and Significance:

Moral injury is a significant risk factor for a range of psychological syndromes and functional impairments.[5-7] Exposure to morally injurious events creates heightened risk for PTSD, depression, substance abuse, and suicidal ideation and behavior.[1-4] Veterans reporting distress related to exposure to morally injurious events also endorse significant difficulties in daily functioning including disengagement from spirituality, disconnection in relationships, difficulties in the workplace, and disinterest in physical self-care.[5-7] Furthermore, **moral injury is highly prevalent among Veterans and military personnel**. Twenty seven percent of Active Duty soldiers endorsed facing ethical dilemmas during their service.[8] Among combat Veterans, 11% acknowledged engaging in morally transgressive events while deployed, 26% reported experiencing transgressions by others, and 26% indicated moral betrayal.[9] **Given the high prevalence and significant consequences of morally injurious events, it is crucial to develop therapies that efficiently and effectively treat the psychological processes set in motion by moral injury.**

Given the relevance of moral injury to several psychological syndromes, we propose an explicitly transdiagnostic, group based psychotherapy targeting moral emotions for the treatment of moral injury (Acceptance and Commitment Therapy for Moral Injury; ACT-MI). Acceptance and Commitment Therapy (ACT) is a functional contextual treatment that is recovery-oriented and evidence-based.[36] It has been designed for Veterans reporting difficulties in functioning following exposure to morally injurious events (See Table 1).[37, 15]

ACT is rooted in a highly researched theory of human language and cognition (Relational Frame Theory [RFT]) where internal events (thoughts, emotions, memories, urges) are viewed as actions that can be predicted and influenced.[38-39] RFT explains how relationships between language and an event are derived, relationships that can be generated whether an event is directly experienced (e.g., killing another human) or if it is indirectly learned about (e.g., hearing about an atrocity). Once a person experiences or learns about an event and has language to describe it, relational networks are created between that event and other internal events (e.g., relationships between the experience and thoughts, emotions, urges, sensations). For example, if a combat Veteran witnesses an event in combat that he views as morally wrong (e.g., the killing of a child), he will automatically generate relational networks between that event and events that are directly or indirectly related. Additionally, each time he accesses that event, related thoughts, memories, images, and sensations will be evoked. Thus, without actually experiencing the event again, the Veteran could feel moral pain from just thinking about the event. Because of how these networks develop and how pervasively they spread, altering the function of thoughts, emotions, and sensations associated with these networks is arguably a more potent means of addressing these events in treatment than challenging their content.[38] Rather than attempting to falsify or get rid of unwanted thoughts, memories, images, and sensations; in ACT skills like mindfulness help individuals change the ways in which they relate to thoughts (e.g., looking at one's thoughts rather than from one's thoughts). In ACT clients practice identifying thoughts and emotions for what they are (e.g., temporary internal experiences) rather than what the mind says they are (permanent truths or facts that are absolutely certain). Clients learn to accept these experiences rather than trying to control, reduce, or get rid of them. In turn, this can result in increased volitional control over one's behavior and enhanced psychosocial functioning. In ACT the goal is to help clients identify and act consistently with their values while experiencing their pain, unlike the goal of traditional Cognitive Behavioral Therapies which emphasize symptom reduction. In this way, **ACT directly targets functional recovery as clients learn to identify and engage in their values regardless of internal events (e.g., thoughts, emotions, and memories).**[42]

Applying ACT to Moral Injury:

Acceptance and Commitment Therapy for Moral Injury (ACT-MI) was explicitly developed to target the social functions of moral emotions for Veterans reporting experiences consistent with moral injury,[15] thus addressing a significant gap in the literature. Instead of identifying moral emotions like guilt and shame as signs of psychopathology, ACT-MI targets the individual's behavior in response to these emotions. In the case of a Veteran killing an enemy in war, current approaches to moral injury would emphasize challenging painful beliefs thereby reducing emotions related to this experience (e.g., shame is not justified because the Veteran was also in danger). In contrast, ACT-MI highlights the importance of shame as an indicator of acting outside of personally- and socially-informed values, explains the purpose of this emotion and its action tendencies (e.g., avoiding social disapproval), and leaves room to respond to shame in a functional manner (e.g., engaging in meaningful contributions to the group). With respect to killing in war, an ACT-MI approach would emphasize learning to separate one's self from unworkable beliefs (e.g., "I deserve to suffer because of my past mistakes"), identifying the values inherent within moral pain (e.g., kindness), and promoting behavior consistent with values even in the presence of discomfort.[15] Veterans are taught how to interact with moral emotions differently in order to foster meaningful lives. In particular, committed action through values-consistent social interaction is encouraged in ACT-MI through

its group format and its emphasis on enacting socially meaningful behaviors outside of session, thereby offering multiple in-vivo opportunities for new social learning. The factors described in Table 1 highlight ACT-MI as a novel offering for the treatment of moral injury that is uniquely situated to help Veterans learn to experience moral emotions in the context of rebuilding their lives.

Table 1. Existing Barriers, Needs, and Support for ACT-MI

Barrier	Need	ACT-MI as Solution
Extant interventions may not adequately target moral emotions.	Theoretically grounded interventions that explicitly target moral emotions.	ACT-MI is based on social functional theory of moral emotions. Using experiential exercises, metaphors, and skills practice between sessions, ACT-MI capitalizes upon opportunities for learning.
Several potential symptom pathways can lead to moral injury.	Moral injury specific, transdiagnostic interventions.	ACT-MI is a transdiagnostic intervention structured to address moral injury regardless of its etiology (e.g., suited to address moral betrayal or moral perpetration) or diagnoses with which it is associated (e.g., PTSD, substance use disorders, depression).
Extant interventions focus primarily on symptom reduction rather than the need to foster recovery.	Recovery-oriented interventions that promote tolerance of moral emotions AND reintegration with relationships and the community.	ACT-MI directly targets functional recovery by assisting Veterans in identifying and engaging in value-consistent behaviors despite associated moral pain via aversive thoughts, emotions, sensations, and/or urges.
Moral emotions are social in nature. Individual treatment modalities limit opportunities for social interaction.	Interventions that include opportunities for social interaction with peers.	ACT-MI is based on a social functional theory of moral emotions and is delivered in a group format to provide maximal opportunities for new social learning in the presence of both values and pain.

The ACT-MI protocol consists of the following content across twelve group therapy sessions: **Session one** will consist of psychoeducation about moral injury and define constructs associated with moral injury. The values blocked by behaviors consistent with moral suffering will be explored and the concept of moral healing introduced. Veterans will engage in a values card sort as an experiential exercise prior to session two to help them become aware of their values and behaviors that are potentially blocking these values. In **session two** the unworkability of current behavior in response to moral pain will be explored through creative hopelessness. Veterans and facilitators will generate a list of control strategies used to avoid moral pain and will discuss the effects of these strategies on their lives. Discussion will include consideration of what it would be like to shift away from control strategies and into willingness to live a life with moral pain. The concept of bold moves (committed action to engage with values even in the presence of moral pain) will be introduced. As a practice exercise prior to the next session, Veterans will be asked to generate a list of possible bold moves. **Session three** will consist of contact with the present moment where Veterans and facilitators will discuss what it means to enter into the present moment and how to do so. An experiential exercise will be practiced where Veterans are asked to mindfully slow down and focus their attention on the breath. As a practice

exercise Veterans will be asked to review their bold moves list and create a bold moves ladder, ranking bold moves based on expected difficulty and importance. Veterans will be asked to engage in at least one bold move each day. In **session four** Veterans and facilitators will discuss the limits of control strategies and the process of acceptance will be introduced as a values-oriented alternative. Veterans and facilitators will engage in a mindfulness exercise to practice building an accepting stance towards moral pain. Veterans will be asked to name their moral injury and identify where moral pain is felt in the body, assigning a shape, color, texture and weight to it. The limitations of control will be discussed and a metaphorical exercise focused on a "tug-of-war" with a "monster" representing moral pain will introduce willingness to experience moral pain (i.e., "dropping the rope") as an alternative to a life dominated by fighting internal experiences. Veterans will be asked to complete a practice exercise between sessions focused on identifying how their moral pain is experienced in addition to continuing to engage in bold moves. **Session five** consists of content and exercises emphasizing defusion from internal experiences, in particular thoughts. Noticing and describing thoughts for what they are (thoughts) is emphasized. Veterans are asked to practice noticing internal experiences three times a day and to continue practicing bold moves daily. In **session six,** anger is identified as a form of moral pain. Behaviors associated with anger are discussed and its workability is explored. The flip side of anger, vulnerability, is identified. The practice exercise for between sessions again is to engage in one bold move each day. Additionally, Veterans are asked to complete an exercise identifying the goals and results of anger, and to engage in a practice identifying the self. **Session seven** focuses on understanding the development of the self, beginning with values formation in childhood and then transitioning to joining the military, during the military, and after the military. Veterans are asked to explore how the next chapter of their lives might unfold. Bold moves are assigned as practice prior to the next session. In **session eight,** defusion from stories about the self is emphasized. Putting the self in context and describing events of one's history for what they are is practiced. As a practice exercise Veterans are asked to continue to practice one bold move a day and to write two versions of the story of their life, one of which emphasizes if things stayed the same for the Veteran and the other if the Veteran moved forward while still acknowledging the past. **Session nine's** focus is on establishing the connection between pain and values. The functions of pain, and pain and values as two sides of the same stone are discussed. Distinctions are made between pain and suffering (pain + nonacceptance). As a practice exercise, Veterans are given a stone and asked to put a word related to their moral injury on one side of the stone and a value on the other side of the stone. They are asked to carry this stone around with them and reflect on their experience. In **session ten,** the idea of pain as a signal for social connection is explored. Pain is described as a bridge to empathy and connection. Veterans are next asked to construct and walk around with a ball representing their shame and notice what this experience is like. They are asked to imaginally practice self-compassion while carrying the shame ball. As a practice exercise, in addition to one bold move daily Veterans are asked to practice compassion for others. **Session eleven** explores practicing compassion for the self. Self-compassion is described as acceptance of one's pain, acknowledging that pain is a common human experience and that the Veteran is not alone in their experience. For a practice exercise, guided meditation focusing on self-compassion is assigned. Veterans are also asked to create a personal mission statement emphasizing bold moves directed at contributing to or supporting others and focusing on what they want the rest of their lives to stand for. The final session, **session twelve**, focuses on how Veterans will continue to boldly move towards their values after

treatment. The meaning of the group will be discussed. A continued approach to acceptance as a moment-by-moment choice rather than a destination will be emphasized.

