

AWARD NUMBER: W81XWH-15-1-0331

TITLE: Trauma-Informed Guilt Reduction (TrIGR) Intervention

PRINCIPAL INVESTIGATOR: Christy Capone, PhD

CONTRACTING ORGANIZATION: Brown University
Providence, RI 02912

REPORT DATE: October 2019

TYPE OF REPORT: Annual

PREPARED FOR: U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

DISTRIBUTION STATEMENT: Approved for Public Release;
Distribution Unlimited

The views, opinions and/or findings contained in this report are those of the author(s) and should not be construed as an official Department of the Army position, policy or decision unless so designated by other documentation.

REPORT DOCUMENTATION PAGE		<i>Form Approved</i> <i>OMB No. 0704-0188</i>	
Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing this collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to Department of Defense, Washington Headquarters Services, Directorate for Information Operations and Reports (0704-0188), 1215 Jefferson Davis Highway, Suite 1204, Arlington, VA 22202-4302. Respondents should be aware that notwithstanding any other provision of law, no person shall be subject to any penalty for failing to comply with a collection of information if it does not display a currently valid OMB control number. PLEASE DO NOT RETURN YOUR FORM TO THE ABOVE ADDRESS.			
1. REPORT DATE Oct 2019		2. REPORT TYPE Annual	
		3. DATES COVERED 9/30/2018 - 09/29/2019	
4. TITLE AND SUBTITLE Trauma Informed Guilt Reduction (TrIGR) Intervention		5a. CONTRACT NUMBER	
		5b. GRANT NUMBER W81XWH-15-1 - 0331	
		5c. PROGRAM ELEMENT NUMBER	
6. AUTHOR(S) : Christy Capone, PhD E-Mail: christy.capone@va.gov or christy_capone@brown.edu		5d. PROJECT NUMBER	
		5e. TASK NUMBER	
		5f. WORK UNIT NUMBER	
7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES) Brown University Norm J Herbert 1 Prospect St Providence, RI 02912-0279		8. PERFORMING ORGANIZATION REPORT NUMBER	
9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES) U.S. Army Medical Research and Materiel Command Fort Detrick, Maryland 21702-5012		10. SPONSOR/MONITOR'S ACRONYM(S)	
		11. SPONSOR/MONITOR'S REPORT NUMBER(S)	
12. DISTRIBUTION / AVAILABILITY STATEMENT Approved for Public Release; Distribution Unlimited			
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. 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**

U

b. ABSTRACT

U

c. THIS PAGE

U

**17. LIMITATION
OF ABSTRACT**

UU

**18. NUMBER
OF PAGES****19a. NAME OF RESPONSIBLE PERSON**
USAMRMC**19b. TELEPHONE NUMBER** (include area
code)

Table of Contents

	<u>Page</u>
1. Introduction	5
2. Keywords	5
3. Overall Project Summary	5
4. Key Research Accomplishments	6
5. Conclusion	6
6. Publications, Abstracts, and Presentations	6
7. Inventions, Patents and Licenses	7
8. Reportable Outcomes	7
9. Other Achievements	7
10. References	7
11. Appendices	7

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

Subtask 1: Enroll 75 at Providence site (Months 6-34)

Progress: We are continuing to enroll participants and have received a one-year no-cost extension in order to continue recruitment and meet our target sample size.

Subtask 2: Randomize to study condition (TrIGR or SCT) (Months 6-34).

Progress: We randomized 12 participants during the reporting period (48 participants total)

Subtask 3: Deliver study interventions (Months 6-36)

Progress: 9 participants initiated or completed the study interventions during the reporting period; 2 withdrew from the study after randomization, 1 is currently active in treatment.

Subtask 4: Conduct assessments (Months 8-42)

Progress: We continue to conduct study assessments, including baseline and follow-ups.

Subtask 5: Data collection (6 -42)

Progress: Data collection and data entry is underway

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 data collection (expected to be completed in March 2020), we are planning to submit several publications related to this project. The first is a manuscript detailing the methods used in this study and this is currently underway. Once we are able to break the study blind and analyze our data, we plan to submit a paper on our primary outcomes in the study, 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:

(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.

Nothing to report.

- 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://cdmrp.org/Program_Announcements_and_Forms/ and under “Forms” on <https://www.usamraa.army.mil>) should be updated and submitted with attachments.

MARKING OF PROPRIETARY INFORMATION: Data that was developed partially or exclusively at private expense shall be marked as “Proprietary Data” and Distribution Statement B included on the cover page of the report. Federal government approval is required before including Distribution Statement B. The recipient/PI shall coordinate with the GOR to obtain approval. REPORTS NOT PROPERLY MARKED FOR LIMITATION WILL BE DISTRIBUTED AS APPROVED FOR PUBLIC RELEASE. It is the responsibility of the Principal Investigator to advise the GOR when restricted limitation assigned to a document can be downgraded to “Approved for Public Release.” DO NOT USE THE WORD “CONFIDENTIAL” WHEN MARKING DOCUMENTS. See term entitled “Intangible Property – Data and Software Requirements” and https://mrmc.amedd.army.mil/index.cfm?pageid=researcher_resources.technical_reporting for additional information.