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PRINCIPAL INVESTIGATOR: Sonya Norman, PhD

CONTRACTING ORGANIZATION: Veterans Medical Research Foundation

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Sonya Norman, Ph.D.

E-Mail: snorman@ucsd.edu

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Veterans Medical Research Foundation
3350 La Jolla Village Drive (151A)
San Diego, CA 92161

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14. ABSTRACT

Posttraumatic guilt and shame are common among Veterans and have been implicated in the development and maintenance of posttraumatic distress and a range of adverse outcomes, including posttraumatic stress disorder (PTSD), depression and suicidality, and alcohol/substance use disorders**.** There is a pressing need for effective treatments targeting transdiagnostic mechanisms such as guilt. We developed Trauma Informed Guilt Reduction (TrIGR) therapy as a therapeutic tool to help Veterans accurately appraise deployment-related guilt and to re-identify and re-engage with their values. The overall objective of this study is to examine the efficacy of TrIGR in reducing deployment-related guilt. The overarching hypothesis is that TrIGR will reduce guilt, shame, and related distress, and these improvements will be significantly greater than in the comparison condition, Supportive Care Therapy (SCT). The study is a Stage 2 randomized, controlled trial of TrIGR compared to SCT. Recruitment of participants takes place at two VA Medical Centers (San Diego, CA and Providence, RI). 150 OEF/OIF Veterans will be randomized to TrIGR or SCT (at least 75 in San Diego). All eligible participants complete an in-person baseline assessment, receive 6 sessions of TrIGR or SCT in individual format, complete brief bi-weekly self-report measures during treatment, and complete follow-up assessments immediately post-treatment, and 3- and 6-months later.

15. SUBJECT TERMS
Guilt, shame, deployment, posttraumatic, distress, PTSD, depression, functioning, psychotherapy, intervention

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1. INTRODUCTION:

Posttraumatic guilt and shame are common among Veterans and have been implicated in the development and maintenance of posttraumatic distress and a range of adverse outcomes, including posttraumatic stress disorder (PTSD), depression and suicidality, and alcohol/substance use disorders. There is a pressing need for effective treatments targeting transdiagnostic mechanisms such as guilt. We developed Trauma Informed Guilt Reduction (TrIGR) therapy as a therapeutic tool to help Veterans accurately appraise deployment-related guilt and to re-identify and re-engage with their values. Our previous pilot studies of TrIGR with OEF/OIF/OND Veterans and active duty Marines showed reductions in guilt distress and severity, PTSD symptoms, and depression with medium to large effect sizes. The overall objective of this study was to examine the efficacy of TrIGR in reducing deployment-related guilt. The overarching hypothesis was that TrIGR will reduce guilt, shame, and related distress, and these improvements will be significantly greater than in the comparison condition, Supportive Care Therapy (SCT). The study was a Stage 2 randomized, controlled trial of TrIGR compared to SCT. Recruitment of participants took place at two VA Medical Centers (San Diego, CA and Providence, RI). 145 OEF/OIF/OND Veterans were randomized to TrIGR or SCT across two sites (92 in San Diego). All eligible participants completed an in-person baseline assessment, were randomized to receive 6 sessions of TrIGR or SCT in individual format, completed brief bi-weekly self-report measures during treatment, and were invited to complete follow-up assessments immediately post-treatment, and 3- and 6-months later. We have now published the primary outcome manuscript and have submitted secondary manuscripts.

We also were approved to run a pilot RCT of the same two treatments for guilt from events in the pandemic. For this extension, we conducted a prospective, randomized, controlled pilot trial examining the efficacy of TrIGR compared to SCT for the treatment of guilt and distress related to a COVID-19 stressor. 72 male and female Veterans of OEF/OIF/OND were randomized at the San Diego, Providence, and Boston VAs. Participants completed a baseline assessment, received 6 weekly sessions of TrIGR or SCT, and completed a follow-up assessment post-treatment, and 1-month later. Study visits were conducted over telehealth. Study recruitment, enrollment, intervention, and data collection are now complete. The results were presented at an international meeting and a manuscript is in progress of being published.

2. KEYWORDS

Guilt, shame, deployment, posttraumatic, distress, PTSD, depression, functioning, psychotherapy, intervention

3. ACCOMPLISHMENTS

- **What were the major goals of the project?**

Per our Statement of Work (SOW) all of the major goals of this project have been completed. See below for a comprehensive summary of the goals and outcomes throughout the course of the study:

<u>Conduct RCT – San Diego</u>

Major Task 1: Start-up Activities
Subtask 1: Prepare Regulatory Documents and Research Protocol (Month 1).
Progress: Subtask 1 completed.
Subtask 2: Obtain regulatory approvals (VA, DoD, affiliated institutions) (Months 2-3).
Progress: Completed.
Subtask 3: Hire and train all study personnel (Months 0-6).

Progress: Completed.
Subtask 4: Set up data entry and management procedures (Months 3-7).
Progress: Completed.

Major Task 2: Conduct RCT
Subtask 1: Enroll 75 at San Diego site (Months 6-34).
Progress: Completed.
Subtask 2: Randomize to study condition (TrIGR or SCT) (Months 6-34).
Progress: Completed.
Subtask 3: Deliver study interventions (Months 6-36).
Progress: Completed.
Subtask 4: Conduct assessments (Months 8-42).
Progress: Completed.
Subtask 5: Data collection (6 -42).
Progress: Completed.

Major Task 2 - Conduct Pilot RCT Related to COVID-19 – San Diego

Subtask 1: Enroll 24 at San Diego site (Months 6-34).
Progress: We enrolled 39 participants.

Subtask 2: Randomize to study condition (TrIGR or SCT) (Months 6-34).
Progress: We randomized 25 participants.

Subtask 3: Deliver study interventions (Months 6-36).
Progress: 25 participants completed treatment.

Subtask 4: Conduct assessments (Months 8-42).
Progress: Assessments have been completed.

Subtask 5: Data collection (6 -42).
Progress: Data collection has been completed.

Major Task 2 - Conduct Pilot RCT Related to COVID-19 – Boston

Subtask 1: Enroll 24 at Boston site (Months 6-34).
Progress: We enrolled 35 participants.

Subtask 2: Randomize to study condition (TrIGR or SCT) (Months 6-34).
Progress: We randomized 24 participants.

Subtask 3: Deliver study interventions (Months 6-36).
Progress: 24 participants completed treatment.

Subtask 4: Conduct assessments (Months 8-42).
Progress: Assessments have been completed.

Subtask 5: Data collection (6 -42).
Progress: Data collection has been completed.

RCT – San Diego

472 participants have been recruited/referred to the study. We screened 214 participants. Of these, 176 screened eligible and 38 screened ineligible. 258 of the referred participants were not screened (122 could not be reached, 110 were not interested in screening after the study was explained, 2 had moved out of the area so screening was not conducted, 24 were not screened after chart review determined they were not OOO). 1 screened eligible but was not enrolled due to COVID.

We consented 117 participants and randomized 92. The original planned target was 75. Of the 176 participants who screened eligible, 59 were not consented by 9/30/20: 52 decided not to proceed with the study (39 could not be reached to schedule consent appointment, 18 are no longer interested in the study, 1 moved out of the area, 1 was not consented due to COVID-19). 25 of the 117 consented participants were not randomized – 9 were not eligible after baseline assessments, 12 were not able to be reached after the consent/baseline appointment, 4 were no longer interested after baseline assessments.

Of the 117 consented participants 10 were female and 107 were male. 39 were Hispanic, 46 were White, 2 was Native Hawaiian or Pacific Islander, 13 were Black/African American, 10 were Asian, 3 were multiracial, 4 declined to identify a race/ethnicity.

Of the 92 randomized participants, 8 were female and 84 were male. 28 were Hispanic, 40 were White, 2 were Native Hawaiian or Pacific Islander 10 were Black/African American, 8 were Asian, 2 was multiracial, 2 declined to identify a race/ethnicity.

92 of the 92 randomized participants have completed the study.

RCT Related to COVID-19 – San Diego

244 participants were recruited/referred to the study. We screened 110 participants since we launched recruitment. Of these, 61 screened eligible and 49 screened ineligible. 134 of the referred participants were not screened (85 could not be reached, 16 were not interested in screening after the study was explained, 33 were not screened after the participant disclosed information indicating they would not be eligible prior to screening).

We consented 39 participants and randomized 25. The original planned target was 24. Of the 61 participants who screened eligible, 22 were not consented by 9/30/22: 17 could not be reached to schedule consent appointment, 5 are no longer interested in the study. 14 of the 39 consented participants were not randomized – 12 were not eligible after baseline assessments, 2 were not able to be reached after the consent/baseline appointment, 0 are still conducing baseline appointments.

Of the 39 consented participants 8 were female and 31 were male. 12 were Hispanic, 16 were White, 0 were Native Hawaiian or Pacific Islander, 3 were Black/African American, 2 were Asian, 6 declined to identify a race/ethnicity.

Of the 25 randomized participants, 3 were female and 22 were male. 8 were Hispanic, 12 were White, 0 were Native Hawaiian or Pacific Islander 1 was Black/African American, 2 were Asian, 2 declined to identify a race/ethnicity.

25 of the 25 randomized participants have completed the study.

RCT Related to COVID-19 – Boston

232 participants were recruited/referred to the study. We screened 79 participants since we launched recruitment. Of these, 42 screened eligible and 37 screened ineligible. 153 of the referred participants were not screened (137 could not be reached, 7 no longer interested, 9 were not OEF/OIF/OND or otherwise did not meet enrollment criteria and therefore were not screened).

We consented 35 participants and randomized 24. The original planned target was 24. Of the 42 participants who screened eligible, 7 were not consented by 9/30/22: 7 could not be reached to schedule consent appointment. 11 of the 35 consented participants were not randomized – 5 were not eligible after baseline assessments, 6 were not able to be reached after the consent/baseline appointment, 0 are still conducing baseline appointments.

Of the 35 consented participants 9 were female and 26 were male. 7 were Hispanic, 13 were White, 0 were Native Hawaiian or Pacific Islander, 6 were Black/African American, 1 were Asian, 2 were Native Alaskan/American Indian, and 6 declined to identify a race/ethnicity.

Of the 24 randomized participants, 6 were female and 18 were male. 6 were Hispanic, 9 were White, 0 were Native Hawaiian or Pacific Islander, 6 was Black/African American, 0 were Asian, 2 were Native Alaskan/American Indian, and 1 declined to identify a race/ethnicity.

24 of the 24 randomized participants have completed the study.

- **What was accomplished under these goals?**
  During the course of the original study, we completed all major activities per our statement of work (see above for a breakdown of all study goals and outcomes). We published the primary outcome paper and completed a number of secondary analyses papers and presentations (see a summary of results below each citation in the "Products" section and the attached pdfs of the publications, presentations and abstracts for more detail).

  During the course of the COVID-19 supplement study, we also completed all major activities per our statement of work (see above for a breakdown of all study goals and outcomes). For the COVID-19 supplement, primary outcome data analyses are complete and the manuscript is being finalized for publication. The findings have been presented at an international conference.

- **What opportunities for training and professional development has the project provided?**
  During the course of the study, we trained several psychology trainees (doctoral student, post-doctoral fellows, volunteers) in conducting randomized clinical trials.

- **How were the results disseminated to communities of interest?**
  During the course of the study, results were disseminated through peer-reviewed publications and conference presentations. Results will continue to be disseminated. Citations and summaries of results thus far are presented in the "Products" section and final copies are included at the end of this report.

- **What do you plan to do during the next reporting period to accomplish the goals?**
  All SOW goals have been accomplished. This is the final reporting period.

4. IMPACT

- **What was the impact on the development of the principal discipline(s) of the project?**
  We have evidence from the primary study that TrIGR is effective in reducing trauma related guilt, PTSD symptoms, and depression symptoms.

  We have evidence from the COVID-19 supplement study that both TrIGR and supportive care therapy were comparably effective at reducing pandemic-related guilt. Exploratory analyses suggest TrIGR may be more effective at decreasing guilt in long-term follow-up in those with a baseline PTSD diagnosis.

- **What was the impact on other disciplines?**
  Nothing to Report

- **What was the impact on technology transfer?**
  Nothing to Report

- **What was the impact on society beyond science and technology?**
  Nothing to Report

5. CHANGES/PROBLEMS

Nothing to report

6. PRODUCTS

- **Publications, conference papers, and presentations**
  - Capone, C., Norman, S.B., Haller, M., Davis, B., Shea, M.T., Browne, K., Lang, A.J., Schnurr, P.P., Golshan, S., Afari, N., Pittman, J., Allard, C.B., Westendorf, L. (2021). Trauma informed guilt reduction (TrIGR) therapy for guilt, shame, and moral injury resulting from trauma: Rationale, design, and methodology of a two-site randomized controlled trial. Contemporary Clinical Trials. doi: 10.1016/j.cct.2020.106251
    - This paper presents the rationale, design, and methodology of this two-site randomized controlled trial (RCT) examining the efficacy of TrIGR compared to Supportive Care Therapy (SCT) in a sample of U.S. veterans (N = 145) who endorse guilt related to a traumatic event that occurred during military deployment. This study is the first RCT powered to investigate TrIGR's efficacy on reducing posttraumatic guilt, as measured by the Trauma Related Guilt Inventory (TRGI), in comparison to an active control condition. In addition, the study will examine a range of secondary and exploratory outcomes including shame, quality of life, and PTSD and depression symptoms. Findings from this efficacy study will be essential in informing future efficacy and effectiveness trials.
  - Norman, S.B., Capone, C., Panza, K.E., Haller, M., Davis, B.C., Schnurr, P.P., Shea, M.T., Browne, K.C., Norman, G.J., Lang, A.J., Kline, A.C., Golshan, S., Allard, C.B. & Angkaw, A.C. (2022). A clinical trial comparing trauma-informed guilt reduction therapy (TrIGR), a brief intervention for trauma-related guilt, to supportive care therapy. Depression and Anxiety. http://doi.org/10.1002/da.23244
    - A total of 184 veterans seeking VA mental health services were enrolled across two sites; 145 veterans (mean age: 39.2 [8.1]; 92.4% male; 84.8% with PTSD) who endorsed guilt related to a traumatic event that occurred during a post 9/11 Iraq or

Afghanistan deployment were randomized and assessed at baseline, posttreatment, 3- and 6-month follow-up. Linear mixed models using intent-to-treat analyses showed guilt decreased in both conditions with a greater decrease for TrIGR (treatment × time, −0.22; F1, 455.2 = 18.49, p = .001; d = 0.92) than supportive therapy. PTSD and depressive symptoms showed the same pattern. TrIGR had significantly higher likelihood of PTSD treatment response (67% vs. 40%), loss of PTSD diagnosis (50% vs. 14%), and meaningful change in depression (54% vs. 27%) than supportive therapy. Psychological distress and trait shame improved in both conditions.

- Norman, S. B. (2022). Trauma-informed guilt reduction therapy: Overview of the treatment and research. Current Treatment Options in Psychiatry. DOI 10.1007/s40501-022-00261-7
    - The purpose of this review is to describe Trauma-Informed Guilt Reduction Therapy (TrIGR), the Non-Adaptive Guilt and Shame (NAGS) model that underlies TrIGR, and the research supporting the use of TrIGR to treat the guilt and shame components of moral injury. This review found that TrIGR is efficacious in reducing guilt that is common to moral injury as well as PTSD and depression symptoms among combat veterans. The next steps in the program of research to develop and evaluate TrIGR are studies with diverse trauma types and populations as well as relative effectiveness studies comparing TrIGR to other evidence-based treatments for moral injury and PTSD.
- Capone, C., Panza, K.E., Luciano, M.T., Lang, A.J., & Norman, S.B., (November 2021). Behavioral disengagement mediates the association between trauma-related guilt and mental health problems in a sample of OEF/OIF/OND veterans. In J. McCann (Chair), Understanding and Treating Trauma-Related Guilt and Shame in PTSD. Symposium presented at the annual convention of the Association for Behavioral and Cognitive Therapies. Virtual meeting.
    - In this study, we present cross-sectional associations between trauma-related guilt, behavioral disengagement, and four outcomes – PTSD symptom severity (Clinician Administered PTSD Scale; CAPS-5), depressive symptoms (Patient Health Questionnaire; PHQ-9), SUD diagnosis (Structured Clinical Interview for DSM 5; SCID-5), and suicide intensity (Columbia Suicide Severity Rating Scale; C-SSRS). We also examined whether behavioral disengagement mediated these relationships. The sample consisted of 184 veterans screened for a transdiagnostic intervention study to treat trauma-related guilt stemming from a post 9/11 deployment. In the sample, 84% (n = 152) met criteria for PTSD with a mean CAPS-5 total score of 37.33 (SD = 10.01). The mean PHQ-9 score was 14.51 (SD = 6.39), suggesting moderately severe depressive symptoms, and 44% (n = 80) met criteria for a SUD. Nearly half the sample endorsed current suicidal ideation (49.5%), with an average C-SSRS intensity score of 6.37 (SD = 7.00). Examination of bivariate correlations indicated that trauma-related guilt (Trauma Related Guilt Inventory; TRGI) was significantly associated with three of the outcomes (CAPS-5 r = .45; PHQ-9 r =31; C-SSRS r = .23) as well as the putative mediator, behavioral disengagement (Brief COPE Inventory r = .33). Contrary to our hypothesis, SUD diagnosis was not related to trauma-related guilt (r = .03). Results of mediation analyses showed that behavioral disengagement mediated the relationship between guilt and suicide intensity (B = .94, SE = .34, 95% CI = .35 to 1.68), and partially mediated the relationships with PTSD (B = .93, SE = .35, 95% CI = .32 to 1.65) and depressive symptoms (B = 1.24, SE = .33, 95% CI = .62 to 1.91).
- Norman, S.B., Luciano, M.T., Panza, K.E., Lang, A.J., Schnurr, P.P., Angkaw, A.C., Davis, B.C., Haller, M., Browne, K.C., & Capone, C. (November 2021). Relationship between trauma-related guilt, moral injury, and PTSD symptom severity in a treatment seeking sample of veterans who served in Iraq and Afghanistan. In J. McCann (Chair), Understanding and Treating Trauma-Related Guilt and Shame in PTSD. Symposium presented at the annual convention of the Association for Behavioral and Cognitive Therapies. Virtual meeting.
    - This study examined trauma-related guilt (as measured by the Trauma-Related Guilt Inventory; TRGI), moral injury - including transgressions by self and transgressions

by others (Moral Injury Events Scale; MIEs) - and PTSD severity (Clinician Administered PTSD Scale; CAPS-5) among 184 veterans who were screened for a study to treat guilt stemming from traumatic events that occurred during post 9/11 deployments. Results showed that trauma-related guilt was significantly correlated with the MIEs total score (r = .46), and the transgressions by others (r = .25) and transgressions by self-subscales (r = .52). Results of the mediation revealed that both transgressions by self (r = .34) and trauma-related guilt (r = .45) were correlated with PTSD symptom severity. There was a significant indirect effect for transgressions by self on PTSD severity through trauma-related guilt (B = .27, SE = .07, 95% CI = .14 to .41) such that trauma-related guilt fully mediated the relationship between transgression by self and PTSD symptom severity.

- Johnson, E.C., Kline, A.C., Panza, K.E., Davis, B.C., Capone, C., & Norman, S.B. (November 2021). Reintegration stress among post-9/11 veterans: Relationships with moral injury, PTSD symptoms, and guilt. Poster presentation at the annual convention of the International Society of Traumatic Stress Studies. Virtual meeting.
    - 184 Veterans of post-9/11 conflicts (94% male; mean age 39.1 (SD = 8.4); 62% White) were screened for a transdiagnostic guilt intervention study. Multiple regression was used to evaluate the association between PTSD symptoms (CAPS-5), trauma-related guilt (Trauma-Related Guilt Inventory; TRGI), and reintegration stress (Military to Civilian-Questionnaire; M2C-Q). Correlations were used to explore association between morally injurious events and reintegration stress. It was found that trauma-related guilt and PTSD symptoms explained 42% of the variance in reintegration stress, $F(2, 174) = 63.41$, $p < .001$. When entered into the same regression model, PTSD symptoms ($\beta = 0.61$, $p < .001$), but not trauma-related guilt ($\beta = 0.09$, $p = 0.16$), was significantly associated with reintegration stress. Correlations between morally injurious events scale and reintegration stress found a positive association between all forms of moral injury including transgressions by others ($r = 0.20$, $p = .01$), transgressions by self ($r = 0.36$, $p < .001$), and betrayal ($r = 0.16$, $p = 0.03$).
- Kline, A. C., Panza, K. E., Johnson, E., Davis, B. C., Capone, C. C., & Norman, S. B. (November 2022). Reintegration stress outcomes among post-9/11 veterans in a clinical trial for trauma-related guilt. In S. Stoycos (Chair), The Impact of Treatment for PTSD and Trauma-Related Guilt on Co-Occurring Conditions. Symposium to be presented at the annual convention of the International Society for Traumatic Stress Studies. Atlanta, GA.
    - This study evaluated reintegration outcomes in a clinical trial comparing Trauma-Informed Guilt Reduction Therapy (TrIGR) and Supportive Counseling Therapy (SCT) among 145 Veterans endorsing trauma-related guilt stemming from an event on deployment to Iraq/Afghanistan. Reintegration stress was assessed at baseline, post-treatment, and 3- and 6-month follow-up via the Military to Civilian Questionnaire. Intent to treat analyses using mixed models indicated TrIGR produced greater reductions in reintegration stress compared to SCT between baseline and 6-month follow-up (treatment*time interaction $p<.05$), with effects of TrIGR increasing from post-treatment ($d=0.11$) to 3-month ($d=0.37$) and 6-month ($d=0.57$) follow-up.
- Norman, S.B, Capone, C., Harle, K., Wachen, J.S., Davis, B.C., Shea, T.M., Haller, M., Galovski, T.E., Schnurr, P.P., Panza, K.E., Pitts, M., Luciano, M.T. (2023, June). A Pilot Randomized Controlled Trial to Address Guilt and Moral Injury Resulting from Pandemic Related Events. Invited Presentation in Symposium titled Understanding and Addressing Mental Health Reactions to a Global Pandemic (Norman, S. B. chair). Presented at 17th European Society of Traumatic Stress Conference in Belfast, Northern Ireland.
    - Objective: To evaluate whether TrIGR, compared to supportive therapy, would reduce guilt, shame, PTSD and depressive symptoms among people experiencing guilt from pandemic-related events.
    - Results: While these are still preliminary, overall results of linear mixed models using intent-to-treat analyses found the time x treatment interaction is significant for guilt, with a steeper decrease for those in the TrIGR condition but no mean group

difference at post/follow-up. There were no group differences for depression or PTSD outcomes. Exploratory analyses suggest TrIGR may be more effective at decreasing guilt in long-term follow-up in those with a baseline PTSD diagnosis, whereas SCT is more effective with those without PTSD diagnosis.

- Morse, J. L., Wooldridge, J.S., Afari, N., Angkaw, A.C., Schnurr, P.P., Lang, A.J., Capone, C., & Norman, S.B. (2023). Associations among meaning in life, coping, and distress in trauma-exposed U.S. military veterans. Psychological Services. https://doi.org/10.1037/ser0000755
    - Associations among meaning in life, avoidant coping, and psychological distress in a sample of trauma-exposed veterans were examined. Secondary cross-sectional analyses were conducted on data from veterans exposed to a traumatic event(s) who experienced clinically meaningful guilt (N = 145). Questionnaires on meaning in life, avoidant coping, and psychological distress were administered, and structural equation modeling was used to test direct effects. Path analysis revealed that greater meaning was associated with lower depression, anxiety, and posttraumatic stress symptomatology, while higher avoidant coping was associated with greater depression, anxiety, posttraumatic stress, and somatization symptomatology. Participants who report more meaning in life and report lower avoidant coping post trauma may experience less psychological distress. If replicated longitudinally, results could suggest cultivating meaning in life and reducing avoidant coping may decrease psychological distress.

- One paper is under review and four are in preparation for submission.

- **Website(s) or other Internet site(s)**
  Nothing to Report
- **Technologies or techniques**
  TrIGR manual published.
- **Inventions, patent applications, and/or licenses**
  Nothing to Report
- **Other Products**
  Nothing to Report

7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

- **What individuals have worked on the project?**

Name: Sonya Norman, PhD
Project Role: Principal Investigator
Researcher Identifier (e.g. ORCID ID): 0000-0002-4751-1882
Nearest person month worked: 26 CM
Contribution to Project: Dr. Norman oversees all aspects of the study including recruitment, enrollment, and data collection.
Funding Source: Trauma Informed Guilt Reduction (TrIGR) Intervention Grant W81XWH-15-1-0330

Name: Brittany C Davis, PhD
Project Role: Co-Investigator
Research Identifier (e.g. ORCID ID): N/A
Nearest person month worked: 11 CM
Contribution to Project: Dr. supervises and trains therapists.
Funding Source: Trauma Informed Guilt Reduction (TrIGR) Intervention Grant W81XWH-15-1-0330

Name: Shahrokh Golshan, PhD
Project Role: Statistician
Researcher Identifier (e.g. ORCID ID): N/A
Nearest person month worked: 8 CM
Contribution to Project: Dr. Golshan prepared databases and prepared the data entry system.
Funding Source: Trauma Informed Guilt Reduction (TrIGR) Intervention Grant W81XWH-15-1-0330

Name: Laura Westendorf, MPH
Project Role: Project Coordinator
Research Identifier (e.g. ORCID ID): N/A
Nearest person month worked: 49 CM
Contribution to Project: Laura Westendorf is responsible for coordinating all aspects of the study, is recruiting and consenting patients, managing day-to-day tasks for the study and is responsible for supporting study staff where needed.
Funding Source: Trauma Informed Guilt Reduction (TrIGR) Intervention Grant W81XWH-15-1-0330

Name: Moira Haller, PhD
Project Role: Co-Investigator
Research Identifier (e.g. ORCID ID): N/A
Nearest person month worked: 8 CM
Contribution to Project: Dr. Haller supervises and trains therapists.
Funding Source: Trauma Informed Guilt Reduction (TrIGR) Intervention Grant W81XWH-15-1-0330

Name: Carolyn Allard, PhD
Project Role: Co-Investigator
Researcher Identifier (e.g. ORCID ID): N/A
Nearest person month worked: 4 CM
Contribution to Project: Dr. Allard ran supervision meetings.
Funding Source: Trauma Informed Guilt Reduction (TrIGR) Intervention Grant W81XWH-15-1-0330

Name: Ariel Lang, PhD
Project Role: Co-Investigator
Researcher Identifier (e.g. ORCID ID): 0000-0002-2468-115X
Nearest person month worked: 4 CM
Contribution to Project: Dr. Lang meets with the assessors weekly and reviews all assessments.
Funding Source: Trauma Informed Guilt Reduction (TrIGR) Intervention Grant W81XWH-15-1-0330

Name: Paula Schnurr, PhD
Project Role: Co-Investigator
Researcher Identifier (e.g. ORCID ID): 0000-0002-6195-716X
Nearest person month worked: 5 CM
Contribution to Project: Dr. Schnurr provided consultation on the clinical trial design and implementation issues.
Funding Source: Trauma Informed Guilt Reduction (TrIGR) Intervention Grant W81XWH-15-1-0330

Name: Kendall Browne, PhD
Project Role: Co-Investigator

Researcher Identifier (e.g. ORCID ID): 0000-0002-5305-2897
Nearest person month worked: 9 CM
Contribution to Project: Dr. Browne rated session recordings for fidelity.
Funding Source: Trauma Informed Guilt Reduction (TrIGR) Intervention Grant W81XWH-15-1-0330

Name: Amy Jak, PhD
Project Role: Co-Investigator
Researcher Identifier (e.g. ORCID ID):
Nearest person month worked: 1 CM
Contribution to Project: Dr. Jak provides consultation on study procedures.
Funding Source: Trauma Informed Guilt Reduction (TrIGR) Intervention Grant W81XWH-15-1-0330

Name: Kimberly Hodge
Project Role: Research Assistant (SIBCR)
Research Identifier (e.g. ORCID ID): N/A
Nearest person month worked: 6 CM
Contribution to Project: Assists the investigators with work on the intervention condition of the study.
Funding Source: Trauma Informed Guilt Reduction (TrIGR) Intervention Grant W81XWH-15-1-0330

Name: Briana Boyd, PhD.
Project Role: Study Therapist
Research Identifier (e.g. ORCID ID): N/A
Nearest person month worked: 4 CM
Contribution to Project: Dr. Boyd is a study therapist and administers the interventions to eligible participants.
Funding Source: Trauma Informed Guilt Reduction (TrIGR) Intervention Grant W81XWH-15-1-0330

Name: Colleen Kennedy, PhD.
Project Role: Study Therapist
Research Identifier (e.g. ORCID ID): N/A
Nearest person month worked: 17 CM
Contribution to Project: Dr. Kennedy is the main study therapist and administers the interventions to eligible participants.
Funding Source: Trauma Informed Guilt Reduction (TrIGR) Intervention Grant W81XWH-15-1-0330

Name: Danielle K Zuest, M.A.
Project Role: Study Assessor
Research Identifier (e.g. ORCID ID): N/A
Nearest person month worked: 6 CM
Contribution to Project: Ms. Zuest is the main study assessor and conducts all intake and follow-up assessments.
Funding Source: Trauma Informed Guilt Reduction (TrIGR) Intervention Grant W81XWH-15-1-0330

Name: Robert Lyons
Project Role: Graduate Student

Research Identifier (e.g. ORCID ID): N/A
Nearest person month worked: 7 CM
Contribution to Project: Robert Lyons assisted with study assessments and conducted intake and follow-up assessment interviews.
Funding Source: Trauma Informed Guilt Reduction (TrIGR) Intervention Grant W81XWH-15-1-0330

Name: Mary Linges, B.A.
Project Role: Study Assessor
Research Identifier (e.g. ORCID ID): N/A
Nearest person month worked: 43 CM
Contribution to Project: Mary Linges assists with screening and consenting participants and is the main study assessor and conducts all intake and follow-up assessments.
Funding Source: Trauma Informed Guilt Reduction (TrIGR) Intervention Grant W81XWH-15-1-0330

Name: Jennifer Wachen, PhD
Project Role: Site PI
Researcher Identifier (e.g., ORCID ID): N/A
Nearest person month worked: 5 CM
Contribution to Project: Dr. Wachen oversees all aspects of the Boston site including recruitment, enrollment, and data collection.
Funding Source: Trauma Informed Guilt Reduction (TrIGR) Intervention Grant W81XWH-15-1-0330

Name: Tara Galovski, PhD
Project Role: Site Co-I
Researcher Identifier (e.g., ORCID ID): N/A
Nearest person month worked: 2 CM
Contribution to Project: Dr. Galovski assists with all aspects of the Boston site study.
Funding Source: Trauma Informed Guilt Reduction (TrIGR) Intervention Grant W81XWH-15-1-0330

Name: Kaitlyn Panza, PhD
Project Role: Study Therapist
Researcher Identifier (e.g., ORCID ID): N/A
Nearest person month worked: 5 CM
Contribution to Project: Dr. Panza will treat study participants with the study condition, TrIGR, or the control condition, SCT. She is also responsible for helping coordinate some aspects of the study, managing day-to-day tasks for the study and supports study staff where needed.
Funding Source: Office of Academic Affiliations Interprofessional Advanced Fellowship in Addiction Treatment

Name: Rachel Zelkowitz, PhD
Project Role: Study Therapist
Researcher Identifier (e.g., ORCID ID): N/A
Nearest person month worked: 7 CM
Contribution to Project: Dr. Zelkowitz will treat study participants with the study condition, TrIGR, or the control condition, SCT.