The proposed pilot study is a vital first step in the successful development and evaluation of the efficacy of ACT-MI, a transdiagnostic group treatment for moral injury. Methodologically rigorous pilot studies are increasingly being recognized as a crucial component of the evaluation of interventions. As Areán and Kraemer indicate, "pilot studies are an integral part of the research process and feasibility studies ensure that the trial can be successfully done as proposed" (p. 90).[17] Rather than moving prematurely to assessing the efficacy of ACT-MI, it will be critical to run the proposed "dress rehearsal" of the efficacy study. The proposed pilot study will allow us to make final revisions to the ACT-MI manual, test the acceptability of ACT-MI, and ensure the feasibility of the study design. After the completion of two ACT-MI groups, acceptability data will be examined and used to inform any necessary revisions to the manual. We will test the acceptability and feasibility of the revised ACT-MI manual. Related to feasibility of the study design, the proposed pilot will help us understand issues related to recruitment, retention, and provider adherence associated with ACT-MI.

PCT-MI was developed as an active control condition to facilitate hope, emotional support, and increased mastery.[67, 82] In the current study, PCT-MI will be implemented as an active comparison condition including twelve, 90-minute group psychotherapy sessions. The first session of group-based PCT-MI will involve group orientation and psychoeducation where providers will educate Veterans about common symptoms associated with moral injury. Elements PTSD, depression, substance abuse, and suicidal behavior will be discussed in relation to the transdiagnostic construct of moral injury. Veterans will be given information about the rationale for the present focus of PCT-MI. Following the psychoeducation session the remaining eleven PCT-MI sessions will follow a similar structure. First Veterans will participate in a check-in where they identify daily life issues. Following this check-in Veterans will discuss these problems. Facilitators will ask questions to identify the situations in which these issues occur and with whom, how the Veteran responds to these experiences, and potential alternative ways of responding. Where relevant, problems are linked to moral injury. In addition to this content area, the following strategies for intervening with patients/group issues are employed in PCT-MI: enlisting the group, reframing, reflective listening, redirecting, interrupting, representing/reflecting the negative side of ambivalence, confronting, setting limits, taking a "one-down" position, pacing of structured presentations, and process comments. Because PCT-MI has been established as an evidence-based active control condition, it is likely to serve as a beneficial transdiagnostic intervention in its own right.[82] PCT-MI could provide another treatment option that might be preferable to some Veterans and promote patient choice. Additionally, PCT-MI would require less clinician training and specialization than ACT-MI. Using PCT-MI as an active comparison condition will determine whether it is necessary to train clinicians in ACT-MI or if therapists with exposure to supportive problem-solving therapy approaches can lead a group that impacts functioning among Veterans reporting moral injury-related distress.

III. Preliminary Studies/Progress Report:

ACT-MI has been formally proposed as an intervention well suited to treat moral injury.[37, 15] We are continuing to revise the ACT-MI protocol. Thus far the intervention has been

used at the Palo Alto VAMC (n = 14 Veterans)[15] and the Denver VAMC (n = 22 Veterans completed; n = 4 current cohort). These initial groups have informed early iterations of the ACT-MI manual. Dr. Borges and the team integrated manuals across sites and began using the manual included in this proposal as part of the treatment offered at the Denver VAMC. Program evaluation data have been collected. Acceptability data was collected in the most recent ACT-MI cohort at the Denver VAMC (n = 5 Veterans) that Dr. Borges and Dr. Farnsworth co-facilitated. All five Veterans rated the intervention to be well above the Client Satisfaction Questionnaire (CSQ) acceptability cutoff of ≥ 24 with scores ranging from 30 to 32-points. In particular, all Veterans endorsed "yes, they helped a great deal" when asked, "have the services you received helped you to deal more effectively with your problems?" All Veterans also reported "yes definitely," when asked, "if a friend were in need of similar help, would you recommend the program to him or her?" Another measure of acceptability we administered was the Narrative Evaluation of Intervention Interview (NEII). Below are responses to items from the NEII in each content domain (responses from each patient are included).

Table 2. Acceptability Data from most recent ACT-MI Cohort

Content Domain of NEII	***Patients' Responses***
<u>Description of the intervention process</u> "What change, if any, took place during participation in the intervention? If a change did not take place, please describe what happened during participation in the intervention?"	"My change was acceptance. I am not admitting what happened was right but that it happened and is in the past." "I have got myself out of isolation." "I am not alone." "The way I look at things. Now I'm bigger picture." "Increase in self-esteem."
"How does this intervention differ from other interventions you attended in the past?"	"This one worked on the pain and not the memory." "More direct input and ideas from others."
<u>Description of the intervention outcome</u> "Please describe what the intervention contributed to you. What was its impact after the intervention was completed?"	"It helped me feel much better about who I am as a person." "Gave me ideas of how to move forward in life and how to make sense of the pain." "It started with me forgiving myself."
<u>Evaluation of the intervention process</u> "What did you do during the intervention that helped you?"	"Opened up to other people." "Participate." "Listened. Absorbed. Learned." "[Promoted] comradery and structure."

Evaluation of the intervention outcome "What components of the intervention were helpful?"	"All of them had an influence on me. From defining my values to naming the rock." "Bold moves, values, learning to write my own future."
"What if any were the undesirable effects of the intervention?"	"None worth changing." "Seeing reflections of who I was. It was necessary for me to make my new path."
"Would you recommend others to participate in this intervention? Why?"	"Yes. Learn about yourself." "Yes. It is helpful to learn your values in life."

IV. Research Methods:

A. Outcome Measure(s):

Aim 1 Measures: Acceptability. The ***Client Satisfaction Questionnaire*** (CSQ-8)[19] is a self-report measure that will be used to assess participants' satisfaction with ACT-MI and PCT-MI. (*Duration:* 5 minutes; *Administration:* Post-Treatment; One-Month Follow-Up; Three-Months Follow-Up). The ***Narrative Evaluation of Intervention Interview*** **(NEII)**[20] is a 16-item semi-structured interview assessing each participant's perspective of the impact of the intervention. Additionally, the NEII will be used to measure helpful and unhelpful components of ACT-MI and PCT-MI for comparison to other interventions. This yields rich information regarding how the intervention can be modified to better meet patients' needs (*Duration:* 15 minutes; *Administration:* Post-Treatment). Participants who withdraw from treatment, but agree to remain in the study will also complete the ***Reasons for Termination (Client and Therapist versions;*** **RT-C/RT-T)**[74] scale, which assesses the impact of 19 common reasons why patients terminate therapy. Study clinicians will also complete the RT-T (*Duration:* 5 minutes; *Administration:* Following withdrawal from treatment).

Aim 2 Measures: Feasibility. A ***treatment fidelity checklist*** was developed for the current study to monitor clinician adherence to the treatment manual after each recorded session. It was modeled off of fidelity checklists included in trials of other cognitive behavioral therapies and incorporates treatment competency items from an ACT fidelity measure used in the ACT for Depressed Veterans roll out.[59] A fidelity checklist was also developed for PCT-MI based on previous PCT-MI treatment fidelity checklists.[61]

Aim 3 Measures: Select measures and calculate necessary sample size for a future efficacy study. The following measures will be included as candidate outcome measures for a future efficacy trial, and be administered at baseline, post-treatment, one-month, and three-month assessment sessions. Candidate measures will include assessments of three domains.

Baseline measures to diagnostically characterize the sample: To characterize the sample at baseline the Structured Clinical Interview for the DSM-5, the Columbia-Suicide

Severity Rating Scale, and the Moral Injury Outcome Scale will be administered. ***Structured Clinical Interview for DSM 5 Research Version*** **(SCID-5-RV)- Modules A, D, E, F, and L** is a diagnostic interview used to determine DSM-5 disorders. All participants will be administered the SCID-5-RV during the baseline assessment session. Specifically we will administer the following modules: A- Mood Episodes, D- Differential Diagnosis of Mood Disorders, E- Substance Use Disorders, F- Anxiety Disorders, and L- Trauma- and Stressor-related Disorders. This will provide a broader diagnostic characterization of the participants. *Approximate time to complete: 30 minutes.* **The Columbia-Suicide Severity Rating Scale (C-SSRS)** (Posner, Brown, Stanley, Brent, Yershova, Oquendo, Currier, Melvin, Greenhill, Shen, & Mann 2011): The C-SSRS is a clinician-administered measure that assesses for suicidal ideation and attempt behavior based on established definitions. The C-SSRS assesses intensity of suicidal ideation, specifically asking about frequency, duration, intrusiveness, controllability, and deterrents, as well as suicide-related behavior, such as actual attempts and aborted attempts. *Approximate time to complete: 10 minutes.* **Moral Injury Outcome Scale (MIOS)** (Lits, Phelps, Frankfurt, Murphy, Nazarov, Houle, Levi-Belz, Zerach, Dell, Hosseiny & members of the *Moral Injury Outcome Scale Consortium* 2021): The MIOS is a 32-item self-report measure used to assess the type of morally injurious event experienced, as well as the extent to which that event has affected functioning. The MIOS assesses the impact a morally injurious event has had on trust, guilt, self-doubt, and faith in relation to the self, others, and spiritual practices. *Approximate time to complete: 10 minutes.*

Measures of Functional Recovery. The first area to be assessed at baseline, post-treatment, one-month, and three-month sessions will be functional recovery. The ***Valued Living Questionnaire (VLQ)***[75] is a self-report measure that assesses participants' values as well as the consistency with which they believe they have been living life according to their values. Participants rate the importance of ten domains of living (e.g., citizenship/community life). Following this, participants rate their behavior over the past week based on how consistently they have acted on each valued domain (*Duration:* 10 minutes). The ***Outcome Questionnaire-45 (OQ-45)***[76] assesses functioning within the last week across three psychosocial domains which include symptom distress (e.g., "I feel nervous), interpersonal relationships (e.g., "I have frequent arguments"), and social role functioning (e.g., "I find my work/school satisfying"). Reliability and validity for the 45-item self-report measure has been established in Veteran samples. This scale is ideal for transdiagnostic assessment as it does not require participants to make ascriptions to the causes of their functional impairments. (*Duration:* 15 minutes). The ***Inventory of Psychosocial Functioning (IPF)***[98,99] assesses impairment within the last 30 days across a range of psychosocial domains (e.g., work, socializing etc.). The 80-item self-report measure was developed and validated in a sample of Veterans. The scale does not require respondents to make attributions regarding the cause of impairments and is therefore ideal for transdiagnostic assessment of functioning (*Duration:* 15 minutes). The ***PROMIS Short Form v2.0- Satisfaction with Social Roles and Activities 8a***[78] is an eight-item self-report measure that assesses satisfaction with respondents' ability to perform various social activities (*Duration:* 3 minutes). ***PROMIS v2.0- Social Isolation***[80] is a 14-item self-report measure that assesses feelings of social isolation (*Duration:* 3 minutes).

