AWARD NUMBER: W81XWH-15-1-0331

TITLE: Trauma-Informed Guilt Reduction (TrIGR) Intervention

PRINCIPAL INVESTIGATOR: Christy Capone, PhD

CONTRACTING ORGANIZATION: Brown University, Providence, RI

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Fort Detrick, Maryland 21702-5012

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6. AUTHOR(S)

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7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)

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13. SUPPLEMENTARY NOTES

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. 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 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). 145 OEF/OIF/OND Veterans were randomized to TrIGR or SCT across two sites (53 in Providence). 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. We completed data collection at the Providence site in December 2020.

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

16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES	19a. NAME OF RESPONSIBLE PERSON
a. REPORT	b. ABSTRACT	c. THIS PAGE			USAMRDC
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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 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). 145 OEF/OIF/OND Veterans were randomized to TrIGR or SCT across two sites (53 in Providence). 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. We completed data collection at the Providence site in December 2020.

We were also approved to conduct a pilot study of the same intervention for guilt from events during the COVID-19 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 VA, Boston VA, and Brown University in Providence. 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. Recruitment at the Providence site began in February 2021 and enrollment and all data collection are now complete. We are in the process of cleaning the data and preparing for data analyses and a manuscript examining the primary study outcomes.

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), effort was expended on the following milestones and subtasks during the past year:

Major Task 2 - Conduct Pilot RCT Related to COVID-19 – (months 60-72)

Subtask 1: Enroll 24 at Providence site (Months 63-69).

Progress: Completed. We enrolled 39 participants.

Subtask 2: Randomize to study condition (TrIGR or SCT) (Months 63-69).

Progress: Completed. We randomized 23 participants.

Subtask 3: Deliver study interventions (Months 63-70).

Progress: Completed. 23 participants have completed treatment.

Subtask 4: Conduct follow-up assessments (Months 64-71).
Progress: Completed. 18 completed post-treatment follow-up and 22 completed 1-month follow-up. All 23 participants completed at least one follow-up visit.
Subtask 5: Data collection (64-71).
Progress: Data collection was completed in September 2022.

162 participants were recruited/referred to the study. We screened 88 participants during the recruitment period. Of those, 52 screened eligible, 32 screened ineligible, and 4 declined to participate. We consented 39 participants and randomized 23. The original planned target was 24. 16 of the 39 consented participants were not randomized – 11 were not eligible after baseline assessment or MI, and 5 were no longer interested or were unable to be reached after baseline assessments. 23 of 23 randomized participants have completed the study.

Of the 39 consented participants, 11 were female and 28 were male. Regarding race/ethnicity, 4 were Hispanic/Latino, 31 were non-Hispanic/Latino, and 4 declined to answer; 31 were White, 0 were Native Hawaiian or Pacific Islander, 3 were Black/African American, 2 were Asian, 0 were Native Alaskan/American Indian, 2 identified as Other (biracial), and 1 declined to answer.

Of the 23 randomized participants, 3 were female and 20 were male. Regarding race/ethnicity, 21 were non-Hispanic/Latino and 2 declined to answer; 18 were White, 0 were Native Hawaiian or Pacific Islander, 2 were Black/African American, 2 were Asian, 0 were Native Alaskan/American Indian, 1 identified as Other (biracial).

***Please see Figure 2 at the end of this document for a visual representation of these data.**

- **What was accomplished under these goals?**
  The major activities of for the past FY were completing study recruitment, enrollment, intervention and follow-up visits, and data collection for the pilot study.

  We continued secondary data analyses and manuscript preparation for the original study. (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).

- **What opportunities for training and professional development has the project provided?**
  We have had several psychology trainees (postdoctoral fellows) participating in study activities to learn about how to conduct randomized clinical trials and to be trained as study therapists and assessors.

- **How were the results disseminated to communities of interest?**
  Results were disseminated through peer-reviewed publications and conference presentations. Citations and summaries of results 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?**
  During the next reporting period, we will continue to focus on the milestones and subtasks described in our SOW. Accordingly, we will continue to conduct secondary data analyses and disseminate findings via manuscripts and conference presentations from the

primary study. For the COVID-19 supplement, we are beginning data cleaning and analyses, and will work to disseminate findings through manuscripts and conference presentations.

4. IMPACT

- **What was the impact on the development of the principal discipline(s) of the project?**
  Findings from the primary study indicate that TrIGR is effective in reducing trauma related guilt, PTSD, and depressive syptoms.

- **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
    a. 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. 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. Quality of life did not change.

- 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
    a. 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.
    a. 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.
    a. 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.
    a. 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 ($r = 0.16$, $p = 0.03$).

- **Website(s) or other Internet site(s)**
  Nothing to Report

- **Technologies or techniques**
  Nothing to Report

- **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: Christy Capone, PhD
Project Role: Principal Investigator
Researcher Identifier (e.g. ORCID ID): 0000-0002-1720-171X
Nearest person month worked: 2.4CM
Contribution to Project: Dr. Capone continues to oversee project staff and all study protocols and procedures.
Funding Source: Trauma Informed Guilt Reduction (TrIGR) Intervention Grant W81XWH-15-1-0331

Name: M. Tracie Shea, PhD
Project Role: Co-Investigator
Researcher Identifier (e.g. ORCID ID): N/A

Nearest person month worked: 1CM
Contribution to Project: Dr. Shea conducts therapist trainings on the SCT condition and provides regular supervision calls with therapists across sites.

Name: Lauren DeMoss, MS
Project Role: Project Coordinator
Researcher Identifier (e.g. ORCID ID): N/A
Nearest person month worked: 10CM
Contribution to Project: Ms. DeMoss is responsible for coordinating all aspects of the study, recruiting and consenting patients, conducting baseline assessments, and managing day-to-day tasks for the study.

Name: Maureen McDonnell, PhD
Project Role: Study Therapist
Researcher Identifier (e.g. ORCID ID): N/A
Nearest person month worked: 1CM
Contribution to Project: Dr. McDonnell is a study therapist and has completed training in both interventions (SCT and TrIGR). She delivers both therapies to study participants and participates in regular supervision meetings.