Funding Source: Women's Health Sciences Division Women's Health Fellowship

Name: Joseph Carpenter, PhD
Project Role: Study Therapist
Researcher Identifier (e.g., ORCID ID): N/A
Nearest person month worked: 1 CM
Contribution to Project: Dr. Carpenter will treat study participants with the study condition, TrIGR, or the control condition, SCT
Funding Source: Women's Health Sciences Division Women's Health Fellowship

Name: Lauren McSweeney, PhD
Project Role: Study Therapist
Researcher Identifier (e.g., ORCID ID): N/A
Nearest person month worked: 1 CM
Contribution to Project: Dr. McSweeney will treat study participants with the study condition, TrIGR, or the control condition, SCT
Funding Source: Women's Health Sciences Division

Name: Allison Cole
Project Role: Project Coordinator
Researcher Identifier (e.g., ORCID ID): N/A
Nearest person month worked: 8 CM
Contribution to Project: Allison Cole assists with coordinating study activities such as preparing study materials, study recruitment, enrollment, etc.
Funding Source: Trauma Informed Guilt Reduction (TrIGR) Intervention Grant W81XWH-15-1-0330

- **Has there been a change in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period?**
  Nothing to Report

- **What other organizations were involved as partners?**
  Organization Name: Providence VA Medical Center
  Location of Organization: Providence, RI
  Partner's contribution to the project:
  Financial Support: N/A
  In-Kind Support: N/A
  Facilities: N/A
  Collaboration: Partnering PI
  Personnel exchanges: N/A
  Other: N/A

8. Special Reporting Requirements

A. Collaborative Awards

- Providence VA Medical Center will submit a separate report.

B. Quad Charts

- Attachment 1

9. Appendices

* Copies of manuscripts, presentations and abstracts included.

Trauma Informed Guilt Reduction (TrIGR) Intervention

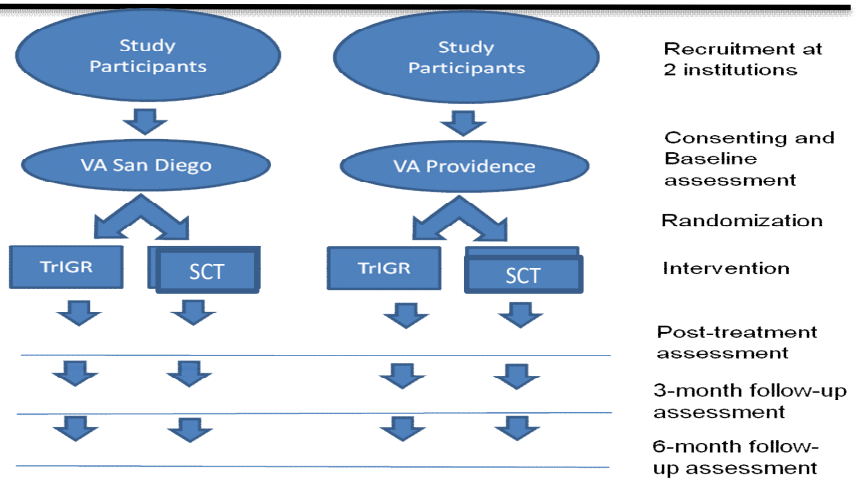
PI: Sonya Norman, PhD **Org:** Veterans Medical Research Foundation **Award Amount:** $2,698,865

Study/Product Aim(s)

- Conduct a randomized clinical trial to determine if a six-session treatment, Trauma Informed Guilt Reduction (TrIGR), relative to supportive care therapy (SCT) at post-treatment, 3- and 6-month follow up:
  - Reduces guilt (primary aim)
- As secondary and exploratory aims, assess if TrIGR:
  - reduces distress and shame, improves quality of life
  - reduces disorder specific symptoms (PTSD, MDD)
  - reduces suicidal ideation and alcohol/substance use

Approach

We propose a stage 2 randomized clinical trial across 2 VA Medical Centers (San Diego, Providence). 150 male and female Veterans of OEF/OIF reporting guilt related to a combat event will be randomized to TrIGR or SCT and followed through treatment, 3- and 6-month follow-up. Hypotheses are that TrIGR, relative to SCT, will reduce guilt, distress, shame, disorder specific symptoms, and SI and alcohol/substance use and improve Quality of Life.



Study PI recently completed two open-label trials to evaluate the effectiveness of TrIGR. Participants showed significant reductions in guilt and distress over the course of treatment. Satisfaction with the intervention was extremely high.

Timeline and Cost

Activities	FY1	FY2	FY3	FY4	FY5	FY6
Finalize procedures and approvals, hire and train staff						
Recruit, enroll, collect data						
Data analysis, report preparation						
Estimated Total Budget ($2.515.565)*	527k	492k	503k	468k	525k	183k

Updated: 12/28/2023

Goals/Milestones

Study Year 1 Goal – Prepare regulatory documents and research protocol
- ☑ Sign contracts, prepare protocol, and obtain approval from VA sites and USAMRMC
- ☑ Prepare, program, purchase and test all forms for study documentation
- ☑ Recruit and train research staff

Study Year 2 Goals – Participant recruitment, randomization, intervention
- ☑ Participant recruitment, randomization, pre-assessment and TrIGR/SCT
- ☑ Post-intervention, 3-month and 6-month post-treatment follow-up assessment
- ☑ Validate audio recordings of TrIGR and SCT sessions

Study Year 3 Goals – Complete enrollment and validation of TrIGR/SCT sessions
- ☑ Complete recruitment, randomization, pre-assessment, and TrIGR/SCT
- ☑ Continue post-intervention and follow up assessments at 3- and 6-months

Study Year 4 Goals – Analyze data and prepare manuscripts
- ☑ Complete follow up assessments and data entry
- ☑ Ensure data integrity
- ☑ Data analysis and manuscript preparation

Study Year 6 Goals – Conduct COVID-19 extension
- ☑ Prepare regulatory documents and research protocol
- ☑ Participant recruitment, randomization, intervention
- ☑ Complete enrollment and validation of TrIGR/SCT sessions
- ☑ Analyze data and prepare manuscripts

Projected Expenditure: $2,698,865.00
Actual Expenditure: $2,642,703.05

Trauma Informed Guilt Reduction (TrIGR) Intervention
Pandemic Extension
Boston Site

Reporting Period – Y8Q4
(7/1/23-9/29/23)

Cumulative
(10/1/20 – 9/29/23)

Recruited/Screened

recruited/planned target (n=0/NA)

screened/planned target (n=0/NA)

recruited/planned target (n=232/NA)
- Unable to screen recruit: (n=153)

screened/planned target (n=79/NA)
- Excluded: (n=44)
  - Not Eligible (n=37)
  - Declined (n=7)

Enrolled (consented)

enrolled/planned target (n=0/0)
- Ineligible after baseline (n=0)
- Declined (n=0)

enrolled/planned target (n=35/24)
- Excluded: (n=11)
  - Not eligible after baseline (n=5)
  - Declined (n=6)

Randomized

randomized/planned target (n =0/NA)

TrIGR (n=0)	SCT (n=0)
Completed Tx (n=0)	Completed Tx (n=0)
Withdrew from Tx (n=0)	Withdrew from Tx (n=0)
In Progress (n=0)	In Progress (n=0)

randomized/planned target (n =24/24)

TrIGR (n=14)	SCT (n=10)
Completed Tx (n=10)	Completed Tx (n=8)
Withdrew from Tx (n=4)	Withdrew from Tx (n=2)
In Progress (n=0)	In Progress (n=0)

Follow-up

who completed Post Tx Follow up/Total # of participants due (n=0/0)

who completed 1 month Follow up/Total # of participants due (n=0/0)

who completed Post Tx Follow up/Total # of participants due (n=17/24)

who completed 1 month Follow up/Total # of participants due (n=16/24)

Trauma Informed Guilt Reduction (TrIGR) Intervention Pandemic Extension
San Diego Site: 10/1/20-09/29/23

Recruited/Screened

recruited/planned target (n=244/NA)
- Unable to screen recruit: (n=134)

screened/planned target (n=110/NA)
- Excluded: (n=71)
  - Not Eligible (n=49)
  - Declined (n=22)

Enrolled (consented)

enrolled/planned target (n=39/24)
- Excluded: (n=14)
  - Not eligible after baseline (n=12)
  - Declined (n=2)

Randomized

randomized/planned target (n =25/24)

TrIGR (n=13)	SCT (n=12)
Completed Tx (n=11)	Completed Tx (n=12)
Withdrew from Tx (n=2)	Withdrew from Tx (n=0)
In Progress (n=0)	In Progress (n=0)

Follow-up

who completed Post Tx Follow up/Total # of participants due (n=19/25)

who completed 1 month Follow up/Total # of participants due (n=19/25)

BEHAVIORAL DISENGAGEMENT MEDIATES THE ASSOCIATION BETWEEN TRAUMA-RELATED GUILT AND MENTAL HEALTH PROBLEMS IN A SAMPLE OF OEF/OIF/OND VETERANS

PRESENTER: CHRISTY CAPONE, PHD

ASSISTANT PROFESSOR OF PSYCHIATRY AND HUMAN BEHAVIOR

BROWN UNIVERSITY

PROVIDENCE VA MEDICAL CENTER

AUTHORS: CHRISTY CAPONE, KAITLYN E. PANZA, MATTHEW T. LUCIANO, ARIEL J. LANG, & SONYA B. NORMAN

BACKGROUND

- Trauma-related guilt has cognitive and affective components
- It is a common and distressing emotion following a traumatic event, and linked with several mental health problems (e.g., PTSD, depression, substance use)
- Higher rates of suicidality among those with guilt
- Guilt cognitions have been linked to aggressive behavior and violence
- Predicts poorer outcomes in empirically supported therapies (e.g., PE, CPT)
- Recent study concluded that guilt (related to justification) is a common residual symptom after PTSD tx completion (Larsen et al., 2018)

BACKGROUND

- Little is known about the mechanisms underlying these associations
- Guilt is so aversive that many individuals engage in avoidant forms of coping, including behavioral disengagement (Held, Owens & Anderson, 2015)
- Behavioral disengagement is conceptualized as the giving up on trying to cope with a stressor and/or pulling away from available resources (Riolli & Savicki, 2010)

THE PRESENT STUDY

We examined cross-sectional associations between trauma-related guilt, behavioral disengagement, and four outcomes:

- PTSD symptom severity
- Depressive symptoms
- SUD diagnosis
- Suicide intensity

We also examined whether behavioral disengagement mediated these relationships in a cross-sectional analysis

METHOD

- The sample consisted of 184 veterans who enrolled in a RCT to treat trauma-related guilt stemming from a post 9/11 deployment
  - Baseline data was utilized for the present analyses
- The study was conducted at VA Medical Centers in Providence, RI and San Diego, CA
- Veterans in the sample were reflective of the complex and severe clinical presentation observed in many VA settings

MEASURES AND ANALYSES

- Measures
  - Behavioral disengagement -- Brief COPE; Carver, 1997
  - Trauma-related guilt -- Trauma-Related Guilt Inventory (TRGI); Kubany et al., 1996
  - PTSD symptom severity -- Clinician Administered PTSD Scale (CAPS-5); Weathers et al., 2018
  - Depressive symptoms -- Patient Health Questionnaire (PHQ-9); Kroenke et al., 2001
  - SUD diagnosis -- Structured Clinical Interview for DSM 5 (SCID-5); First et al., 2002
  - Suicide intensity -- Columbia Suicide Severity Rating Scale (C-SSRS); Posner et al., 2008
- Analytic Plan
  - We conducted mediation analyses with guilt as the independent variable, behavioral disengagement as the mediator, and three mental health variables as the dependent variables (in three separate models).

RESULTS

Table 1. Demographics	
	M (SD) or %
Age	39.14 (SD=8.44)
Gender (Male)	94%
Ethnicity	
Hispanic/Latino	25.3%
Non-Hispanic	63.8%
Declined to Answer	10.9%
Race	
White/Caucasian	69.5%
Black/African American	11.5%
Asian	10.3%
Other Identified Race	9.7%

Table 1. Demographics (Continued)	
	M (SD) or %
Number of Deployments	2.01 (SD=1.20)
Branch	
Army	36.7%
Air Force	6.2%
Marines	27.1%
National Guard	5.1%
Navy	24.9%
CAPS-5	37.33 (SD=10.01)
PHQ-9	14.51 (SD=6.39)
C-SSRS	6.37 (SD=7.00)
PTSD Dx	84%
Substance Use Dx	44%

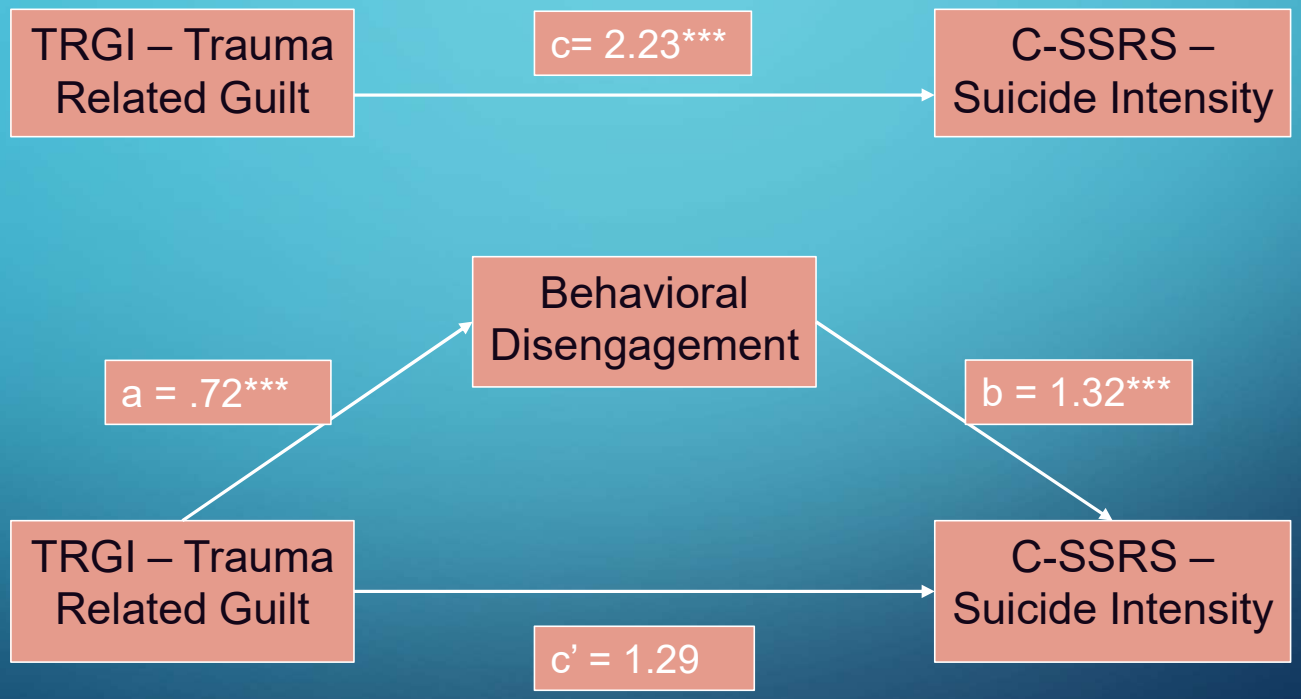
RESULTS

Table 2. Correlations

	1	2	3	4	5	6
1. Trauma-Related Guilt (TRGI)	--					
2. PTSD Severity (CAPS-5)	.45***	--				
3. Depression (PHQ-9)	.31***	.62***	--			
4. Suicide Risk Intensity (C-SSRS)	.23***	.35***	.44***	--		
5. Substance Use Disorder (SCID)	.04	.01	.09	.16*	--	
6. Behavioral Disengagement (B-COPE)	.31***	.33***	.49***	.34***	.21**	--

Note: *p<.05; **p<.01; **p<.001; TRGI = Trauma-Related Guilt Inventory; CAPS-5 = Clinician Administered PTSD Scale for DSM-5; PHQ-9 = Patient Health Questionnaire; C-SSRS = Columbia Suicide Severity Rating Scale; SCID = Structured Clinical Interview for DSM-5; B-COPE = Brief Coping Orientation to Problems Experienced Inventory

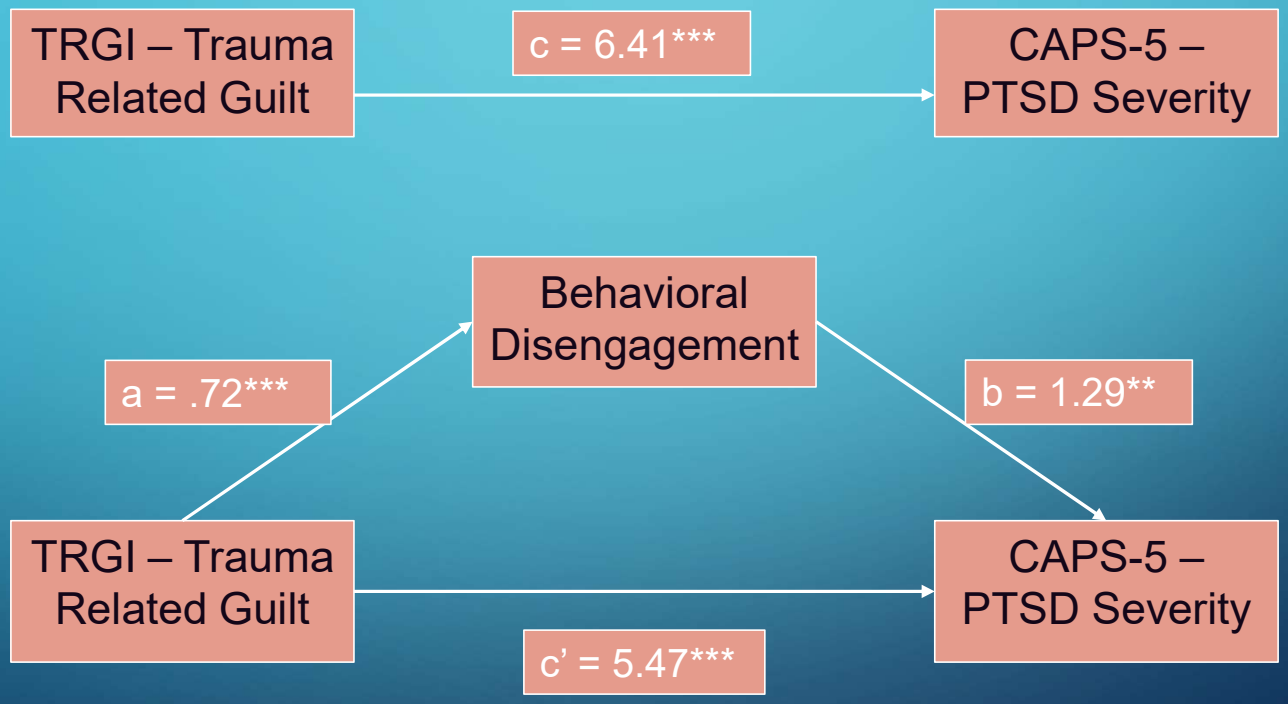
RESULTS



Indirect Effect= .94, 95% CI: .36, 1.69

Note: ***p≤.001

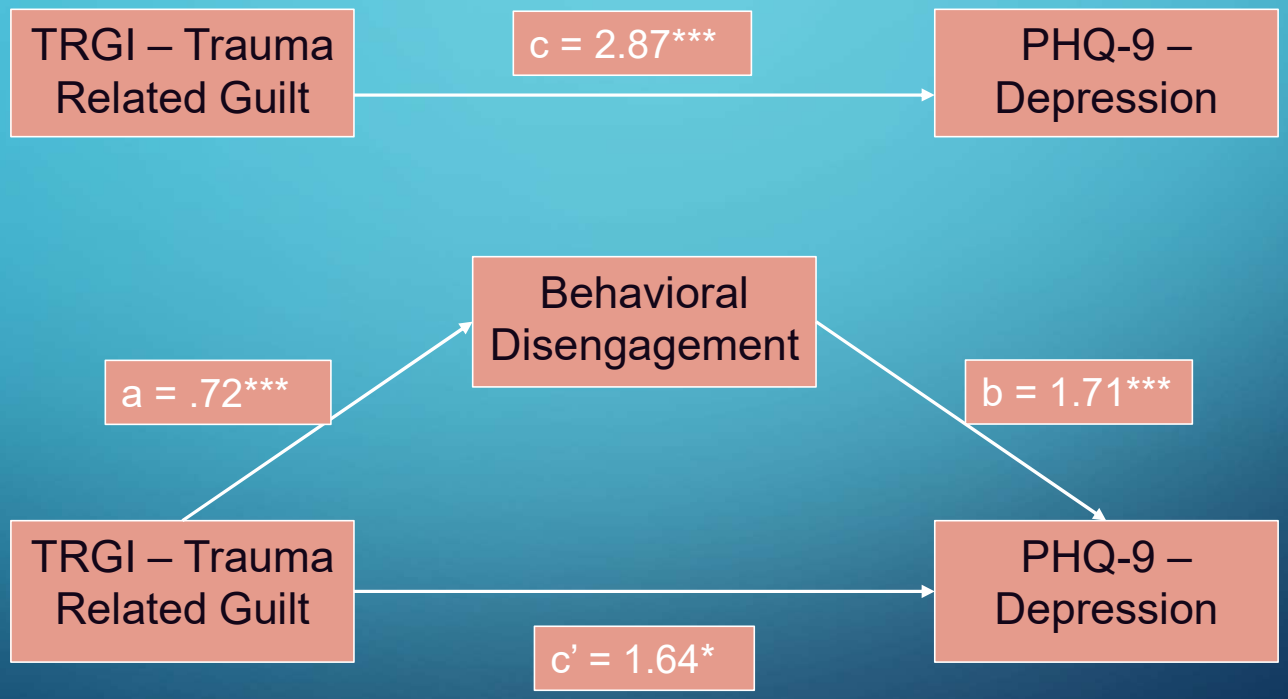
RESULTS



Note: **p≤.01
***p≤.001

Indirect Effect= .93, 95% CI: .32, 1.63

RESULTS



Note: *p≤.05
***p≤.001

Indirect Effect= 1.24, 95% CI: .62, 1.93

SUMMARY OF FINDINGS

- Trauma-related guilt was significantly associated with three of the outcomes (PTSD, depression, suicidality) as well as the putative mediator, behavioral disengagement
- Contrary to our hypothesis, SUD diagnosis was not related to trauma-related guilt
- Results of mediation analyses showed that behavioral disengagement mediated the relationship between guilt and suicide intensity, and partially mediated the relationships with PTSD and depressive symptoms

FUTURE DIRECTIONS AND CONCLUSIONS

- Consistent with previous research, trauma-related guilt was related to common posttraumatic mental health problems
- Our findings, though cross-sectional, may help to elucidate how trauma-related guilt may lead to mental health problems
- May also be that mental health issues (e.g., avoidance, mistrust, hopelessness) lead veterans to turn away from help, which in turn causes them to feel guilty
  - Longitudinal research is needed to clarify directionality
- These results highlight a potentially important treatment target and may be particularly relevant to suicide prevention efforts

FUTURE DIRECTIONS AND CONCLUSIONS

- Future research should better understand WHY trauma-related guilt causes veterans to turn away from resources
  - Perhaps because they don't feel like they deserve help? For fear of stigma/judgment?
- Because turning away from helpful resources is associated with strong guilt reactions and mental health issues, it may be important to utilize more opportunistic interventions that can be delivered in other settings (e.g., primary care)
- With 57-85% of the variance in the total effects explained by behavioral disengagement, additional explanatory variables connecting guilt and mental health outcomes should be evaluated

ACKNOWLEDGEMENTS

- This research was funded by the Department of Defense W81XWH-15-1-0330 and W81XWH-15-1-0331 (PIs: Norman and Capone)
- Thank you to the incredible teams at both study sites and to the veterans who participated in this research

- Contact: Christy_Capone@brown.edu

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Manuscript_c81e74b61724d3073d3b7aa7ed875117

Trauma Informed Guilt Reduction (TrIGR) therapy for guilt, shame, and moral injury resulting from trauma: Rationale, design, and methodology of a two-site randomized controlled trial

Christy Capone, PhD [a,b*]
[a] Providence VA Medical Center, 830 Chalkstone Ave, Providence, Rhode Island 02908 USA
[b] Department of Psychiatry and Human Behavior, Center for Alcohol and Addiction Studies, Warren Alpert School of Medicine, Brown University, Providence, Rhode Island, USA

Sonya B. Norman, PhD[c,d,e*]
[c]National Center for PTSD, Executive Division, VA Medical Center, 215 North Main Street, White River Junction, VT 05009 USA
[d]VA Center of Excellence for Stress and Mental Health; Veterans Affairs San Diego Healthcare System, Research Service (MC116B), 3350 La Jolla Village Dr, San Diego CA 92161 USA
[e]University of California, San Diego, Department of Psychiatry, 9500 Gilman Drive, San Diego, CA 92093, USA

Moira Haller, PhD[e,f]
[e]University of California, San Diego, School of Medicine, Department of Psychiatry, 9500 Gilman Drive, San Diego, CA 92093, USA
[f]Veterans Affairs San Diego Healthcare System, Research Service (MC116B), 3350 La Jolla Village Dr, San Diego CA 92161 USA

Brittany Davis, PhD[g,h]
[g]James A. Haley Veterans Hospital, 13000 Bruce B. Downs Blvd., Tampa, FL 33612 USA
[h]Department of Psychiatry and Behavioral Neurosciences, University of South Florida, 3515 E. Fletcher Ave, Tampa FL 33613 USA

M. Tracie Shea, PhD[a,i]
[a]Providence VA Medical Center, 830 Chalkstone Ave, Providence, Rhode Island 02908 USA
[i]Department of Psychiatry and Human Behavior, Warren Alpert School of Medicine, Brown University, Providence, Rhode Island, USA

Kendall Browne, PhD[j,k,l]
[j]Center of Excellence in Substance Addiction Treatment and Education, Corporal Michael J. Crescenz VA Medical Center; 21 S. University Ave, Philadelphia, PA 19104 USA
[k]Center of Excellence in Substance Addiction Treatment and Education, VA Puget Sound Health Care System, 1660 S. Columbian Way, MC: S-116-ATC, Seattle, WA 98136 USA
[l]Department of Psychiatry & Behavioral Sciences, University of Washington, 1959 NE Pacific St, Seattle, WA 98195 USA

Ariel J. Lang, PhD, MPH[e,f]
[e]University of California, San Diego, School of Medicine, Department of Psychiatry, 9500 Gilman Drive, San Diego, CA 92093, USA
[f]Veterans Affairs San Diego Healthcare System, Research Service (MC116B), 3350 La Jolla Village Dr, San Diego CA 92161 USA

Paula P. Schnurr, PhD[c,m]
[c]National Center for PTSD, Executive Division, VA Medical Center, 215 North Main Street, White River Junction, VT 05009 USA
[m]Department of Psychiatry, Geisel School of Medicine at Dartmouth, Dartmouth-Hitchcock Medical Center, One Medical Center Drive, Lebanon, NH 03756 USA

Shahrokh Golshan, PhD[e,f]
[e]University of California, San Diego, School of Medicine, Department of Psychiatry, 9500 Gilman Drive, San Diego, CA 92093, USA
[f]Veterans Affairs San Diego Healthcare System, Research Service (MC116B), 3350 La Jolla Village Dr, San Diego CA 92161 USA

Niloofar Afari, PhD[d,e]
[d]VA Center of Excellence for Stress and Mental Health; Veterans Affairs San Diego Healthcare System, Research Service (MC116B), 3350 La Jolla Village Dr, San Diego CA 92161 USA
[e]University of California, San Diego, Department of Psychiatry, 9500 Gilman Drive, San Diego, CA 92093, USA

James Pittman, PhD, LCSW[d,e]
[d]VA Center of Excellence for Stress and Mental Health; Veterans Affairs San Diego Healthcare System, Research Service (MC116B), 3350 La Jolla Village Dr, San Diego CA 92161 USA
[e]University of California, San Diego, Department of Psychiatry, 9500 Gilman Drive, San Diego, CA 92093, USA

Carolyn B. Allard, PhD, ABPP[f,n]
[f]Veterans Affairs San Diego Healthcare System, Research Service (MC116B), 3350 La Jolla Village Dr, San Diego CA 92161 USA
[n]California School of Professional Psychology at Alliant International University, 10455 Pomerado Rd, San Diego CA 92131 USA

Laura Westendorf, MPH[f]
[f]Veterans Affairs San Diego Healthcare System, Research Service (MC116B), 3350 La Jolla Village Dr, San Diego CA 92161 USA

Author Notes

Correspondence concerning this article should be addressed to Dr. Christy Capone, Mental Health and Behavioral Sciences Service (MHBSS), Department of Veterans Affairs Medical Center, 830 Chalkstone Ave (116B), Providence RI 02908.

Email: christy_capone@brown.edu.

*Dr. Christy Capone and Dr. Sonya Norman are co-first authors of this article.

Abstract

Guilt, shame, and moral injury (MI) are common reactions following exposure to traumatic events and are associated with greater severity of several mental health problems, including posttraumatic stress disorder (PTSD), depression, increased risk of suicidal ideation and poorer psychosocial functioning. Trauma-Informed Guilt Reduction (TrIGR) is a transdiagnostic psychotherapy to address guilt, shame, and MI stemming from traumatic events. The primary goals of TrIGR are to help patients accurately appraise their trauma and to re-engage with their values in order to lead a more meaningful life. This paper presents the rationale, design, and methodology of a two-site randomized controlled trial (RCT) examining the efficacy of TrIGR compared to Supportive Care Therapy (SCT) in a sample of U.S. veterans (N = 145) who endorse guilt related to a traumatic event that occurred during military deployment. This study is the first RCT powered to investigate TrIGR's efficacy on reducing posttraumatic guilt, as measured by the Trauma Related Guilt Inventory (TRGI), in comparison to an active control condition. In addition, the study will examine a range of secondary and exploratory outcomes including shame, quality of life, suicidal ideation, substance use, and PTSD and depression symptoms. Findings from this efficacy study will be essential in informing future efficacy and effectiveness trials.

Keywords: trauma, guilt, shame, psychotherapy, veterans

1. Introduction

Guilt, shame, and moral injury (MI) are common following traumatic events (e.g., Friedman et al., 2011). Guilt arises when trauma survivors blame their actions or inactions for all or part of the trauma (i.e., "If I had done x instead of y, my fellow soldier would be alive") (Kubany & Watson, 2003). Shame is when trauma survivors judge not just their actions but their entire self as bad or damaged because of their role in the trauma (i.e., "I am a bad person" or "I'm damaged goods") (Tangney, Stuewig, & Mashek, 2007). MI refers to the painful emotional aftermath of experiences where someone acted or witnessed acts that went against deeply held morals or values and is characterized by strong reactions of guilt and shame (Litz et al., 2009; Griffin et al., 2019). In addition to causing emotional distress, posttraumatic guilt, shame, and MI are risk factors for greater severity of several mental health problems, including posttraumatic stress disorder (PTSD), depression, suicidal ideation, and poorer psychosocial functioning (Browne et al., 2015; Bryan et al., 2018; Griffin et al., 2019; Koenig et al., 2018; Marx et al., 2010; Norman et al., 2018).

In the latest Diagnostic and Statistical Manual (DSM-5; American Psychiatric Association, 2013), guilt and shame were included in the diagnostic criteria for PTSD for the first time and, in recognition of the many ways PTSD may present, the diagnosis is no longer considered an anxiety disorder. These changes facilitate the examination of different PTSD phenotypes, such as one characterized by guilt and shame, and raise the possibility that different phenotypes may respond better to specific treatments. Trauma-related guilt is one of the symptoms most likely to persist after successful PTSD treatment (Larsen, Fleming & Resick, 2019; Kubany et al., 2004), suggesting intervention targeting posttraumatic guilt may be warranted. Also critical is that not all who experience trauma-related guilt, shame, or MI have

PTSD. Posttraumatic distress presents in many forms, including depression and suicidality, arguing for transdiagnostic interventions that reach across disorders. However, to date, most treatments for posttraumatic psychological health have been primarily disorder specific, most commonly PTSD (Lang et al., 2012).

For these reasons, we developed Trauma-Informed Guilt Reduction (TrIGR), a brief transdiagnostic psychotherapy to address guilt, shame, and MI from traumatic events (Norman et al., 2019; Norman, Wilkins, Myers & Allard, 2014). Because trauma survivors often overestimate how much control they had during a traumatic event, TrIGR helps survivors consider what they truly knew and were capable of doing at the time (Kubany et al., 2004). TrIGR helps patients identify and re-engage with values (particularly those that may have been violated during the trauma). The goal is for patients to understand the full context of their traumatic experience and develop positive ways to express values rather than through suffering. This paper presents the rationale, design, and methodology of an RCT to examine TrIGR compared to Supportive Care Therapy (SCT) in veterans who endorse guilt from a traumatic event during deployment.