Measures of ACT Processes. The second area measured will be with scales related to ACT processes. **Process measures EMA** To measure behavioral changes associated with functioning and ACT processes, ***Ecological Momentary Assessment*** (EMA) will be employed to improve upon the sensitivity of self-report measures of behavioral change.[81, 94] EMA will utilize a mobile application (i.e., app participants can install on their phone or tablet or an iPod borrowed for this study) designed to measure changes in three domains related to moral injury, selected based on previous EMA research in Veteran samples.[94] One domain to be assessed will be behavioral engagement since the last assessment period. They will be asked to record their responses to "what did you spend time doing in the past four hours."[94] Participants will be given the option to either type or use the audio record function on their mobile device to document responses to ensure that limitations associated with typing text do not impede responding. Another domain to be assessed will be participant affect. Participants will be asked, "what emotions are you feeling right now" and will be able to type their responses. After indicating their current emotional state, participants will be asked to respond to items from a modified version of the Positive and Negative Affect Scale-Expanded Form (PANAS-X).[33] PANAS-X items will be used to assess the presence and intensity of moral emotions. Participants will be asked to rate their current self-directed negatively valenced moral emotions (i.e., guilty, ashamed, disgusted with myself, and angry at myself), other directed negatively valenced moral emotions (i.e., disgusted by others, contempt for others, angry at others), and positively valenced moral emotions (i.e., proud, compassion for others, compassion for myself, grateful, inspired, admiration). These items will be rated by participants on a 1 (very slightly or not at all) to 5 (extremely) Likert scale.[13, 33] Another domain to be assessed will include questions about how participants are responding to their emotions and other internal experiences. Immediately after responding to PANAS-X items, participants will be asked, "overall how much have these feelings impacted what you have done today?" They will be asked to respond on a 1 (these feelings haven't impacted what I've done today) to 5 (these feelings have significantly impacted what I've done today) scale. Following the completion of this item, participants will be presented a modified version of the Acceptance and Action Questionnaire-II (AAQ-II)[79, 94] to evaluate participants' experiential avoidance.[94] Participants will be asked to rate the extent to which they find statements like "my painful memories have prevented me from feeling fulfilled" to be true in the past 4-hour period of time on a 1 (never true) to 5 (always true) scale. See below for a description of the original AAQ-II. Each EMA data collection period will last one week and will include three surveys per day, administered at random times during three fixed 4-hour intervals, sampling a 12-hour period during the participant's normal waking hours. Related to the PANAS-X and AAQ-II items, participants will receive random items at each testing period to minimize testing fatigue and disengagement from the moment. Participants will receive each PANAS-X and AAQ-II item at least once each day. (*Duration:* 10 minutes; Administration; baseline, post-treatment).

In addition to measuring ACT processes via EMA methods, we will also measure hypothesized processes associated with change before the start of every treatment group. **Process Measures Pre-Treatment Groups.** ACT processes will also be measured through traditional self-report methods, including the ***Multidimensional Experiential Avoidance Scale-30 item version*** (MEAQ-30).[83] Machine learning via genetic algorithms was used to abbreviate the original 62-item MEAQ so that fidelity to the six dimensions of

experiential avoidance including behavioral avoidance (e.g., "I won't do something if I think it will make me feel uncomfortable"), distress aversion (e.g., "happiness means never feeling any pain or disappointment"), procrastination (e.g., "I won't do something until I absolutely have to"), distraction and suppression (e.g., "I work hard to keep out unpleasant feelings"), repression/denial (e.g., "I feel disconnected from my emotions"), and distress endurance (e.g., "I don't let pain and discomfort stop me from getting what I want") was maintained. The MEAQ-30 was found to perform similarly to the original MEAQ in a large, nationally representative survey of North Americans demonstrating reliability and validity in this context (n = 7884). A version of the MEAQ-30 asking participants to respond based on their experiences in the past-week will also be administered. (*Duration:* 15 minutes). *The* ***Acceptance and Action Questionnaire-II (AAQ-II)***[79] is a 7-item scale designed to assess experiential avoidance (e.g., "I told myself I shouldn't be feeling the way I'm feeling). The original version of the AAQ-II will be used during pre and post treatment assessment. A version of the AAQ-II asking participants to respond based on their experiences in the past-week will also be administered. *Duration for each AAQ-II version: 3 minutes.* The ***Philadelphia Mindfulness Scale*** (PHLMS)[84] is a 20-item self-report measure designed to assess trait mindfulness via awareness (e.g., "I am aware of what thoughts are passing through my mind") and acceptance (e.g., "I wish I could control my emotions more easily") of internal experiences. Reliability and validity have been established for the PHLMS in community and clinical samples (mixed psychiatric outpatient and eating disorder inpatient). The PHLMS has also been used as a process measure in a study comparing ACT and Cognitive Therapy (*Duration:* 10 minutes).[85] A version of the ***Cognitive Fusion Questionnaire***[86] for moral injury (CFQ-MI) will be used to assess cognitive fusion related to beliefs involving morally injurious content. The original CFQ is a 7-item scale that was validated in clinical and community samples. For the proposed study, the instructions and wording of the items have been revised slightly to focus specifically on fusion with thoughts relevant to moral injury. The CFQ-MI measures the degree to which an individual takes the content of their moral injury-related thoughts literally (e.g., "My thoughts about violations of my morals cause me distress or emotional pain"). A version of the CFQ-MI asking participants to respond based on their experiences in the past-week will also be administered. (*Duration:* 5 minutes).

Measures of Psychopathology. The third area of candidate outcomes assessed at baseline, post-treatment, one-month, and three-month sessions will be symptoms of psychopathology related to the construct of moral injury. ***Posttraumatic Stress Disorder Checklist for the DSM-5*** (PCL-5).[88] The PCL-5 is a 20-item self-report scale that assesses PTSD symptoms as conveyed in the DSM-5. Respondents report the degree to which they have been bothered by symptoms of PTSD including re-experiencing, avoidance of trauma related stimuli, negative thoughts or feelings that have been worsened by the trauma, and alterations in arousal related to the trauma (*Duration:* 10 minutes). The ***Patient Health Questionnaire-9*** (PHQ-9)[89] is a 9-item self-report measure that screens for symptoms of depression. The measure is widely implemented in VHA and was validated in a sample of 6000 primary care Veterans *(Duration:* 5 minutes). The ***Alcohol Use Disorders Identification Test*** (AUDIT)[90] is a 10-item self-report measure developed by the World Health Organization that screens for symptoms of Alcohol Use Disorder. The AUDIT has demonstrated reliability and validity in Veteran samples[91] (*Duration:* 5 minutes). The

Brief Addiction Monitor-Revised (BAM-R)[100-101] is a 17-item self-report measure developed by researchers at the Philadelphia Veterans' Administration Medical Center to assess symptoms of Substance Use Disorder. The BAM-R can be scored using a three-factor structure (substance use severity, risk factors, and protective factors) and shows reliability and validity in Veteran samples (*Duration:* 5 minutes). ***Adult Suicidal Ideation Questionnaire*** (ASIQ)[92] is a 25-item self-report measure of suicidal ideation that will be used to assess changes in suicidal ideation. Reliability and validity have been demonstrated in clinical and community samples[93] (*Duration:* 10 minutes). *The* ***Expressions of Moral Injury Scale*** *(E-MIS)*[87] is a 17-item self-report scale that is used to measure expressions of moral injury related to how experiencing morally injurious events may affect one's emotional well-being, relationships and quality of life. The E-MIS measures self-directed (e.g., "I am ashamed of myself because of things I did/saw during my military service") and other-directed (e.g., "I feel anger over being betrayed by someone who I had trusted while I was in the military") subtypes of moral injury. (Duration: 7 minutes). The ***Global Ratings of Change Scale*** *(GC)* is a 6-item scale developed for the proposed study to assess self-report change following the interventions (e.g., "my current ability to live consistently with my values is _____ than my ability to live consistently with my values before I enrolled in the study."). The GC uses a 15-point Likert-type rating scale ranging from -7, "a great deal worse," to +7, a great deal better. The GC follows guidelines for an anchor-based approach to determining the minimally clinically important difference.[34] (Duration: 3 minutes; Administration: Post-Treatment, One-month follow-up, Three-months follow-up).

B. Description of Population to be Enrolled:

All data will be collected from eligible and willing Veterans that meet the following eligibility criteria:

Inclusion Criteria: 1) Eligible for VHA care (information obtained from review of medical record)**,** 2) Age 18-89 (information obtained from review of medical record)**,** 3) Has been deployed to a warzone (information obtained from Veteran self-report/screening interview), 4) Has experienced a morally injurious event which continues to interfere with functioning (information obtained from Moral Injury Events Scale [MIES], Moral Injury Questionnaire-Military Version [MIQ-M], and self-report/screening interview), and 5) Willing to be randomized and participate in either of the two conditions (information obtained from Veteran self-report/screening interview). 6) When groups are only being offered through videoconferencing, participants will need a computer/smartphone capable of accessing the VA approved videoconferencing platform in a private setting.

Exclusion Criteria: 1) Inability to demonstrate understanding of the postcard consent (as evidenced by inability to respond correctly to postcard consent questions or medical record review), 2) Inability to complete study measures (e.g., due to significant acute intoxication/withdrawal symptoms, mania, psychosis, aggression, catatonia, cognitive impairment) (results of veteran self-report, screening, or discretion of interviewer), 3) Imminent suicide risk (medical record or UWRAP), 4) Membership in a vulnerable population (e.g., pregnant women) (medical record or self-report), 5) History of significant violence towards VA staff (medical record), 6) Participation in another psychotherapy research study, (medical record

or self-report), and 7) Current participation in an EBP for a condition related to moral injury (medical record or self-report).

C. Study Design and Research Methods

Design: We are proposing a two arm, randomized, controlled pilot study to assess the feasibility of a future randomized clinical trial (RCT) evaluating the efficacy of ACT-MI. Candidate measures for a future efficacy trial will be administered at baseline, post-treatment, and one- and three-month follow-ups. Measures of acceptability will be administered following treatment completion/discontinuation. Veterans who are eligible to receive treatment at the VA ECHCS and who are eligible and interested in participating in the study will be enrolled and randomized to: (1) Present Centered Therapy (PCT-MI) or (2) ACT-MI.

Description of Treatment Conditions. Description of Treatment Conditions. *Present Centered Therapy (PCT-MI).* See p. 6 of this protocol for a description of PCT-MI. ***Acceptance and Commitment Therapy for Moral Injury (ACT-MI).*** See p. 4-5 of this protocol for a description of ACT-MI.

Measures:

The following measures were selected based on their content validity and other psychometric properties. **Descriptive Measure.** The ***Rocky Mountain MIRECC Demographics Form*** will be used to assess demographic variables such as age, sex, and ethnicity, as well as variables related to education, employment, housing, and military history (*Duration:* 5 minutes; *Administration:* Baseline assessment).