Name: Simone Arent, PhD
Project Role: Study Therapist
Researcher Identifier (e.g. ORCID ID): N/A
Nearest person month worked: 1CM
Contribution to Project: Dr. Arent is a study therapist and has completed training in both interventions (SCT and TrIGR). She delivers both therapies to study participants and participates in regular supervision meetings.

- **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: VA San Diego
  Location of Organization: San Diego, CA
  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
- VA San Diego will submit a separate report.

B. Quad Charts
- Attachment 1

9. Appendices

- Consort Diagram – COVID-19 Pilot RTC – Attachment 2
- Copies of manuscripts, presentations, and abstracts

Trauma Informed Guilt Reduction (TrIGR) Intervention

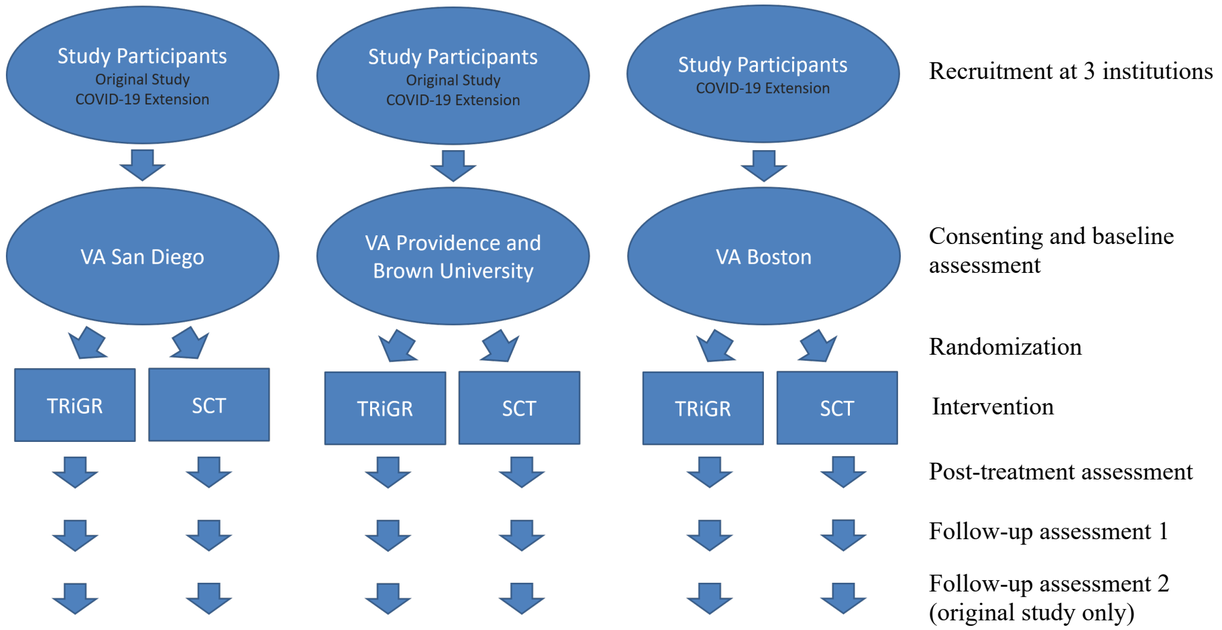
PI: Christy Capone, PhD **Org:** Brown University **Award Amount:** $1,292,682 direct

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 deployment-related guilt
- In COVID-19 extension, the primary aim is to examine the efficacy of TrIGR for reducing COVID-19 related guilt and shame in Veterans.

Approach

The primary study is 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. The COVID-19 extension is a randomized clinical trial across 3 sites (San Diego VA, Brown University/Providence VA, and Boston VA). 72 Veterans will be enrolled. 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. Study PI is currently awaiting IRB approval to begin recruitment for COVID-19 extension.

Timeline and Cost

Activities	FY 1	FY 2	FY 3	FY 4	FY 5	FY 6
Finalize procedures and approvals, hire and train staff						
Recruit, enroll, collect data						
Data analysis, report preparation						
Estimated Total Budget ($K)*	235 k	243 k	251 k	207 k		269 k

Updated: 10/01//2021

Original project COVID-19 extension

Goals/Milestones

Study Year 1 Goals –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-mo and 6-mo post-tx follow-up assessments
- ☑ 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 ups 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 – in process

Study Year 6 Goals –Conduct COVID-19 extension
- ☑ Prepare regulatory documents and research protocol
- ☑ Complete enrollment, study interventions and data collection
- ☐ Analyze data and prepare manuscripts – in process

Expenditures to date:
$1,279,972
Projected Expenditure:
$1,292,682

See slides below for components in case they need editing. Only include Slide 1 in final document to submit.

Study Participants
Original Study
COVID-19 Extension

Study Participants
Original Study
COVID-19 Extension

Study Participants
COVID-19 Extension

VA San Diego

VA Providence and Brown University

VA Boston

TRiGR

SCT

TRiGR

SCT

TRiGR

SCT

Trauma Informed Guilt Reduction (TrIGR) Intervention

PI: Christy Capone, PhD **Org:** Brown University **Award Amount:** $935,978 direct