1.1 Research objectives and hypotheses

The primary objective of this study is to evaluate the efficacy of TrIGR in reducing trauma-related guilt in a sample of veterans who served in military operations following the 9/11 terrorist attacks. Our primary hypothesis is that veterans receiving TrIGR, compared to those receiving SCT, will report significantly greater reductions in guilt severity at the end of treatment and at follow-up. A secondary aim of this study is to examine TrIGR's effects on shame and quality of life. Accordingly, our secondary hypothesis is that veterans in the TrIGR group will exhibit greater reductions on measures of shame as compared to the SCT group, and greater

improvement in their quality of life at the end of treatment and at follow-up. By including veterans with a variety of post-deployment mental health problems, we are able to conduct exploratory analyses to examine TrIGR's effects on PTSD and depressive symptom severity, suicidal ideation, and alcohol/substance use. At the time the study was initiated, we were not able to identify a validated measure of change in MI through treatment. However, we were able to measure MI experiences related to deployment using a validated assessment and will therefore be able to evaluate how such experiences relate to posttraumatic guilt and shame.

2. Materials and methods

2.1 Research design

This is a prospective, randomized, controlled trial designed to assess the efficacy of TrIGR as compared to an active control (SCT) for the treatment of guilt related to a traumatic event that occurred during deployment among male and female veterans. Both treatment conditions involve individual therapy delivered in weekly sessions. After providing written informed consent, all eligible participants complete an in-person baseline assessment, receive 6 sessions of TrIGR or SCT, with weekly measures related to the primary and secondary aims, and complete follow-up assessments immediately post-treatment, and 3- and 6-months later.

2.2 Participants

A total of 145 participants will be enrolled across two study sites –VA Medical Centers in San Diego, CA, and Providence, RI. Participants are randomized by the study statistician at the individual level using masked allocation, stratified by site and gender. Inclusion criteria are as follows: (1) having been deployed during Operation Enduring Freedom (OEF), Operation Iraqi Freedom (OIF), or Operation New Dawn (OND); (2) endorsing trauma-related guilt as indicated by a score of 2 or higher (" true" to "extremely true") on at least one item measuring

guilt severity or scoring 2 or higher ("true" to "extremely true") on at least one guilt cognition (hindsight bias/responsibility, wrongdoing, or lack of justification) on the Trauma Related Guilt Inventory (TRGI; Kubany et al., 1996); (3) English literacy; (4) intention to stay in the local area during study participation; and (5) if meeting diagnostic criteria for mild or moderate alcohol or substance use disorder, willingness to set goals to reduce use.

Exclusion criteria are kept to a minimum in order to maximize generalizability of the findings and included only factors that would impede study participation: (1) moderate or severe cognitive impairment on the Montreal Cognitive Assessment (MoCA; Nasreddine et al., 2005); (2) acute risk of suicide; (3) severe substance use disorder in the past two months; (4) current psychosis or mania; (5) residence greater than 50 miles from the nearest study site; (6) life threatening or unstable medical illness, and (7) currently receiving trauma-focused treatment (those currently in treatment could qualify following completion).

Veterans with mild to moderate alcohol and substance use disorders, suicidal ideation without acute risk of suicide, and anxiety and depressive disorders are not excluded due to the high co-occurrence with posttraumatic guilt. Those with mild cognitive impairment are not excluded given research showing that individuals with mild to moderate traumatic brain injury (TBI) can benefit from cognitive behavioral treatments (Chard et al., 2011).

We allow participants to continue to engage in treatment as usual (TAU), other than trauma-focused treatments, as we do not expect TrIGR to be a stand-alone treatment for disorder specific conditions. Participants may continue receiving substance use and mental health treatment as needed, including pharmacotherapy. However, we exclude veterans who are currently receiving other trauma focused treatment such as Prolonged Exposure (PE) or Cognitive Processing Therapy (CPT) as these PTSD treatments may also address guilt and

shame. All treatment received during the treatment and follow-up phases of the study is carefully tracked during the post-treatment assessment, including types of psychotherapy and medication. If counts of specific types of treatments received differ significantly across sites or conditions, we will include that variable as a fixed effect in subsequent data analyses.

2.3 Study procedures

The study procedures were reviewed and approved by the Institutional Review Boards (IRBs) at VA San Diego Healthcare System, Providence VA Medical Center, Brown University, and the Human Research Protections Office (HRPO) at the Department of Defense.

Recruitment and Screening. Study participants are recruited through referrals from clinicians at both study sites, and through self-referral in response to advertisements posted in public areas throughout the medical centers. Project coordinators contact interested veterans and conducted a brief phone screening to assess for broad eligibility (e.g., service era). If an interested veteran meets preliminary eligibility criteria, he or she is invited to attend an in-person visit during which written informed consent is obtained and the baseline assessment is completed. Data collection for this study began in June 2016 and is expected to be completed in December 2020.

Assessment Procedures. Semi-structured interviews are conducted by trained assessors (bachelor- masters- or doctoral-level) who are blind to the treatment condition of the participants. Assessor training involves completing the National Center for PTSD online CAPS-5 training and additional training with a study co-investigator, scoring standardized mock assessments to high inter-rater reliability, shadowing other assessors, and completing a minimum of 3-4 assessments in the presence of an experienced assessor to allow for feedback. Training for the Timeline Follow-back for substance use and the Columbia-Suicide Severity Rating Scale for suicidal

ideation and behaviors include observation of an experienced assessor followed by role playing and then administering the assessments under live supervision until fidelity is achieved.

Self-report measures are completed via the VA eScreening program, a secure electronic platform for collection of self-report data developed at the VA Center of Excellence for Stress and Mental Health (Pittman et al, 2017). eScreening provides customized and automated data collection by presenting assessment items for veterans to answer on a mobile tablet (iPad). eScreening has built-in protections against missing data, as well as algorithms for automated scoring of common questionnaires. For this study, sociodemographic questions and the self-reported primary, secondary, and exploratory outcome measures were programmed into eScreening. Participants at both sites use an iPad connected to the VA secure WiFi to complete the relevant measures at each assessment time point. The data are collected using an individual study ID and stored on a VA secure server and accessible by the study team. Overall, the time spent collecting clinical interview and self-report data at baseline is approximately three hours; two hours for follow-up assessments.

2.4 Measures

Primary Outcome. The primary outcome measure for this study is the TRGI, a 32-item, validated, self-report questionnaire assessing traumatic guilt related to an index event. The TRGI has three scales – Global Guilt, Distress, and Guilt Cognitions; the Guilt Cognitions scale has three subscales (Hindsight Bias/Responsibility, Lack of Justification, and Wrongdoing). Change in global Guilt (which includes items assessing frequency and severity of guilt with scores ranging from 0 to 4) will be the primary outcome of interest. We will also examine clinically meaningful change using previously established criteria of reduction from above 1.75 to 1.0 or less (Nishith, Nixon, & Resick, 2005). Participants are instructed to reference the same event at

each timepoint when completing the TRGI. Internal consistency is high for the TRGI (guilt severity = .90, distress = .86, guilt cognitions = .86; Kubany et al., 1996).

Secondary Outcomes. The Internalized Shame Scale (ISS; Cook et al., 2001) is a 30-item self-report measure assessing shame proneness scored on a 5-point Likert scale. The ISS yields sum scores for two subscales, self-esteem and internalized shame, and has been well-validated with research and clinical populations. The Trauma Related Shame Inventory (TRSI; Øktedalen, Hagtvet, Hoffart, Langkaast, & Smucker, 2014) is a 24-item self-report measure assessing trauma-related shame on a 4-point Likert scale with internal and external shame subscales. The World Health Organization Quality of Life (WHO-QOL-BREF; WHOQOL Group, 1998) is a 26-item measure of quality of life across four domains: physical, psychological, social relationships, and environment. The WHO-QOL-BREF has excellent internal validity and test-retest reliability.

Exploratory Outcomes. The Clinician-Administered PTSD Scale for DSM-5 (CAPS-5; Weathers et al., 2018) is a semi-structured interview used to assess PTSD diagnostic criteria and severity. The CAPS-5 assesses each of the 20 items from the DSM-5 criteria B, C, D, and E and has demonstrated high levels of internal consistency, good interrater reliability, and excellent convergent validity. The CAPS-5 can be administered in about 60 minutes, and it has the advantages of categorical (diagnostic) or continuous scoring of PTSD. The CAPS-5 is administered at baseline and at each of the follow-ups post-treatment.

The PTSD Checklist-5 (PCL-5; Weathers et al., 2013) is a self-report instrument that assesses PTSD symptom severity. It consists of 20 items, scored on a 5-point scale (0 = not at all to 5 = extremely), that correspond to the DSM-5 symptoms of PTSD. Research demonstrates sound psychometric properties of the PCL-5 for use with military veterans (Bovin et al., 2016).

The Patient Health Questionnaire (PHQ-9; Kroenke & Spitzer, 2002) is a self-report scale assessing common symptoms of depression. The PHQ-9 is among the most widely used self-report depression measure in clinical populations and has demonstrated strong diagnostic validity and sensitivity (Spitzer et al., 1999).

The Timeline Follow-back (TLFB; Sobell & Sobell, 1992) is utilized at all assessment points to assess alcohol and other substance use during the 90 days preceding each interview. The Quantity-Frequency Index (Q-F; Room, 1990) will be calculated for alcohol use; drug use indices will be similarly derived for opioids, cannabis, and other substances. The TLFB is used at each follow-up to establish percent days heavy drinking (PDHD), percent days abstinent (PDA), and current alcohol/drug use pattern. The TLFB is considered a gold standard interview for gathering retrospective self-report data on alcohol use and its reliability regarding other substance use is well established (Robinson et al., 2014).

The Columbia-Suicide Severity Rating Scale (C-SSRS; Posner et al., 2008) is a clinician-administered interview designed to track suicidality during a treatment trial and covers the wide spectrum of suicidality including ideation and intent. The C-SSRS has demonstrated sound psychometrics with respect to validity as well as sensitivity and specificity for suicidal behavior classification (Posner et al., 2011). For the present study, the C-SSRS assesses suicidality over the past 3 months at baseline, and since the previous assessment at all follow-ups.

To assess MI experiences, participants complete the Moral Injury Events Scale (MIES; Nash et al., 2013) at baseline. The MIES asks whether participants endorse any of nine potentially morally injurious events or beliefs that occur in wartime. Participants respond on a 6-point Likert scale (strongly agree to strongly disagree). The scale shows strong internal, discriminant, and concurrent validity and strong test re-test reliability (Nash et al., 2013).

2.5 Treatment conditions

Trauma Informed Guilt Reduction (TrIGR). TrIGR is delivered over six 90-minute individual sessions (see Table 1). The first module (delivered over 2 sessions) includes an overview of common reactions to trauma and provides psychoeducation regarding posttraumatic guilt, shame, and MI. The Non-Adaptive Guilt and Shame (NAGS) model that underlies TrIGR (see Norman et al., 2014) is reviewed along with common sources of deployment-related traumatic guilt and shame (Kubany, 1994), such as taking part in or witnessing atrocities, being unable to prevent a traumatic event, or surviving when a someone else was killed. Module 2 (delivered over 2 sessions) uses cognitive restructuring to help participants evaluate four types of cognitive errors contributing to posttraumatic guilt identified in prior research (Kubany et al., 2004). These cognitive errors include hindsight-bias (believing that the outcome was known at the time of the trauma), lack of justification (believing there was no or little justification for the course of action one chose to take), responsibility (believing one was solely or mostly responsible for the traumatic event), and wrongdoing (believing one purposely did something that was wrong or violated important values). The TrIGR protocol allows for more than one traumatic event to be processed if indicated.

Module 2 concludes with a discussion regarding the function of guilt and shame in the patient's life (e.g., "It's my duty to remember how my buddy died" or "If I didn't feel bad about it I would really be a bad person"), and what it would be like to feel less guilt/shame going forward. This discussion helps to identify values that were violated during the trauma which allows for the transition to Modules 3 and 4 (one session each) where the focus is on identifying the patient's values and setting goals to live a more value-driven life. Positive ways to express

values rather than through guilt and shame are discussed with an aim of setting goals toward value driven growth. Norman and colleagues (2014) describe the protocol in more detail.

Supportive Care Therapy (SCT). SCT is a present-centered, non-directive therapy that emphasizes principles of unconditional positive regard, genuineness, and empathic understanding. The manual used in this study is based on the supportive components of Present Centered Therapy (PCT; Shea et al., 2003) but excludes the problem solving component and daily diary usually included in PCT. SCT is delivered in six sessions, approximately 90 minutes each, in order to parallel the dose of TrIGR. Following the initial session during which psychoeducation regarding common trauma reactions to trauma and guilt, participants are free to choose the content of each session. If participants elect to discuss their traumatic experience or feelings of guilt, therapists respond to this as they would any other content area – with a validating and nonjudgmental stance while gently redirecting to present-focused content. Therapists are explicitly instructed not to provide advice, assign activities, or engage in strategies and techniques employed in TrIGR or other evidenced-based interventions. At the end of each session, the therapist offers an integrative summary of the session's content and process. The rationale for using SCT is to provide a credible therapeutic comparison condition to TrIGR (see Shea et al., 2020). SCT controls for the nonspecific aspects that characterize most forms of therapy and are distinct from the hypothesized active mechanisms of TrIGR.

2.6 Training and supervision of study therapists

Therapists are masters or doctoral level trainees or licensed mental health providers (psychologists, mental health counselors) who deliver both therapy conditions. Co-investigators train study therapists on both TrIGR and SCT using didactics, videos, audio recordings, and role plays. Therapists are supervised via audio recordings of therapy sessions and participation in

weekly clinical supervision meetings. Supervisory psychologists listen to all sessions for therapists' first two cases; thereafter, 10 percent of sessions are listened to for treatment adherence.

Treatment Fidelity. Our approach to treatment fidelity and adherence utilizes accepted standards including: (1) using treatment manuals with weekly objectives, outcomes, and agendas; (2) therapist training (to avoid bias, therapists are trained to deliver both interventions); and (3) ongoing evaluation of treatment fidelity through review of audio-recording of therapy sessions and weekly supervision. A member of the study team provides ratings on 10% of the audio-recorded sessions randomly selected by the study statistician. Finally, therapists keep a session-by-session tracking form that included self-ratings about the "% of time" of each session spent "using the manual" and covering the relevant module content.

2.7 Data analytic plan

All participants will be included in the analyses (intent to treat) regardless of the amount of treatment they received. Successful randomization will be assessed by performing a series of analysis of variance (ANOVA), Wilcoxon-rank sum tests, χ^2 or Fisher's exact tests to compare the groups on demographic and initial baseline clinical characteristics. Our data analysis methods are robust with respect to missing data and dropout; nonetheless, we will use pattern-mixture modeling to detect bias due to drop out or missing data according to procedures detailed by Hedeker and Gibbons (1997).

2.8 Primary outcome analyses

We hypothesized that participants in TrIGR, compared to participants in SCT, will report significantly greater reductions in guilt severity (as indicated by the TRGI) at the end of treatment and the follow-up period. This hypothesis will be tested using mixed effects models.

Specifically, we will examine random regression models (RRM) and mixed model analysis of variance (MMANOVA). RRM assumes that change over time is linear while MMANOVA considers time as a categorical classification variable and does not assume any specific profile between the outcome variable and time. Each outcome variable will be graphed versus time for each subject to evaluate what function of time bests describes the data. If the change is linear, we will precede with the RRM structure. If the time pattern is not immediately apparent, we will proceed with the MMANOVA. A fully saturated treatment x time model will be utilized for inference. Co-variance structure will be chosen based on Akaike's Information Criterion (AIC). Random group level treatment effects will also be evaluated for importance based on the model AIC.

Responses at baseline through the 6-month follow-up will be nested within subjects. Slope (change in outcome over time) will be entered into the model as a random factor and interacted with treatment group. Intercept and slope will be modeled as random effects nested within subject, and treatment group will be a fixed effect. If needed based on preliminary analyses, baseline covariates (e.g., demographics) will also be entered as fixed effects. Site and the treatment x site interaction will be included as "nuisance parameters;" that is, they will be included to account for possible overall site effects or possible site differences in treatment effects. To test our secondary and exploratory hypotheses, we will use a similar data analysis strategy (i.e. mixed effects models) as for our primary aim.

2.9 Power analysis

Overall, assumptions for our sample size estimation are: (1) sufficient power to test different hypotheses using different analytical models; (2) the reality of recruiting subjects and conducting the study; (3) project cost considerations; and (4) study duration. Therefore, for

Hypotheses 1 and 2, we performed our calculations using several different methods (e.g., Hedeker & Gibbons, 1999) and selected a sample size that provided us with a minimum of 80% power for medium to large effect sizes in each case. To detect a medium effect size with 80% power and a two-tailed alpha of .05 would require a sample size of 59 participants per group. The addition of 12 participants per group would account for up to 20% attrition at p = .05. Thus, a total sample size of 145 subjects provides us with a minimum of 80% power to detect the medium effect size for our primary hypothesis and 80% for our secondary hypothesis. The minimum power estimation is based on sample size calculation for 10% to 20% attrition, correlations of 0.2, 0.5, and 0.8 between the repeated measures, and for medium and large effect sizes.

3. Discussion

This paper reviews the rationale, design, and methodology of a two-site RCT examining the efficacy of TrIGR, as compared to SCT, in reducing trauma-related guilt, shame, and common posttraumatic mental health problems. Given the significant associations among posttraumatic guilt, shame, MI and multiple mental health problems, we developed TrIGR as a transdiagnostic treatment, rather than a disorder-specific intervention, based on an underlying model that non-adaptive guilt and shame (NAGS) contribute to the development and severity of multiple forms of posttraumatic psychiatric distress and impairment (Norman et al., 2019; 2014). The current study gives us the opportunity to test aspects of the NAGS model, including the role of reducing guilt and shame in reducing common posttraumatic problems.

The trial described here is the first to our knowledge to take a transdiagnostic approach to examining the effects of addressing guilt and shame in treatment across the spectrum of diagnoses and functional problems commonly associated with trauma. Evaluating interventions

to address trauma-related guilt, shame and MI is important for a number of reasons. First and foremost, we will be able to evaluate whether treating these is an effective way to reduce distress and impairment across a number of diagnoses commonly associated with trauma. Second, trauma-related guilt and shame do not always respond to current effective treatments for PTSD, even when treatment is otherwise successful (Larsen, Fleming & Resick, 2019). Guilt, shame, and MI are also associated with greater depression symptom severity, substance use, and suicidal ideation (Bryan et al., 2015; Bryan et al., 2018; Griffin et al., 2019; Koenig et al., 2018; Wilkins et al., 2013), but treatments for these problems typically do not include processing of traumatic events that give rise to these emotions. Processing traumatic events is a key component of the most highly recommended treatments for posttraumatic distress (VA/DoD, 2017). Additionally, the self-medication hypothesis suggests that substance use may begin in an effort to cope with and ameliorate emotional distress following trauma, including guilt and negative affect (Brown & Wolfe, 1994; Khantzian, 1985), resulting in a cycle of negative reinforcement. If avoidance of and distress related to guilt, shame and MI are contributing to alcohol and other substance use, resolution or amelioration of these may help alcohol/substance use treatment to be fully effective. Finally, while evidence-based treatments for PTSD can reduce posttraumatic guilt and be effective when MI is present (e.g., Clifton, Feeny, & Zoellner, 2017; Resick et al., 2002; Held et al., 2018), additional effective methods will add value when using shared decision making with patients and in having additional options when a particular treatment is not desired or did not prove to be effective for reducing guilt.

Studying a treatment for a transdiagnostic mechanism rather than for a specific diagnosis (i.e., PTSD) raised some unique design considerations. We contemplated having PTSD symptom severity as our primary outcome as this is a measure familiar to those studying posttraumatic

reactions and we anticipated that most participants would have significant PTSD symptoms even if they did not have the full diagnosis. However, since there was a well validated measure of trauma-related guilt and this was the primary target of the intervention, we elected to use the TRGI as our primary outcome measure. We measure PTSD symptoms as an exploratory outcome and will have the opportunity to examine the relationship between change in guilt and change in PTSD symptoms. We similarly considered whether PTSD symptoms needed to be part of the study inclusion criteria as an additional marker of posttraumatic distress. We ultimately decided to require only criterion A of the PTSD diagnosis (i.e., that participants had guilt from a traumatic event that met the DSM-5 definition), since TrIGR is designed for trauma-related guilt. We made this decision because we wanted to study TrIGR's efficacy for a variety of posttraumatic presentations.

If our hypotheses are supported, findings from this efficacy study will be important in informing future efficacy and effectiveness trials, including examination of TrIGR compared with other trauma focused treatments such as PE or CPT, with treatments for other comorbid disorders, for other treatments of moral injury, and with non-military traumas. Generalizability will also be important to examine in future research. Guilt and shame, long part of the diagnostic criteria for depression, were added to DSM-5 in recognition that they often occur following a wide variety of trauma types (Friedman et al., 2011). Examples of guilt, shame, and MI-inducing events outside of military experiences could include killing someone in a motor vehicle accident or exposing children to an abusive situation. An example that is highly relevant to the current COVID-19 pandemic involves healthcare workers (Campbell, Ulrich & Grady, 2016; Greenberg, Docherty, Gnanapragasam & Wessely, 2018) who cared for patients and may be at risk for subsequent guilt, shame, or MI. They may feel guilty about not being able to save a patient's life,

surviving while others died, or infecting others, even if they did the best they could under unprecedented and difficult circumstances. If TrIGR is effective in reducing guilt and shame in the current study, it would be valuable to evaluate it with healthcare workers who experience guilt and shame from such events (Haller et al., 2020).

Further research can examine TrIGR's effectiveness both prior to and following other interventions for posttraumatic distress and be used to develop guidance regarding sequencing of TrIGR relative to other treatments. For those who continue to experience distress related to guilt and shame after completing disorder specific empirically supported treatments, TrIGR may be an effective tool for continued focus and processing of these emotions. Conversely, it is possible that for patients who may not want to engage in a longer treatment, TrIGR may be a gateway to the next step of treatment. For some presenting with posttraumatic guilt, shame, and MI, no further treatment may be needed. Such research will help determine sequencing of TrIGR with other interventions, when TrIGR may be useful after disorder specific interventions, and when TrIGR may be most appropriate as a first line treatment.

In summary, TrIGR is a brief, transdiagnostic intervention based on a cognitive behavioral model. It targets a common and impairing source of posttraumatic distress. If shown to be effective, these factors will make TrIGR potentially useful to many patients with trauma-related and other disorders, and easy to disseminate in the VA Healthcare System, to active duty mental health providers, and across a variety of healthcare settings.

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Conflicts of Interest

Some of the authors (CC, SN, BD, KB, and CA) earn royalties from Elsevier Press.

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Table 1. TrIGR Modules

Module	Description
1. Psycho-Education (2 sessions)	• Present psychoeducation on common reactions to trauma, flight/flight/freeze response, definitions of guilt and shame • Present psychoeducation on NAGS Model, role of guilt in PTSD and other problems, and common types of guilt following a traumatic event
2. Guilt Debrief (2 sessions)	• Participant completes Attitudes About Guilt Survey (AAGS) • Identify participant's guilt cognitions • Evaluate each of four guilt-related beliefs (foreseeability/preventability, justification for actions taken, causal responsibility, violation of values/wrongdoing) • Identify possible function of holding on to guilt (e.g., honoring someone's memory, punishing oneself)
3. Identifying Values (1 session)	• Identification of values across ten life domains (career, family, etc.) • Identify values that may have been violated during the traumatic event • Examine if/how participant is currently living according to values
4. Value-Driven Growth (1 session)	• Assist participant in generating goals that are in accordance with values • Troubleshoot obstacles, review goal monitoring strategies • Make commitment to behave in accordance with values

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Reintegration Stress Among Post-9/11 Veterans: Relationships with Moral Injury, PTSD Symptoms, and Guilt

Erica Johnson[1], Alexander Kline[2], Kaitlyn Panza[2], Brittany Davis[3], Christy Capone[4], Sonya Norman[2,5,6]
[1]VA Northern CA Health Care System, Sacramento, CA
[2]VA San Diego Healthcare System, San Diego, CA
[3]James A. Haley Veteran's Hospital, Tampa, FL
[4]Brown University, Providence, RI
[5]National Center for PTSD, White River Junction, VT
[6] University of California San Diego, San Diego, CA.

INTRODUCTION:

- PTSD symptoms have been associated with worse mental health, reintegration stress, and functional outcomes. Both trauma-related guilt and moral injury are associated with worse mental health; and may also negatively impact reintegration difficulties.
- We aim to examine the relationships between MI, PTSD symptoms, trauma-related guilt and reintegration stress in a group of combat Veterans.

METHOD:

- 184 Veterans of post-9/11 conflicts (94% male; mean age 39.1 (SD = 8.4); 62% White) screened for a transdiagnostic guilt intervention study.
- We examined associations among moral injury (Morally Injurious Events Scale; MIES), PTSD symptoms (CAPS-5), trauma-related guilt (Trauma-Related Guilt Inventory; TRGI), and reintegration stress (Military to Civilian-Questionnaire; M2C-Q).
- Multiple regression was used to evaluate the association between PTSD symptoms, trauma-related guilt, and reintegration stress.
- Correlations were used to explore association between morally injurious events and reintegration stress.

RESULTS:

- TRGI and CAPS-5 total scores explained 42% of the variance in M2C-Q, $F(2, 174) = 63.41$, $p < .001$.
- When entered into the same regression model, CAPS-5 total scores ($\beta = 0.61$, $p < .001$), but not TRGI ($\beta = 0.09$, $p = 0.16$), was significantly associated with M2C-Q.
- Correlations between MIES and M2C-Q found a positive association between all forms of MI including transgressions by others ($r = 0.20$, $p = .01$), transgressions by self ($r = 0.36$, $p < .001$), and betrayal ($r = 0.16$, $p = 0.03$).

DISCUSSION:

- PTSD symptoms were associated with greater reintegration stress. Trauma-related guilt was not found to uniquely contribute to reintegration stress when accounting for PTSD symptoms.
- Morally injurious events were associated with greater reintegration stress.
- Future research is needed to further explore how MI and PTSD symptoms impact reintegration stress and the relationship between MI and PTSD with specific reintegration domains.
- It is of interest how the construct of shame, rather than guilt, may impact reintegration stress.
- Limitations include the use of cross-sectional data. The sample consists of primarily white males, and only post 9/11 era Veterans. As such, results may not generalize.

PTSD symptoms and experiencing **morally injurious events** are related to increased **reintegration stress.**

Means and Correlations of MI and Reintegration Stress

Variable	*M*	*SD*	1	2	3	4
1. Reintegration Stress	2.12	0.89	-			
2. Transgressions by self	15.83	7.09	0.36**	-		
3. Transgressions by others	9.27	3.09	0.20**	0.64**	-	
4. Betrayal	10.83	4.99	0.16**	0.48**	0.38**	-

*$p < .05$, **$p < .01$

PTSD symptoms were associated with reintegration stress ($\beta = 0.61$, $p < .001$), whereas trauma-related guilt was not ($\beta = 0.09$, $p = 0.16$).

Contact: erica.johnson2@va.gov

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Reintegration Stress Outcomes Among Post-9/11 Veterans in a Clinical Trial for Trauma-Related Guilt

Alexander Kline, Ph.D.[1,2]
Kaitlyn Panza, Ph.D.[1,2]
Erica Johnson, Ph.D.[3]
Brittany Davis, Ph.D.[4,5]
Christy Capone, Ph.D.[6,7]
Sonya Norman, Ph.D.[1,2,8]

[1] VA San Diego Healthcare System
[2] University of California, San Diego
[3] VA Northern California Health Care System
[4] James A. Haley Veterans Hospital
[5] University of South Florida
[6] Providence VA Medical Center
[7] Brown University
[8] National Center for PTSD

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VA SAN DIEGO HEALTHCARE SYSTEM

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I, Alexander Kline, have no commercial relationships to disclose.