Safety Monitoring Measure. The ***University of Washington Risk Assessment Protocol (UWRAP)***[71] is a structured clinical interview that evaluates participants' acute emotional state prior to the study and capacity to complete the study procedures. At the end of the study, the UWRAP debriefing protocol will be initiated (See Appendix 1). Members of the research team will evaluate responses and access additional assistance as necessary (*Duration:* 10 minutes; *Administration:* All Assessments).

Baseline measures to diagnostically characterize the sample: To characterize the sample at baseline the Structured Clinical Interview for the DSM-5 and the Columbia-Suicide Severity Rating Scale will be administered. ***Structured Clinical Interview for DSM 5 Research Version*** **(SCID-5-RV)- Modules A, D, E, F, and L** is a diagnostic interview used to determine DSM-5 disorders. All participants will be administered the SCID-5-RV during the baseline assessment session. Specifically we will administer the following modules: A- Mood Episodes, D- Differential Diagnosis of Mood Disorders, E- Substance Use Disorders, F- Anxiety Disorders, and L- Trauma- and Stressor-related Disorders. This will provide a broader diagnostic characterization of the participants. *Approximate time to complete: 30 minutes; Administration: Baseline.* **The Columbia-Suicide Severity Rating Scale (C-SSRS)** (Posner, Brown, Stanley, Brent, Yershova, Oquendo, Currier, Melvin, Greenhill, Shen, & Mann 2011): The C-SSRS is a clinician-administered measure that assesses for suicidal ideation and attempt behavior based on established definitions. The C-SSRS assesses intensity of suicidal ideation, specifically asking about frequency, duration, intrusiveness, controllability, and deterrents, as well as suicide-related behavior, such as actual attempts and aborted attempts. *Approximate time*

to complete: 10 minutes; Administration: Baseline. **Moral Injury Outcome Scale (MIOS)** (Lits, Phelps, Frankfurt, Murphy, Nazarov, Houle, Levi-Belz, Zerach, Dell, Hosseiny & members of the *Moral Injury Outcome Scale Consortium* 2021): The MIOS is a 32-item self-report measure used to assess the type of morally injurious event experienced, as well as the extent to which that event has affected functioning. The MIOS assesses the impact a morally injurious event has had on trust, guilt, self-doubt, and faith in relation to the self, others, and spiritual practices. *Approximate time to complete: 10 minutes; Administration: Baseline.*

Morally Injurious Event Screeners. The ***Moral Injury Questionnaire-Military Version*** (MIQ-M)[72] is a 20-item self-report measure that will be used to screen for exposure to morally injurious events (e.g., "I saw/was involved in the death(s) of children") in the context of warzone deployments. Participants are asked to rate how frequently they experienced each event. The MIQ-M was developed and validated in community and clinical samples of Iraq and Afghanistan war Veterans (*Duration:* 10 minutes; *Administration:* Screening). The ***Moral Injury Events Scale*** (MIES)[73] is a 9-item self-report measure that will be used to screen for exposure to morally injurious events associated with warzone deployment. The measure is comprised of two subscales, perceived transgressions (e.g., "I acted in ways that violated my own moral code or values") and perceived betrayals (e.g., "I feel betrayed by leaders who I once trusted") which comport with Litz's[22] model of moral injury. The MIES was developed using data from active duty service members and its validity has been established in Marine, Air Force, and National Guard samples (*Duration:* 5 minutes; *Administration:* Screening). The MIQ-M and the MIES are well suited to assess exposure to potentially morally injurious events, but do not assess impairment in functioning and moral pain. We will use the MIQ-M, MIES, and participant self-report about exposure to morally injurious events outside of the warzone to identify exposure to at least one morally injurious event and then use a semi-structured interview (see Moral Injury Interview below) to assess functional impairment and moral pain. This method is consistent with past moral injury research,[22] recent moral injury assessment recommendations,[26] and recruitment for our past ACT-MI patients. The ***Moral Injury Interview*** within the screening consent will be used to evaluate current functioning, desired change, pre-deployment functioning, and exposure to morally injurious events.[26] We will also provide information about the intervention and assess Veterans' willingness to approach moral pain as part of increasing behavioral functioning *(Duration: 15-30 minutes; Administration: Screening).* Additionally, the moral injury interview will provide a definition of moral injury and facilitate a discussion of this construct. Veterans will then be given information about the structure of ACT-MI and PCT-MI, and the goals of these interventions, which will emphasize the importance of Veterans' generation of their own recovery-oriented goals to work towards in the context of ACT-MI or PCT-MI. Expectations of the Veterans within the ACT-MI and PCT-MI group interventions will be discussed.

Aim 1 Measures: Acceptability. The ***Client Satisfaction Questionnaire*** (CSQ-8)[19] is a self-report measure that will be used to assess patients' satisfaction with ACT-MI and PCT-MI. (*Duration:* 5 minutes; *Administration:* Post-Treatment). The ***Narrative Evaluation of Intervention Interview*** **(NEII)**[20] is a 16-item semi-structured interview assessing each participant's perspective of the impact of the intervention. Additionally, the NEII will be used to measure helpful and unhelpful components of ACT-MI and PCT-MI for comparison to other interventions. This yields rich information regarding how the intervention can be modified to

better meet patients' needs (*Duration:* 15 minutes; *Administration:* Post-Treatment). Participants who withdraw from treatment, but agree to remain in the study will also complete the ***Reasons for Termination (Client and Therapist versions;* RT-C/RT-T)**[74] scale, which assesses the impact of 19 common reasons why patients terminate therapy. Study clinicians will also complete the RT-T (*Duration:* 5 minutes; *Administration:* Following withdrawal from treatment).

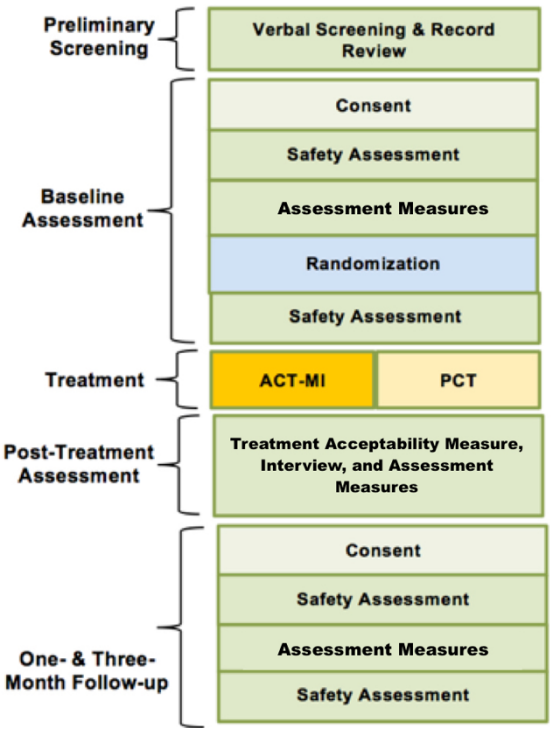
Aim 2 Measures: Feasibility. A ***treatment fidelity checklist*** was developed for the current study to monitor clinician adherence to the treatment manual after each recorded session. It was modeled off of fidelity checklists included in trials of other cognitive behavioral therapies and incorporates treatment competency items from an ACT fidelity measure used in the ACT for Depressed Veterans roll out.[59] A fidelity checklist was also developed for PCT-MI based on previous PCT-MI treatment fidelity checklists.[61]

Aim 3 Measures: Select measures and calculate necessary sample size for a future efficacy study. The following measures will be included as candidate outcome measures for a future efficacy trial, and be administered at baseline, post-treatment, one-month, and three-month assessment sessions. Candidate measures will include assessments of three domains. The first area to be assessed will be measures associated with functional recovery. The ***Valued Living Questionnaire (VLQ)***[75] is a self-report measure that assesses participants' values as well as the consistency with which they believe they have been living life according to their values. Participants rate the importance of ten domains of living (e.g., citizenship/community life). Following this, participants rate their behavior over the past week based on how consistently they have acted on each valued domain (*Duration:* 10 minutes). The ***Outcome Questionnaire-45 (OQ-45)***[76] assesses functioning within the last week across three psychosocial domains which include symptom distress (e.g., "I feel nervous), interpersonal relations (e.g., "I have frequent arguments"), and social role functioning (e.g., "I find my work/school satisfying"). Reliability and validity for the 45-item self-report measure has been established in Veteran samples. This scale is ideal for transdiagnostic assessment as it does not require participants to make ascriptions to the causes of their functional impairments. (*Duration:* 15 minutes). The ***PROMIS Short Form v2.0- Satisfaction with Social Roles and Activities 8a***[78] is an eight-item self-report measure that assesses satisfaction with respondents' ability to perform various social activities (*Duration:* 5 minutes). ***PROMIS v2.0- Social Isolation***[80] is a 14-item self-report measure that assesses feelings of social isolation (*Duration:* 5 minutes). The second area measured will be with scales related to ACT processes. To measure behavioral changes associated with functioning and ACT processes, ***Ecological Momentary Assessment*** (EMA) will be employed to improve upon the sensitivity of self-report measures of behavioral change.[81, 94] EMA will utilize a mobile application participants can install on their phone or tablet. The EMA app is designed to measure changes in three domains related to moral injury, selected based on previous EMA research in Veteran samples.[94] One domain to be assessed will be behavioral engagement since the last assessment period. They will be asked to record their responses to "what did you spend time doing in the past four hours."[94] Participants will be given the option to either type or use the audio record function on their mobile device to document responses to ensure that limitations associated with typing text do not impede responding. Another domain to be assessed will be participant affect. Participants will be asked, "what emotions are you feeling right now" and will be able to type their responses. After indicating their current emotional state, participants will be asked to respond to items from a modified version of the Positive and Negative Affect Scale-Expanded Form (PANAS-X).[33] PANAS-X items will be used to assess the presence and