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

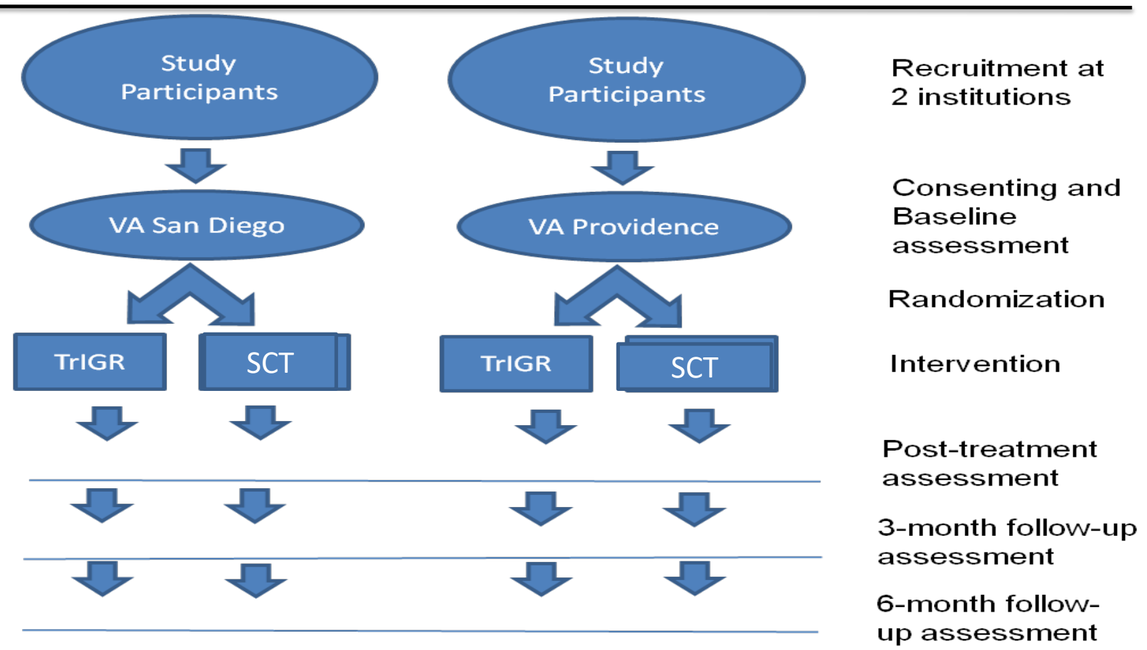
Approach

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.

Timeline and Cost

Activities	FY1	FY2	FY3	FY4
Finalize procedures and approvals, hire and train staff				
Recruit, enroll, collect data				
Data analysis, report preparation				
Estimated Total Budget ($K)*	235 k	243 k	251 k	207 k

Updated: 07/08/2020



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.

Goals/Milestones

Study Year 1 Goals – 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 – **complete**

☐ Post-intervention, 3-mo and 6-mo post-tx follow-up assessments – **in progress**

☑ Validate audio recordings of TrIGR and SCT sessions – **complete**

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 ups at 3- and 6- months – **in progress**

Study Year 4 Goals – Analyze data and prepare manuscripts

☐ Complete follow up assessments and data entry

☐ Ensure data integrity – **in progress**

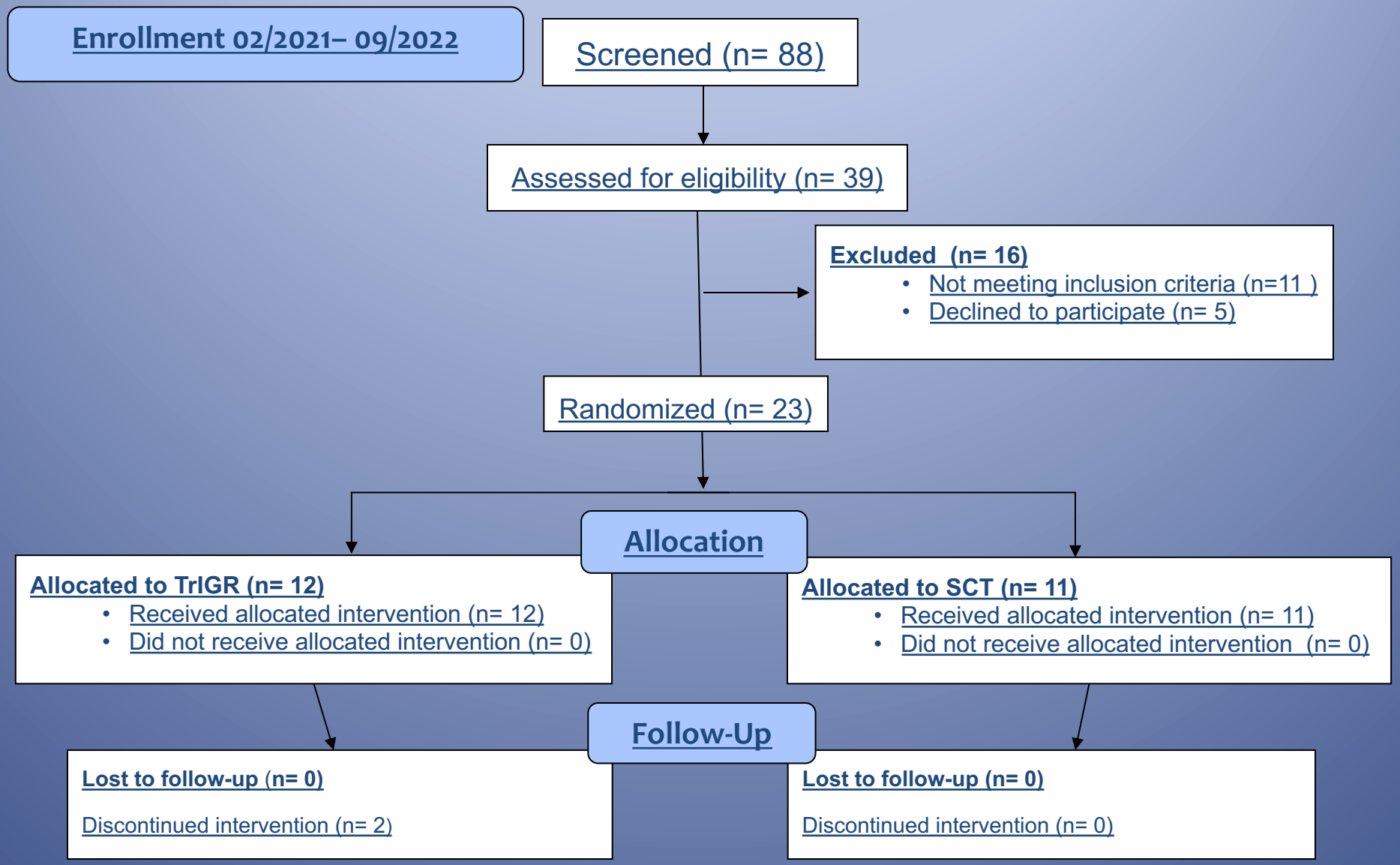
☐ Data analysis and manuscript preparation