ISTSS International Society for Traumatic Stress Studies

Reintegration stress

- **200k veterans annually transition from military to civilian life[1]**
- **Reintegration stress is common among veterans[2,3]**
  - ~40% of returning post-9/11 veterans using VA services report difficulties readjusting to civilian life[4]
  - Not specific to veterans with a likely mental health diagnosis
- **'Reintegration' encompasses broad domains[5-7]**
  - Interpersonal relationships with friends and family
  - Productivity at work/school or home
  - Community participation or belongingness in civilian society
  - Perceived meaning and purpose in life

1 Edwards et. al, 2022
2 Morin, 2011
3 Mobbs et al., 2018
4 Sayer et al., 2010
5 Sayer et al., 2011
6 Milliken et al., 2007
7 Larson et al., 2014

Reintegration stress

- **Reintegration a key consideration for veterans returning home, independent of mental health diagnoses**
  - Among 754 post-9/11 veterans using VA services, 96% reported interest in services to help readjust to civilian life[1]
- **Significant impact on daily life,** with mental health correlates including PTSD, depression, and problematic drug and alcohol use[2-5]
- In one study of returning veterans (N=232), **reintegration stress uniquely associated with suicidal ideation,** over and above symptoms of PTSD and depression[5]

1 Sayer et al., 2010
2 Sayer et al., 2014
3 Shea et al., 2010
4 Kline et al., 2011
5 Haller et al., 2016

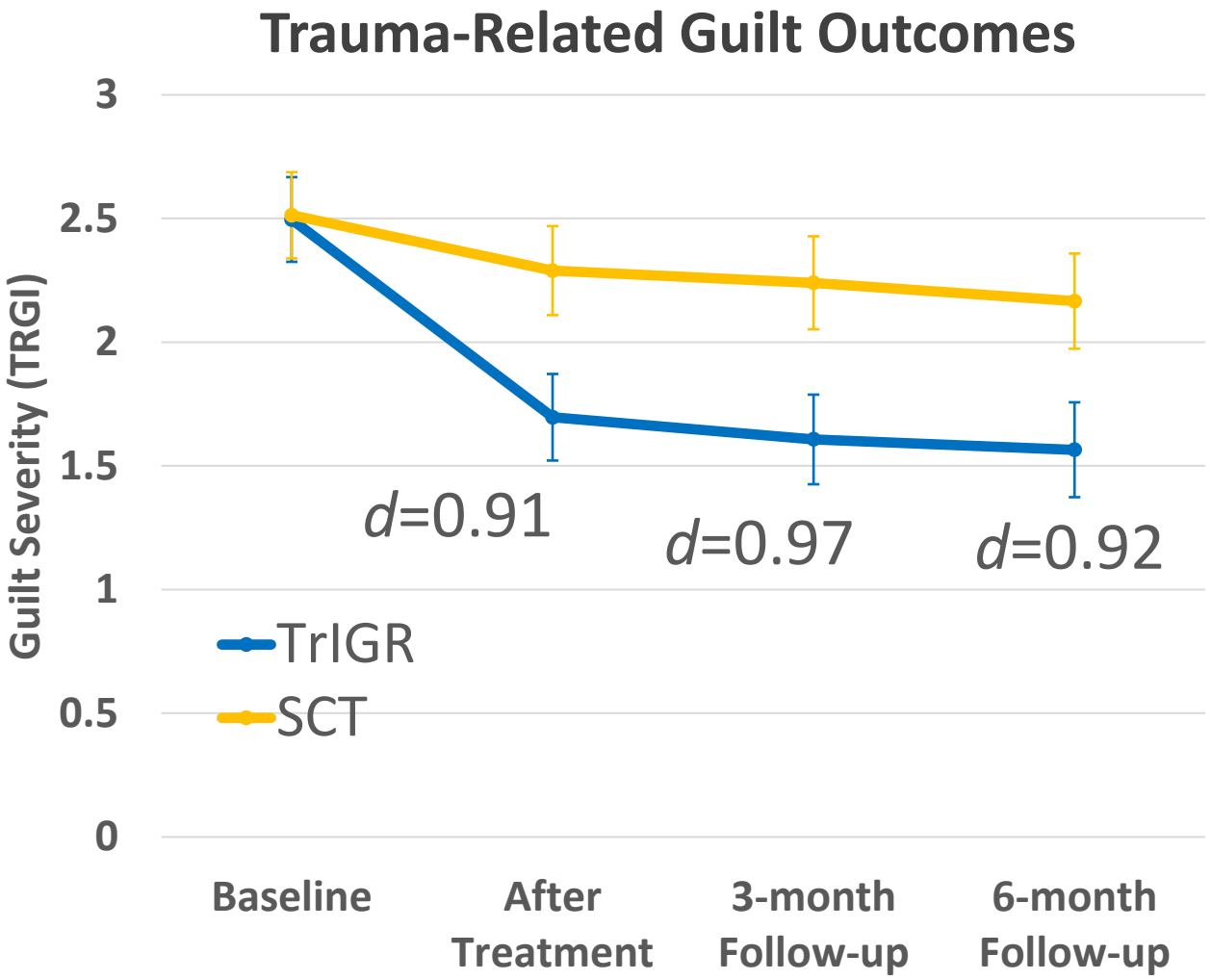
Reintegration stress and guilt

- **Interventions to reduce reintegration stress are needed**
  - Possible pathway is treating trauma-related guilt (TRG), also common among post-9/11 veterans[1]
    - TRG: Distressing emotions related to negative appraisals regarding one's actions/inactions during a traumatic event[2]
- **TRG may contribute to reintegration stress**
  - Positively associated with PTSD, depression, psychological distress, suicidal ideation, functional impairment, and feelings of shame[3-8]
  - Associated with global, negative attributions about self
  - Interferes with routines and relationships

1 Miller et al., 2013
2 Kubany et al., 2003
3 Browne et al., 2015
4 Bannister et al., 2019
5 Bryan et al., 2013
6 Norman et al., 2016
7 Marx et al., 2010
8 Pugh et al., 2015

Treating TRG

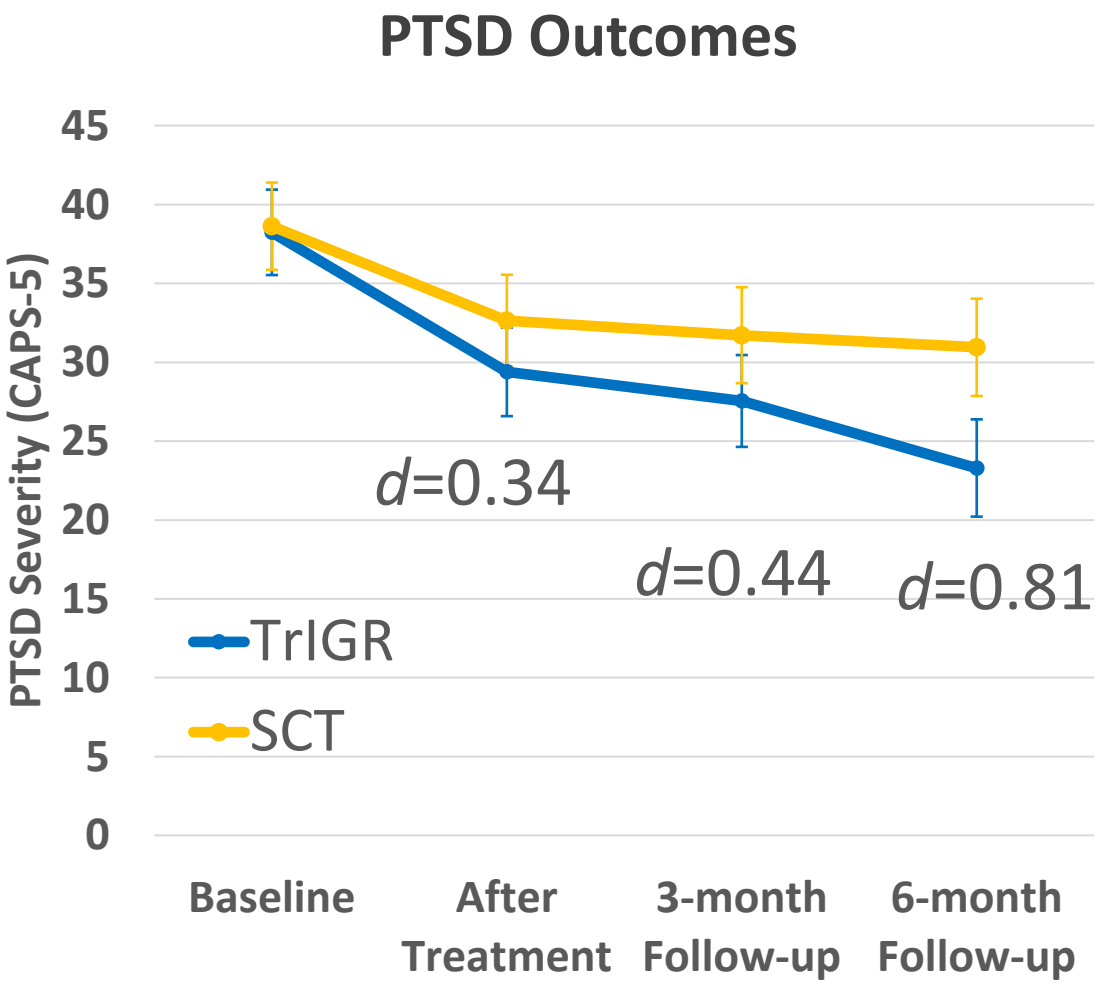
- Given prevalence and impact of TRG on veterans, **Trauma Informed Guilt Reduction Therapy (TrIGR)**[1] developed
  - 6 session transdiagnostic cognitive behavioral therapy targeting trauma-related guilt and shame
- Recently completed RCT (n=145) compared TrIGR with Supportive Counseling Therapy (SCT)[2]

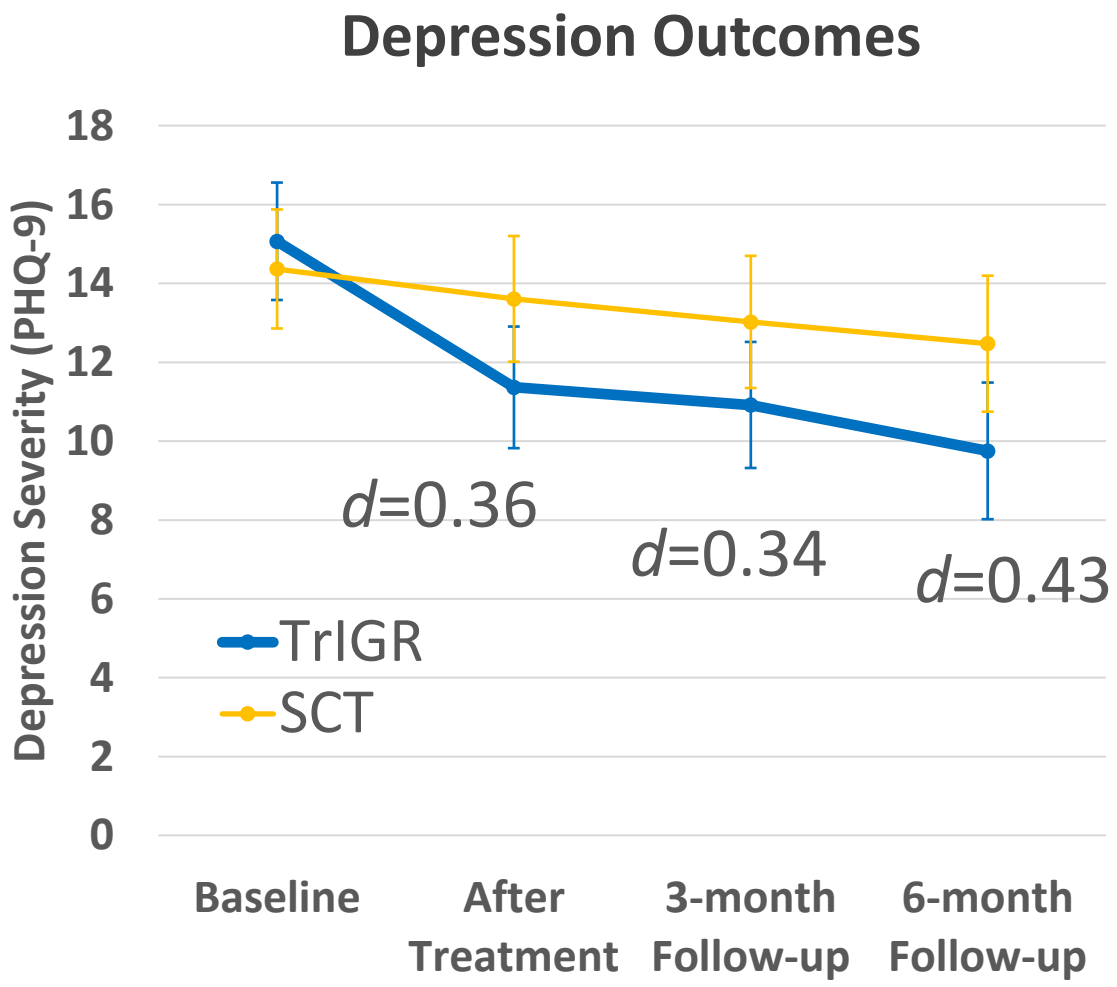


1 Norman et al., 2014

2 Norman et al., 2022

Treating TRG





Study aims

- Current study drew from this RCT comparing Trauma Informed Guilt Reduction Therapy (TrIGR) vs. Supportive Care Therapy (SCT)[1]
  - 1) Examine baseline relationships among reintegration stress, TRG, and symptoms of PTSD and depression
  - 2) Compare the effectiveness of TrIGR and SCT in reducing reintegration stress at post-treatment and 3- and 6-mo follow-up

1 Norman et al., 2022

Participants and procedures

- 145 adult veterans
- Endorsed trauma-related guilt from an event while deployed as part of OIF/OEF/OND
  - PTSD diagnosis not required
- Completed baseline intake, MI session, then randomized to TrIGR or SCT

Characteristic	*M* (SD) or *n* (%)
Age	39.2 (8.1)
Male	136 (93.8)
Married	64 (45.8)
College graduate	74 (51.0)
Hispanic Ethnicity	33 (23.6)
Caucasian Race	92 (63.4)
% combat exposure	137 (94.5)
PTSD severity (CAPS-5)	38.4 (9.5)
% PTSD diagnosis	124 (85.5)
# sessions attended (out of 6)	5.3 (1.7)

Full study procedures and exclusion/inclusion criteria in Capone et al., 2021

Method

- **Measures:** Completed at baseline, posttreatment, and 3- and 6-month follow-up
  - **Trauma-related guilt:** Trauma-Related Guilt Inventory (TRGI)[1]
  - **PTSD symptom severity:** Clinician-Administered PTSD Scale for DSM-5 (CAPS-5)[2]
  - **Depressive symptom severity:** Patient Health Questionnaire-9 (PHQ-9)[3]
  - **Reintegration stress:** Military to Civilian Questionnaire (M2C-Q)[4]
- **Treatments:** 90 min, individual, weekly sessions
  - Patients randomized to receive 6 sessions of therapy
    - Trauma-Informed Guilt Reduction Therapy (TrIGR)[5]
    - Supportive Care Therapy (SCT)[6]

1 Kubany et al., 1996
2 Weathers et al., 2013
3 Kroenke et al., 2001
4 Sayer et al., 2011
5 Norman et al., 2014
6 Belsher et al., 2019

Treatments: TrIGR

- Session 1-2: Presentation of **treatment rationale**, standardized interview, **psychoeducation** regarding common sources of TRG
- Sessions 3-4: Cognitive appraisal exercises targeting **guilt- and shame-related cognitions** that maintain TRG
- Sessions 5-6 (values): Identify connection between guilt and their **values**, and cultivate adaptive/constructive ways to express other than through guilt

Treatments: TrIGR

- **Guilt cognitions targeted in TrIGR**
  - Justification: Insufficient justification for action taken
    - e.g., “I should have disobeyed that order”
  - Hindsight bias: Outcome known at time of the trauma
    - e.g., “I should have known we would hit an IED on that route”
  - Responsibility: Sole responsibility for causing the trauma
    - e.g., “I pulled the trigger, so it is all my fault”
  - Wrongdoing: One purposely did something that was wrong or violated important values
    - e.g., “I am a monster” despite having no intent to cause the outcome

Treatments: SCT

- **Supportive care therapy (SCT)**
  - Present-centered and non-directive
    - Similar to present-centered therapy (PCT), without problem-solving component and daily diary
  - Common, non-specific aspects of psychotherapy
    - Unconditional positive regard, genuineness, empathy
  - Components
    - Information-gathering interview in session 1
    - Common reactions to trauma and guilt in session 2
    - Sessions 3-6 patients guide content and discussions

Data analytic plan

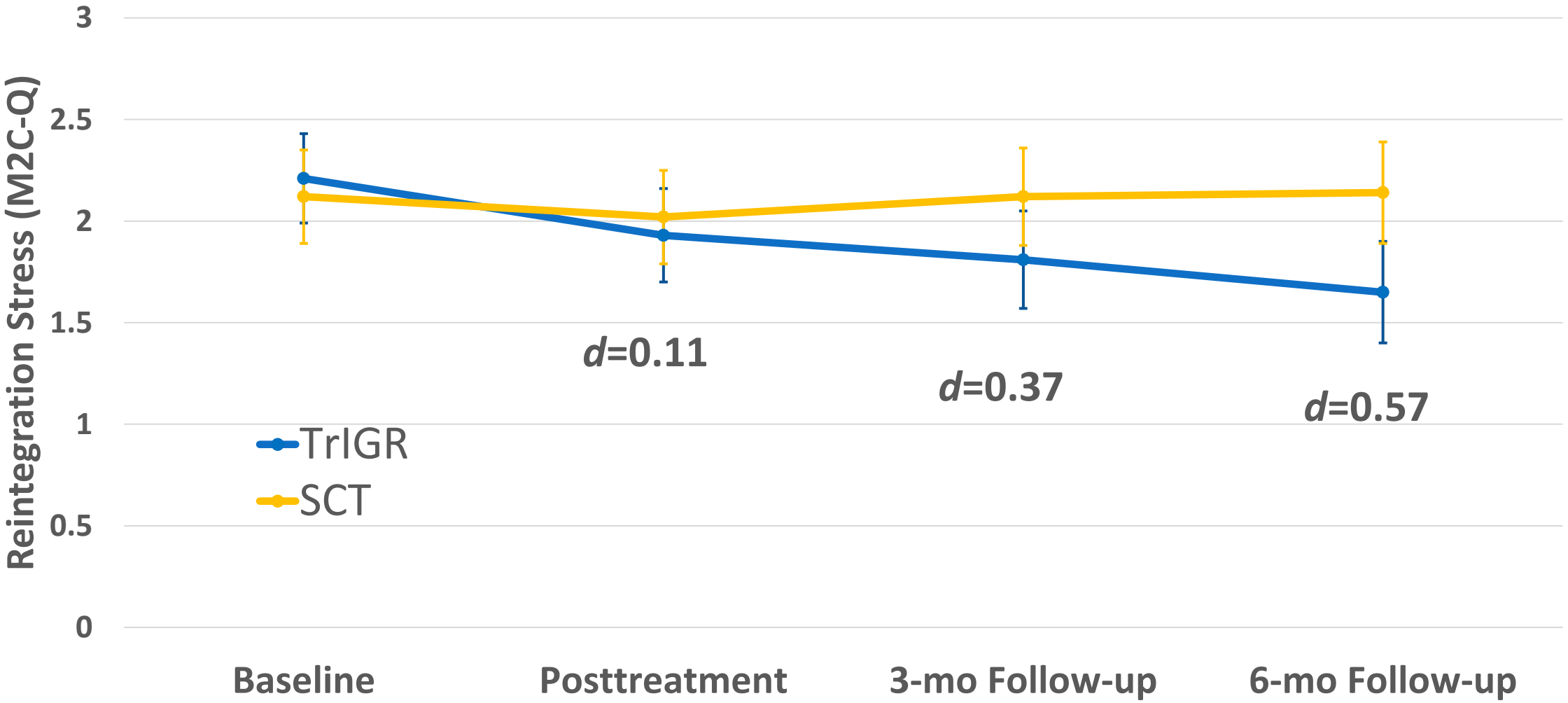
- **Bivariate correlations to examine relationships among reintegration stress, TRG, and symptoms of PTSD and depression**
- **Linear mixed models to compare treatment effects on reintegration stress outcomes at post-treatment and 3- and 6-month follow-up**
  - Fixed effects of time, treatment, and their interaction
  - Intercept specified as random effect
  - All models intent to treat with maximum likelihood estimation
  - Between-treatment condition effect sizes calculated per Cohen's *d*

Results: Baseline relationships (N=145)

Variable	1. M2C-Q	2. CAPS-5	3. PHQ-9	4. TRGI
1. M2C-Q	—			
2. CAPS-5	.61***	—		
3. PHQ-9	.73***	.61***	—	
4. TRGI	.23**	.34***	.21*	—

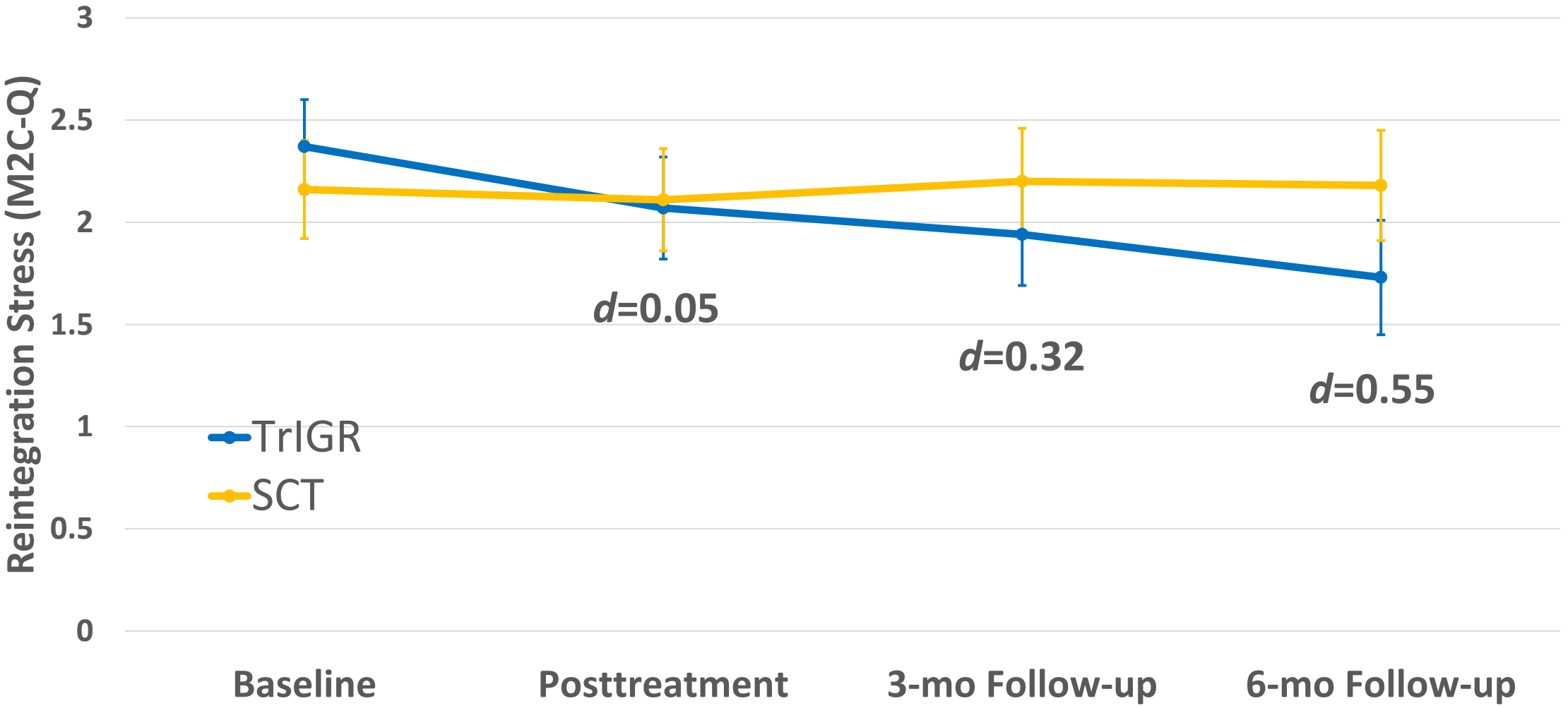
* $p < .05$ ** $p < .01$ *** $p < .001$

Results: Longitudinal outcomes (N=145)



Condition x Time interaction p = .003

Results: PTSD-only subsample (n=124)



Condition x Time interaction p = .003

Discussion

- **Among veterans with TRG, TrIGR may be an effective treatment option for reducing reintegration stress**
  - Despite brevity of intervention (6 sessions), substantive improvements in important life domains following treatment
  - Found identical results in PTSD-only subsample
- **Reintegration stress as a patient-centered outcome**
  - Complement to symptom-focused outcomes
  - Improving aspects of veterans' lives meaningful to them[1]
- **As expected, positive association between reintegration stress and TRG at baseline**
  - Reintegration stress showed stronger baseline relations with PTSD and depression compared to TRG

1 Sayer et al., 2010

Clinical implications

- **TrIGR facilitated downstream reductions in reintegration stress**
- **Future steps- What are the components of TrIGR driving improvements in reintegration outcomes?**
  - e.g., targeting specific types of guilt cognitions?
  - e.g., prescribing personalized exercises to reconnect with values?
- **Treatment effects increased during follow-up period**
  - Time possibly needed for changes in beliefs, behaviors, and routines to positively impact reintegration
  - Assurance to providers and patients if reported changes in reintegration stress not immediate

Limitations

- **Sample generalizability**
  - Mostly male combat veterans, all from OIF/OEF/OND
    - More diverse samples needed
  - Focus on deployment-related guilt specifically
    - Investigation of other types of guilt needed
- **Reintegration stress outcome measure (M2C-Q)**
  - Self-report rather than interview measure or other indices of reintegration
  - Less utilization in longitudinal research
  - Developed with OIF/OEF/OND veterans

Conclusions

- **TrIGR superior to SCT in reducing reintegration stress, with effects increasing over time**
  - Among veterans experiencing TRG, TrIGR may be an effective, brief intervention in boosting adjustment to civilian life
- **Study results complement strong outcomes for TrIGR on TRG, PTSD, and depression[2]**
- **Future steps**
  - Examining active ingredients and mechanisms of change in TrIGR
  - Investigating how and why TrIGR reduces TRG, PTSD, depression, and reintegration stress

1 Norman et al., 2022

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Psychological Services

Associations Among Meaning in Life, Coping, and Distress in Trauma-Exposed U.S. Military Veterans

Jessica L. Morse, Jennalee S. Wooldridge, Niloofar Afari, Abigail C. Angkaw, Paula P. Schnurr, Ariel J. Lang, Christy Capone, and Sonya B. Norman

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Associations Among Meaning in Life, Coping, and Distress in Trauma-Exposed U.S. Military Veterans

Jessica L. Morse[1, 2], Jennalee S. Wooldridge[1, 2, 3], Niloofar Afari[1, 2, 3], Abigail C. Angkaw[1, 2, 4], Paula P. Schnurr[4, 5], Ariel J. Lang[2, 3], Christy Capone[6, 7], and Sonya B. Norman[1, 2, 3, 4]

[1] VA San Diego Healthcare System, San Diego, California, United States
[2] Department of Psychiatry, University of California, San Diego
[3] VA Center of Excellence for Stress and Mental Health, San Diego, California, United States
[4] National Center for PTSD, VA Medical Center, White River Junction, Vermont, United States
[5] Department of Psychiatry, Geisel School of Medicine at Dartmouth
[6] Providence VA Medical Center, Providence, Rhode Island, United States
[7] Department of Psychiatry and Human Behavior, Center for Alcohol and Addiction Studies, Warren Alpert School of Medicine, Brown University

Experiencing meaning in life may be particularly relevant following traumatic experiences as individuals who report meaning post trauma report less psychological distress. Engaging in avoidant coping, however, may be a sign of underlying psychological distress in the aftermath of traumatic experiences. We sought to examine associations among meaning in life, avoidant coping, and psychological distress in a sample of trauma-exposed veterans. Secondary cross-sectional analyses were conducted on data from veterans exposed to a traumatic event(s) who experienced clinically meaningful guilt ($N = 145$). Questionnaires on meaning in life, avoidant coping, and psychological distress were administered, and structural equation modeling was used to test direct effects. Path analysis revealed that greater meaning was associated with lower depression, anxiety, and posttraumatic stress symptomatology, while higher avoidant coping was associated with greater depression, anxiety, posttraumatic stress, and somatization symptomatology. Participants who report more meaning in life and report lower avoidant coping post trauma may experience less psychological distress. If replicated longitudinally, results could suggest cultivating meaning in life and reducing avoidant coping may decrease psychological distress.

Impact Statement
Efforts to understand how resilience and coping relate to veterans' experiences following exposure to traumatic events is crucial to optimizing psychological interventions. Results suggest cultivating meaning in life and reducing engagement in avoidant coping may promote veterans' psychological well-being.

Keywords: meaning in life, coping, trauma, anxiety, military service

Meaning in life, defined as experiencing one's life as having purpose, mattering, and making sense (Martela & Steger, 2016), is considered a correlate of and contributor to well-being and a protective factor in the face of stressors and traumatic events (Krause, 2007; Park, 2010; Zika & Chamberlain, 1992). Specifically, meaning can protect against the onset and maintenance of depression (Goodman et al., 2019), and a greater sense of meaning in life is associated with less severe depressive symptomatology (Blackburn & Owens, 2015; Kleftaras & Psarra, 2012), anxiety (Haugan, 2014), and symptoms of posttraumatic stress

Jessica L. Morse https://orcid.org/0000-0001-6800-7290

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Correspondence concerning this article should be addressed to Sonya B. Norman, Department of Psychiatry, University of California, San Diego, 9500 Gilman Drive, 0603, San Diego, CA 92093, United States. Email: snorman@health.ucsd.edu

disorder (PTSD; Owens et al., 2009). Findings among veteran samples align with research on U.S. civilian samples, indicating veterans who experience their lives as meaningful tend to report less severe PTSD, depression, suicidal ideation, and anxiety (Blackburn & Owens, 2015; Fischer et al., 2020; Owens et al., 2009; Straus et al., 2019) and report fewer somatic complaints (Kinney et al., 2020). Additionally, research indicates meaning in life is protective against PTSD, depression, and suicidal ideation following military sexual trauma (Gross et al., 2019) as well as following moral injury, which is experiencing or acting in ways inconsistent with one's values or morals (Currier et al., 2015; Frankfurt & Frazier, 2016; Hall et al., 2022).

While having a strong sense overall that one's life is meaningful (global meaning) buffers against psychological distress, individuals' appraisals of specific experiences (situational meaning) also influence psychological adjustment (Park, 2022). According to Park (2010, 2022), when individuals experience a potentially traumatic event as consistent with their global meaning, they do not experience distress in response to the event and maintain their existing meaning framework(s). In these cases, individuals' global meaning frameworks are not disrupted, as the individual can make sense of the traumatic experience using their extant meaning framework, resulting in no substantial or lasting loss of global meaning and less posttraumatic distress. When individuals experience a potentially traumatic event as inconsistent with their global meaning framework, they tend to experience distress (Park, 2022). This distress may provoke meaning-making efforts (e.g., reframing), which may result in meaning made and a restored global meaning framework (Park, 2022). Thus, upon experiencing a traumatic event, individuals with greater global meaning in life may be less likely to experience a disruption in their global meaning framework(s) and may more easily restore global meaning. Alternatively, less global meaning in life in the aftermath of a traumatic experience could be a result of chronically low levels of meaning in life or could represent a decline in global meaning as a result of difficulty reconciling this new experience with one's preexisting meaning framework (Fischer et al., 2020; Park, 2010, 2022).

Individuals' global meaning framework(s) are one factor that may affect responses to traumatic experiences. Another factor that may relate to levels of distress in response to traumatic experiences is individuals' coping style(s). When people experience traumatic events, some may respond by trying to make sense of the experience (e.g., meaning-making; Fischer et al., 2020; Park, 2010, 2022), while others may respond by trying to avoid distressing thoughts and emotions (e.g., avoidant coping; Fischer et al., 2020; Kashdan & Kane, 2011). Avoidant coping (e.g., via substance use, self-distraction, disengagement) can exacerbate distress through compounding negative views of oneself, the world, and others (Fullerton & Ursano, 2005) and/or increasing feelings of loneliness and inefficacy (Hawkley & Cacioppo, 2010). In fact, one study found the relationship between trauma exposure and somatic symptoms to be partially mediated by avoidance (Morina et al., 2018). Additionally, research suggests experiencing elevated trauma-related guilt contributes to greater engagement in avoidance behaviors and is associated with higher prevalence of PTSD and other forms of psychological distress (Norman et al., 2014, 2018). Trauma-related guilt is prevalent among combat veterans, with one study reporting 41% of veterans exposed to trauma reported guilt in the prior month (Miller et al., 2013). When trauma-exposed individuals come to believe they are not worthy of living a "good life" and/or experience "survivor's guilt," they may act in ways (i.e., detrimental avoidance behaviors) that align with those beliefs, further exacerbating psychological distress.

The critical next question in this line of research is how individuals' global sense of meaning in life and their level of engagement in avoidant coping are uniquely related to psychological distress after traumatic experiences. Extant research supports that high global meaning in life is associated with less psychological distress (Blackburn & Owens, 2015; Fischer et al., 2020; Goodman et al., 2019; Haugan, 2014; Kleftaras & Psarra, 2012; Owens et al., 2009; Straus et al., 2019) and that high engagement in avoidant coping is associated with more psychological distress (Fischer et al., 2020; Morina et al., 2018). Understanding the roles of avoidant coping and meaning in life in contributing to or buffering against distress after traumatic experiences is important to identifying intervention targets. To our knowledge, no prior studies have examined the role of avoidant coping and meaning in life together in association with psychological distress after traumatic experiences.

The aims of the present study were to examine (a) bivariate associations among meaning in life, avoidant coping, and multiple indicators of psychological distress (depression, anxiety, posttraumatic stress, and somatization symptoms) in a sample of Operation Enduring Freedom, Operation Iraqi Freedom, and Operation New Dawn veterans with traumatic exposure and (b) a multivariate path model with both meaning in life and avoidant coping directly associated with multiple indicators of psychological distress. We hypothesized that greater meaning in life and lower avoidant coping would be associated with lower depression, anxiety, posttraumatic stress, and somatization symptomatology in bivariate and multivariate analyses.

Method

Participants and Procedure

A total of 145 participants were enrolled in a randomized controlled trial to assess the efficacy of a transdiagnostic psychotherapy, Trauma-Informed Guilt Reduction, to address posttraumatic guilt and shame stemming from a deployment experience. Inclusion criteria were as follows: (a) deployment in service of conflicts in Iraq and Afghanistan; (b) a score of 2+ on items measuring guilt severity and guilt cognition on the Trauma-Related Guilt Inventory; (c) English literacy; (d) intention to remain in the area during the course of the study; and (e) willingness to set goals to reduce use if meeting diagnostic criteria for mild or moderate alcohol or substance use disorder. Exclusion criteria included the following: (a) moderate or severe cognitive impairment on the Montreal Cognitive Assessment; (b) acute suicide risk; (c) severe substance use disorder in the past 2 months; (d) current psychosis or mania; (e) residing 50+ miles from the nearest study site; (f) life threatening or unstable medical illness, and (g) currently receiving trauma-focused treatment (Capone et al., 2021).

Study participants were recruited through self and clinician referrals at study sites. Interested veterans were screened for broad eligibility, and those who met preliminary eligibility criteria were scheduled for an in-person visit to consent and complete the baseline assessment. Data collection occurred between June 2016 and December 2020. Data used for the present analyses were obtained

at baseline, prior to any study interventions. All participants provided informed consent. The study procedures were approved by the Institutional Review Boards at VA San Diego Healthcare System, Providence VA Medical Center, Brown University, and the Human Research Protections Office at the Department of Defense.

Measures

Demographic Variables

Participants self-reported demographic characteristics including age, sex, ethnicity, race, relationship status, income, and military service history.