intensity of moral emotions. Participants will be asked to rate their current self-directed negatively valenced moral emotions (i.e., guilty, ashamed, disgusted with myself, and angry at myself), other directed negatively valenced moral emotions (i.e., disgusted by others, contempt for others, angry at others), and positively valenced moral emotions (i.e., proud, compassion for others, compassion for myself, grateful, inspired, admiration). These items will be rated by participants on a 1 (very slightly or not at all) to 5 (extremely) Likert scale.[13, 33] Another domain to be assessed will include questions about how participants are responding to their emotions and other internal experiences. Immediately after responding to PANAS-X items, participants will be asked, "overall how much have these feelings impacted what you have done today?" They will be asked to respond on a 1 (these feelings haven't impacted what I've done today) to 5 (these feelings have significantly impacted what I've done today) scale. Following the completion of this item, participants will be presented a modified version of the Acceptance and Action Questionnaire-II (AAQ-II)[79, 94] to evaluate participants' experiential avoidance.[94] Participants will be asked to rate the extent to which they find statements like "my painful memories have prevented me from feeling fulfilled" to be true in the past 4-hour period of time on a 1 (never true) to 5 (always true) scale. See below for a description of the original AAQ-II. Each EMA data collection period will last one week and will include three surveys per day, administered at random times during three fixed 4-hour intervals, sampling a 12-hour period during the participant's normal waking hours. Related to the PANAS-X and AAQ-II items, participants will receive random items at each testing period to minimize testing fatigue and disengagement from the moment. Participants will receive each PANAS-X and AAQ-II item at least once each day. (*Duration:* 10 minutes; Administration; baseline, post-treatment). ACT processes will also be measured through traditional self-report methods, including the ***Multidimensional Experiential Avoidance Scale-30 item version*** (MEAQ-30).[83] Machine learning via genetic algorithms was used to abbreviate the original 62-item MEAQ so that fidelity to the six dimensions of experiential avoidance including behavioral avoidance (e.g., "I won't do something if I think it will make me feel uncomfortable"), distress aversion (e.g., "happiness means never feeling any pain or disappointment"), procrastination (e.g., "I won't do something until I absolutely have to"), distraction and suppression (e.g., "I work hard to keep out unpleasant feelings"), repression/denial (e.g., "I feel disconnected from my emotions"), and distress endurance (e.g., "I don't let pain and discomfort stop me from getting what I want") was maintained. The MEAQ-30 was found to perform similarly to the original MEAQ in a large, nationally representative survey of North Americans demonstrating reliability and validity in this context (n = 7884) (*Duration:* 15 minutes). A version of the MEAQ-30 asking participants to respond based on their experiences in the past-week will also be administered. *The* ***Acceptance and Action Questionnaire-II*** *(AAQ-II)*[79] is a 7-item scale designed to assess experiential avoidance (e.g., "I told myself I shouldn't be feeling the way I'm feeling). The original version of the AAQ-II will be used during pre and post treatment assessment. Another version of the AAQ-II was created for this study to comport with ecological momentary assessment procedures. The AAQ-II was modified for the purposes of this study to sample experiential avoidance during 4-hour assessment blocks. Participants will be given the instructions "below you will find a list of statements. Please rate how true each statement is for you by circling the number next to it. Use the scale below to make your choice. Please respond to each item keeping the past 4-hour time frame in mind. In the past 4 hours…" Participants will rate their responses on a 1 (never true) to 7 (always true) Likert scale. AAQ-II items have been modified to reflect participants' experiences within the past 4 hours (e.g., "I'm afraid of my feelings" changed to "I have felt

afraid of my feelings"). A version of the AAQ-II asking participants to respond based on their experiences in the past-week will also be administered. *Duration for each AAQ-II version: 3 minutes.*. The ***Philadelphia Mindfulness Scale*** (PHLMS)[84] is a 20-item self-report measure designed to assess trait mindfulness via awareness (e.g., "I am aware of what thoughts are passing through my mind") and acceptance (e.g., "I wish I could control my emotions more easily") of internal experiences. Reliability and validity have been established for the PHLMS in community and clinical samples (mixed psychiatric outpatient and eating disorder inpatient). The PHLMS has also been used as a process measure in a study comparing ACT and Cognitive Therapy (*Duration:* 10 minutes).[85] A version of the ***Cognitive Fusion Questionnaire***[86] for moral injury (CFQ-MI) will be used to assess cognitive fusion related to beliefs involving morally injurious content. The original CFQ is a 7-item scale that was validated in clinical and community samples. It measures the degree to which an individual takes the content of their thoughts literally (e.g., "My thoughts about violations of my morals cause me distress or emotional pain"). A version of the CFQ-MI asking participants to respond based on their experiences in the past-week will also be administered. (*Duration:* 5 minutes). The third area of candidate outcomes assessed will be symptoms of psychopathology related to the construct of moral injury which include a psychodiagnostic measure to characterize the same. ***Posttraumatic Stress Disorder Checklist for the DSM-5*** (PCL-5).[88] The PCL-5 is a 20-item self-report scale that assesses PTSD symptoms as conveyed in the DSM-5. Respondents report the degree to which they have been bothered by symptoms of PTSD including re-experiencing, avoidance of trauma related stimuli, negative thoughts or feelings that have been worsened by the trauma, and alterations in arousal related to the trauma (*Duration:* 10 minutes). The ***Patient Health Questionnaire-9*** (PHQ-9)[89] is a 9-item self-report measure that screens for symptoms of depression. The measure is widely implemented in VHA and was validated in a sample of 6000 primary care Veterans *(Duration:* 5 minutes). The ***Alcohol Use Disorders Identification Test*** (AUDIT)[90] is a 10-item self-report measure developed by the World Health Organization that screens for symptoms of Alcohol Use Disorder. The AUDIT has demonstrated reliability and validity in Veteran samples[91] (*Duration:* 5 minutes). The ***Brief Addiction Monitor-Revised*** (BAM-R)[100] is a 17-item self-report measure developed by the Philadelphia Veterans' Administration Medical Center to assess symptoms of Substance Use Disorder. The BAM-R can be scored using a three- factor structure (substance use severity, risk factors, and protective factors) and shows reliability and validity in Veteran samples (*Duration:* 5 minutes). The ***Adult Suicidal Ideation Questionnaire*** (ASIQ)[92] is a 25-item self-report measure of suicidal ideation that will be used to assess changes in suicidal ideation. Reliability and validity have been demonstrated in clinical and community samples[93] (*Duration:* 10 minutes). *The* ***Expressions of Moral Injury Scale*** *(E-MIS)*[87] is a 17-item self-report scale that is used

Figure 1. Research Procedures



to measure expressions of moral injury related to how experiencing morally injurious events may affect one's emotional well-being, relationships and quality of life. The E-MIS measures self-directed (e.g., "I am ashamed of myself because of things I did/saw during my military service") and other-directed (e.g., "I feel anger over being betrayed by someone who I had trusted while I was in the military") subtypes of moral injury. *(Duration: 7 minutes)*

The ***Global Ratings of Change Scale*** *(GC*) is a 6-item scale developed for the proposed study to assess self-report change following the interventions (e.g., "my current ability to live consistently with my values is _____ than my ability to live consistently with my values before I enrolled in the study."). The GC uses a 15-point Likert-type rating scale ranging from -7, "a great deal worse," to +7, a great deal better. The GC follows guidelines for an anchor-based approach to determining the minimally clinically important difference.[34] *(Duration: 3 minutes; Administration: Post-Treatment, One-month follow-up, Three-months follow-up).*

Procedures:

Preliminary Screening. Preliminary screening will occur in person or by telephone. After detailed information about the study is shared, potential participants will be given the option to provide verbal consent and complete a verbal screening interview based on inclusion and exclusion criteria. Research personnel will also review the Veteran's medical records to further evaluate study eligibility. Following the screening, potential participants will be scheduled for their Baseline Assessment. Their appointment may also be confirmed via text message. ***Baseline Assessment Session and Randomization.*** Baseline assessment sessions will be conducted in person when possible. When necessary, baseline sessions will be conducted online using REDCap and telephone/videoconferencing. A waiver of consent and HIPAA are being requested to allow for a consent process with a postcard consent rather than a formal physical signed consent form. After demonstrating understanding of the postcard consent and indicating willingness to participate, participants will complete the safety measure (UWRAP) and then assessment measures (SCID-5 modules, C-SSRS, VLQ, PROMIS, OQ-45, PHLMS, AAQ-II, AAQ-II past week MEAQ-30, MEAQ-30 past week, CFQ-MI, CFQ-MI past week, PHLMS, PHQ-9, PCL-5, E-MIS, AUDIT, BAM-R and ASIQ). Participants and the study assessor will be blind to condition. At the conclusion of the assessment session, participants will be randomized to ACT-MI or PCT-MI. The study biostatistician will predetermine group assignment through block randomization to ACT-MI or PCT-MI (block size = 4); stratified to condition based on previous participation in an Evidence-Based Psychotherapy (EBP). We chose to stratify participants based on past EBP participation as we believe previous treatment engagement could significantly impact responsivity to treatment and thus want to ensure that the groups are as evenly distributed as possible based on this variable. We felt this was more important to prioritize than stratifying for diagnosis given the transdiagnostic nature of the proposed intervention. Randomization results will be concealed in a sealed envelope until the end of the baseline assessment session. ***Treatment Participation.*** Participants randomized to either ACT-MI or PCT-MI will complete the intervention in an outpatient context. When necessary, ACT-MI and PCT-MI will be conducted over a VA approved videoconferencing platform. The treatments will be delivered across twelve group sessions. Investigators will attempt to offer treatment as quickly as possible, however, this will be dependent on group start dates. Participants will

receive up to eighteen hours of group psychotherapy across twelve group sessions. Prior to each treatment group, participants will complete process measures (PHLMS, AAQ-II, MEAQ-30 and CFQ-MI). On odd weeks participants will complete the AAQ-II and PHLMS and on even weeks participants will complete the MEAQ-30 and CFQ-MI. These will be assigned on odd and even weeks to minimize participant fatigue and to determine which measures might be most sensitive to change over time for use in a future efficacy trial. Groups will be randomly assigned to receive either the original measures or the measures with altered instructions (e.g, to identify experiences in the past week) so that we can better understand responding on these measures based on providing temporal instructions. At baseline and post-treatment for 7 days, 3 times per day, participants will complete EMA assessments. EMA will be structured to minimize its impact as a potential treatment procedure and instead will be explicitly designed to assess behavioral changes without necessarily prompting values driven behavior. ***Post-treatment Assessment Session.*** A study assessor will meet with participants in the ACT-MI and PCT-MI conditions and administer the treatment acceptability measures (CSQ-8, NEII, RT-C) and candidate outcome measures (VLQ, PROMIS, OQ-45, PHLMS, AAQ-II, AAQ-II past week MEAQ-30, MEAQ-30 past week, CFQ-MI, CFQ-MI past week, PHQ-9, PCL-5, E-MIS, AUDIT, BAM-R, ASIQ, and GC). **One-Month and Three-Month Follow-ups.** Participants will have the option to complete follow-up assessments via survey link (i.e., REDCap), mail, or phone/videoconferencing. In person follow-up appointments may still be offered, dependent on contact restrictions and recommendations related to the COVID pandemic. A different assessor, still blind to condition, will administer the one- and three-month follow-up measures (VLQ, PROMIS, OQ-45, PHLMS, AAQ-II, AAQ-II past week MEAQ-30, MEAQ-30 past week, CFQ-MI, CFQ-MI past week, PHQ-9, PCL-5, E-MIS, AUDIT, BAM-R, ASIQ, GC, and CSQ).