Expenditures to date: **$869,422**

Projected Expenditure: **$935,978**

Attachment 2

CONSORT Diagram – Providence – COVID-19 Pilot RTC



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%

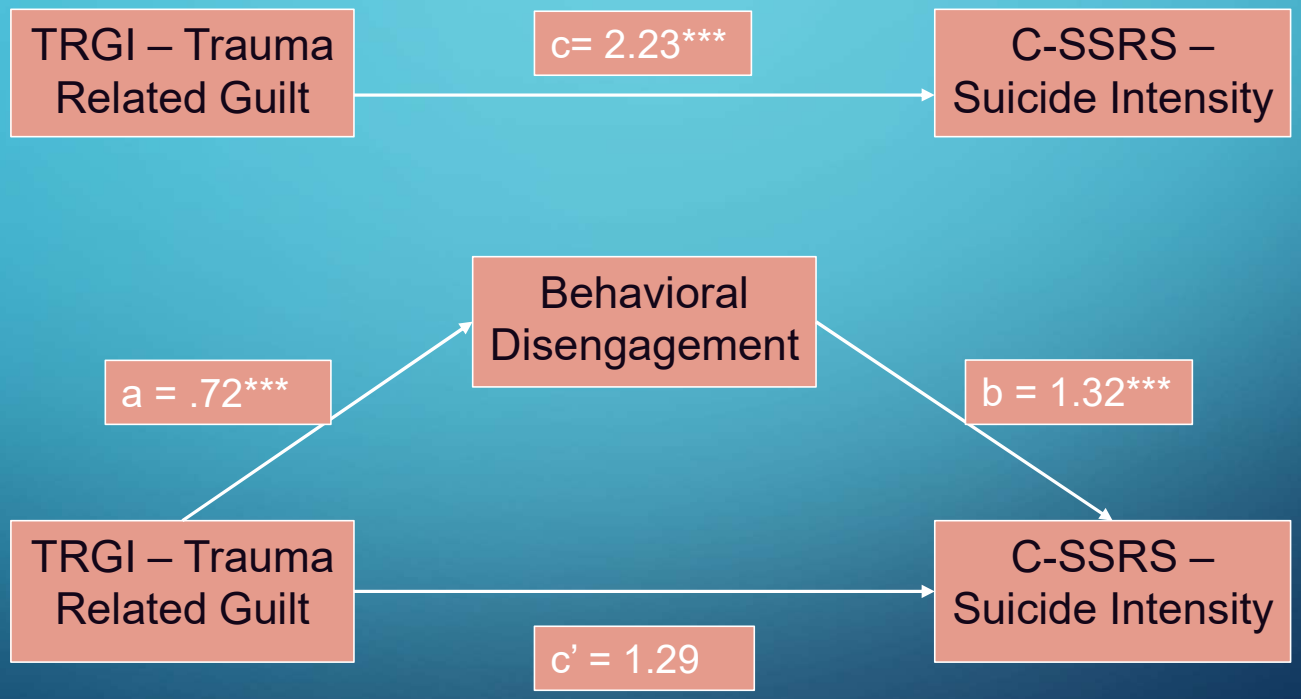
RESULTS

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

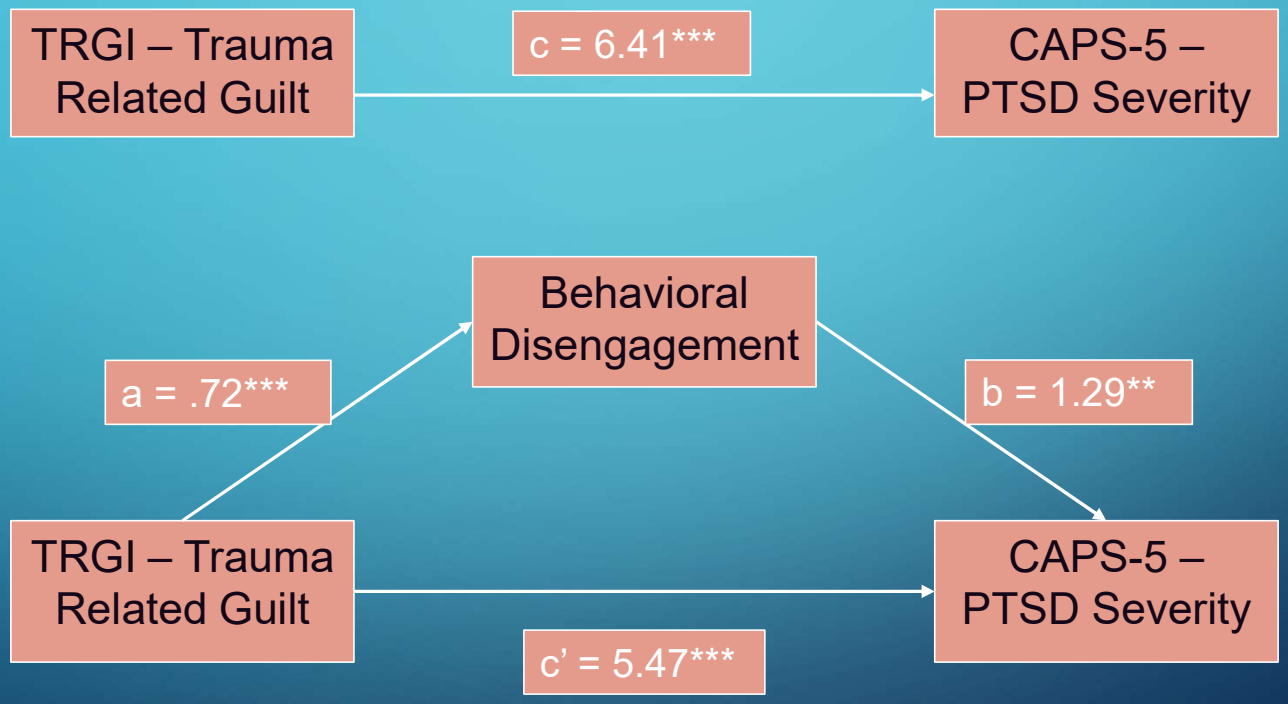
RESULTS



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