Meaning in Life

Each participant completed the 26-item World Health Organization Quality of Life (WHOQOL-BREF; The WHOQOL Group, 1998) measure assessing health status across four domains: physical, psychological, social, and environmental. For this study, we used Item 6, "to what extent do you feel your life to be meaningful," scored on a scale from 0 = *not at all* to 4 = *an extreme amount*, to assess participants' global meaning in life. A prior study reported strong psychometric properties of this single-item measure of global meaning in life in university students (Atroszko et al., 2015), and the item has been used in other studies to examine meaning in life and health care utilization among older adults and to examine adaptation to the COVID-19 pandemic (Hajek & König, 2019; Nes et al., 2022). In the study of university students, the item had high test–retest reliability (α = .86) and construct validity, such that meaning in life was strongly positively correlated with satisfaction with life ($r = .76$) and moderately negatively correlated with perceived stress ($r = -.41$), depressive symptoms ($r = -.44$), anxiety symptoms ($r = -.36$), and loneliness ($r = -.40$; Atroszko et al., 2015).

Coping

Participants completed the Brief COPE Inventory (Carver, 1997), consisting of 28 items designed to measure a broad range of coping styles, extending beyond the simple dichotomy of emotion- versus problem-focused coping to include an avoidant coping subscale. Participants rated the extent to which they engaged in coping behaviors on a scale from 1 = *I have not been doing this at all* to 4 = *I have been doing this a lot*. For the present study, we used the eight-item avoidant subscale of the Brief COPE. Internal consistency in this sample was low (α = .66).

Psychological Distress

Participants completed the Brief Symptom Inventory–18 items (BSI-18; Derogatis & Melisaratos, 1983), a shortened version of the original 53-item BSI, with three subscales: depression, anxiety, and somatization. Items are scored on a scale from 0 = *not at all* to 4 = *extremely*. The BSI-18 is a psychometrically sound measure (Derogatis & Fitzpatrick, 2004), and internal consistency ($\alpha_{depression} = .88$; $\alpha_{anxiety} = .89$; $\alpha_{somatization} = .82$) in this sample was good.

Participants also completed the Posttraumatic Stress Disorder Checklist for the fifth edition of the *Diagnostic and Statistical Manual of Mental Disorders* (PCL-5; Weathers et al., 2013) questionnaire. It consists of 20 items that correspond to *DSM-5* PTSD symptoms, assessing the extent to which participants have been bothered by symptoms in the past month on a scale from 0 = *not at all* to 4 = *extremely*. Research on the PCL-5 in military veterans found it is psychometrically sound (Bovin et al., 2016) and internal consistency (α = .92) in this sample was excellent.

Statistical Analyses

Bivariate correlations were calculated to examine relationships among meaning in life, avoidant coping, and psychological distress variables. Next, structural equation modeling path analysis using the statistical package Mplus Version 8.0 (Muthén, 2021) was conducted to test hypotheses that meaning in life and avoidant coping are directly associated with depression, anxiety, posttraumatic stress, and somatization symptoms. Data across all measures were scored on continuous scales and were normally distributed, thus no data transformations were conducted. Missing data were accounted for using full information maximum likelihood and bootstrapping was used to correct for standard errors and to construct confidence intervals around parameter estimates (Muthén, 2021). Statistical significance was determined by confidence intervals not containing zero (Bollen & Stine, 1990).

To evaluate overall model fit, we used model fit criteria suggested by Hu and Bentler (1999) including the Tucker–Lewis index (TLI) > .95, root-mean-square error of approximation (RMSEA) < .06, and standardized root-mean-square residual (SRMR) < .08. Following Kline's (2015) recommendation, the unstandardized β coefficient, its standard error and *p* value, and the standardized β coefficients and confidence intervals for direct effects are reported.

Results

The sample consisted of 145 U.S. military veterans who were exposed to a traumatic event(s) and experienced clinically meaningful guilt. Participants' age ($M = 39.23$, $SD = 8.12$) ranged from 25 to 58 years, and the majority of the sample was male (93.8%). Most participants identified as White (67.6%) with 11.7% identifying as Black, 10.3% as Asian, 2.1% as American Indian/Alaska Native, 0.1% as Native Hawaiian/Pacific Islander, and 6.2% as other. Regarding ethnicity, 22.8% identified as Hispanic/Latino, 64.1% did not, and 13.1% declined to answer. Socioeconomic status was measured by total combined family income, with most participants endorsing family income ranging from $30,000 to $44,999.

Bivariate Correlations

Means, standard deviations, and bivariate correlations of the study variables are presented in Table 1. As expected, meaning in life was significantly negatively correlated with avoidant coping, depression, anxiety, posttraumatic stress, and somatization symptoms, while avoidant coping was significantly positively correlated with depression, anxiety, posttraumatic stress, and somatization symptoms.

Multivariate Path Analysis

Overall, model fit indices suggested excellent fit (TLI = .99, SRMR = .050, RMSEA = .018; Hu & Bentler, 1999). Table 2 provides the unstandardized path coefficients of the direct effects,

Table 1
Means, Standard Deviations, and Bivariate Correlations Among Study Variables

Measure	Meaning in life	Avoidant coping	Depression	Anxiety	Posttraumatic stress	Somatization
Meaning in life	—					
Avoidant coping	−.30**	—				
Depression	−.54**	.49**	—			
Anxiety	−.29**	.42**	.66**	—		
Posttraumatic stress	−.39**	.52**	.67**	.78**	—	
Somatization	−.26*	.47**	.56**	.71**	.64**	—
M	2.67	16.47	14.50	11.53	49.28	7.05
SD	1.01	4.34	7.38	6.12	14.58	5.42

* $p < .05$. ** $p < .001$.

and Figure 1 presents the standardized path coefficients. As hypothesized, the direct effects of meaning in life on psychological distress variables were significant such that greater meaning in life was significantly associated with lower avoidant coping, depression, anxiety, and posttraumatic stress symptomatology and approached significance in association with somatization ($p = .086$; Table 2). Higher engagement in avoidant coping was significantly directly associated with greater depression, anxiety, posttraumatic stress, and somatization symptomatology (Table 2; Figure 1). Thus, when examined together, both global meaning in life and avoidant coping were uniquely significantly associated with multiple indicators of psychological distress among trauma-exposed veterans with clinically elevated guilt.

Discussion

The purpose of this study was to examine associations among meaning in life, avoidant coping, and psychological distress among U.S. military veterans enrolled in a randomized trial for treatment of guilt related to a deployment-related traumatic event. We found that global meaning in life was associated with most manifestations of psychological distress and avoidant coping was associated with all manifestations of distress. Specifically, a greater overall sense of meaning in life was associated with lower depression, anxiety, and posttraumatic symptoms, while higher endorsement of engaging in avoidant coping was associated with higher depression, anxiety, posttraumatic stress, and somatization symptoms. These findings are consistent with previous research linking greater meaning in life broadly to lower psychological distress (Blackburn & Owens, 2015; Fischer et al., 2020; Goodman et al., 2019; Haugan, 2014; King & Hicks, 2021; Kinney et al., 2020; Kleftaras & Psarra, 2012; Krause, 2007; Martela & Steger, 2016; Owens et al., 2009; Ryff, 1995; Straus et al., 2019; Zika & Chamberlain, 1992) and, more specifically, higher meaning in life to lower psychological distress post trauma (Currier et al., 2015; Frankfurt & Frazier, 2016; Gross et al., 2019; Hall et al., 2022; Janoff-Bulman, 2010). Additionally, our results are in line with previous research linking higher engagement in avoidant coping with more psychological distress (Holahan et al., 2005).

Meaning in life and avoidant coping are significantly negatively associated, which is consistent with previous research on the association between meaning and engagement in avoidance post trauma (Holahan et al., 2005; Kashdan & Kane, 2011). Research suggests when people experience life as meaningful, they are less likely to engage in avoidant behaviors (King & Hicks, 2021). Although global meaning and avoidant coping are each independently associated with distress, the results herein could also imply that participants who reported high global meaning engaged in fewer efforts to disengage from stressors via self-distraction, denial, substance use, and/or behavioral disengagement, which may contribute to lower depression, anxiety, posttraumatic stress, and somatization symptoms. Alternatively, participants with lower global meaning may be more likely to cope with psychological distress via avoidant coping or perhaps experience more psychological distress as a consequence of avoidant coping behaviors. Future studies should further examine the nature of these relationships using longitudinal models to better understand the additive versus interactional and temporal dynamics of these associations.

While previous research has revealed small to moderate-sized negative effects in associations among meaning in life and depression, anxiety, and posttraumatic symptoms (Blackburn & Owens, 2015; Fischer et al., 2020; Haugan, 2014; Kleftaras & Psarra, 2012; Owens et al., 2009), we are not aware of any studies examining the association of meaning in life with somatization symptoms. Even though the bivariate association between meaning in life and somatization symptoms was significant, the direct effect between

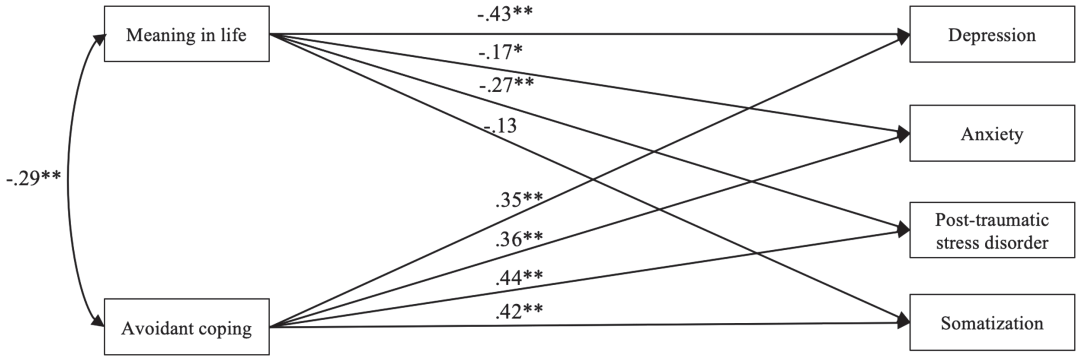
Table 2
Path Analysis: Parameter Estimates, Confidence Intervals, and Significance for Direct Effects

	Depression			Anxiety			Posttraumatic stress			Somatization		
Direct effects	*b*	95% CI	*p*	*b*	95% CI	*p*	*b*	95% CI	*p*	*b*	95% CI	*p*
Meaning in life	**−3.09**	**[−4.16, −1.98]**	**<.001**	**−1.05**	**[−2.02, −.10]**	**.02**	**−3.80**	**[−5.82, −1.68]**	**<.001**	−.71	[−1.54, .09]	.086
Avoidant coping	**.59**	**[.35, .81]**	**<.001**	**.51**	**[.30, .70]**	**<.001**	**1.47**	**[.97, 1.94]**	**<.001**	**.53**	**[.33, .72]**	**<.001**

Note. *b* = unstandardized estimate coefficients; CI = confidence interval. Bold values represent statistically significant paths.

Figure 1

Path Model of the Direct Effects of Meaning in Life and Avoidant Coping on Psychological Distress



Note. Standardized coefficients for all direct paths are shown.
* $p < .05$. ** $p < .001$.

meaning in life and somatization symptoms only trended toward significance in the multivariate analysis. This could be due to the greater strength of associations between meaning in life and depression, anxiety, and posttraumatic symptoms and between avoidant coping and somatization; thus, when examined altogether, these associations reduced the amount of variance in somatization explained by meaning in life. More research with larger samples and more robust measures of meaning in life and somatization symptoms are needed to further examine the links between meaning in life and somatic forms of psychological distress.

While additional research is needed to examine the directionality of these relationships, results of the present study can be used to inform future research directions for clinical treatment of patients exposed to traumatic events, especially veterans experiencing posttraumatic distress and elevated guilt. Given the links between global meaning in life and avoidant coping with each other and with psychological distress post trauma, interventions focused on orienting individuals to increase their overall sense of meaning in life and reducing engagement in avoidant coping may be useful in reducing psychological distress. Many studies highlight the deleterious mental health consequences of low levels of meaning in life (King & Hicks, 2021). Interventions that facilitate the development of global meaning may promote reductions in psychological distress (Park, 2013, 2022; Steger & Park, 2012) as well as avoidant coping. Similarly, interventions directly aimed at reducing the use of avoidant coping strategies and engaging in adaptive coping may lessen psychological distress (Sikkema et al., 2013) and perhaps promote an increase in global meaning. Thus, results of this study point to the importance of both promoting meaning in life and reducing engagement in avoidant coping strategies to decrease psychological distress and improve psychological well-being. Given that not all existing trauma-focused interventions work equally well for all individuals, findings from this study also can inform the development of novel interventions that focus on both increasing meaning and decreasing avoidant coping.

Strengths of this study include the sample of military veterans who were exposed to traumatic event(s) as well as the focus on potentially modifiable targets for psychological intervention: meaning in life and avoidant coping. Nonetheless, there are several limitations. The sample was largely White and male with no information regarding time since traumatic exposure, all of which may affect relationships among examined variables. The use of a single-item measure of global meaning may not adequately or reliably capture global meaning and does not provide information about how traumatic events have affected participants' global meaning. Future studies should seek to utilize a comprehensive measure of global meaning as well as measures of situational meaning and meaning-making processes to elucidate posttraumatic meaning-making longitudinally. The low internal consistency of the avoidant coping subscale in this sample suggests that this subscale may measure more than one construct or that this subscale may not be the most reliable measure of avoidant coping in individuals with high levels of guilt. Finally, given the sample was recruited for elevated levels of guilt, we did not include a measure of guilt in this study due to the truncated variability in guilt among participants. It is possible that the experience of posttraumatic guilt alters one's global perception of meaning and/or affects coping strategies as well as increases psychological distress symptoms. Thus, findings from this study may not generalize to a broader sample of traumatized individuals.

In sum, this study is the first to examine both global meaning in life and avoidant coping as unique correlates of psychological distress in a sample of trauma-exposed veterans with clinically elevated guilt. Results of this study highlight the potential protective role of meaning or the impact of psychopathology on meaning—either of which underscores the importance of addressing meaning in life via interventions that promote restoration of meaning in populations that have experienced potentially "meaning-shattering" traumatic events. Results also point to the importance of minimizing the use of or replacing avoidant coping strategies as an intervention to reduce psychological distress.

Compliance With Ethical Standards

Informed consent was obtained from all individual participants included in the study. All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards.

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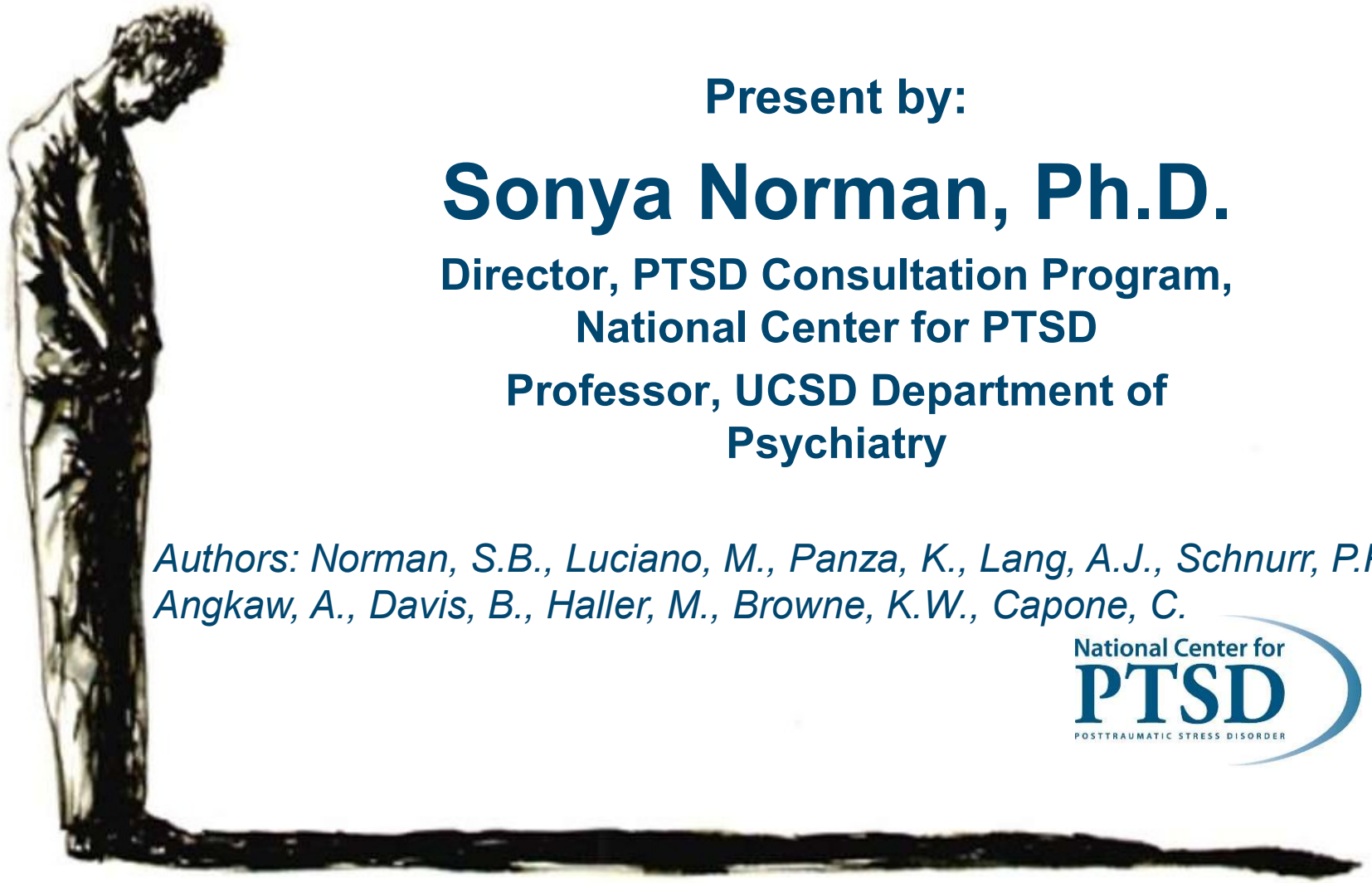
Relationship between Trauma-Related Guilt, Moral Injury, and PTSD Symptom Severity in a Treatment Seeking Sample of Veterans Who Served in Iraq and Afghanistan



Present by:

Sonya Norman, Ph.D.

Director, PTSD Consultation Program, National Center for PTSD

Professor, UCSD Department of Psychiatry

Authors: Norman, S.B., Luciano, M., Panza, K., Lang, A.J., Schnurr, P.P., Angkaw, A., Davis, B., Haller, M., Browne, K.W., Capone, C.

National Center for PTSD
POSTTRAUMATIC STRESS DISORDER

What is Moral Injury?

An **event** occurs where someone's values and morals are violated by perpetrating, failing to prevent, or bearing witness to acts that transgress deeply held moral beliefs and values.

The person feels **moral distress** (involving emotions and cognitions – guilt, shame, betrayal) in response to the event.

Sometimes there is lasting psychological, biological, spiritual, behavioral, and/or social **impact** of the morally distressing event.

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How common is MI?

- From a nationally representative sample of combat Veterans (Wisco, et al., 2017)
  - 26% betrayal
  - 26% transgression by others
  - 11% transgression by self

Moral Injury and Mental Health Problems

- Moral Injury is not a disorder, but it is linked to mental health disorders
- Moral injury is related to increased likelihood of depression, substance misuse, and suicidal thoughts and behaviors
- Moral Injury is related to increased likelihood of PTSD
  - A traumatic event that causes PTSD can be morally injurious
  - 75% of U.S. combat veterans with PTSD reported moral injury
    - 59% reported betrayal 53.8% reported witnessing transgressions by others
    - 39% reported transgressions by self
- Moral injury can occur in the absence of PTSD
  - 32.9% of U.S. combat veterans without PTSD reported moral injury
- 19% of Veterans with moral injury have PTSD (v. 4% without)

*Thank you to Robert Pietrzak and NHRVS

Definition of Moral Injury

- **There is no consensus definition**
- **Most widely used is by Litz and colleagues, 2009**
  - **Moral injury** is the distressing psychological, behavioral, social, and sometimes spiritual aftermath of traumatic events in which a person has perpetrated, failed to prevent, or witnessed acts that contradict deeply held moral beliefs and expectations
- Guilt and shame are central reactions in all definitions and all aspects of moral injury
  - Transgressions by self
  - Transgressions by others
  - Betrayal

Moral Injury

The moral injury syndrome was proposed to describe the constellation of shame and guilt-based disturbances that some combat veterans experience after engaging in wartime acts of commission (e.g., killing) or omission (e.g., failing to prevent atrocities)

Frankfurt & Frazier, 2016

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Next Steps in Moral Injury Research

- We need to understand the emotional underpinnings of moral injury to understand how to intervene
- We have testable models
  - Moral injury is conceptually characterized by strong reactions of guilt but no studies yet have examined the relationship between moral injury and trauma-related guilt, or how they both relate to PTSD

Trauma-related guilt

Common following trauma and combat

- 54% endorse posttraumatic guilt in their lifetime
- 41% endorse current posttraumatic guilt
- 35% report being moderately to extremely bothered by their guilt

Miller et al., 2012

Can exacerbate posttraumatic distress

Persists without treatment

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Aims and Hypotheses

- Aim: To examine trauma-related guilt, moral injury - including transgressions by self and transgressions by others - and PTSD among 184 who deployed post 9/11
- Hypothesis: Trauma-related guilt would be highly correlated with moral injury, particularly transgressions by self, and would mediate the relationship between transgressions by self and PTSD symptom severity

Method

- 184 OEF/OIF Veterans completed baseline assessments for a study to treat trauma-related guilt
  - Moral Injury Events Scale (MIES)
  - Trauma Related Guilt Inventory (TRGI)
  - Clinician Administered PTSD Scale (CAPS-5)
- Sites were San Diego and Providence VAs

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Demographics

Table 1. Demographics	
	M (SD) or %
Age	39.14 (SD=8.44)
Gender (Male)	94%
Ethnicity	
Hispanic/Latino	25.3%
Non-Hispanic	63.8%
Declined to Answer	10.9%
Race	
White/Caucasian	69.5%
Black/African American	11.5%
Asian	10.3%
Other Identified Race	9.7%

Table 2. Military Characteristics	
	M (SD) or %
Number of Deployments	2.01 (SD=1.20)
Branch	
Army	36.7%
Air Force	6.2%
Marines	27.1%
National Guard	5.1%
Navy	24.9%

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Results

Table 2. Correlations					
	1	2	3	4	5
1. TRGI (Guilt) Average	--				
2. Moral Injury Events Total	.455**	--			
3. MIE Transgressions by Self	.247**	.759**	--		
4. MIE Transgressions by Other	.515**	.909**	.635**	--	
5. CAPS-5 (PTSD) Total	.451**	.305**	.169*	.336**	--

Notes: *p< .05; **p< .001; TRGI = Trauma-related Guilt Inventory; MIE = Moral Injurious Events Scale; CAPS = Clinician Administered PTSD Scale for DSM-5

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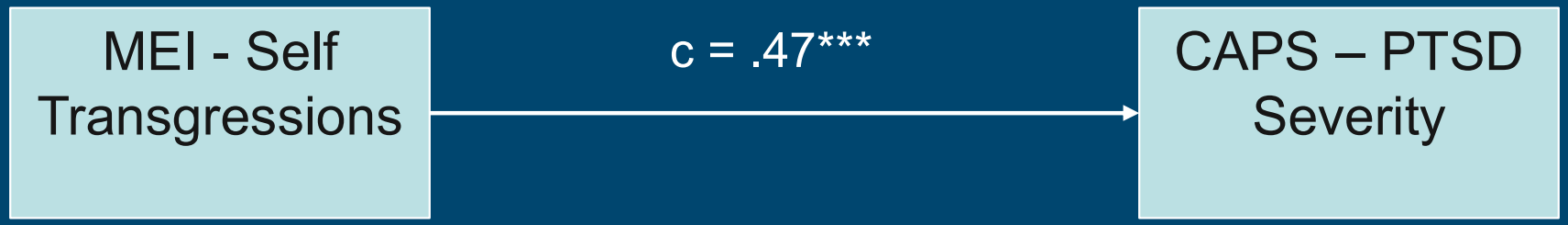
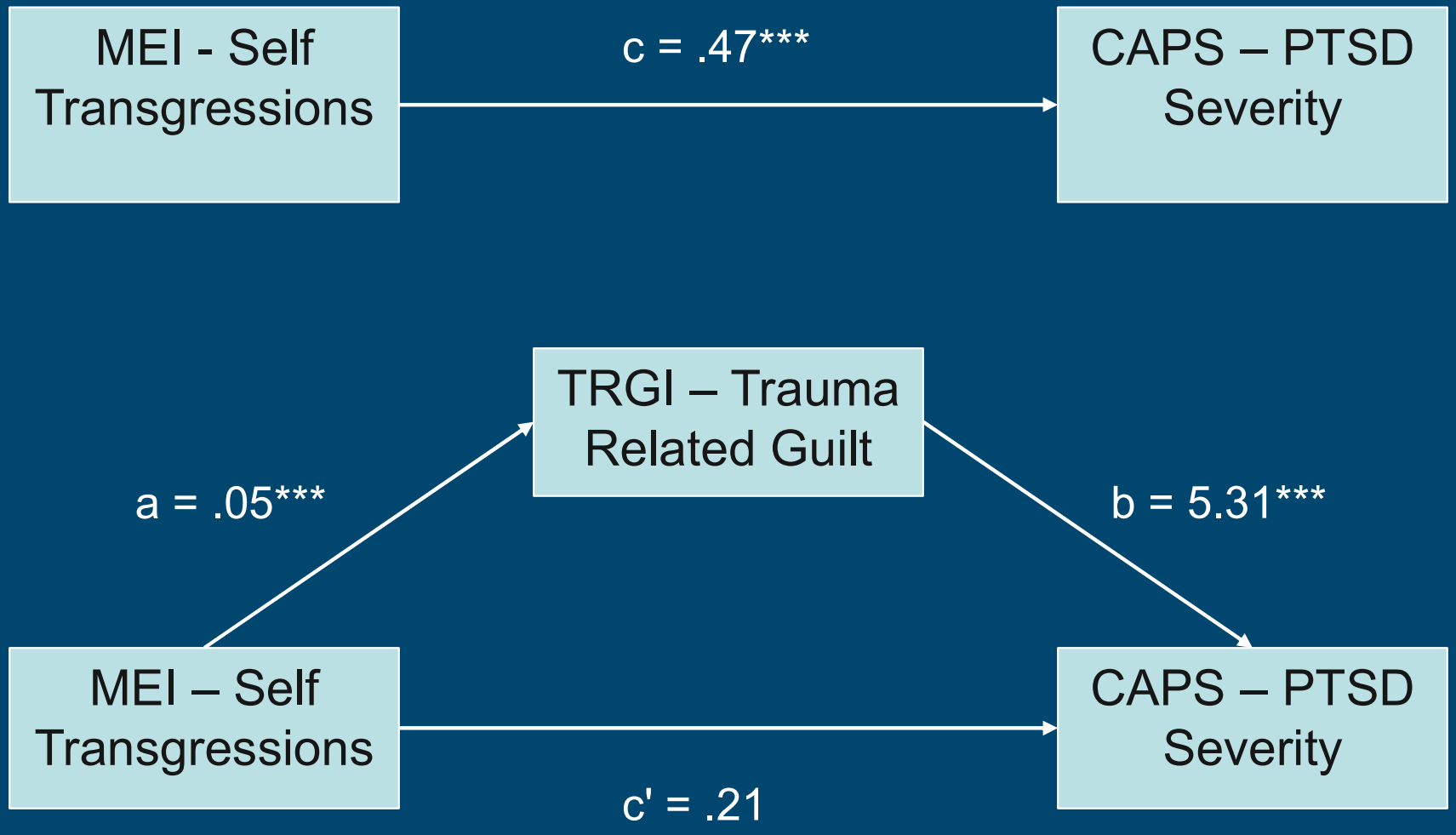
Results



Note: ***p≤.001

Results



Indirect Effect= .26, 95% CI: .141, .416

Note: ***p≤.001

Discussion and Implications

- First study to look at the role guilt plays in moral injury and its relationship to PTSD.
- Guilt was strongly related to moral injury and fully mediated the relationship between transgressions by self and PTSD.
- Addressing trauma-related guilt in treatment may help to reduce suffering from moral injury.
- Measures that assess change in moral injury needed.
- More research needed to understand underpinnings of moral injury to understand how to intervene.

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RESEARCH ARTICLE

ANXIETY AND DEPRESSION ASSOCIATION OF AMERICA WILEY

A clinical trial comparing trauma-informed guilt reduction therapy (TrIGR), a brief intervention for trauma-related guilt, to supportive care therapy

Sonya B. Norman[1,2,3,4] | Christy Capone[5,6] | Kaitlyn E. Panza[2,4] | Moira Haller[2,4] | Brittany C. Davis[7,8] | Paula P. Schnurr[1,9] | M. Tracie Shea[5,6] | Kendall Browne[10,11,12] | Gregory J. Norman[4] | Ariel J. Lang[2,3,4] | Alexander C. Kline[2,4] | Shahrokh Golshan[2,4] | Carolyn B. Allard[2,13] | Abigail Angkaw[2,4]

[1]Executive Division, National Center for PTSD, Hartford, Vermont, USA

[2]Department of Mental Health, VA San Diego Healthcare System, San Diego, California, USA

[3]Clinical Research Division, VA Center of Excellence for Stress and Mental Health, San Diego, California, USA

[4]Department of Psychiatry, University of California, San Diego, La Jolla, California, USA

[5]Department of Mental Health, Providence VA Medical Center, Providence, Rhode Island, USA

[6]Department of Psychiatry and Human Behavior, Center for Alcohol and Addiction Studies, Warren Alpert School of Medicine, Brown University, Providence, Rhode Island, USA

[7]Department of Mental Health, James A. Haley Veterans Hospital, Tampa, Florida, USA

[8]Department of Psychiatry and Behavioral Neurosciences, University of South Florida, Tampa, Florida, USA

[9]Department of Psychiatry, Geisel School of Medicine at Dartmouth, Dartmouth-Hitchcock Medical Center, Lebanon, New Hampshire, USA

[10]Department of Research, Center of Excellence in Substance Addiction Treatment and Education, Corporal Michael J. Crescenz VA Medical Center, Philadelphia, Pennsylvania, USA

[11]Center of Excellence in Substance Addiction Treatment and Education, VA Puget Sound Health Care System, Seattle, Washington, USA

[12]Department of Psychiatry & Behavioral Sciences, University of Washington, Seattle, Washington, USA

[13]Department of Clinical Psychology, California School of Professional Psychology at Alliant International University, San Diego, California, USA

Correspondence

Sonya Norman, University of California San Diego, 3350 La Jolla Village Drive, MC116B, San Diego, CA 92161, USA.
Email: snorman@ucsd.edu

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Abstract

Introduction: Trauma-related guilt is common, associated with posttraumatic mental health problems, and can persist after posttraumatic stress disorder (PTSD) treatment. We compared the efficacy of two six-session psychotherapies, Trauma-Informed Guilt Reduction (TrIGR) and Supportive Care Therapy (SCT), for reducing trauma-related guilt. TrIGR helps patients accurately appraise their role in the trauma and re-engage in values. In SCT, patients guide session content.

Methods: A total of 184 veterans seeking VA mental health services were enrolled across two sites; 145 veterans (mean age: 39.2 [8.1]; 92.4% male; 84.8% with PTSD) who endorsed guilt related to a traumatic event that occurred during a post 9/11

Trial Registration: ClinicalTrials.gov Identifier: NCT02512445

Iraq or Afghanistan deployment were randomized and assessed at baseline, post-treatment, 3- and 6-month follow-up.

Results: Linear mixed models using intent-to-treat analyses showed guilt decreased in both conditions with a greater decrease for TrIGR (treatment × time, −0.22; $F_{1,\ 455.2} = 18.49$, $p = .001$; $d = 0.92$) than supportive therapy. PTSD and depressive symptoms showed the same pattern. TrIGR had significantly higher likelihood of PTSD treatment response (67% vs. 40%), loss of PTSD diagnosis (50% vs. 14%), and meaningful change in depression (54% vs. 27%) than supportive therapy. Psychological distress and trait shame improved in both conditions. Quality of life did not change.

Conclusions: Targeting guilt appears to be an effective means for reducing posttraumatic symptoms and distress.