Recruitment:

We will recruit across outpatient clinics, community based outpatient clinics, and Veteran centers. We will request referrals from clinicians in the PTSD Clinical Team (PCT), Substance Abuse Treatment Program (SATP), and Mental Health Clinic (Dr. Farnsworth is a clinician in the PCT-MI and SATP) and other providers who might have contact with Veterans with moral injury. In addition to clinician referrals, we plan to utilize targeted recruitment mailings. Using the VA-DoD Identity Repository (VADIR), VA corporate data warehouse (CDW), and VA electronic medical records (e.g., CPRS, JLV, VISTA, TIU) we will mail discrete invitation letters to Veterans who were active during military conflicts, have been diagnosed with disorders often associated with moral injury (e.g., PTSD, depression, substance use) or have a history of suicidal behaviors (e.g., Suicide Behavior Report Notes), or whose medical records indicate other variables potentially related to exposure to morally injurious events. The discrete invitation to participate in the research, an informal flyer, and a pre-addressed and postmarked Opt Out/In postcard will be mailed to Veterans. Veterans can use the Opt Out/In postcard to indicate that they do not wish to receive additional mailings about this study or that they would like to be called by a study team member. Two additional reminder letters may be sent to potential participants who neither indicate interest in the study nor return the Opt Out/In card. Veterans who indicate interest in the study will be contacted, provided specific details about the study, and- if still interested in participation- be screened for study eligibility.

Enrollment:

Informed Consent. Participation will be voluntary, and potential participants will have ample time to review the postcard consent with trained staff and to ask questions about the study. Research staff will assess patients' understanding of the postcard consent, based on whether they can adequately respond to the following questions about the study:

1) *What are you being asked to do?*
2) *Finish this sentence - The purpose of this study is to find out…*
3) *True or False: After beginning this study, you can decide not to continue at any time, without penalty.*
4) *What should you do if you have questions about this study?*
5) *Who should you call if you feel you have been harmed in this study?*
6) *What are the risks of participating in this study?*
7) *What are the benefits of participating in this study?*

Veterans who cannot adequately answer these questions will be excluded from participating.

Participants will have had the option during the screening and verbal consent to receive text message PHI/PII-free text message reminders for their baseline appointment. During the baseline appointment consent process, participants will select their reminder and scheduling preferences for the one- and three-month follow-up appointments. Participants will receive reminder phone calls and letters. They will select the level of detail that can be used for the reminder phone calls (please see consent form for details). As in COMIRB #15-0346, #16-0350, and #17-0603 participants will also be given the option of receiving text message reminders stating "REMINDER: You have a research appointment on [month, day, year] at [time]. Please call [contact phone number] if you have any questions." If the study team has been unable to reach a participant to schedule or reschedule a follow-up appointment, the participant will be sent a text message stating "REMINDER: Please contact our research coordinator to schedule your appointment [contact phone number]." Text messages will not contain PII or PHI.

Protected Health Information (PHI). PHI to be collected may include: first and last name, date of birth, mailing address, and full social security number. This information is needed to access participants' medical records to collect data for this study. Additional PHI will include demographic information (including military history), use of VA services, and medical and mental health history.

Authorization Procedures. A waiver of consent and a HIPAA Waiver of Authorization is being requested for the entire study. This will allow members of the research team to view medical charts of potentially eligible patients. The medical records will be reviewed to screen potential participants to determine study eligibility and appropriateness to participate in the intervention. Review of the medical records also allows members of the research team to screen for other criteria that would exclude participation (e.g., safety-related issues, psychiatric distress) and reduce burden on ineligible patients. The consent and HIPAA waiver will also allow study participants to complete the study online when face-to-face sessions are not able to be offered.

V. Description, Risks and Justification of Procedures and Data Collection Tools:

All participants will be provided with ample time to ask questions prior to enrolling in the study. As noted above, a series of questions will assess participants' understanding of the study in order to ensure that participants have adequately comprehended the critical information (e.g., risks/benefits, voluntary nature) and are able to complete the consent process. Participants will be clearly informed that the study is voluntary and that they can withdraw from the study at any time, with no penalty. Additionally, all research staff have been trained in human subjects research. The main risk to participating in the study is potential emotional discomfort during the assessments. ACT-MI and PCT-MI participation may also be associated with some emotional discomfort, but this is not anticipated to be any more severe than the emotional discomfort associated with psychotherapy used in standard care.

Adverse events

Significant adverse events are not expected. For the purposes of this study, adverse events are defined as any newly identified medical diagnoses noted by medical personnel, or symptoms reported by the participant, which are *directly related to participation in the study and occur during the administration of testing/treatment or appear within two weeks of testing/treatment*. Participants will be instructed to contact the principal investigator if they believe they have potentially experienced an adverse event. Any adverse event will be reported to COMIRB by the PI in keeping with COMIRB regulations.

Risks

As noted above, adverse events are not expected. The anticipated risks and discomfort associated with research procedures are not greater than those that would be ordinarily encountered during routine clinical care or psychological assessment, in which discussion of mental health and past traumatic events is the standard of care. Participants are at elevated risk for emotional distress and related sequelae by virtue of the fact that they have moral injury. For participants who reveal any imminent suicidality during the baseline assessment, or active suicidal ideation during the follow-up visits, the appropriate follow-up actions will be implemented by Drs. Barnes, Borges, or other designated clinician with expertise in suicide risk assessment. Please see "Safety Monitoring" section below for more details. Participants also have the potential to become frustrated, fatigued, or distressed while completing study measures. Members of the research team will be trained to minimize psychological distress while assisting individuals in completing the protocol.

There is a potential loss of confidentiality and/or privacy. Minimizing risks to data security will be achieved by employing safeguards built into the framework of the VA Office of Research and Development (R&D).

Benefits

The primary benefit of this study is generalizable knowledge to help better understand the acceptability and feasibility of ACT for Moral Injury. Although ACT for Moral Injury is empirically informed, its efficacy has not been evaluated; therefore, no direct benefits to the

participants can necessarily be anticipated. Similarly, PCT-MI has not been used in a group format for moral injury and has not had its efficacy evaluated; therefore, direct benefits for participants in PCT-MI can not necessarily be anticipated.

Safety Monitoring

The UWRAP will be used to assess and address any potential risk associated with participating in the study. In completing the UWRAP, participants will be asked to articulate pre-test potential stressors (Pre-Assessment Risk Assessment Questions). Following the assessment or treatment session, the UWRAP debriefing checklist and protocol will be administered. Using results from the debriefing, a trained member of the research team will evaluate responses and access additional assistance, if necessary. A trained clinical member of the research team would then conduct additional assessment of the participant's safety using the UWRAP and expertise in clinical suicide risk assessment.

Thus, a formal risk assessment protocol and standard operating procedure will be implemented for participants who endorse current suicidal ideation on the UWRAP or if the assessor is concerned about the participant's safety risk based on other statements made or responses to other assessment items.

Participants deemed to be at imminent risk for suicide will be referred to their clinician (if applicable) and/or be taken to Psychiatric Emergency Services, as indicated. If participation is occurring remotely (e.g., using videoconferencing) the study team will confirm the participant's physical location and address. If emergency services are needed, study staff and/or the MIRECC clinician on duty will assist the participant in accessing emergency services (e.g., by calling 911). Additionally, for participants deemed to be at imminent risk of suicide, imminent risk may be documented in their VA electronic medical record (e.g., by entering a note into their medical record). All research staff will be trained on the risk assessment protocol prior to enrolling or screening any participants. See Appendix 1 for a detailed Safety Monitoring Plan.

Additionally, contact information for the PI and COMIRB will be provided to all participants to report any potential adverse events.

Discontinuation of Study Participation

Study participation will be discontinued if any members of the study team determine that the participant meets exclusion criteria or the participant decides to withdraw from the study. For example, if a participant is unable to answer the postcard consent questions prior to the one or three month follow-up assessments, the session will be rescheduled or the participant will be unenrolled from the study, at the study team's discretion.

Data Security and Storage

Data security.

Electronic data will be stored on a local ECHCS server within the VA firewall. Electronic data will also be stored in REDCap, which meets VA security requirements for data collection and

storage. Data will only be able to be retrieved from within the VA network. Files will be user-restricted and/or password protected so that only members of the research team can access the data. [Any data administered on laptops will be done on VA laptops that meet the VA standards for encryption, anti-virus protection, and firewall security.]

The UCD Anschutz Campus CCTSI REDCap may also be used to facilitate data collection. The UCD Anschutz Campus REDCap is hosted by the Colorado Clinical and Translational Sciences Institute (CCTSI). Data collected or stored for this study that is placed on the CCTSI REDCap Database will not be accessed or used for any other study or purposes, and will only be accessed by VA-credentialed personnel. The CCTSI REDCap Database is a highly secure, nationally-utilized data management system, and it is housed within the highly-secure environment at the University of Colorado Denver. In specific, the UCD Anschutz Campus CCTSI REDCap may be used to facilitate online data collection or reminders to facilitate data collection. If the Veteran chooses to provide their email address or telephone number to facilitate online data collection throughout the study, the email address or telephone number may be shared with Twilio, a secure Cloud application that facilitates data collection for CCTSI REDCap. No other identifying information will be shared, stored, or collected via Twilio. Specifics regarding this will be outlined in the postcard consent.

Electronic data may also be stored on a centralized research data repository such as the VA Informatics and Computing Infrastructure (VINCI). To ensure the protection of Veterans' data, VINCI maintains compliance with the guidelines set forth by Veterans Health Administration (VHA) Handbook 1200. 12, Use of Data and Data Repositories in VHA Research and all other applicable VA and VHA policies and regulations. In addition, VINCI has undergone all security certification activities in support of obtaining an Authorization to Operate (ATO).

An approved videoconferencing platform will be used as necessary given developments with the COVID pandemic. Guidelines provided by the VA for maximizing data security will be followed.

Related to the EMA procedures, all data will be collected from a mobile application (Esmi). If participants wish to take part in the EMA assessment portion of the study, they will download and install the EMA app on their personal mobile device (e.g., phone or tablet). In the event that participants do not have a compatible mobile device they will be offered the option to borrow a study iPod (and complete the VA equipment loan form FL_10-219). If the participant does not have a compatible mobile device and does not wish to borrow a study iPod they will not take part in the EMA assessment portion of the study. Furthermore all participants will be notified in the postcard consent that: "Participation at all assessment time points is voluntary. If you choose to answer questions by audio recording or if you include identifying information in your responses, it is possible that mobile device could contain information that would identify you. These data will remain on your mobile device until you provide it to the VA research team. If you would like to avoid including identifying information or voice recording, you may do so. It is important that you understand that we cannot guarantee the security of the information you enter into your mobile device while it is in your possession. At the end of the week period, you will bring your phone or tablet to the study team so that your data can be stored securely behind the VA firewall

and then erased from your device." Data will be uploaded at weeks 2 and 13 to a password protected, secured database behind the VA firewall. If contact restrictions prevent participants from meeting with a study team member to provide EMA data, the participant will be given the opportunity to provide these data at a later time after the contact restrictions have been lifted.