Note: ***p≤.001

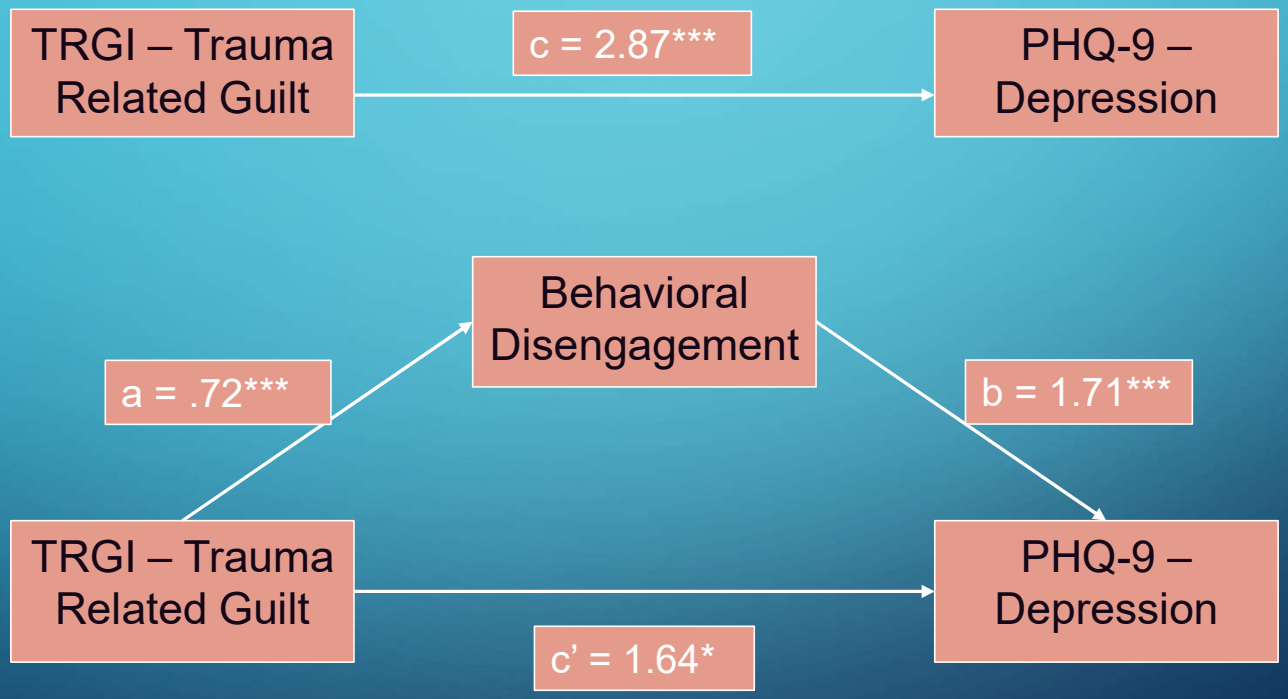
RESULTS



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

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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

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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, $F(1, 117.9) = 22.4$, $p < .001$;