KEYWORDS
depression, PTSD, trauma, treatment

1 | INTRODUCTION

Feelings of guilt arise when trauma survivors blame themselves for their actions or inactions during a traumatic event (Kubany & Watson,). Trauma-related guilt is common (Miller et al., 2013) and has direct relationships with severity of posttraumatic stress disorder (PTSD), depression, psychological distress, suicidal ideation, poor psychosocial functioning, and feelings of shame (Bannister et al., 2019; Browne et al., 2015; Bryan et al., 2013; Marx et al., 2010; Norman et al., 2018; Pugh et al., 2015). While guilt can be a consequence of any trauma, studies indicate it is particularly common among treatment-seeking veterans, especially among those who served in warzones (Bannister et al., 2019; Browne et al., 2015; Norman et al., 2018; Pugh et al., 2015). In one study, 41% of trauma-exposed VA-enrolled veterans reported past-month guilt (Miller et al., 2013). This high prevalence may be because traumatic events that can cause moral injury (the painful emotional aftermath of experiences where one acted in ways that went against deeply held values) are common in the context of war, and moral injury is characterized by prominent guilt (Griffin et al., 2019; Litz et al., 2009; Williamson et al., 2021). In fact, researchers have noted the need for treatments for veterans that specifically target the moral impacts of war, including guilt (Steenkamp et al., 2015, 2020).

Multiple lines of research point to trauma-related guilt as a promising target for intervention. PTSD and other trauma-related disorders moved from anxiety disorders to "trauma and stressor-related disorders" between the fourth and fifth editions of the *Diagnostic and Statistical Manual* (DSM; American Psychiatric Association, 2013) in part to encourage research focused on common posttraumatic presentations other than those characterized by anxiety, such as those with prominent guilt (Friedman et al., 2011a, 2011b). Reduction in trauma-related guilt during PTSD treatment is associated with subsequent reduction in PTSD symptoms (Allard et al., 2018, Allard et al., 2021) suggesting that intervening on guilt may be a way to reduce posttraumatic symptoms and distress. Among those with PTSD, trauma-focused PTSD treatment such as Cognitive Processing Therapy (CPT) and Prolonged Exposure (PE) (both typically 12-sessions) can reduce trauma-related guilt (Allard et al., 2021; Capone et al., 2020; Nishith et al., 2005) However, trauma-related guilt is one of the symptoms likely to persist even when patients otherwise responded to PTSD treatment such as PE and CPT (Larsen et al., 2019; Owens et al., 2008) indicating a guilt-focused intervention may be warranted. In addition, for those with prominent guilt or guilt in the absence of a PTSD diagnosis, a brief transdiagnostic intervention aimed at reducing trauma-related guilt may be adequate for recovery and may engage those who do not want a full course of PTSD treatment. Finally, because guilt is a prominent feature of moral injury, a treatment focused on reducing trauma-related guilt may help to reduce moral injury.

The goal of this study was to conduct a preliminary efficacy trial to evaluate Trauma-Informed Guilt Reduction (TrIGR; Norman et al., 2014; Norman et al., 2019), a 6-session psychotherapy targeting trauma-related guilt, shame, and moral injury in U. S. veterans who endorsed guilt from a traumatic event on deployment during the Iraq or Afghanistan wars. Although TrIGR was designed to be applicable to guilt from any trauma type, we focused on veterans with deployment traumas in this first study because of the high prevalence of guilt in this population (e.g,. Miller et al., 2013). Our primary aim was to test the hypothesis that TrIGR would reduce guilt more than Supportive Care Therapy (SCT) at posttreatment, 3- and 6-month posttreatment follow-ups. SCT is a nondirective therapy in which patients determine session content. Secondary aims were to evaluate whether TrIGR showed greater reductions in symptoms of PTSD, depression, general psychological distress, trait shame, and quality of life (QoL) compared to SCT. PTSD and depression were selected as secondary outcomes because they are two of the most common posttraumatic mental health problems (Bryant et al., 2010; Rosellini et al., 2021) and are positively associated with guilt severity (Allard et al., 2021; Browne et al., 2015; Marx et al., 2010). Since guilt is a

transdiagnostic target related to posttraumatic distress in a number of forms, we also examined whether treatment was associated with change in general psychological distress and QoL.

2 | MATERIALS AND METHODS

2.1 | Design

This study was a two-site randomized clinical trial comparing two active treatments, TrIGR and SCT, for reducing trauma-related guilt. Methods are described below using CONSORT reporting criteria and published in a methods-focused article (Capone et al., 2021). The study procedures were reviewed and approved by the Institutional Review Boards at VA San Diego Healthcare System, Providence VA Medical Center, Brown University, and the Human Research Protections Office at the Department of Defense.

2.2 | Participants

Table 1 shows demographic characteristics. Participants were 145 veterans (92.4% male) seeking treatment from two large urban Veterans Affairs (VA) medical centers. Inclusion criteria were: (1) deployment in service of conflicts in Iraq and Afghanistan; (2) endorsing guilt from a traumatic event related to deployment as indicated by a score ≥2 ("true" to "extremely true") on at least one item measuring guilt severity or guilt cognitions on the Trauma-Related Guilt Inventory (TRGI; Kubany et al., 1996); (3) English literacy; (4) intention to stay in the local area during study participation; and (5) if meeting diagnostic criteria for mild or moderate substance use disorder (assessed using the Structured Clinical Interview for DSM [SCID]; First et al., 2002), willingness to set goals to reduce use. Exclusion criteria were acute suicide risk assessed using the Columbia-Suicide Severity Rating Scale (Posner et al., 2011), current severe substance use disorder assessed using the SCID, unmanaged psychosis or mania assessed using the SCID, and receiving concurrent trauma-focused PTSD treatment. Participants were allowed to engage in other treatment as usual, including psychotherapy and pharmacotherapy, and were allowed to have previously engaged in trauma-focused therapy if they currently met inclusion criteria. Exclusion criteria were minimal to increase generalizability of findings.

2.3 | Measures

Self-report and clinician-administered measures occurred at baseline, posttreatment, 3- and 6-month follow-up, unless otherwise specified. The primary outcome was severity of trauma-related guilt measured by the TRGI (Kubany et al., 1997), a well validated (Myers et al., 2012) questionnaire assessing trauma-related guilt stemming from an index event. There were several secondary outcomes. PTSD symptoms were assessed using the Clinician-Administered PTSD Scale for DSM-5 (CAPS-5; Weathers et al., 2018). To determine presence of PTSD and PTSD severity, the interview was conducted on each participant's worst trauma as instructed by the CAPS-5. In 91% of cases (n = 132), the trauma on which the CAPS-5 was conducted was also the source of guilt. Interrater reliability, conducted on 8% of randomly selected CAPS-5s, was excellent (κ = 0.87). Depression symptoms were assessed using the Patient Health Questionnaire (PHQ-9; Kroenke et al., 2001). Psychological distress was measured using the Global Severity Index of the Brief Symptom Inventory (BSI-18; Derogatis, 2001) Trait shame was measured using the internalized shame subscale of the Internalized Shame Scale (Cook, 1987). The abbreviated version of the World Health Organization Quality of Life measure (WHO-QOL-BREF) assessed physical health, psychological health, social relationships, and environment (Skevington et al., 2004). Exposure to potentially morally-injurious military events was measured at baseline using the Moral Injury Events Scale (MIES; Nash et al., 2013).

2.4 | Procedures

Participants were recruited through clinician and self-referral from June 2016 to March 2020. Advertisements asked if Veterans had deployed in service of the conflicts in Iraq or Afghanistan and had guilt or regret from deployment experiences. Following a phone screen, participants were enrolled by a study coordinator, provided written informed consent, and completed a baseline assessment with one of the five independent evaluators who worked on the study to assess eligibility. In the consent it was explained to participants that they would be randomized to an intervention that had more structure or one was a more open-ended approach to addressing trauma-related guilt. Participants then met with a study therapist to learn more about the study and treatment process and ask any remaining questions. Participants who opted to proceed were individually randomized by a study statistician using masked allocation and balanced blocks of four or six, stratified by site and gender. Randomization occurred before the first therapy session. Participants were informed of their condition at their first session. Participants engaged in six sessions of TrIGR or SCT and completed follow-up assessments with an independent evaluator blind to treatment condition at posttreatment, 3- and 6-month follow-ups. Compensation was $40 at each assessment. No participants were discharged from the study due to serious adverse events.

2.5 | Treatments

TrIGR and SCT were each delivered in six 90-min individual weekly sessions. One additional off protocol session was allowed during treatment. TrIGR is a cognitive-behavioral intervention to reduce trauma-related guilt and shame, and distress from moral injury (Norman et al., 2014; Norman et al., 2019). It is based on the Nonadaptive Guilt and Shame (NAGS) model (Norman et al., 2014,

TABLE 1 Demographic characteristics of the intention-to-treat sample[a]

Characteristics	Total (*n* = 145)	TrIGR (*n* = 74)	SCT (*n* = 71)
Age, mean (*SD*)	39.2 (8.1)	38.0 (7.6)	40.5 (8.5)
Sex			
Men	134 (92.4)	68 (91.9)	66 (93.0)
Women	9 (6.2)	5 (6.8)	4 (5.6)
Marital status			
Not married	72 (49.7)	41 (55.4)	31 (43.7)
Married	67 (46.2)	30 (40.5)	37 (52.1)
Education			
High school/GED	19 (13.1)	8 (10.8)	11 (15.5)
Some college	52 (35.9)	30 (40.5)	22 (31.0)
Associates degree or higher	73 (50.3)	36 (48.6)	37 (52.1)
Ethnicity			
Hispanic	32 (22.1)	17 (23.0)	15 (21.1)
Non-Hispanic	93 (64.1)	49 (66.2)	44 (62.0)
Race			
White	92 (63.4)	49 (66.2)	43 (60.6)
Black	13 (9.0)	6 (8.1)	7 (9.9)
Asian/Pacific Islander	13 (9.0)	4 (5.4)	9 (12.7)
Biracial/multiracial	8 (5.5)	6 (8.1)	2 (2.8)
Other	15 (10.3)	7 (9.5)	8 (11.3)
Lifetime trauma exposure, mean (SD), No. of types[b]	11.4 (2.8)	11.5 (2.8)	11.3 (2.8)
Event type			
Combat trauma	137 (94.5)	70 (94.6)	67 (94.4)
Sexual trauma	46 (31.7)	21 (28.4)	25 (35.2)
Physical assault	122 (84.1)	65 (87.8)	57 (80.3)
Disaster exposure	109 (75.2)	51 (68.9)	58 (81.7)
Serious accident	104 (71.7)	56 (75.7)	48 (67.6)
Life-threatening illness or injury	83 (57.2)	43 (58.1)	40 (56.3)
Taking psychotropic medication[c]	100 (69.0)	51 (68.9)	49 (69.0)
Previous participation in PE or CPT	70 (48.3)	36 (48.6)	34 (47.9)
Baseline assessment scores, mean (*SD*)[d]			
Trauma-related guilt severity (TRGI)	2.5 (0.7)	2.5 (0.6)	2.5 (0.7)
Interviewer-rated PTSD severity (CAPS-5)	38.4 (9.5)	38.2 (9.5)	38.6 (9.5)
Depressive symptom severity (PHQ-9)	14.7 (6.3)	15.1 (6.5)	14.3 (6.1)
Psychological distress (BSI-18)	53.3 (9.4)	53.1 (9.4)	53.5 (9.5)
Trait shame severity (ISS)	50.5 (21.9)	51.5 (22.3)	49.5 (21.6)
Physical health (WHOQOL-BREF)	49.1 (17.6)	49.0 (16.9)	49.3 (18.3)
Psychological health (WHOQOL-BREF)	44.1 (13.0)	43.7 (13.3)	44.5 (12.8)
Social relationships (WHOQOL-BREF)	40.3 (23.3)	41.1 (21.9)	39.6 (24.8)
Environment (WHOQOL-BREF)	57.5 (17.0)	57.5 (16.7)	57.4 (17.5)

TABLE 1 (Continued)

Characteristics	Total (n = 145)	TrIGR (n = 74)	SCT (n = 71)
Current PTSD diagnosis (CAPS-5)	123 (84.8)	63 (85.1)	60 (84.5)
Moral injury severity (MIES)	4.08 (1.36)	4.03 (1.31)	4.13 (1.42)
No. of sessions attended out of six, mean (*SD*)	5.3 (1.7)	5.3 (1.6)	5.3 (1.8)
No. participants who had an off-protocol session[e]	13 (8.9)	12 (16.2)	1 (1.4)

Abbreviations: BSI-18, Brief Symptom Inventory–18; CAPS-5, Clinician Administered PTSD Scale for DSM-5; CPT, Cognitive Processing Therapy; ISS, Internalized Shame Scale; MIES, Moral Injury Events Scale; PE, Prolonged Exposure; PHQ-9, Patient Health Questionnaire-9; PTSD, posttraumatic stress disorder; SCT, supportive counseling therapy; TRGI, Trauma-Related Guilt Inventory; TrIGR, trauma-informed guilt reduction therapy; WHOQOL-BREF, the abbreviated version of the World Health Organization Quality of Life measure.

[a]Data are expressed as No. (%) unless otherwise indicated. Numbers reflect percentages out of full sample.

[b]Trauma exposure assessed by the Life Events Checklist for DSM-5 (LEC-5). Responses endorsing "witnessed it" or "happened to me" were coded as trauma exposure for that trauma type.

[c]Of the 100 participants who reported taking a psychotropic medication, 43% were on antidepressants, 16% on sleep medication, 15% on mood stabilizers, 8% on anti-anxiety medication, 7% on antipsychotics; 11% reported that they were on a psychotropic but did not report which medication.

[d]For descriptions of score ranges, see Section 2 of the text.

[e]Since participants in SCT decided what would be discussed in session, off protocol sessions were generally not needed to address emergent issues.

Norman et al., 2019), which postulates that guilt can be adaptive when it helps shape one's actions to be more prosocial and values-driven, but becomes nonadaptive when distress is taken as evidence of wrongdoing and leads to avoidance of thinking about the traumatic event. Shame develops when trauma survivors negatively judge not just their actions ("I did something bad") but their entire selves ("I am bad") for their role in the trauma (Haller et al., 2020; Norman et al., 2014; Pugh et al., 2015). This cycle results in common cognitive errors that serve to maintain guilt, shame, and distress indefinitely and is thought to contribute to greater severity of psychopathology.

Sessions 1 and 2 included an overview of the NAGS model and discussion of common sources of trauma-related guilt. Sessions 3 and 4 utilized cognitive restructuring to help participants evaluate four types of cognitions (e.g., hindsight bias) that have been identified in prior research as contributing to posttraumatic guilt (Kubany et al., 1995). Therapists helped participants identify the function guilt has served in expressing important values (e.g., It is how I honor the memory of someone who died, If I didn't feel bad then I would really be a monster). Sessions 5 and 6 focused on identifying adaptive ways to express values other than through guilt, as well as setting realistic goals consistent with important values. TrIGR does not try to convince patients their guilt is inaccurate or that the trauma was not their fault. Rather, the goal is to help people put their actions during a traumatic event into context and help them move toward expressing values in a more positive way marked by less impairment and suffering.

SCT (Walters et al., 2020) is a present-centered, nondirective therapy based on Present Centered Therapy (PCT; Belsher et al., 2019) that excludes the problem solving component and daily diary included in PCT. SCT emphasizes principles of unconditional positive regard, genuineness, and empathic understanding. The first session includes psychoeducation about trauma-related guilt and common reactions. Subsequently, participants are free to choose the content of each session. Participants can discuss guilt and trauma if they choose and therapists respond to this content as they would any other content area—with an open, nonjudgmental stance and unconditional positive regard. We selected SCT as the comparison intervention, because as is recommended for early stage II efficacy trials (Edmond et al., 2018; Guidi et al., 2018; Onken et al., 2014; Schnurr et al., 2005), it would provide a credible therapeutic comparison to control for the nonspecific aspects that characterize most therapy. SCT has been used as a control condition in previous psychosocial interventions trials, including with veterans (e.g., Walters et al., 2020).

Study therapists were 21 licensed psychologists, postdoctoral fellows, and doctoral students who were trained in therapy protocols through didactics, videos, and practice sessions. They received weekly supervision. Ten percent of sessions were randomly selected for fidelity rating. Scores ≥5 indicated strong adherence (1 = 0% of the time, 7 = >90% of the time) and competence (1 = very poor, 7 = excellent). TrIGR (adherence: M = 6.41, SD = 1.00; competence: M = 5.85, SD = 1.13) and SCT (adherence: M = 6.61, SD = 0.97; competence: M = 5.83, SD = 1.19) both showed strong fidelity ratings.

2.6 | Statistical analysis plan

Power analysis based on guilt determined 59 participants per group would provide 80% power to detect a medium standardized effect size with a two-tailed test and alpha at .05. A target total sample of 142 allowed for 17% study attrition.

To test the prespecified primary outcome of change in trauma-related guilt severity, an initial linear mixed model assessed TRGI change between baseline and 6-month follow-up (i.e., baseline to 8 months later) between treatment conditions. Subsequent LMMs analyzed guilt, PTSD, depression, trait shame, QoL total scores and

psychological distress T-scores at baseline, posttreatment, 3- and 6-month follow-up, using SPSS version 26. These models allowed for an intent-to-treat approach where all available data from randomized participants were included to estimate unbiased parameter estimates under the missing at random assumption. Treatment condition, time, and their interaction were treated as fixed effects, and the intercept was specified as a random effect to account for the repeated observations within participants. Analyses were conducted using an identity covariance matrix for the random effects and an autoregressive covariance matrix for the repeated effect of time. Between-group effect sizes (Cohen's *d*) were calculated for the 6-month follow-up visit using the model-based estimated marginal means from the 6-month follow-up visit and variance of all randomized participants at baseline.

Using available data at 6-month follow-up, we compared treatment conditions on PTSD *treatment response* (defined as ≥10-point improvement in severity on the CAPS-5) (Schnurr et al., 2015). For the subset of patients meeting diagnostic criteria for PTSD at baseline ($n = 124$), we compared *loss of diagnosis* (defined as PTSD treatment response, plus no longer meeting DSM-5 symptom criteria and severity <25 on the CAPS-5; Schnurr et al., 2015) and *remission* (defined as loss of diagnosis plus severity <12 on the CAPS-5; Norman et al., 2019). For those with mild or higher depression scores (>5 on the PHQ-9; Löwe et al., 2004; McMillan et al., 2010) at baseline ($n = 138$), we compared *clinically meaningful change in depression* (defined as a ≥5-point reduction on the PHQ-9; Löwe et al., 2004; McMillan et al., 2010).

3 | RESULTS

Figure 1 shows the Consort Diagram; 184 Veterans were enrolled with 145 ultimately randomized. TrIGR and SCT did not statistically differ on background variables or baseline measures of the primary outcomes (Table 1). Mean number of sessions attended [TrIGR $M = 5.3$, $SD = 1.6$; SCT $M = 5.3$, $SD = 1.8$), $t(143) = 0.15$, $p = .88$] and rates of treatment completion, a priori designated as attendance of 4+ on protocol sessions, [TrIGR $n = 63$; 85.1%; SCT $n = 61$; 85.9%), $\chi^2(1, N = 145) = 0.02$, $p = .90$], did not differ between conditions.

TrIGR showed greater change in guilt than SCT between baseline and 6-month follow-up (treatment × time interaction = −0.63, 95% confidence interval [CI]: −0.89, −0.37, $F(1, 117.9) = 22.4$, $p < .001$;

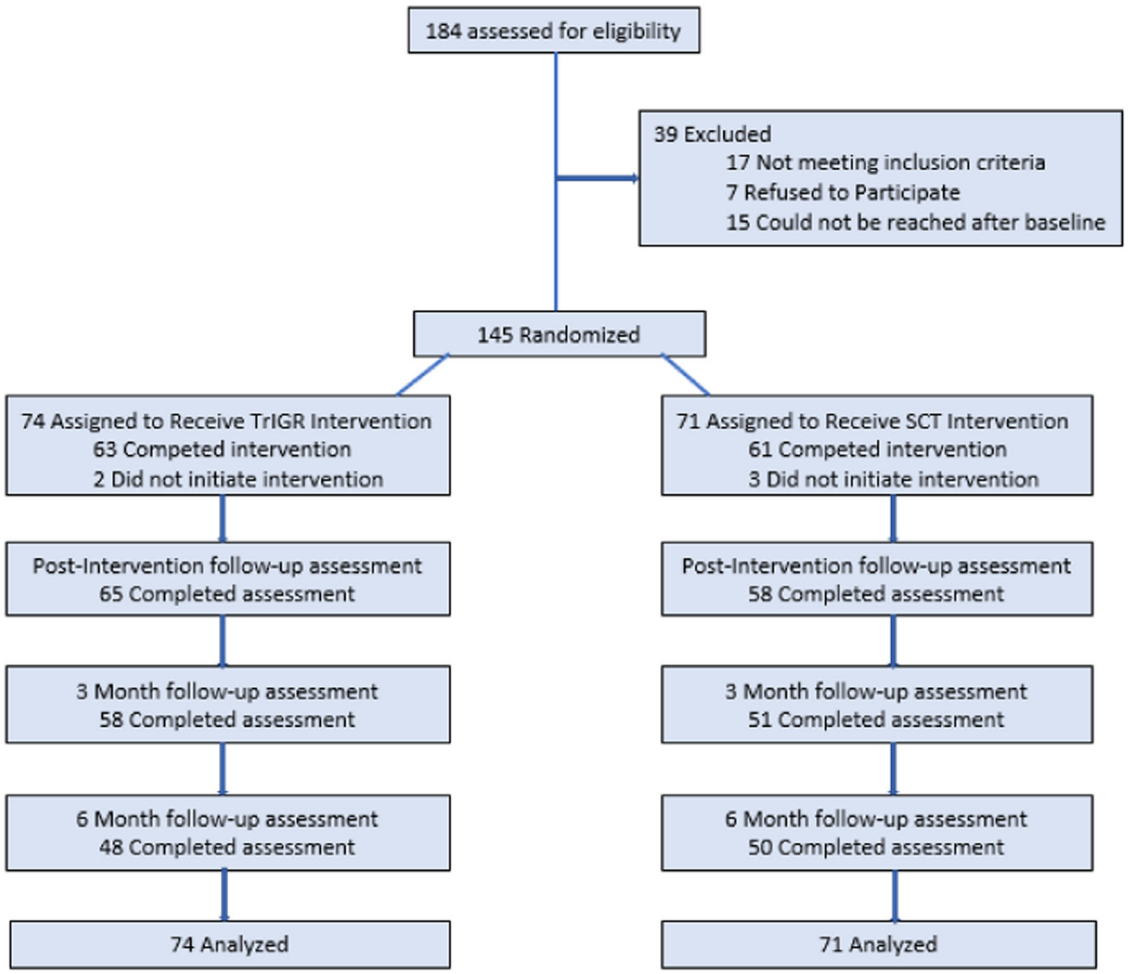

FIGURE 1 Consort Flow Diagram. SCT, supportive care therapy; TrIGR, trauma-informed guilt reduction therapy

$d = 0.99$). The estimated marginal means (and 95% CIs) from the mixed models for outcomes overall time points are shown in Table 2. Guilt scores decreased in both conditions, with a significantly greater decrease for TrIGR (treatment × time, −0.22; $F(1, 455.2) = 18.49$, $p = .001$; $d = 0.92$) (Figure 2). PTSD symptom severity showed the same pattern of results (treatment × time, −2.26; $F(1, 468.3) = 6.76$, $p = .010$; $d = 0.81$), as did depression (treatment × time, −1.28; $F(1, 454.6) = 7.51$, $p = .006$; $d = 0.43$) (Figure 2). Psychological distress and trait shame decreased significantly, but these changes were not statistically different between conditions. There were no significant treatment, time, or treatment × time interaction effects for any of the QoL domains (physical health, psychological health, social relationships, or environment).

Between baseline and 6-month follow-up, TrIGR had significantly higher likelihood than SCT of PTSD treatment response (67% vs. 40%), loss of PTSD diagnosis (50% vs. 14%), and clinically meaningful change in depression (54% vs. 27%). Treatment conditions did not differ statistically on rates of PTSD remission (Figure 3).

4 | DISCUSSION

We evaluated whether TrIGR, a relatively brief intervention targeting trauma-related guilt, would reduce guilt, PTSD and depression symptoms, general psychological distress, trait shame, and QoL in a sample of military veterans. Consistent with our hypotheses, veterans who received TrIGR showed greater reduction in guilt and PTSD symptoms (with a large between-group effect size) and depression (with a moderate effect size) than veterans who received supportive therapy. As seen in Figure 3, we saw greater reductions in guilt for TrIGR compared to SCT by the end of treatment, while differences in PTSD and depression symptoms between treatments grew larger over the follow-up time points. This pattern is consistent with the NAGS model which presupposes that as guilt reduces so does avoidance and that as people engage in more valued activities, decreased avoidance and increased behavioral activation may also contribute to symptom reduction (Norman et al., 2014).

While a PTSD diagnosis was not a requirement, most of the sample (84.8%) met criteria for PTSD. Half of participants in TrIGR with PTSD lost their PTSD diagnosis and more than two-thirds showed clinically meaningful response. Among those who endorsed moderate or higher depressive symptoms at baseline, more than half had clinically meaningful change. These findings are notable given that TrIGR focuses primarily on trauma-related guilt, not PTSD or depression broadly. We considered whether these findings may be because more people who received TrIGR went on to other evidence-based PTSD treatment available at the study sites during the trial (specifically, these were PE or CPT) in the follow-up period, but did not find significant differences (four people in TrIGR and five people in SCT went on to PE or CPT during follow-up). Results suggest that for many with PTSD who report trauma-related guilt, addressing the guilt can lead to meaningful improvements in PTSD and depression as well.

TABLE 2 Prespecified study outcomes at all assessment time points

Outcome and time point	Marginal mean from linear mixed models (95% CI) TrIGR	SCT
Guilt severity (TRGI)[a]		
Baseline	2.5 (2.3–2.7)	2.5 (2.3–2.7)
After treatment	1.7 (1.5–1.9)	2.3 (2.1–2.5)
3-month follow-up	1.6 (1.4–1.8)	2.2 (2.1–2.4)
6-month follow-up	1.6 (1.4–1.8)	2.2 (1.9–2.4)
PTSD severity (CAPS-5)[b]		
Baseline	38.2 (35.5–40.9)	38.6 (35.9–41.4)
After treatment	29.4 (26.6–32.2)	32.6 (29.7–35.6)
3-month follow-up	27.6 (24.6–30.5)	31.7 (28.7–34.8)
6-month follow-up	23.3 (20.2–26.4)	30.9 (27.9–34.0)
Depressive symptom severity (PHQ-9)[c]		
Baseline	15.1 (13.6–16.6)	14.4 (12.9–15.9)
After treatment	11.4 (9.8–12.9)	13.6 (12.0–15.2)
3-month follow-up	10.9 (9.3–12.5)	13.0 (11.3–14.7)
6-month follow-up	9.8 (8.0–11.5)	12.5 (10.8–14.2)
Psychological distress (BSI-18)[d]		
Baseline	53.1 (50.9–5.3)	54.0 (51.7–56.3)
After treatment	48.5 (46.2–50.8)	50.3 (47.9–52.7)
3-month follow-up	47.8 (45.4–50.1)	52.3 (49.9–54.8)
6-month follow-up	47.3 (44.8–49.9)	49.0 (46.5–51.6)
Trait shame severity (ISS)[e]		
Baseline	51.4 (46.3–56.6)	49.6 (44.3–54.8)
After treatment	39.2 (33.9–44.4)	43.7 (38.2–49.1)
3-month follow-up	37.9 (32.4–43.3)	43.9 (38.3–49.6)
6-month follow-up	37.4 (31.6–43.1)	41.9 (36.1–47.7)
Physical health (WHOQOL-BREF)[f]		
Baseline	49.0 (44.8–53.3)	49.2 (44.9–53.6)
After treatment	54.2 (49.8–58.6)	51.8 (47.2–56.3)
3-month follow-up	53.9 (49.4–58.5)	48.1 (43.3–52.8)
6-month follow-up	53.9 (49.1–58.8)	49.4 (44.5–54.2)
Psychological health(WHOQOL-BREF)[g]		
Baseline	43.7 (40.5–46.9)	44.5 (41.3–47.8)
After treatment	47.2 (43.9–50.6)	47.4 (43.9–50.8)
3-month follow-up	46.8 (43.4–50.2)	46.6 (42.9–50.2)
6-month follow-up	48.3 (44.6–51.9)	44.4 (40.7–48.0)
Social relationships (WHOQOL-BREF)[h]		
Baseline	41.1 (35.7–46.5)	39.6 (34.0–45.1)
After treatment	44.5 (38.8–50.1)	41.1 (35.3–46.8)

(Continues)

TABLE 2 (Continued)

Outcome and time point	Marginal mean from linear mixed models (95% CI)	
	TrIGR	SCT
3-month follow-up	47.5 (41.7–53.2)	38.9 (32.9–45.1)
6-month follow-up	45.9 (39.9–52.1)	37.9 (31.9–44.1)
Environment (WHOQOL-BREF)[i]		
Baseline	57.5 (53.6–61.5)	57.4 (53.3–61.4)
After treatment	61.5 (57.3–65.6)	56.7 (52.4–60.9)
3-month follow-up	61.6 (57.4–65.9)	57.9 (53.3–62.4)
6-month follow-up	62.2 (57.6–66.7)	55.5 (50.9–59.9)

Note: Time is coded 0 = Baseline, 1 = After treatment, 2 = 3-month follow-up, 3 = 6-month follow-up.

Abbreviations: BSI-18, Brief Symptom Inventory–18; CAPS-5, Clinician Administered PTSD Scale for DSM-5; CI, confidence interval; CPT, Cognitive Processing Therapy; ISS, Internalized Shame Scale; MIES, Moral Injury Events Scale; PE, Prolonged Exposure; PHQ-9, Patient Health Questionnaire-9; PTSD, posttraumatic stress disorder; SCT, supportive counseling therapy; TRGI, Trauma-Related Guilt Inventory; TrIGR, trauma-informed guilt reduction therapy; WHOQOL-BREF, the abbreviated version of the World Health Organization Quality of Life measure.

[a]Slope = −0.12 (95% CI: −0.19 to −0.05); group × time interaction = −0.22 (95% CI: −0.32 to −0.12).

[b]Slope = −2.75 (95% CI: −3.96 to −1.53); group × time interaction = −2.26 (95% CI: −3.97 to −0.55).

[c]Slope = −0.65 (95% CI: −1.30 to 0.01); group × time interaction = −1.28 (95% CI: −2.21 to −0.36).

[d]Slope = −1.59 (95% CI: −2.56 to −0.62); group × time interaction = −0.63 (95% CI: −1.98 to 0.72).

[e]Slope = −2.88 (95% CI: −4.99 to −0.78); group × time interaction = −2.54 (95% CI: −5.49 to 0.40).

[f]Slope = 0.27 (95% CI: −1.48 to 2.01); group × time interaction = 1.78 (95% CI: −0.68 to 4.23).

[g]Slope = 0.20 (95% CI: −1.19 to 1.59); group × time interaction = 1.50 (95% CI: −0.45 to 3.46).

[h]Slope = −0.46 (95% CI: −2.70 to 1.78); group × time interaction = 2.75 (95% CI: −0.40 to 5.91).

[i]Slope = −0.26 (95% CI: −2.05 to 1.53); group × time interaction = 2.32 (95% CI: −0.20 to 4.85).

Reductions in overall psychological distress and trait shame did not differ by treatment condition. It is possible that both interventions are comparable at reducing these or that more time is needed to see downstream differences in the interventions. In the case of the BSI-18, baseline T-scores in our sample were in the normal range ($M = 53.3$, psychological distress is considered ≥63; Derogatis, 2001), which suggests that the BSI did not capture the type of distress participants were experiencing. PTSD and other trauma-related disorders were removed from anxiety disorders between DSM-IV and DSM-5 because of recognition that there were phenotypes of posttraumatic distress not characterized by prominent anxiety. Our findings of a distressed sample with high guilt but normal range BSI-18 scores lend support to this notion.

