

AWARD NUMBER: W81XWH-15-1-0331

TITLE: Trauma-Informed Guilt Reduction (TrIGR) Intervention

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14. ABSTRACT

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

15. SUBJECT TERMS

Veterans, guilt, shame, psychotherapy, randomized clinical trial

16. SECURITY CLASSIFICATION OF:

a. REPORT

b. ABSTRACT

c. THIS PAGE

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17. LIMITATION OF ABSTRACT

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USAMRMC**19b. TELEPHONE NUMBER** *(include area code)*

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1. **INTRODUCTION:** Narrative that briefly (one paragraph) describes the subject, purpose and scope of the research.

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). 150 OEF/OIF Veterans will be randomized to TrIGR or SCT. 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.

2. **KEYWORDS:** Provide a brief list of keywords (limit to 20 words).

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

3. **OVERALL PROJECT SUMMARY:** Summarize the progress during appropriate reporting period (single annual or comprehensive final). This section of the report shall be in direct alignment with respect to each task outlined in the approved SOW in a summary of Current Objectives, and a summary of Results, Progress and Accomplishments with Discussion. Key methodology used during the reporting period, including a description of any changes to originally proposed methods, shall be summarized. Data supporting research conclusions, in the form of figures and/or tables, shall be embedded in the text, appended, or referenced to appended manuscripts. Actual or anticipated problems or delays and actions or plans to resolve them shall be included. Additionally, any changes in approach and reasons for these changes shall be reported. **Any change that is substantially different from the original approved SOW (e.g., new or modified tasks, objectives, experiments, etc.) requires review by the Grants Officer's Representative and final approval by USAMRAA Grants Officer through an award modification prior to initiating any changes.**

Per our approved Statement of Work (SOW), effort was expended on the following milestones and subtasks during the past year:

Major Task 2: Conduct RCT (months 6-46)

Subtask 1: Enroll 75 at Providence site

Progress: We completed enrollment of study participants in March 2020 (enrollment ended 3 weeks early due to COVID-19 pandemic)

Subtask 2: Randomize to study condition (TrIGR or SCT).

Progress: We randomized 5 participants during the reporting period (53 participants total)

Subtask 3: Deliver study interventions

Progress: 6 participants initiated or completed the study interventions during the reporting period; 1 withdrew from the study after randomization.

Subtask 4: Conduct assessments (Months 8-46)

Progress: We continue to conduct follow-up assessments for the three remaining participants who are in the follow-up period.

Subtask 5: Data collection (6-46)

Progress: Data collection and data entry is almost complete (pending the remaining follow-up data)

Major Task 3: Dissemination (months 46-48)

Subtask 1: Data cleaning and checking

Progress: We been working closely with the study statistician on the process of data cleaning and checking of the baseline data

Subtask 2: Conduct data analyses

Progress: Once data cleaning/checking is complete for the baseline data we will begin analyses.

Subtask 3: Prepare conference presentations and manuscripts

Progress: We have submitted a manuscript detailing the rationale and methods of this trial (currently under review) and plan to start working on a paper examining baseline characteristics and associations once data cleaning is complete on the baseline data.

4. **KEY RESEARCH ACCOMPLISHMENTS:** Bulleted list of key research accomplishments emanating from this research. Project milestones, such as simply completing proposed experiments, are not acceptable as key research accomplishments. Key research accomplishments are those that have contributed to the major goals and objectives and that have potential impact on the research field. For each section, 4 through 9, if there is no reportable outcome, state “Nothing to report.”

Nothing to report at this time.

5. **CONCLUSION:** Summarize the importance and/or implications with respect to medical and /or military significance of the completed research including distinctive contributions, innovations, or changes in practice or behavior that has come about as a result of the project. A brief description of future plans to accomplish the goals and objectives shall also be included.