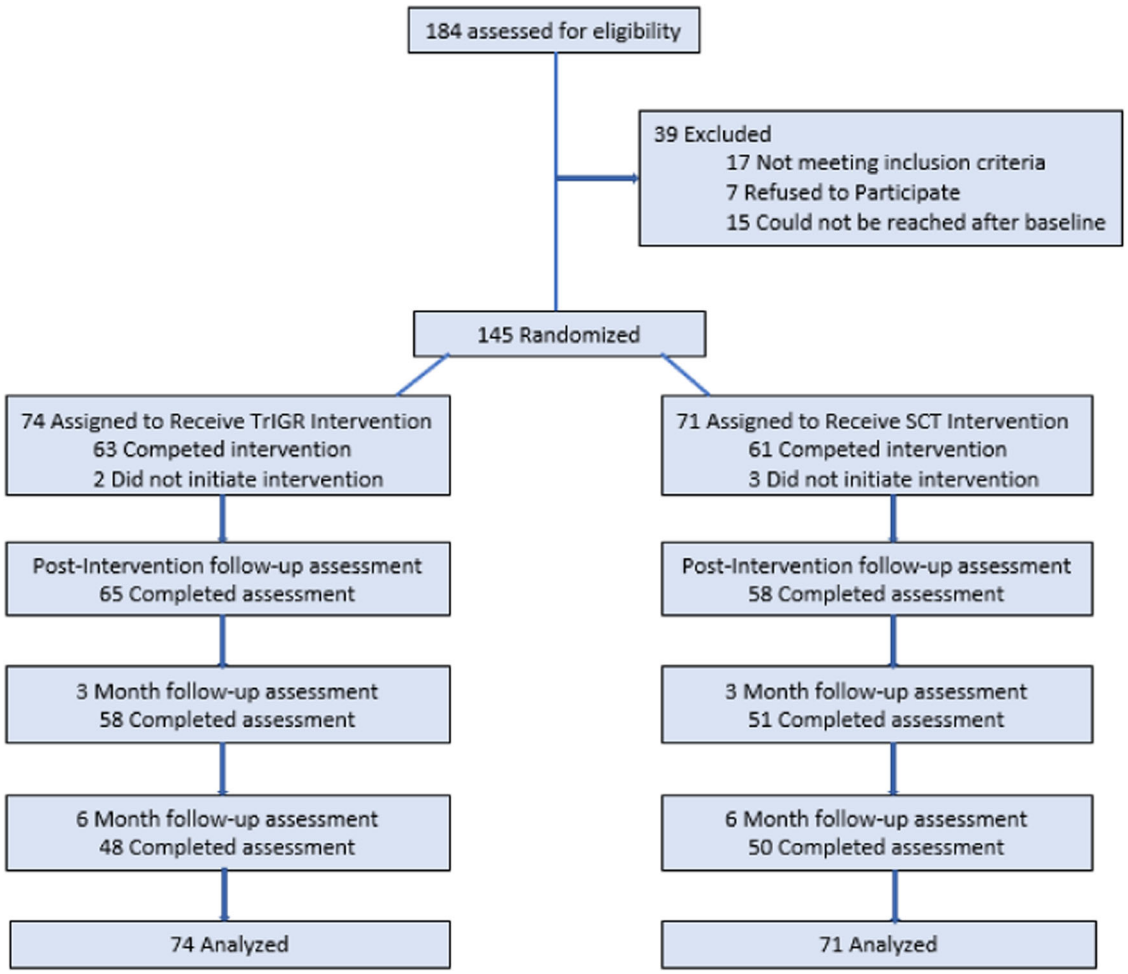

FIGURE 1 Consort Flow Diagram. SCT, supportive care therapy; TrIGR, trauma-informed guilt reduction therapy

$d = 0.99$). 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

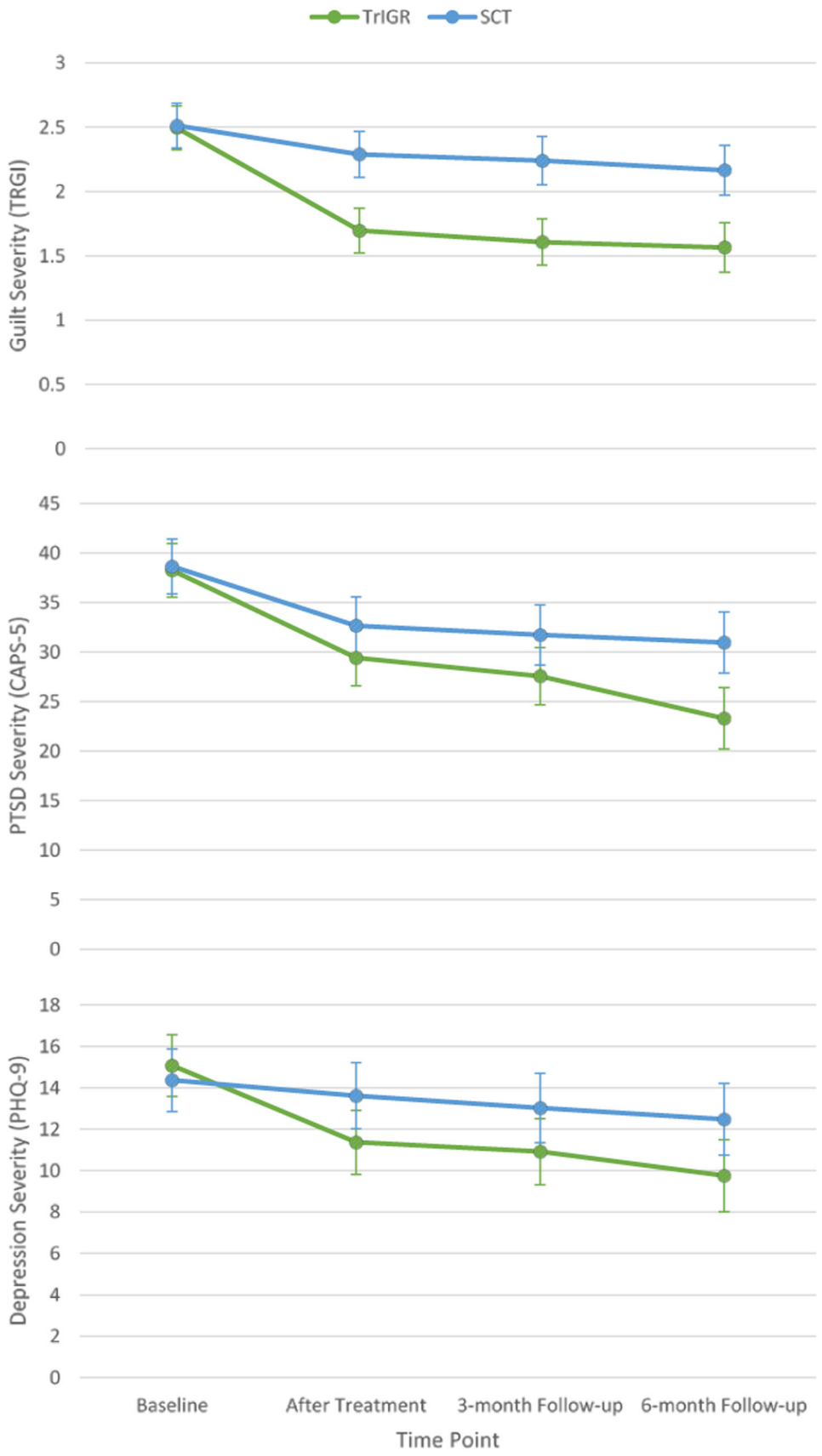

FIGURE 2 (See caption on next page)