At the time we planned this study, a measure of trauma-related shame was not yet available (there is one now, Øktedalen et al., 2014, which we added mid-way through the study). Thus, we selected a well-validated scale of trait shame to examine shame in some form (Cook, 1987; Rybak & Brown, 1996). Trait shame, however, is likely not caused by trauma and likely not sensitive to trauma-focused intervention. In fact, trait shame may be a moderator of trauma-related shame, possibly contributing to severity or impacting treatment response.

QoL did not change significantly in the trial. How to interpret this is challenging because there has been limited use of the WHO-QOL-BREF in PTSD treatment research (Fortin et al., 2021). It is possible neither intervention improved QoL, more time is needed to see improvement in QoL, or that the WHO-QOL-BREF did not capture change that occurred.

Attendance in both conditions was high (over 5 of 6 sessions), which is notable in a sample of post-9/11 veterans, a demographic group known to be challenging to retain in psychotherapy (Erbes et al., 2009; Goetter et al., 2015; Mott et al., 2014). The focus on guilt may have contributed to high attendance if it was seen by participants as highly relevant to their experiences. Another possibility is that the brevity of the intervention contributed to low dropout. Written Exposure Therapy, a PTSD intervention of similar length, has similarly high attendance rates (Sloan et al., 2018). If patients find it easier to complete a shorter intervention, length may be an important factor for investigators to consider when developing new interventions.

Over the past decade the concept of moral injury has garnered a great deal of interest and attention. Guilt is considered a prominent feature of moral injury (Griffin et al., 2019; Litz et al., 2009; Williamson et al., 2021). The high mean MIES scores show that the study drew a sample high in exposure to moral injury. Unfortunately, validated measures of change in moral injury are not yet available, thus we were not able to examine in this study if TrIGR is effective in reducing moral injury. Such measures are under development so that future studies will be able to examine if TrIGR is effective in reducing moral injury.

Limitations include a homogenous sample of predominantly male, non-Hispanic, majority white (63%) veterans with deployment traumas, which may limit generalizability of the findings to more diverse and nonveteran populations and other trauma types. In addition to reducing trauma-related guilt, TrIGR is intended to reduce trauma-related shame and distress from moral injury (Haller et al., 2020; Norman et al., 2014; Norman et al., 2019) Unfortunately, validated assessments sensitive to measuring change in these constructs were not available when we planned the study and, as a result, we did not assess TrIGR's efficacy in regard to these. Many participants (48.3%) reported previous receiving PE or CPT. However, we did not collect information about how long ago participants received these therapies, whether they completed them, or if they received any other evidence-based psychotherapies for PTSD. While reengaging in valued activities is proposed to be an important component of TrIGR, whether participants reengaged in

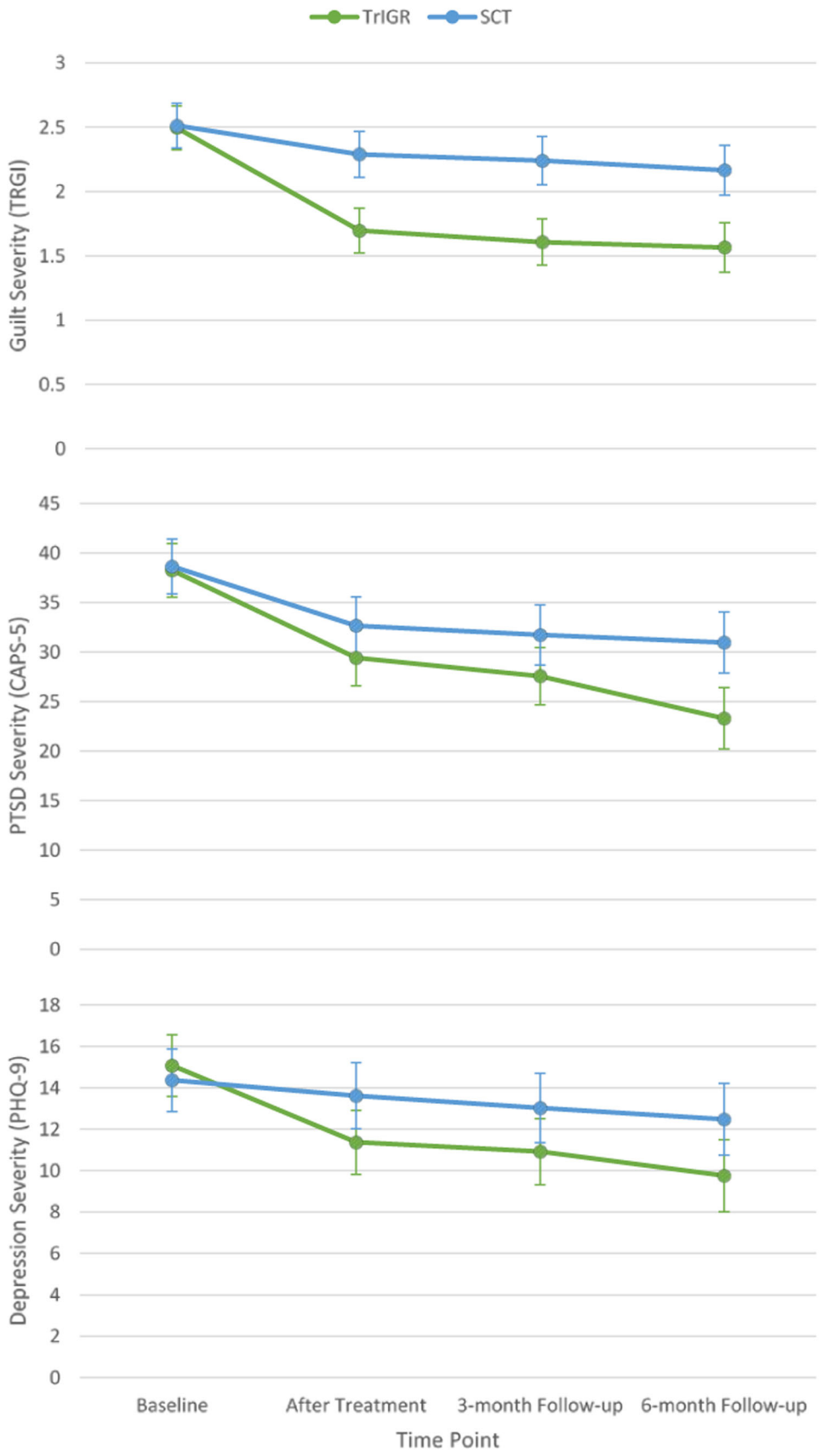

FIGURE 2 (See caption on next page)

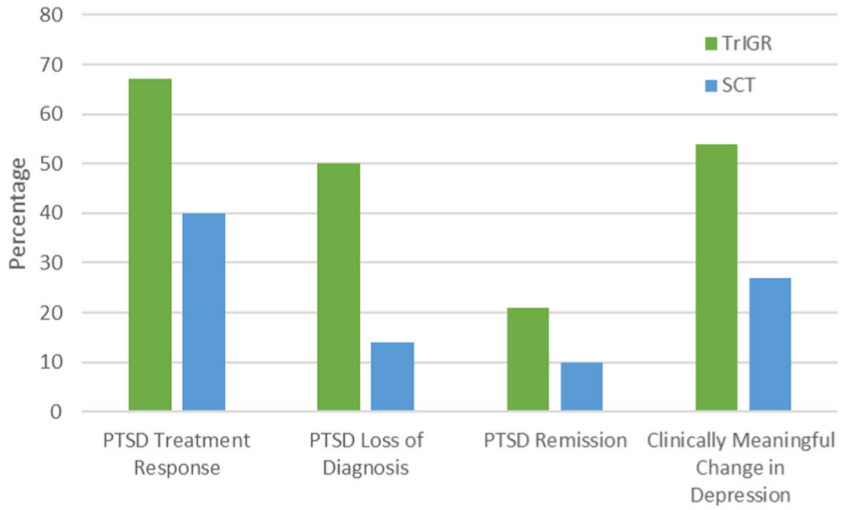

FIGURE 3 Percentage of treatment response, loss of diagnosis, and remission in PTSD and clinically meaningful change in depression by treatment condition at the 6-month follow-up visit. Between baseline and 6-month follow-up, TrIGR had significantly higher likelihood relative to SCT of *PTSD treatment response* (odds ratio [OR] [95% confidence interval {CI}] = 3.00 [1.32–6.84], $p = .015$), l*oss of PTSD diagnosis* (OR [95% CI] = 6.21 [2.23–17.29], $p = .001$), and *clinically meaningful change in depression* (OR [95% CI] = 3.05 [1.27–7.34], $p = .023$). Treatments did not differ on rates of *PTSD remission* (OR [95% CI] = 3.03 [0.88–10.42], $p = .259$). PTSD, posttraumatic stress disorder; SCT, supportive counseling therapy; TrIGR, trauma-informed guilt reduction therapy

values was not assessed. Measuring reengagement in values and related behavior change is important for future studies.

5 | CONCLUSION

Trauma-related guilt is common, associated with greater severity of mental health symptoms, impairment, and distress, and can be challenging to treat. Veterans in particular have documented vulnerability to experiencing guilt and related problems. Our results suggest TrIGR can add value to existing treatments options because it targets a highly prevalent source of distress that may persist even after successful PTSD treatment, can be used to treat posttraumatic mental health problems even when a PTSD diagnosis is not present, and has high attendance and completion rates. Additional research is needed to understand for whom TrIGR is most effective and when in regard to other treatment options. Future studies that include nonveterans and guilt from any trauma types will help to understand the broader efficacy of TrIGR. A broad implication of this study is that targeting a prominent symptom presentation, such as one characterized by guilt, can be an effective method to reduce posttraumatic symptoms and distress. This study further raises questions about when it may be most effective to target a prominent symptom presentation such as guilt versus targeting a diagnosis such as PTSD. Comparing TrIGR to an effective PTSD treatment for those with a prominent guilt presentation would help to answer this question.

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DATA AVAILABILITY STATEMENT

Data is not available.

PEER REVIEW

The peer review history for this article is available at https://publons.com/publon/10.1002/da.23244

FIGURE 2 Guilt, posttraumatic stress disorder, and depression symptom severity estimated marginal means by treatment condition at each time point. Error bars indicate 95% CIs. CAPS-5, Clinician Administered PTSD Scale for DSM-5; CI, confidence interval; PHQ-9, Patient Health Questionnaire; PTSD, posttraumatic stress disorder; SCT, supportive counseling therapy; TRGI, Trauma-Related Guilt Inventory; TrIGR, trauma-informed guilt reduction therapy

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Understanding and Addressing Mental Health Reactions to a Global Pandemic

Jinhee Hyun, PhD
Nicole Nugent, PhD
Erika Felix, PhD
Sonya Norman, PhD

Talks

- Jinhee Hyun – Population level data measured quarterly throughout 2022 on prevalence of PTSD, depression and suicidal thoughts in South Korea

- Nicole Nugent - Prevalence of PTSD and ways of seeking support before and during the pandemic among adolescents recruited from an emergency department following a potentially traumatic event

Talks

- Erika Felix – Findings from a needs assessment of teachers' experiences during the pandemic and a training to help administrators respond to teachers' needs

- Sonya Norman - Results of a pilot randomized controlled trial of treating guilt and related distress stemming from traumatic or potentially morally injurious pandemic experiences

A Pilot Randomized Trial to Address Guilt and Moral Injury Resulting from Pandemic-Related Events

Sonya Norman, PhD

PTSD Consultation Program Director, National Center for PTSD

Professor, UCSD School of Medicine

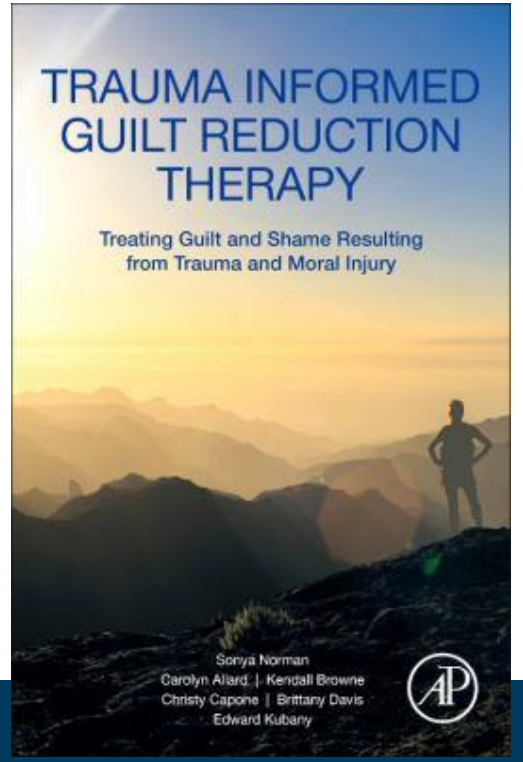
A Pilot Randomized Trial to Address Guilt and Moral Injury Resulting from Pandemic-Related Events

Sonya B. Norman
Christy Capone
Jennifer S. Wachen
Brittany C. Davis
M. Tracie Shea
Moira Haller
Tara E. Galovski
Paula P. Schnurr
Kaitlyn E. Panza
Michelle Pitts
Matthew Luciano

PTSD Consultation Program
FOR PROVIDERS WHO TREAT VETERANS

Disclosure of Conflict of Interest

- I am an author of a book about the intervention to be discussed today. I receive royalties from the book.



Guilt and Moral Injury Can Result From a Range of Traumas

- Guilt is deep regret and distress about an action ("I did something bad") that can also lead to shame ("I am bad")

- Guilt is a core component of moral injury (the lasting pain that can result from perpetrating, not preventing, or witnessing actions that go against deeply held values)

- Guilt and moral injury can result from a variety of traumatic events or morally injurious experiences

Examples of Combat Sources of Guilt or Potentially Morally Injurious Events

- Killing or harming others
- Feeling nothing or exhilaration
- Surviving
- Failing to perform a duty
- Witnessing a harmful act
- Failing to act or report
- Making decisions that affect survival of others

Guilt, Moral Injury & Trauma

- Can exacerbate posttraumatic distress
- Persists without treatment
- Related to PTSD treatment outcomes

Guilt, Moral Injury & Mental Health Problems

- Posttraumatic Stress Disorder (PTSD)
- Depression
    - Mediates relationship between combat exposure and these disorders
- Alcohol and substance use
    - Even when controlling for PTSD and MDD sx
- Suicidal ideation
    - Above and beyond symptoms of PTSD and depression

Posttraumatic Guilt is a potential target to intervene on moral injury, PTSD, depression

- A way to target a core component of moral injury
- Way to target a symptom associated with multiple forms of mental health problems
- Mixed results regarding guilt with existing PTSD treatments
- Not usually targeted in depression treatment

Trauma Informed Guilt Reduction (TrIGR) Protocol

Norman, Allard, Browne, Capone, Davis, Kubany

Module 1. Overview and Psychoeducation

- Introduction of how guilt and shame are associated with mental health post-trauma
- Different types of non-adaptive trauma-related guilt

Module 2. Understanding the Client's Guilt & Shame

- What are some things you feel guilty about?
  - I should have known better
  - I should/shouldn't have…

Module 2. Guilt & Shame Appraisal

- Evaluate:

1. Foreseeability and Preventability
2. Justification
3. Responsibility
4. Wrongdoing

Module 3. Values

- What would it mean to go on with life feeling less guilty?
- Guilt serves a function to identify values
- Identify values in a number of domains
- Set short- and long-term goals that map on to values
    - Trouble shoot
    - Optional: Making Amends/Reparative action

DOI: 10.1002/da.23244

RESEARCH ARTICLE

ANXIETY AND DEPRESSION ASSOCIATION OF AMERICA WILEY

A clinical trial comparing trauma-informed guilt reduction therapy (TrIGR), a brief intervention for trauma-related guilt, to supportive care therapy

Sonya B. Norman[1,2,3,4] | Christy Capone[5,6] | Kaitlyn E. Panza[2,4] | Moira Haller[2,4] | Brittany C. Davis[7,8] | Paula P. Schnurr[1,9] | M. Tracie Shea[5,6] | Kendall Browne[10,11,12] | Gregory J. Norman[4] | Ariel J. Lang[2,3,4] | Alexander C. Kline[2,4] | Shahrokh Golshan[2,4] | Carolyn B. Allard[2,13] | Abigail Angkaw[2,4]

AIMS

- To evaluate the efficacy of TrIGR for reducing trauma-related guilt

- To evaluate the efficacy of TrIGR for reducing PTSD and depression symptoms

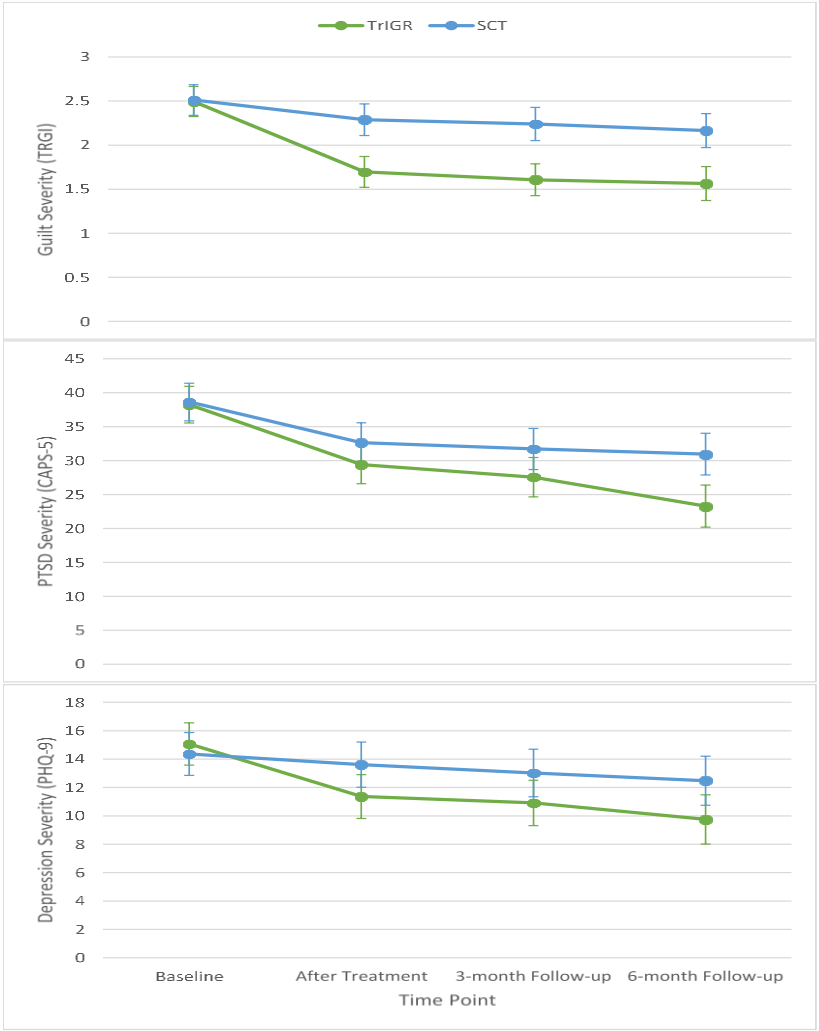
Participants and procedures

- 145 U.S. veterans
- Endorsed trauma-related guilt from an event while deployed as part of OIF/OEF/OND
- PTSD diagnosis not required

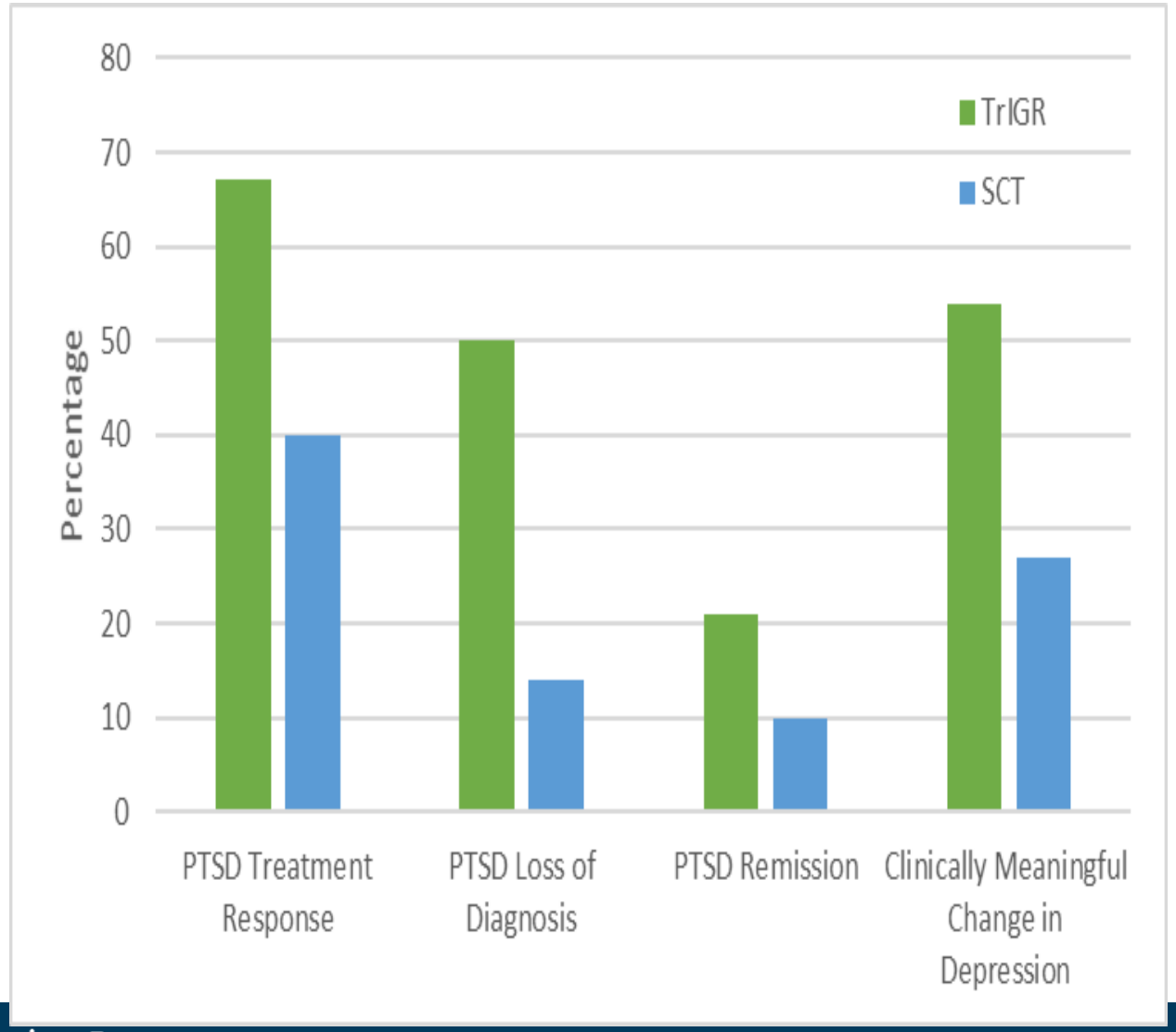
Characteristic	*M* (SD) or *n* (%)
Age	39.2 (8.1)
Male	136 (93.8)
Married	64 (45.8)
College graduate	74 (51.0)
Hispanic Ethnicity	33 (23.6)
Caucasian Race	92 (63.4)
% combat exposure	137 (94.5)
PTSD severity (CAPS-5)	38.4 (9.5)
% PTSD diagnosis	124 (85.5)
# sessions attended (out of 6)	5.3 (1.7)

Full study procedures and exclusion/inclusion criteria in Capone et al., 2021

Results


TrIGR
SCT
Guilt Severity (TRGI)
3
2.5
2
1.5
1
0.5
0
PTSD Severity (CAPS-5)
45
40
35
30
25
20
15
10
5
0
Depression Severity (PHQ-9)
18
16
14
12
10
8
6
4
2
0
Baseline
After Treatment
3-month Follow-up
6-month Follow-up
Time Point

Results


80
70
60
50
40
30
20
10
0
Percentage
TrIGR
SCT
PTSD Treatment Response
PTSD Loss of Diagnosis
PTSD Remission
Clinically Meaningful Change in Depression

What about guilt from pandemic-related events?

- **Working with inadequate tools, resources, training**
- **Infecting others**
- **Witnessing a great deal of suffering and death**
- **Honoring one set of values feels like failing in another (e.g,. work/family)**
- **Parenting in ways that go against values**
- **Witnessing or participating in rituals around dying that go against values**
- **Supervisors making decisions that put others at risk**
- **Feeling numb or nothing**
- **Abiding with policies with which one does not agree**

e.g., Norman… Pietrzak et al., *Anxiety and Depression*, 2021

AIMS: Can TrIGR Efficaciously Reduce Pandemic-Related Guilt?

- To evaluate the efficacy of TrIGR for reducing pandemic-related guilt

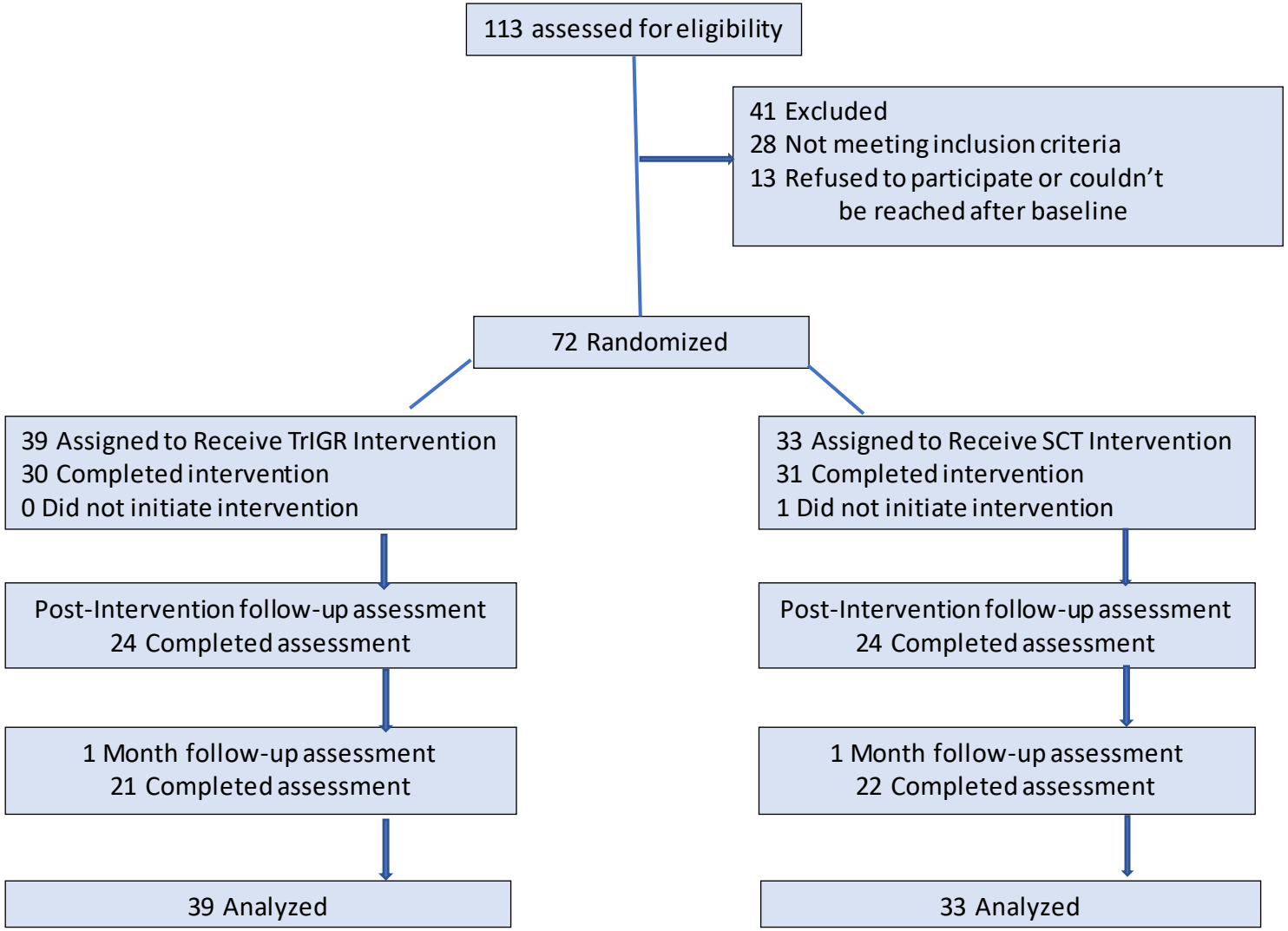
- To evaluate the efficacy of TrIGR for pandemic-related guilt for reducing shame, PTSD, and depression symptoms.