Similar procedures to the EMA application proposed in this protocol (e.g., audio recordings) have been utilized and IRB approved through both the National Center for PTSD/Stanford University and through a Rocky Mountain MIRECC study (COMIRB# 16-0109). For additional details regarding use of the study iPods and transfer of data to the VA Network please see the "iPod Baseline" and "iPod Standard Operating Procedure." These documents have been reviewed and approved by VA Office of Information Technology mobile technology specialists from Endpoint Engineering, Solution Delivery.

Audio files and transcripts. The research team will transcribe EMA audio recorded data and qualitative interviews related to the intervention. Audio files and transcripts will be saved and/or labeled in their entirety with the corresponding UI.

Paper data. All data will be stored within VA ECHCS. Paper data will be stored in locked filing cabinet(s) in a locked office in the MIRECC. Existing consent and HIPAA forms will be stored separately in locked cabinets, separate from participant data (i.e., measures, transcripts).

Aggregate data. Aggregate data with all PHI removed may be shared with collaborators outside of the VA. However, appropriate data sharing agreements and memorandums of understanding will be put in place prior to sharing any data.

Staff training. Procedures designed to maintain confidentiality and data security will include training of all study personnel in regard to data security, research ethics, and study procedures, as well as formal mechanisms for limiting access to all information that can link data to individual participants.

VI. Potential Scientific Problems:

Clinical pilot studies are a critical first step in investigating the utility and value of conducting a full-scale RCT because they provide an opportunity to identify and respond to potential scientific problems. Recruitment for an intervention on moral injury could prove difficult. To buffer against recruitment challenges, we will recruit across outpatient clinics, community based outpatient clinics, and Veteran centers. We have consistently been able to recruit Veterans for clinical ACT-MI groups and have strong working relationships with the PTSD Clinical Team (PCT-MI), Substance Abuse Treatment Program (SATP), and Mental Health Clinic (Dr. Farnsworth is a clinician in the PCT-MI and SATP). These clinics are enthusiastic about ACT-MI and administrators expect that they will be able to support the proposed study. Our patient flow from FY2017 also supports our sample size. However, if necessary, we will also mail potential participants directly based on review of their medical records.

A rigorous evaluation of the efficacy of ACT-MI will require a relevant and potent active control condition. PCT-MI was selected as the comparison condition for several reasons. First, we chose to compare ACT-MI to an active control rather than a waitlist control as this methodology was not acceptable to referring clinics (would delay Veteran care). Second, in the efficacy study it will be important to determine if potential gains are due to the intervention's specific attributes rather than nonspecific effects which a waitlist control would not facilitate. Third, treatment as usual (particularly a transdiagnostic intervention) does not yet exist for moral injury as moral injury interventions are still relatively new. A criticism of PCT-MI in comparison to ACT has been identified based on the equivalent results of Lang and colleagues' (2017) study comparing ACT and PCT-MI. Robyn Walser, one of our Co-I's was also Co-I on the Lang study and identified significant methodological limitations associated with this study. Dr. Walser reported that therapists on the Lang study were trained in both ACT and PCT-MI, which has the potential to contaminate PCT-MI with ACT based principles. Once learned, ACT may be a particularly difficult therapeutic framework to ignore for the sake of applying a different intervention as ACT therapists are taught to target a behavior's function above and beyond other intervention strategies. The possibility for ACT principles extending to the control intervention is particularly relevant for PCT-MI, as PCT-MI is a semi-structured intervention, which provides therapist latitude. We believe that a critical safeguard in differentiating ACT from PCT-MI is in hiring experienced therapists for the PCT-MI condition who do not have a history of training in ACT. Additionally, the Lang study did not adequately assess and address competency in delivering the ACT intervention. Drs. Walser and Drescher will work with the study team as well as review tapes of the sessions to ensure fidelity and competency. PCT-MI has the potential to be a strong comparison condition for ACT-MI in a future efficacy trial given its transdiagnostic structure, group format, and because it is currently been investigated in Litz and colleagues' ongoing Adaptive Disclosure efficacy trial.

Another barrier that was apparent in reviewing the literature was in the measurement of moral injury. To address this barrier our team developed a moral injury interview to help facilitate screening for Veterans to ensure appropriateness for participation in the study. We are taking a multidimensional approach to assessing moral injury to ensure that our measures are sensitive enough to capture changes in functioning. We will be administering measures related to ACT processes repeatedly (e.g., AAQ-II, MEAQ-30) over the course of treatment to help determine which measures might be most sensitive to change over time for a future efficacy trial. Additionally, we will be using EMA via the implementation of a mobile application to measure changes associated with functional outcomes and ACT processes in a more ecologically valid manner. We have consulted with an expert in EMA who has previously collaborated with the Palo Alto VAMC to identify how to utilize a mobile application to detect changes in moral emotions, experiential willingness, and behavioral activation (Tod Dykstra). EMA procedures have been successfully applied to measuring in the moment changes in emotions in Veterans[94] and have also been used to assess experiential avoidance and shame, indicating the relevance and feasibility of this methodology to the goals of the present study.[94-95] Please see the "measures" section for more details about EMA procedures.

VII. Data Analysis Plan:

Data Analysis & Methodological Considerations. Analyses will be descriptive in nature, although variability and precision estimates (95% confidence intervals) will be provided for

acceptability and feasibility summary statistics. Results will be presented across participants and individually for each group. **Sample Size.** Areán and Kraemer recommend sample sizes between 50 and 100 to generate variability estimates for outcome measures and to facilitate a "dress rehearsal for the clinical trial" (p. 95).[17] As this trial serves as a precursor to a larger scale efficacy study and one of our goals is to determine the fit of candidate outcome measures, we will enroll 36 participants per condition (72 participants total) to account for attrition. As a method of data analysis for qualitative measures, thematic content analysis will be used as an iterative process of interpretation for the purposes of scoring, coding, and seeking patterns (themes) across verbal materials so that inferences about characteristics of a group can be generated.[97, 5] First, data will be recorded and coded without identifiers. Reviewers will independently code interviews. Each interview will be coded by at least two reviewers. Reviewers will independently identify themes among codes. Reliability and validity among themes between reviewers will be determined in a consensus meeting. In the consensus meeting the coding team will define and name the themes that best represent the narratives from the individual interviews. This process is consistent with previous qualitative research conducted on moral injury.[5]

Aim 1: Evaluate the acceptability of the ACT-MI intervention for Veterans experiencing impairment in functioning associated with moral injury. We will assess the proportion of participants who find ACT-MI acceptable, defined as ≥ 70% of participants scoring ≥ 24 on the Client Satisfaction Questionnaire (CSQ).[19] The Narrative Evaluation of Intervention Interview (NEII)[20] will be used to inform any necessary revisions to the intervention and refinement of the treatment manual. Qualitative data collected using the NEII will be used to understand the limitations and strengths of the interventions via thematic content analysis. If fewer than 70% of participants find ACT-MI or PCT-MI acceptable, the qualitative data will be examined to determine areas for improvement.[20]

Aim 2: Determine the feasibility of the efficacy study design. Feasibility will be assessed by examining the following outcomes related to recruitment, retention, and provider adherence **a) Participant recruitment rates.** The number of participants approached for the study who are eligible to participate and of those, the number who enroll in the study (i.e., willingness to participate) will be evaluated. Feasibility will defined as ≥ 50% eligible and of these ≥ 30% willing to participate in the proposed time frame. **b) Participant Retention.** Participant completion of ACT-MI will be measured by the percentage of participants who complete treatment and receive an adequate dose (completed a minimum of 70% of the intervention). Reasons for termination will be examined via the RT-C/T. The percentage of participants lost to follow up (LTFU) will be calculated as the percentage of participants who fail to complete one-month and three-month follow-up visits, with ≤ 30% LTFU considered feasible. This will inform the necessary sample size and treatment retention strategies for future studies. **c) Provider adherence.** To examine the extent to which ACT-MI can be delivered as intended (≤ 15% of deviations for each clinician across participants on the treatment fidelity checklist), the proportion of sessions in which each clinician achieved acceptable fidelity out of all of the clinician's sessions will be reported for all study clinicians. Qualitative review of fidelity checklists will be used if treatment fidelity is less than desired and areas of difficulty will be identified to inform training procedures for clinicians and treatment manual revisions.

Aim 3: Select measures and calculate necessary sample size for a future efficacy study. Evaluate candidate measures based on the following factors: (1) Amount of missing data and its distribution for all measures across groups; (2) means, standard deviations, and 95% confidence

intervals for all measures within and across groups; and (3) correlations and 95% confidence intervals between a self-reported clinically significant change measure and candidate measures across groups. Missing data and frequency distributions will be examined to identify measures that have the least amount of missing data, and the extent of outliers or other anomalies. Means and standard deviations will be examined to identify and exclude measures with limited sensitivity to change due to ceiling or floor effects, or restriction of range.[77] Finally, higher correlations between participants' scores on the Global Ratings of Change Scale and the candidate measures will suggest that these measures are more sensitive to clinically significant change. Confidence intervals will be examined to determine how much to emphasize these findings when selecting measures. The study team will work closely with Dr. Forster in considering these various statistics and their limitations when selecting the most promising outcome and mediational measures for the future efficacy study.

After the primary outcome measure has been selected, we will calculate the necessary sample size for the efficacy study. This will require an estimate of variability and effect size in the target sample. We will estimate variability across groups at baseline and the variability of change scores on the outcome measure. The estimate with the greatest variability will be used in our power calculation because it will provide the most conservative (i.e., largest) estimate of the necessary sample size. Unlike estimates of variability that can be based on the entire sample, estimates of effect sizes are limited by the group sizes. Increasingly, methodological experts argue against the use of pilot data to estimate effect sizes because of limitations related to sample size and protocol/intervention changes, leading to invalid estimates. Instead, best practice is to set the effect size in power calculations to whatever value is considered minimally clinically significant.[17] We will use the available literature and consultation with experts on measures of functioning when selecting this effect size and calculating the necessary sample size for the efficacy study.[67]

Aim 4 and Aim 5: The analyses described above for Aim 1 and Aim 2 will be replicated using data collected from Veterans who participated in the intervention and study remotely (i.e., using videoconferencing and REDCap).