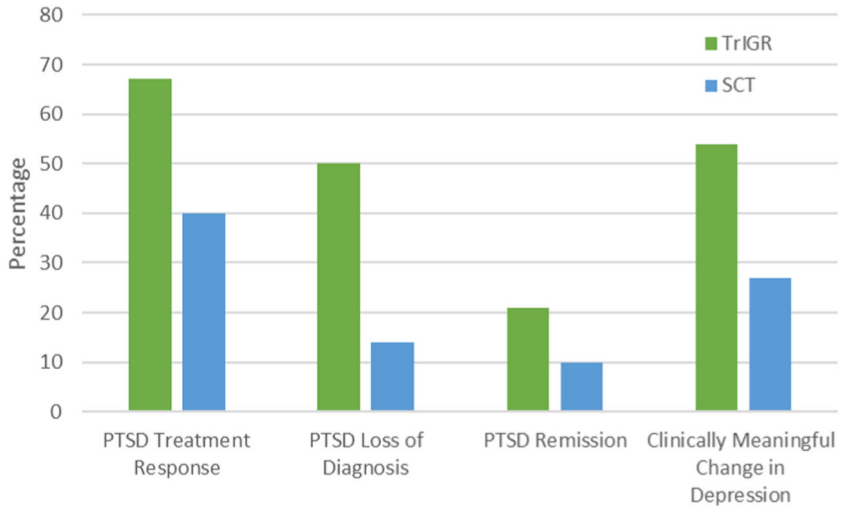

FIGURE 3 Percentage of treatment response, loss of diagnosis, and remission in PTSD and clinically meaningful change in depression by treatment condition at the 6-month follow-up visit. Between baseline and 6-month follow-up, TrIGR had significantly higher likelihood relative to SCT of *PTSD treatment 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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Reintegration Stress Among Post-9/11 Veterans: Relationships with Moral Injury, PTSD Symptoms, and Guilt

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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 ($\beta = 0.09$, $p = 0.16$).

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Moral Injury (JI Harris, Section Editor)

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

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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

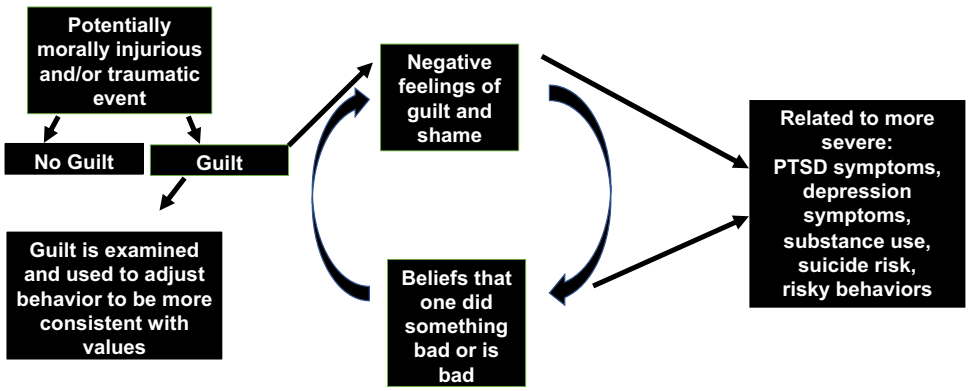

Fig. 1 Non-adaptive guilt and shame (NAGS) model.

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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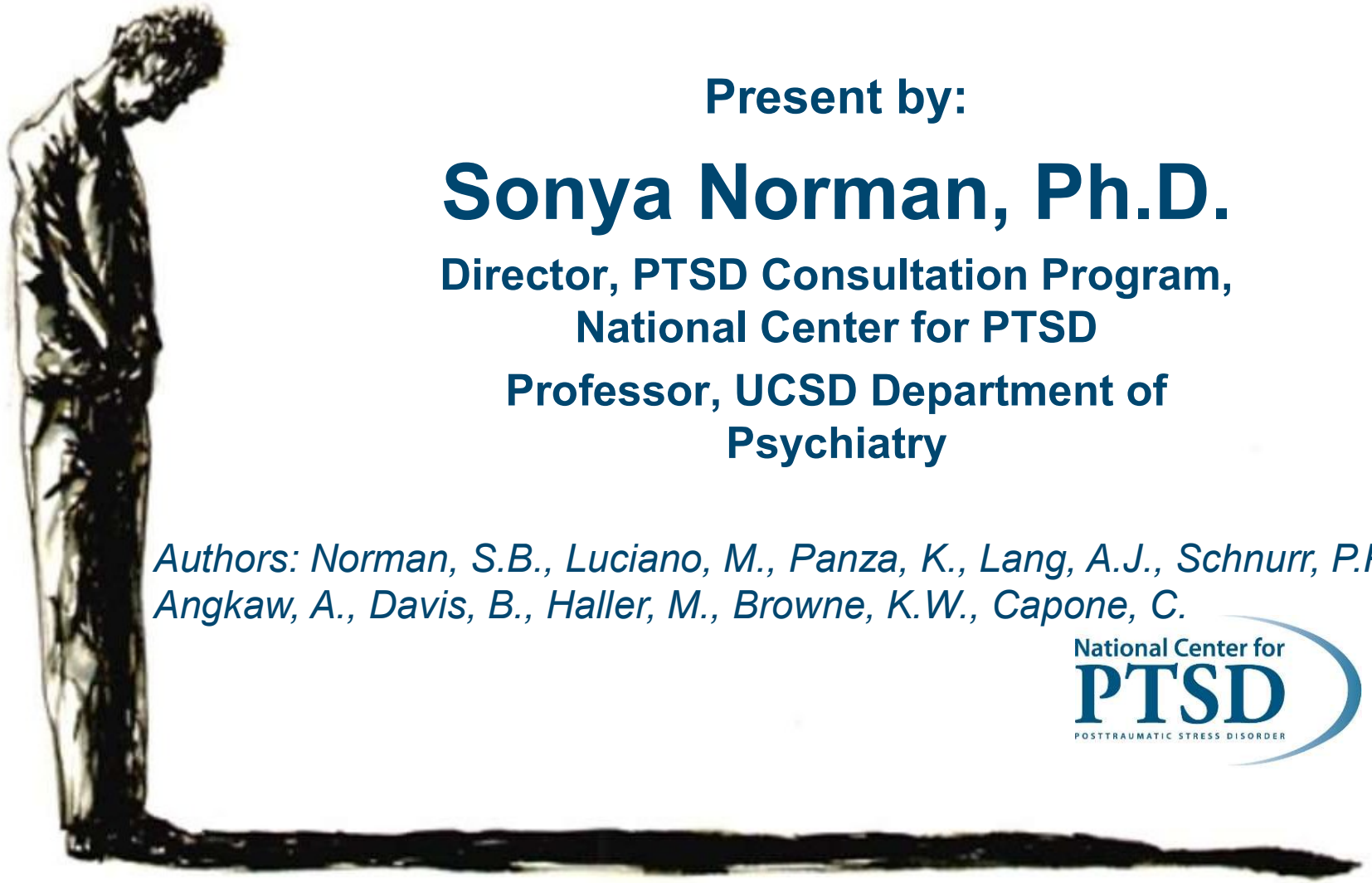
This article tackles why moral injury and guilt in particular may be common consequences of the pandemic and a model to use TrIGR to help resolve the resulting distress.