Inclusion criteria + recruitment

- Measures
  - US Veteran who deployed in service of 9/11
  - Guilt from a pandemic related event
  - Pandemic-related distress - NIH's CRISIS item:

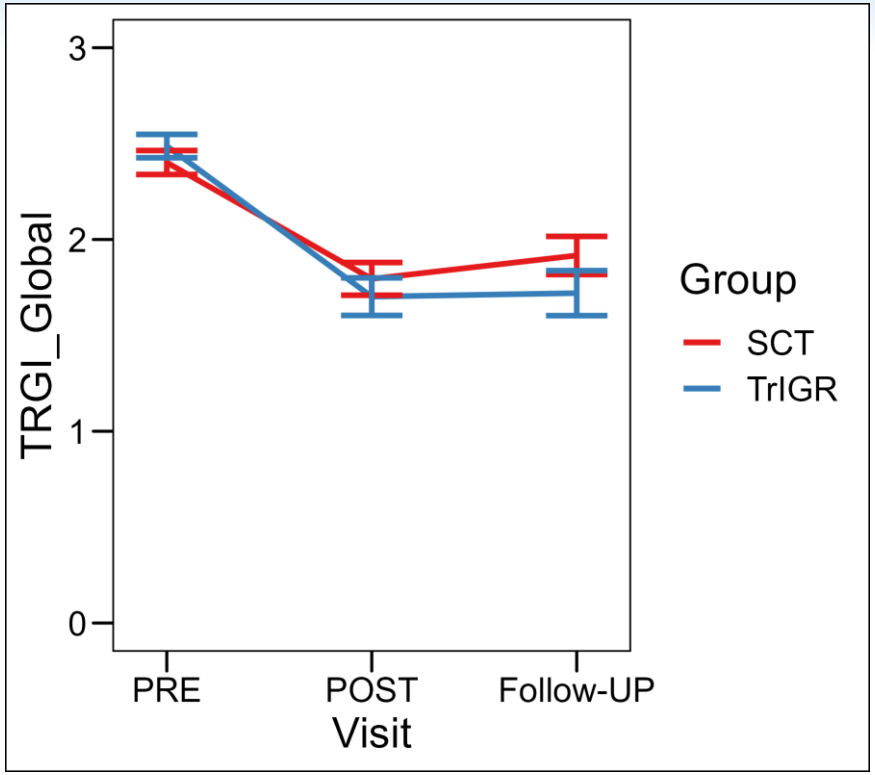
    "In the past two weeks, how much have you been bothered by events that occurred during the COVID-19 pandemic?"
  - Pandemic-related guilt – Trauma-Related Guilt Inventory about a pandemic event
  - Event does not need to be a criterion A, PTSD dx not required

- Recruitment: 3 U.S. VA hospitals and social media

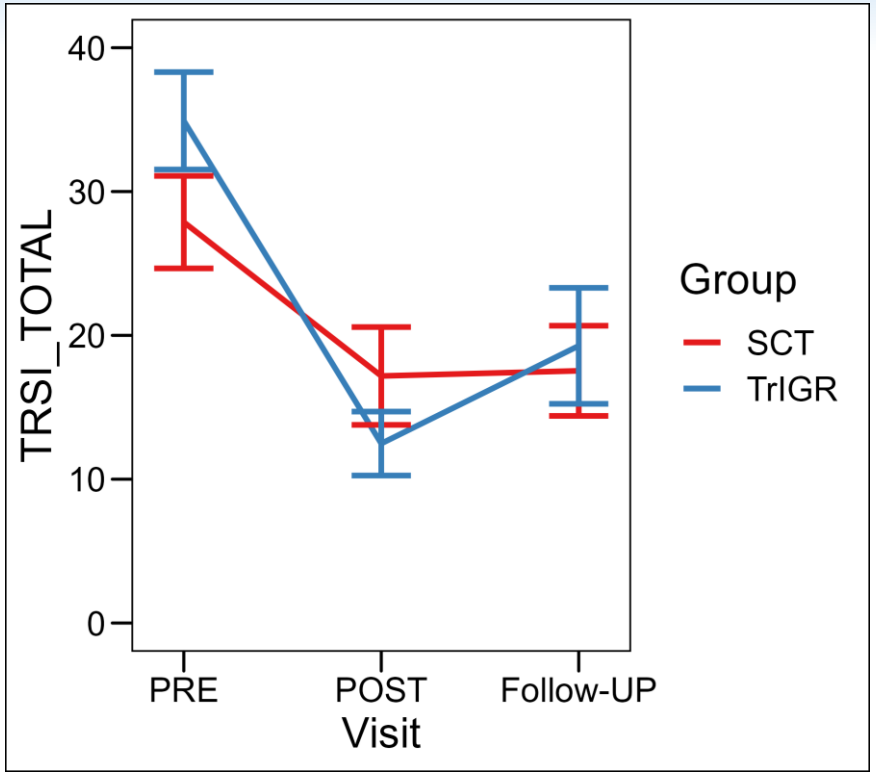

113 assessed for eligibility
41 Excluded
28 Not meeting inclusion criteria
13 Refused to participate or couldn't be reached after baseline
72 Randomized
39 Assigned to Receive TrIGR Intervention
30 Completed intervention
0 Did not initiate intervention
33 Assigned to Receive SCT Intervention
31 Completed intervention
1 Did not initiate intervention
Post-Intervention follow-up assessment
24 Completed assessment
Post-Intervention follow-up assessment
24 Completed assessment
1 Month follow-up assessment
21 Completed assessment
1 Month follow-up assessment
22 Completed assessment
39 Analyzed
33 Analyzed

Characteristics	Total (n=72)	SCT (n=33)	TrIGR (n=39)
Age, mean (SD)	45.00 (8.67)	44.79 (8.93)	45.18 (8.55)
Gender Identity			
Man	59 (83.1)	28 (87.5)	31 (79.5)
Woman	12 (16.9)	4 (12.5)	8 (20.5)
Trans Man/Trans Woman	0 (0)	0 (0)	0 (0)
Sexual Orientation			
Homosexual	2 (2.8)	0 (0)	2 (5.1)
Heterosexual	62 (87.3)	29 (90.6)	33 (84.6)
Bisexual	6 (8.5)	3 (9.4)	3 (7.77)
Other	1 (1.4)	0 (0)	1 (2.6)
Ethnicity			
Hispanic	14 (19.7)	7 (21.9)	7 (17.9)
Non-Hispanic	54 (76.1)	25 (78.1)	29 (74.4)
Decline to answer	3 (4.2)	0 (0)	3 (7.7)
Race			
White	51 (70.8)	24 (72.7)	27 (69.2)
Black	12 (16.7)	5 (15.2)	7 (17.9)
Asian/Pacific Islander	6 (8.3)	4 (12.1)	2 (5.1)
Biracial/multiracial	4 (5.6)	2 (6.1)	2 (5.1)
Current PTSD diagnosis (CAPS-5)	44 (80.0)	17 (73.9)	27 (84.4)

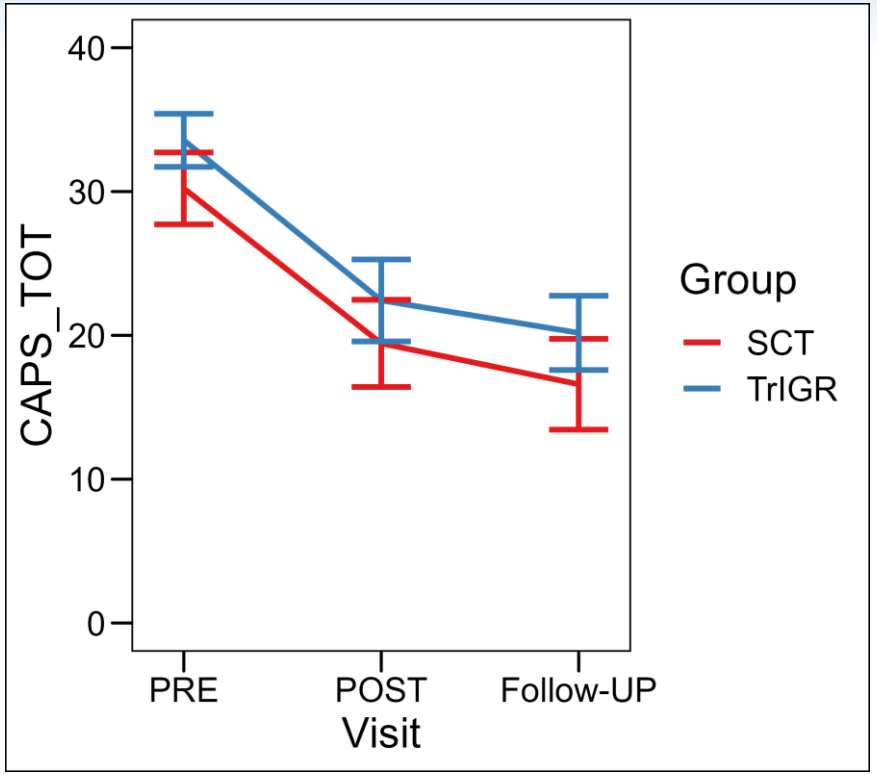
Global Guilt - Full Sample (N=72)



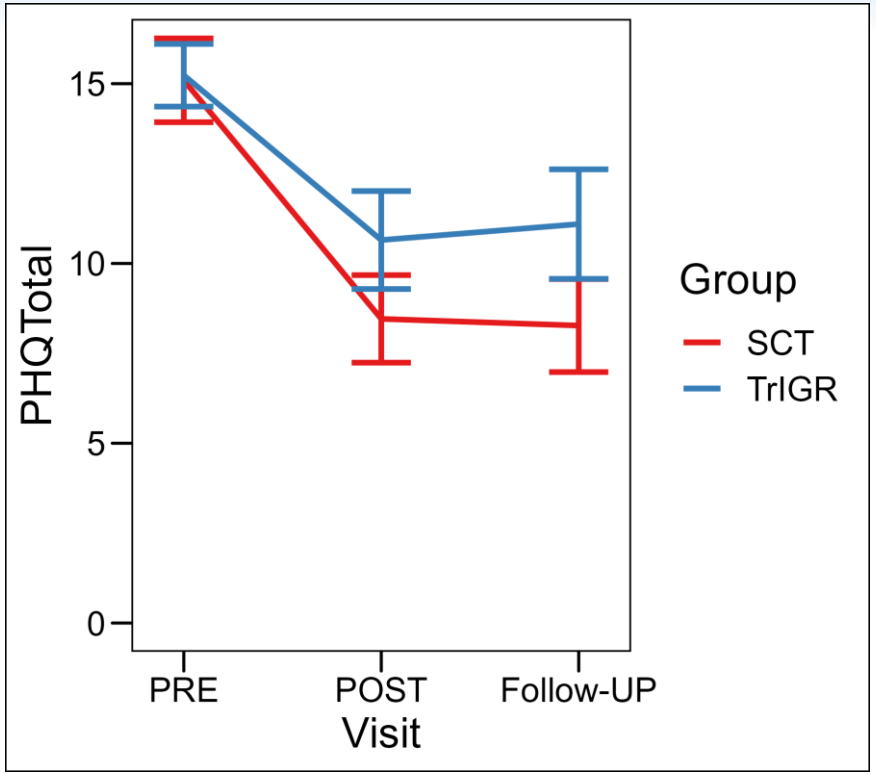
Shame - Full Sample (N=72)



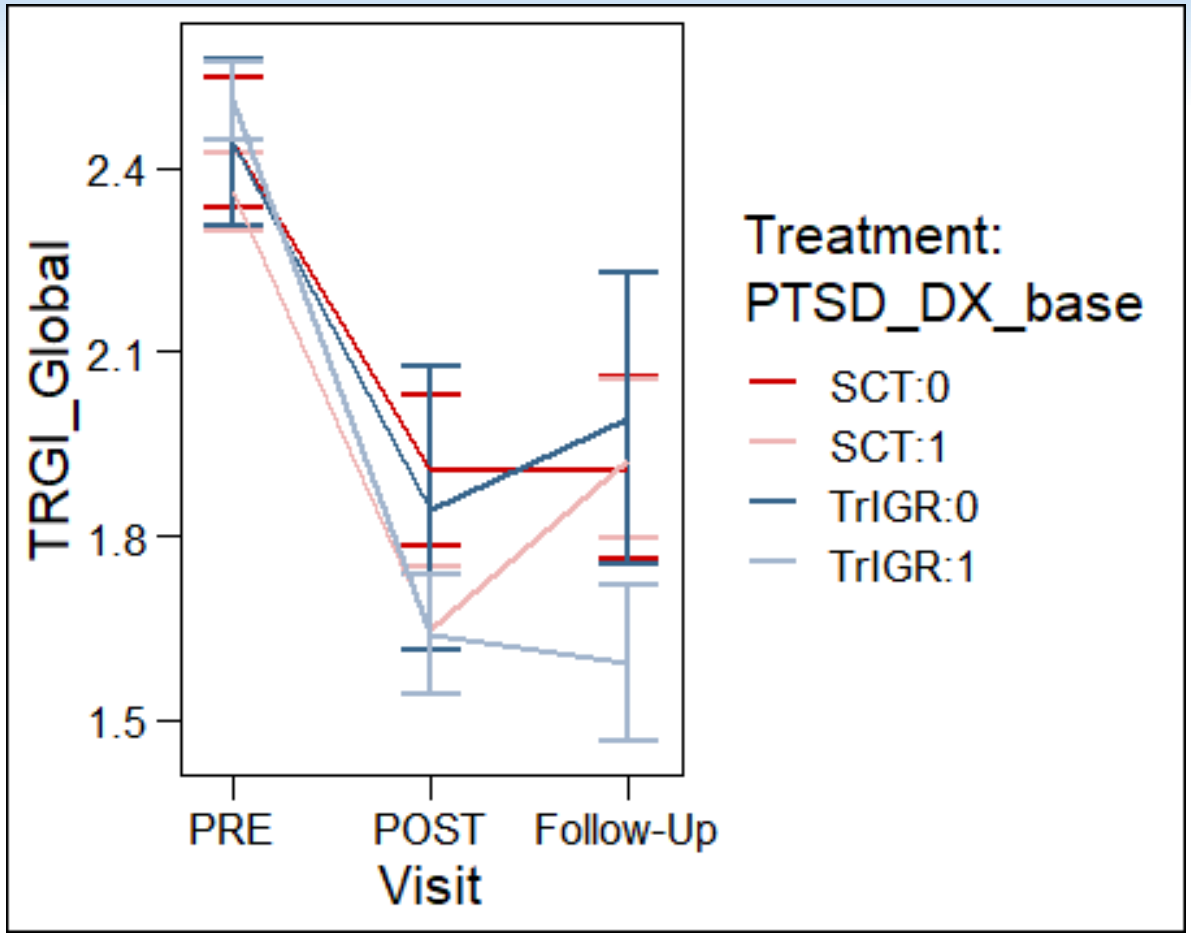
CAPS- Subsample (N=55)



Depression - Full Sample (N=72)



Global Guilt (as a function of Baseline PTSD Dx)



Discussion

- First study where we didn't require a criterion A trauma to see if TrIGR is helpful when guilt source may not be a trauma
  - If no PTSD – doesn't matter if you get SCT or TrIGR
  - If PTSD – TriGR more efficacious
  - TrIGR viable option in either case but supportive therapy may require less training and resources
- Limitations: not fully powered study, recent U.S. veteran, mostly male sample
- Next steps: study TrIGR more as a treatment for PTSD

Thank you!

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Moral Injury (JI Harris, Section Editor)

Trauma-Informed Guilt Reduction Therapy: Overview of the Treatment and Research

Sonya Norman, PhD[1,2,3,*]

Address
[1]Executive Division, National Center for PTSD, White River Junction, VT, USA
Email: snorman@ucsd.edu
[2]Department of Psychiatry, San Diego School of Medicine, University of California, San Diego, CA, USA
[3]VA Center of Excellence for Stress and Mental Health, 3350 La Jolla Village Drive, MC 116B, San Diego, CA 92161, USA

This article is part of the Topical Collection on *Moral Injury*.

Keywords Moral injury · Trauma-related guilt · Trauma-related shame · PTSD · Depression · Psychotherapy

Abstract

Purpose of Review The purpose of this review is to describe Trauma-Informed Guilt Reduction Therapy (TrIGR), the Non-Adaptive Guilt and Shame (NAGS) model that underlies TrIGR, and the research supporting the use of TrIGR to treat the guilt and shame components of moral injury. TriGR is a 6-session individual psychotherapy that helps clients consider their role in the traumatic event and find constructive ways to express important values, so that they no longer need to express values by suffering through guilt and shame.
Recent Findings A recently completed randomized controlled trial of TrIGR versus supportive care therapy included 144 post-9/11 veterans. TriGR showed greater reductions in trauma-related guilt, PTSD symptoms, and depression symptoms. Participants in TrIGR had greater likelihood of losing their PTSD diagnosis and showing clinical meaningful change in PTSD and depression symptoms. Mean attendance was high; 5.3 out of 6 sessions.
Summary TrIGR is efficacious in reducing guilt that is common to moral injury as well as PTSD and depression symptoms among combat veterans. The next steps in the program of research to develop and evaluate TrIGR are studies with diverse trauma types and populations as well as relative effectiveness studies comparing TrIGR to other evidence-based treatments for moral injury and PTSD.

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Introduction

The purpose of this review is to describe Trauma-Informed Guilt Reduction Therapy (TrIGR), the Non-Adaptive Guilt and Shame (NAGS) model that underlies TrIGR, and the research supporting the use of TrIGR to treat the guilt and shame components of moral injury.

Guilt and shame are hallmark features of moral injury

While there is no one consensus definition of moral injury, it is generally considered to be the long-term psychological, behavioral, social, and sometimes spiritual distress that occurs after one experiences an event that violates deeply held morals and values [1, 2•]. Two hallmark symptoms of moral injury are guilt and shame [1, 2•, 3]. Guilt is a hybrid of negative thoughts and emotions that arises when people blames themselves for all or part of the negative outcome of an event (e.g., "I did something bad") [4]. Shame is when one judges not just their actions but their entire self negatively (e.g., "I am bad") [5]. Difficulty forgiving oneself for the transgression of values is also considered common in moral injury [6].

Trauma-related guilt such as that seen in moral injury occurs frequently among trauma survivors [7]. For example, one study of VA enrolled veterans who had experienced trauma found that over 40% reported that they had experienced guilt in the past month [7]. In addition to being common, trauma-related guilt is associated with a variety of negative post-traumatic mental health outcomes. In our research with veterans, we have found that trauma-related guilt is positively associated with the severity of PTSD and depression symptoms [8, 9], with aggression [10], and with poorer overall psychosocial functioning and in the specific domains of interpersonal functioning, professional functioning, and self-care [11]. Extent work shows it is also associated with suicidal ideation, even when controlling for combat exposure or PTSD symptoms [12, 13].

For people with PTSD, trauma-related guilt is one of the symptoms likely to linger, even after successful PTSD treatment [14, 15]. Research with clinicians shows that they find moral injury, and guilt specifically, challenging to treat and an area where they would like more intervention strategies [16, 17]. Less is known about trauma-related shame because a measure to assess such shame was only recently validated and published [18]. However, studies suggest that trauma-related guilt in the absence of shame is rare and that shame may in fact explain much of the variance in the associations between guilt and negative outcomes [10, 19]. Because moral injury and the associated hallmark symptoms of guilt and shame are common, distressing, debilitating, and challenging to treat, we developed Trauma-Informed Guilt Reduction Therapy (TrIGR).

Developing TrIGR

Our study team's attention was first drawn to moral injury and specifically the guilt and shame components in our clinical work with combat veterans who had served in Iraq and Afghanistan. Many were coming in for mental health treatment with primary presentation of moral injury, having to live with something they did or did not do in the context of war that went against their morals and values, with guilt and shame prominent in their clinical presentation. Many had PTSD but some did not, so not all were appropriate for PTSD treatment. Some had completed disorder specific treatment (e.g., PTSD, depression) but still had prominent and debilitating guilt. We saw in our work and in the extent literature [16, 17] that therapists were asking for more information on how to treat this kind of moral injury based, trauma-related guilt.

To develop TrIGR, we first conceived a model of how trauma-related guilt and shame affect mental health which we called the Non-Adaptive Guilt and Shame (NAGS) model (Fig. 1) [9, 20]. According to the NAGS model, some people experience guilt after a traumatic event, while some do not. Among those who do experience guilt, some use the negative feelings of guilt as an opportunity to assess what values were violated (e.g., "What did I do that makes me feel so awful? How do I avoid feeling this way again?"). In such cases, guilt may help people make choices that are more in line with their values. However, sometimes people avoid thinking about the event and guilt feelings. Or their guilt stems from an event where there was no good choice and any choice would have led to a negative outcome (e.g., certain combat situations). The negative feeling of guilt may be seen as evidence that someone did something wrong, and the sense that someone did something wrong may lead to further negative feelings, creating a cycle of feeling more guilt and more guilty. The guilt becomes shame if the person comes to believe that not only did they do something bad, but that they are bad because of what they did. This cycle of negative thoughts and affect contributes to the severity of symptoms of common posttraumatic mental health problems such as PTSD

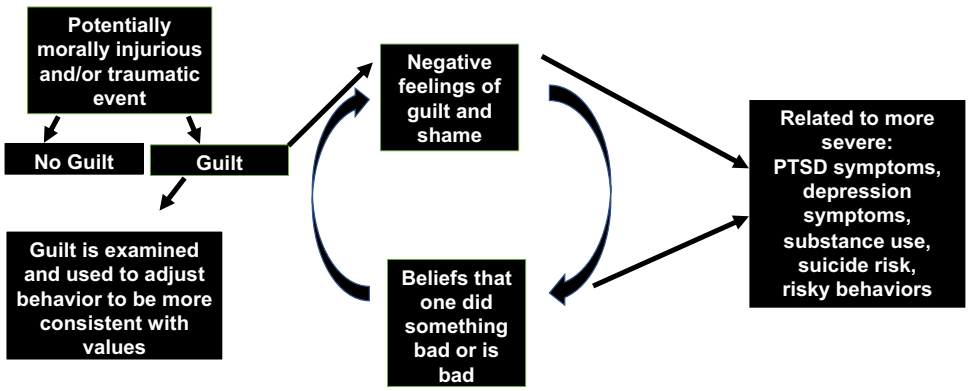

Fig. 1 Non-adaptive guilt and shame (NAGS) model.

and depression. This cycle can also contribute to self-destructive behaviors such as substance use, suicide risk, and high-risk behaviors. It may also contribute to poor or ambivalent engagement in treatment because people may come to believe that they do not deserve to feel good or do well.

We mapped the TrIGR intervention onto the NAGS model to end the cycle of guilt and shame that contributes to the severity of mental health problems and high-risk behaviors [9, 20]. The goal is to target guilt and shame to reduce some of the psychological, behavioral, social, and sometimes spiritual distress of moral injury. The overarching objective of TrIGR is to help clients consider their role in the traumatic event more comprehensively than they have previously and to help them find constructive ways to express important values, so that they no longer need to express values through suffering and high-risk behaviors (e.g., "I did something awful so now I deserve to suffer)." To help clients appraise their role in the trauma, the therapist guides the client through evaluation of four types of cognitions identified by Kubany and colleagues [4, 21]. Hindsight bias (e.g., "I knew exactly how things would turn out that day") is challenged by helping clients remember what they really knew and had the power to do at the time. The therapist and client then examine what options the client had during at the time and how each option may have played out. Clients often come to terms during this exercise with the idea that there were no good options available at the time, and that all options would have led to some bad outcome. We then help people consider the full context of what happened and the many factors that contributed to the outcome. Finally, we help people consider whether they purposely intended the bad outcome that occurred. In the last module of TrIGR, the therapist helps the client find ways to express their values in more positive ways than by feeling guilt and shame, and helps people make plan to spend time doing activities that are meaningful to them and consistent with their values.

In terms of logistics, TriGR is a 6-session individual manualized intervention. The first two sessions of TriGR cover psychoeducation about trauma-related guilt and shame and the NAGS model. The second two sessions focus on processing the trauma and guilt and shame by debriefing the four common cognitions. The final two sessions focus on understanding what values were violated during the trauma, identifying important values, and creating a plan for how to live more in-line with important values. Clients are assigned homework after each session which includes reading psychoeducational materials about guilt, listening to a recording of the session, and keeping a log of cognitions that cause feelings of guilt and shame (e.g., "I should have known better than to…"). Clients track their activities leading into the values portion of the treatment (i.e., the final two sessions) to help identify ways to build more value-driven activities into their schedule. TrIGR can be delivered in person or through video conferencing.

TrIGR was designed to be easy to learn and implement by therapists familiar with cognitive behavioral therapy models. In our research studies, therapists have included clinical psychology pre- and post-doctoral trainees and licensed psychologists and social workers. Therapists new to TrIGR can learn the intervention through the manual and workbook which are published together in one book [20]. The treatment manual walks therapists through delivering the

intervention session by session with clinical examples based on different kinds of traumas. The workbook includes client psychoeducational materials and assignments. The book also includes chapters on preparing clients for TrIGR, troubleshooting clinical situations that may arise, and therapist self-care.

TrIGR is one of several interventions that was developed to address one or more aspects of moral injury. Others include Adaptive Disclosure [22] which focuses on strategies that are consistent with military culture to promote self-forgiveness and reparative action. The therapy is also designed to help with anger and grief from moral injury if they are present. Impact of Killing is a cognitive behavioral intervention focused on moral injury from killing others in combat [23]. The therapy discusses physiology of killing responses, self-forgiveness, spirituality, making amends, and maintaining functional gains. Building Spiritual Strength [24] addresses the spiritual strain of moral injury and works to enhance religious meaning making. The Self-Forgiveness Workbook is a 6-h self-guided intervention designed to facilitate self-forgiveness and reduce self-condemnation among people who perpetrated of interpersonal offenses [25]. TrIGR is best suited when guilt and shame are present and prominent in a client's presentation. If a client prefers to take a more spiritual focus to their guilt and shame, Building Spiritual Strength may be a better choice. If a client's moral injury presents most strongly as anger or loss, Adaptive Disclosure may be the better choice. For someone who prefers self-help, the Self-Forgiveness Workbook may be a good starting point. It is likely that for some clients there is no one right choice. For example, someone who has guilt from killing in combat may benefit from TrIGR or Impact of Killing. If these are both available, shared decision making with the therapist and client may be a good method by which to decide on a treatment direction.

TrIGR research

We set out to evaluate TrIGR using Onken's stages of behavioral treatment development [26]. In summary, stage I is development and preliminary testing of the intervention, usually focused on gathering feasibility and pilot data. Studies at this stage often use single condition pre-post designs. Stage II is efficacy testing in a research setting. Randomized controlled trials are the most common design used for stage II studies. Stage III continues efficacy work while introducing elements of "real world" effectiveness such as conducting the trial in community settings or with community-based providers but maintaining a high level of control to maintain high internal validity. Stage IV moves further into effectiveness and stage V focuses on dissemination and implementation.

First pilot and feasibility study

Our first pilot trial of TrIGR (stage I) was a pre-post study with thirteen veterans who served in Iraq or Afghanistan, had guilt from a combat trauma, and met diagnostic criteria for PTSD [9]. Ten completed the intervention.

We measured trauma-related guilt, PTSD symptoms and depression. Results showed pre to post reductions in all three outcomes. Overall trauma-related guilt distress (from 3.0, SD = .48 to 2.4, SD = .89, *Cohen's d* = 1.37) and trauma-related cognitions (from 2.1, SD = .99 to 1.3, SD = .75, *Cohen's d* = 1.53) as measured by the Trauma-Related Guilt Inventory [27] reduced significantly.

In addition to examining if pre- to post-treatment change in PTSD and depression symptoms was statistically significant, we examined if change in PTSD symptoms was clinically noticeable (computed in previous studies to be a 10-point decrease on the Clinician Administered PTSD Scale for DSM-IV [CAPS] [28]; defined as representing a meaningful improvement in the life of someone with chronic PTSD [29, 30, 31]; and if change in depression was clinically significant (computed in a previous study to be 5-point decrease on the Physician Health Questionnaire-9 [PHQ-9] [32, 33]. Specifically, a 5-point change on the PHQ-9 has been shown to correspond with a moderate effect size on multiple domains of health-related quality of life and functional status [33]. Scores on the CAPS showed clinically meaningful change of over 18 points, from M = 81.4 (SD = 20.3) to M = 62.0 (SD = 36.5). Depression symptom change was also clinically meaningful going from M = 14.2 (SD = 6.4) to 9.3 (SD = 8.04) on the PHQ-9. Both PTSD and depression change showed large effect sizes (Cohen's D = 1.98 and 1.44, respectively). Participants were highly satisfied with the intervention, with a mean of over 28 out of 30 on The Client Satisfaction Questionnaire [34], our measure of treatment satisfaction. These preliminary findings suggested to us that further study of TrIGR using a rigorous randomized controlled trial design (stage II) was warranted.

First randomized controlled trial

We recently completed the first stage II, randomized controlled trial of TriGR [35•]. We randomized 144 Veterans who served in the conflicts in Iraq or Afghanistan and had guilt from a trauma that occurred on a deployment. Veterans were recruited from two sites, the San Diego and Providence VAs, and were randomized to receive either TrIGR or supportive care therapy [36]. In supportive care therapy, clients choose the topics that are discussed in therapy and therapists respond with positive regard and support, but do not offer skills or strategies [36]. Supportive care therapy is similar to Present Centered Therapy but without the active elements of problem solving. There is no homework in this therapy. It was selected as the control condition because it has all of the non-specific elements of good therapy without active intervention strategies. This kind of passive control is appropriate for stage II behavioral intervention studies [26]. Both therapies were delivered in six individual weekly sessions. Therapists delivered both treatments with careful fidelity monitoring for both therapies which included weekly supervision and having supervisors and fidelity raters listen to audio recordings of sessions.

Results using intent-to-treat analyses showed TriGR was more effective than supportive care therapy in reducing trauma-related guilt (treatment ×

time, −0.22; F (1, 455.2) = 18.49, p = .001; d = 0.92) and PTSD (treatment × time, −2.26; F (1, 468.3) = 6.76, p = .010; d = 0.81) and depression symptoms (treatment × time, −1.28; F (1, 454.6) = 7.51, p = .006; d = 0.43). Surprisingly, 50% of people in TrIGR lost their PTSD diagnosis between baseline and 6 months (compared to 14% in supportive care therapy; *OR* [95% *CI*] = 6.21 [2.23–17.29], p = .001), 67% showed clinically meaningful PTSD symptom reduction (compared to 40% in supportive care therapy; defined as a > 10 point improvement in CAPS-5 severity [37]; odds ratio [*OR*] [95% confidence interval {*CI*}] = 3.00 [1.32–6.84], p = .015), and 54% had clinically meaningful depression symptom reduction (compared to 27% in supportive care therapy; defined as >5 on the PHQ-9, [38]; *OR* [95% *CI*] = 3.05 [1.27–7.34], p = .023). These findings suggests that for those with PTSD and/or depression who have high trauma-related guilt, a treatment that is brief but targets the guilt can be effective in treating PTSD and depression symptoms.

We also measured general distress using the Brief Symptom Inventory-18 (BSI-18) [39] and quality of life using the World Health Organization Quality of Life measure [40]. We did not find differences between TrIGR and supportive care therapy. We speculated that the BSI-18, which has heavy emphasis on anxiety and somatization, may not capture the type of distress experienced by our high-guilt sample. Regarding quality of life, it was not clear if the treatments did not improve this outcome, or if this measure, which has not been validated with PTSD samples, did not capture change that may have occurred. We look forward to using more robust measures of quality of life in future studies to try to answer this question.

One surprising result was the high session attendance across both therapies (M = 5.3, SD = 1.6, in TrIGR and also 5.3, SD = 1.8, t (143) = 0.15, p = .88] in supportive care therapy, out of six sessions in both cases). Rates of treatment completion, a priori defined as attending four or more of six sessions, were also high and did not differ between treatment conditions [TrIGR n = 63; 85.1%; SCT n = 61; 85.9%), $\chi 2$ (1, N = 145) = 0.02, p = .90]. Such high attendance is unusual in any PTSD study but in particular in a sample of Iraq and Afghanistan veterans who have shown low attendance and high attrition across PTSD treatment trials [41, 42, 43]. We speculated that this may be because TrIGR is shorter than many PTSD treatments or that the focus on guilt felt more germane to the sample we recruited, and thus they continued to attend therapy.

COVID-19 pandemic study

We have a small stage II–III trial in progress to evaluate TrIGR for guilt from COVID-19 pandemic related events. The pandemic created ethically difficult scenarios for many people where they may have felt like they could not do enough or live up to their own standards [44•]. Examples include not being able to be with a loved who was very ill or dying, exposing someone to infection, or not being able to provide for family financially because of loss of a job or income. Our goal is to see if TrIGR may help reduce guilt from these kinds of ethically difficult, potentially morally injurious

scenarios. We are in the process of randomizing 72 veterans who deployed in service of Iraq or Afghanistan who have guilt from an event that occurred during the pandemic or guilt that got worse due to the pandemic. The goal was to conduct this study quickly during the pandemic; thus, sample size was based on feasibility of recruitment in the study time frame. Participants are recruited to one of three sites — the Boston, Providence or San Diego VA, and randomized to TrIGR or supportive care therapy. This study is allowing us to stretch our understanding of the applicability of TrIGR in several important ways. This study is the first evaluation of TriGR to treat guilt from incidents that may be morally distressing and cause guilt but are do not necessarily meet Criterion A for PTSD. In our previous research, guilt had to stem from a trauma that would meet criterion A. Examples that would not meet criterion A are guilt over parenting or relationship behavior during the pandemic, or not being able to support one's family because of loss of income. It is also our first evaluation of TriGR for non-warzone and non-military events. Also, in our previous studies the events that caused guilt generally occurred years before study entry, whereas in the pandemic study, events often occurred just months before participants entered the study. Thus, results of the trial will help inform if TrIGR can be efficacious to reduce guilt and related symptoms from recent morally distressing events and from non-military events.

Next steps in research

Our goal for the next steps of studying TrIGR is to understand how broadly applicable the treatment may be as the data we have so far are from a specific era of veterans with guilt from a specific type of trauma. This will move us further into stage III and IV research. Specifically, next steps are to evaluate TrIGR's ability to reduce guilt and related symptoms from any type of trauma (e.g., car accidents, assaults) or morally challenging life events, to evaluate its efficacy with people who are not veterans and with veterans from any service era (thus far, our research has been with post-9/11 veterans). We also appreciate that there are several efficacious treatment options for moral injury and for PTSD and believe it is important to understand TrIGR's effectiveness relative to these other treatments. This will allow clients to make informed decisions when presented with treatment options. Thus, another goal is to conduct studies comparing TrIGR to other effective treatments for moral injury and for common co-occurring problems such as PTSD.

We often get asked if there is the ideal time for someone to receive TrIGR relative to other treatments; that is, should it be a first line treatment, should it be offered after a diagnosis specific treatment when there is residual guilt, or should multiple treatments occur concurrently. It is likely that the answer to this question varies person to person based on clinical presentation and client preference, but we also see this as an empirical question that we would like to research in future studies.

Conclusions

TrIGR is a brief intervention focused on the guilt and shame components of moral injury and/or trauma. Evidence thus far suggests it is effective in reducing trauma-related guilt as well as symptoms of PTSD and depression. Future studies will assess its effectiveness with non-veterans, veterans of all eras of service, and with a broad range of traumas and stressors that violate deeply held moral beliefs and values.

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Declarations

Conflict of Interest

This work was supported by a grant from the Department of Defense Congressionally Directed Medical Research Program, Grant # W81XWH-15-1-0330. The author, Sonya Norman, earns royalties from Elsevier Press for a book titled "Trauma Informed Guilt Reduction Therapy: Treating Guilt and Shame Resulting from Trauma and Moral Injury."

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Publisher's Note