As we are nearing the end of follow-up data collection (expected to be completed in November 2020), we are planning to submit several publications related to this project. A manuscript detailing the methods used in this study has been submitted for publication (to *Contemporary Clinical Trials*). Next, we beginning to examine our baseline data and will be drafting one or more manuscripts characterizing the study sample and examining

associations among baseline variables (e.g. PTSD symptoms and substance use). Once we are able to break the study blind and analyze our longitudinal data, we plan to submit a paper on our primary outcomes, namely examination of TrIGR's effects on trauma-related guilt and shame. We will also prepare and submit manuscripts examining our secondary aims, including an examination of treatment effects on PTSD symptoms, substance use, and suicidality.

6. PUBLICATIONS, ABSTRACTS, AND PRESENTATIONS:

- a. List all manuscripts submitted for publication during the period covered by this report resulting from this project. Include those in the categories of lay press, peer-reviewed scientific journals, invited articles, and abstracts. Each entry shall include the author(s), article title, journal name, book title, editors(s), publisher, volume number, page number(s), date, DOI, PMID, and/or ISBN.

(1) Lay Press:

Norman, S.B., Allard, C.B., Browne, K., Capone, C., Davis, B., & Kubany, E. (2019). *Trauma Informed Guilt Reduction Therapy: Treating Guilt and Shame Resulting from Trauma and Moral Injury*. Academic Press.

(2) Peer-Reviewed Scientific Journals:

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

(3) Invited Articles:

(4) Abstracts:

- b. List presentations made during the last year (international, national, local societies, military meetings, etc.). Use an asterisk (*) if presentation produced a manuscript.

Nothing to report.

7. **INVENTIONS, PATENTS AND LICENSES:** List all inventions made and patents and licenses applied for and/or issued. Each entry shall include the inventor(s), invention title, patent application number, filing date, patent number if issued, patent issued date, national, or international.

Nothing to report.

8. **REPORTABLE OUTCOMES:** Provide a list of reportable outcomes that have resulted from this research. Reportable outcomes are defined as a research result that is or relates to a product, scientific advance, or research tool that makes a meaningful contribution

toward the understanding, prevention, diagnosis, prognosis, treatment and /or rehabilitation of a disease, injury or condition, or to improve the quality of life. This list may include development of prototypes, computer programs and/or software (such as databases and animal models, etc.) or similar products that may be commercialized.

Nothing to report.

- 9. OTHER ACHIEVEMENTS:** This list may include degrees obtained that are supported by this award, development of cell lines, tissue or serum repositories, funding applied for based on work supported by this award, and employment or research opportunities applied for and/or received based on experience/training supported by this award.

We have been granted a one-year extension with additional funds in order to study TrIGR's efficacy in reducing pandemic-related guilt and distress in OEF/OIF/OND Veterans.

- 10. REFERENCES:** List all references pertinent to the report using a standard journal format (i.e., format used in *Science*, *Military Medicine*, etc.).

N/A.

- 11. APPENDICES:** Attach all appendices that contain information that supplements, clarifies or supports the text. Examples include original copies of journal articles, reprints of manuscripts and abstracts, a curriculum vitae, patent applications, study questionnaires, and surveys, etc.

N/A.

NOTE:

TRAINING OR FELLOWSHIP AWARDS: For training or fellowship awards, in addition to the elements outlined above, include a brief description of opportunities for training and professional development. Training activities may include, for example, courses or one-on-one work with a mentor. Professional development activities may include workshops, conferences, seminars, and study groups.

COLLABORATIVE AWARDS: For collaborative awards, independent reports are required from BOTH the Initiating Principal Investigator (PI) and the Collaborating/Partnering PI. A duplicative report is acceptable; however, tasks shall be clearly marked with the responsible PI and research site. A report shall be submitted to <https://ers.amedd.army.mil> for each unique award.

QUAD CHARTS: If applicable, the Quad Chart (available on this eReceipt System https://cdmnp.org/Program_Announcements_and_Forms/ and under "Forms" on <https://www.usamraa.army.mil>) should be updated and submitted with attachments.