VIII. Knowledge to be Gained:

The proposed pilot study will provide critical information necessary to inform final revisions to the treatment manual and research design for a future efficacy study on ACT for Moral Injury. This pilot study is the first step in a line of research likely to yield an effective, recovery-oriented intervention tailored for use with a population of Veterans for whom intervention may result in significant improvements in functioning.

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Appendix 1 Safety Monitoring Plan
UWRAP Protocol Guidelines, Decision Rules and Follow-up Procedures

Part I: Pre-risk Assessment of Suicidal Risk

Step 1: Using the Face Sheet, assess subject's mood and suicidality before administering measures or beginning an intervention

On a scale of 1 to 7:

……..what is your level of stress right now?
……..what is your urge to harm yourself now?
……..what is your intent to kill yourself right now?
……..what is your urge to use drugs or alcohol right now?

Step 2: Identify level of suicide risk

Examine participants' responses to suicide specific questions

……..what is your urge to harm yourself now?
……..what is your intent to kill yourself right now?

Step 3: Determine if further risk assessment is warranted

3a. If scores are greater than one, but less than or equal to 4 on either of the two suicide items, yet there are no apparent signs of distress or immediate concerns, continue with the research protocol and utilize the following strategies if needed:

Pace the sessions
Check in with participant to see how they are doing
Allow more frequent breaks if needed

3b. If participants' scores are greater than a 4 on either of the two suicide items

OR

Scores are equal to or less than 4 on either of the two suicide items, but participant appears distressed or exhibits other suicide signs or symptoms

Contact designated clinician to further evaluate risk

Step 4: Conduct further risk assessment if warranted

If indicated in step 3 above, the designated clinician will complete the Suicide Risk Assessment Worksheet (pg. 6-7 of the UWRAP)

Step 5: Initiate the appropriate follow up actions

Based on participant's responses on the suicide risk assessment worksheet, the designated clinician will initiate the appropriate follow up procedures. This may include:

- Referring the participant to the mental health clinic if not in treatment,
- Encouraging participant to check in with his/her mental health, primary care provider, or other health provider
- Walking the participant to urgent care (including Psychiatric Emergency Services) if risk is imminent or contacting 911.
- Continuing with the research protocol and utilizing the following strategies:

  Pace the sessions

Check in with participant to see how they are doing
Allow more frequent breaks if needed

Part II: Debriefing Protocol Suicidal Risk

Step 1: Using the Debriefing Protocol, assess subject's mood and suicidality following administration of study measures

On a scale of 1 to 7:
……..what is your level of stress right now?
……..what is your urge to harm yourself now?
……..what is your intent to kill yourself right now?
……..what is your urge to use drugs or alcohol right now?

Step 2: Identify level of suicide risk
Examine participants' responses to suicide specific questions
……..what is your urge to harm yourself now?
……..what is your intent to kill yourself right now?
*Note changes, and in particular, increase in suicidality from the pre-assessment risk

Step 3: Determine if further risk assessment is warranted
3a. If scores are greater than one, but less than or equal to 4 on either of the two suicide items, yet there are no apparent signs of distress or immediate concerns
Encourage them to contact their mental health or primary care provider if needed

3b. If participants' score is greater than a 4 on either of the two suicide items **OR**
Scores are equal to or less than 4 on either of the two suicide items, but participant reports at least a two points increase since the pre-risk assessment, or appears distressed and exhibits other suicide signs or symptoms
Contact the designated clinician to further evaluate risk

Step 4: Conduct further risk assessment if warranted
If indicated in step 3b above, the designated clinician will complete the Suicide risk assessment worksheet (pg. 6-7 of the UWRAP)

Step 5: Initiate the appropriate follow up actions
Based on participant's responses on the suicide risk assessment worksheet, the designated clinician will initiate the appropriate follow up procedures. This may include:

- Referral to the MH clinic if not in treatment,
- Encouraging participant to check in with his/her mental health, primary care provider, or other health provider
- Walking the participant to urgent care (including Psychiatric Emergency Services) if risk is imminent or calling 911.
- Providing the participant with the VA national crisis hotline number

Study Title: **Thriving in the Midst of Moral Pain: A Moral Injury Treatment Study**

Principal Investigator: **Lauren Borges, Ph.D. and Sean Barnes, Ph.D.**

COMIRB No: **18-0984**

Version Date: **1/17/2023**

This study will evaluate the acceptability and feasibility of psychological treatments for moral injury: Acceptance and Commitment Therapy for Moral Injury and Present Centered Therapy for Moral Injury, designed to help Veterans recover after their morals are violated in the warzone. You are being asked to be in this research study because you are a Veteran eligible for VA healthcare and have experienced a moral injury.

If you join the study, you will be asked to complete a two to three hour initial assessment session at the Rocky Mountain Regional VA Medical Center or online using videoconferencing and UCD Anschutz Campus CCTSI REDCap, in which you would answer questionnaires and interviews about your mental health and mental health related behaviors. If you complete the assessment session via survey link, your email address will be obtained and surveys will be sent from UCD Anschutz Campus CCTS REDCap, a secure web-based application designed for data collection for research studies. At the end of this assessment session you would be randomly assigned to participate in one of the two treatments: (1) ACT for Moral Injury or (2) Present Centered Therapy for Moral Injury; you do not get to choose which group you would like to be assigned to. Treatment groups will be held at the Rocky Mountain Regional VA Medical Center or, if necessary due to the COVID pandemic, online using videoconferencing.

At the end of the initial assessment session you will have the option to download an application onto your mobile device (e.g., iPod, phone or tablet) to answer additional questions for one week before the start of treatment and one week after the end of treatment. If you do not have access to a mobile device that is compatible with the application, you can borrow a study iPod for the length of the study. You will be asked questions via your mobile device so that we can get a better sense of your symptoms in real time, that is as these symptoms occur in your daily life. During these periods, your mobile device will prompt you to respond three times each day, during a 12-hour period of time in which you are awake (you will get to pick the 12-hour period), to fill out very brief assessments on your mobile device about your mood, thoughts, and behavior. These assessments last less than ten minutes and will involve answering multiple choice and short answer assessment questions about your recent thoughts, emotions and behaviors via typing or audio recording your responses. Whether you do or do not have a compatible device, this portion of the study is voluntary.

The participants in both Acceptance and Commitment Therapy for Moral Injury and Present Centered Therapy for Moral Injury will meet in a therapy group either in person or, if necessary, through videoconferencing. Groups will occur once a week, over 12-weeks for 90-minutes. We will audio record all study treatment sessions. At the end of the 12-weeks you will be asked to participate in a post-treatment assessment session, during which, you will be asked questions

about your experience of participating in treatment and complete some additional questionnaires. We will also audio record your responses on a qualitative interview about your experience of treatment. The audio recording about your experience of treatment will transcribed (i.e., typed

out) and analyzed by members of the study team to learn more about your experience of the new treatments. All participants will be asked to complete two additional follow-up assessment sessions (one month and three months after treatment) that can occur in-person, via phone, or via UCD Anschutz Campus CCTSI REDCap survey link. These surveys take approximately two to three hours. You can choose to receive reminders of your study appointments by phone call, email or text message. If you choose to receive text message reminders we would provide your cell phone number to a third party company, Twilio, that we send text message through. Finally, if you enroll in the study, we will ask you for permission to access your medical record over the course of the next year so that we can see how you are doing.

Possible discomforts or risks include:
(1) **Emotional upset.** You may be asked to discuss or think about topics which make you uncomfortable or upset. You might experience some boredom, frustration, distress, or other emotional discomfort from participating in the study.
(2) **Loss of confidentiality of privacy.** Every effort will be made to protect your privacy and confidentiality. Some examples of this include saving and storing your research data separate from your name, password protecting files, storing information on secure computer severs behind the VA firewall, etc. However, there is still some risk of loss of confidentiality or privacy if you participate in the study. In particular, your mobile device likely does not meet VA security and encryption standards. Therefore, there is a greater risk that these data could be revealed. We cannot protect the confidentiality of the information entered into your mobile device while the data remain on the device because it will be in your possession and will not be encrypted. There is also some information that we can't keep private. This would include things such as information about child abuse or neglect, or if you tell us that you are going to physically hurt yourself or someone else. Also, if we get a court order to turn over your study records, we have to follow the court order.
(3) **Unknown risks.** There may be risks the researchers have not thought of.

This study is not designed to benefit you directly. This study is designed for the researchers to learn more about helping Veterans who have experienced moral violations in the warzone that are interfering with their lives.

You will be paid $30 for participating in the initial assessment session. If you have a personal mobile device (i.e., iPhone, iPod, or iPad) compatible with Esmi, a survey application, and choose to participate in the mobile assessment periods, you will be paid for data given to the study team. Specifically, you will be paid $3 each time you complete the questionnaires on your personal device after being prompted and then later provide these data to the study team. Your personal device would prompt you to respond three times a day for one week for both the initial and final mobile assessment periods. You could earn up to $9 a day if you complete each assessment period when prompted by your personal device and then later provide these data to the study team. If you choose to respond to every prompt over the course of a week (3 times per day for 7 days) and provide these data to the study team you would be paid $63. You will be paid $30 for participating in the post-treatment assessment session. If you choose to participate in the final mobile assessment period after treatment, respond every time you are prompted, and provide these data to the study team you would be paid $63 ($3 per response period X 3 times a day X 7 days = $63). You will be paid $30 for participating in the one-month follow-up session, and $60 for the 3-month follow-up session. Payments will be provided in the form of cash,

voucher, check or direct deposit. The total amount paid for participating in the entire study and providing data for every mobile response prompt would be $276.

If you leave the study early, or if we have to take you out of the study, you will be paid only for the assessment(s) you have completed. If you do not respond to every prompt for the mobile assessment, you will still be paid $3 for every period of questions that you respond to and provide to the study team.

This research is being paid for by the VA Office of Rehabilitation Research and Development.

Taking part in this study is voluntary. You can choose to stop participating in this study at any time. **You can also decline to answer any questions that you do not feel comfortable answering.**

The study doctor may decide to stop your participation without your permission, if he or she thinks that being in the study may cause you harm, or for any other reason. If you leave the study early, or if we have to take you out of the study, you will be paid only for the assessment(s) you have completed.

The data we collect will be used for this study but may also be important for future research. Your data may be used for future research or distributed to other researchers for future study without additional consent if information that identifies you is removed from the data.

If you have questions, you can call Lauren Borges, Ph.D. at 303-916-0128 or Sean Barnes, Ph.D. at 720-519-2449.

You may have questions about your rights as someone in this study. If you have questions, you can call COMIRB (the responsible Institutional Review Board) at 303-724-1055.

By participating in the Initial Assessment Session, you are agreeing to participate in this study.