Publisher's Note

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



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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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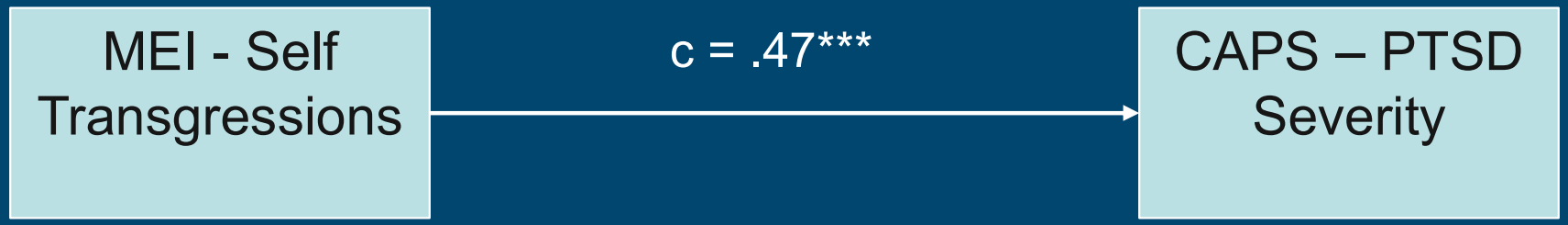
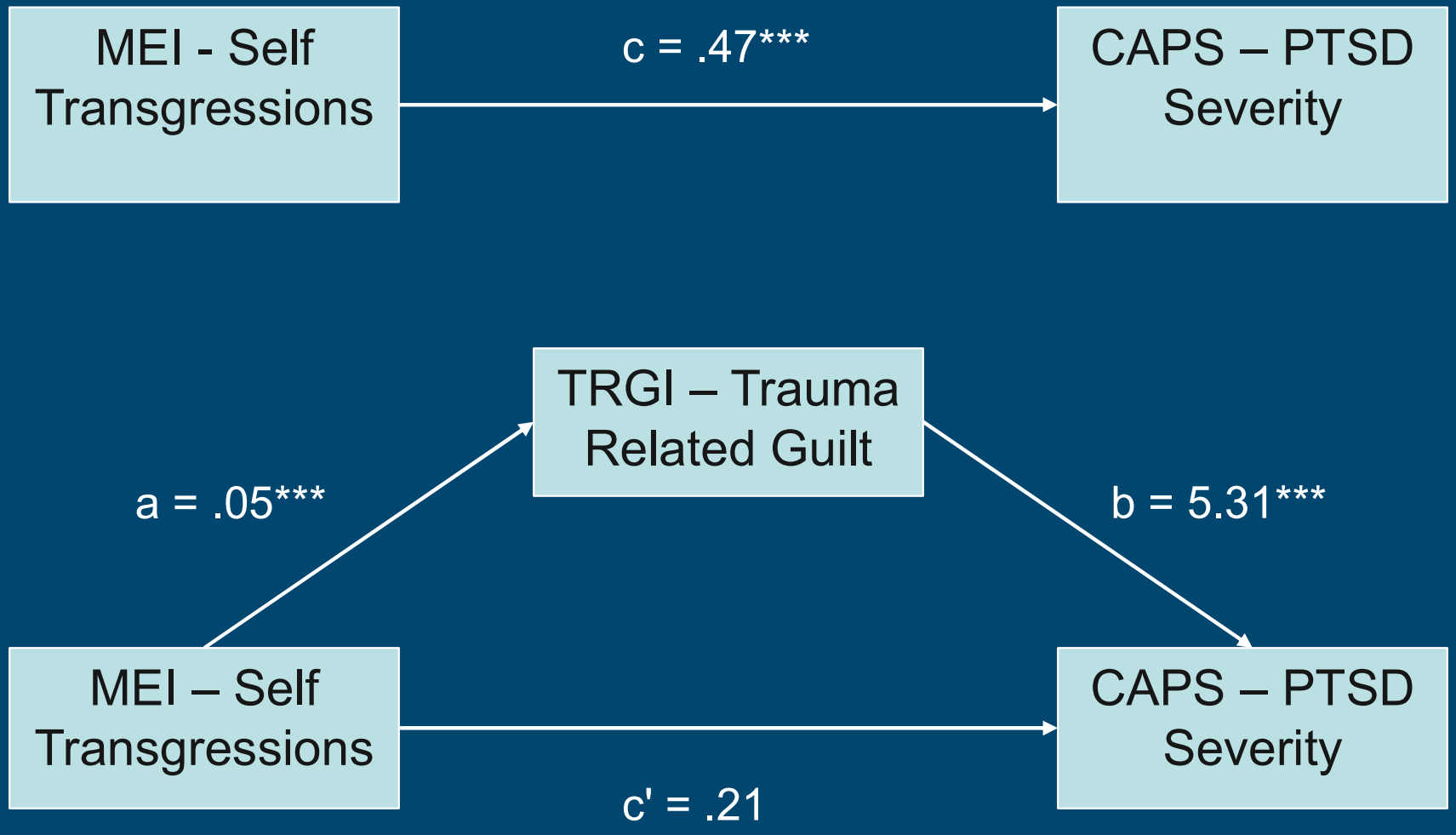
Results



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.