Trauma Informed Guilt Reduction (TriGR) Intervention



PI: Christy Capone, PhD

Org: Brown University

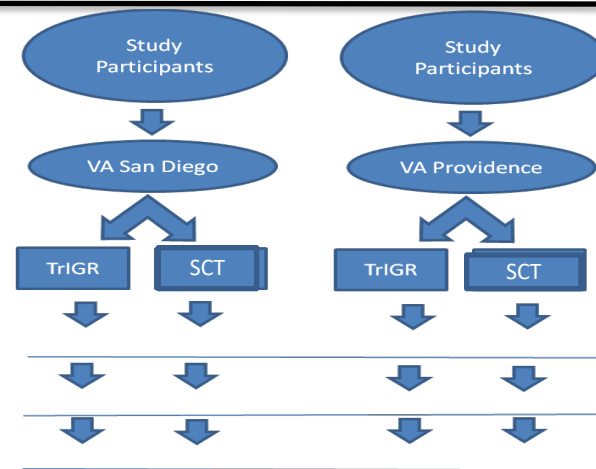
Award Amount: \$935,978 direct

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.



Recruitment at 2 institutions

Consenting and Baseline assessment

Randomization

Intervention

Post-treatment assessment

3-month follow-up assessment

6-month follow-up assessment

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

Timeline and Cost

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

Updated: 10/08/2020

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 – **in progress**
- Validate audio recordings of TriGR and SCT sessions – **in progress**

Study Year 3 Goals – Complete enrollment and validation of TriGR/SCT sessions

- Complete recruitment, randomization, pre-assessment, and TriGR/SCT
- Continue post-intervention and follow up assessments at 3- and 6- months

Study Year 4 Goal s – Analyze data and prepare manuscripts

- Complete follow up assessments and data entry – **in progress**
 - Ensure data integrity – **in progress**
 - Data analysis and manuscript preparation
- Expenditures to date: **\$897,619**
 Projected Expenditure: **\$935,978**

Trauma Informed Guilt Reduction (TrIGR) Intervention Providence Site

Reporting Period - Year 5
(10/01/19 - 09/30/20)

Cumulative
(06/01/16 - 09/30/20)

Recruited/Screened

recruited/planned target (n=26/36)

- Unable to contact (n=10)
- Declined (n=2)
- Not Eligible (n=5)

screened/planned target (n=9/36)

- Excluded (n=4)
 - Not Eligible (n=2)
 - Declined (n=2)

recruited/planned target (n=131/na)

- Unable to reach recruit (n=66)
- Not eligible (n=11)
- Declined screen (n=5)

screened/planned target (n=105/75)

- Excluded (n=33)
 - Not eligible (n=11)
 - Declined (n=22)

Enrolled
(consented)

enrolled/planned target (n=5/36)

- Excluded (n=0)

enrolled/planned target (n=67/75)

- Excluded (n=14)
 - Not eligible after baseline (n=9)
 - Withdrew after baseline (n=5)

Randomized

randomized/planned target (n = 0/9)

TrIGR (n=3)	SCT (n=2)
Completed Tx (n=3)	Completed Tx (n=1)
Withdrew from Tx (n= 0)	Withdrew from Tx (n=1)
Active in Tx (n=0)	Active in Tx (n=0)

randomized/planned target (n = 53/75)

TrIGR (n=27)	SCT (n=26)
Completed Tx (n=23)	Completed Tx (n=21)
Withdrew from Tx (n=4)	Withdrew from Tx (n=5)
Active in Tx (n=0)	Active in Tx (n=0)

Follow-up

who completed Post Tx Follow up/Total # of participants due (n= 6/8)

who completed 3-month Follow up/Total # of participants due (n= 1/9)

who completed 6-month Follow up/Total # of participants due (n= 2 /10)

who completed Post Tx Follow up/Total # of participants due (n=41/53)

who completed 3-month Follow up/Total # of participants due (n=43/53)

who completed 6-month Follow up/Total # of participants due (n=41\50)