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TITLE: Trauma-Informed Guilt Reduction (TrIGR) Intervention

PRINCIPAL INVESTIGATOR: Christy Capone, PhD

CONTRACTING ORGANIZATION: Brown University
Providence, RI 02912

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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. 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:			17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES	19a. NAME OF RESPONSIBLE PERSON USAMRMC
a. REPORT	b. ABSTRACT	c. THIS PAGE	UU	10	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 this first year:

<u>Major Task 2: Conduct RCT</u>
<u>Subtask 1</u>: Enroll 75 at Providence site (Months 6-34)

Progress: We are continuing to enroll participants
Subtask 2: Randomize to study condition (TrIGR or SCT) (Months 6-34).
Progress: We randomized 16 participants during the reporting period (21 participants total)
Subtask 3: Deliver study interventions (Months 6-36)
Progress: 16 participants initiated or completed the study interventions during the reporting period.
Subtask 4: Conduct assessments (Months 8-42)
Progress: We continue to conduct study assessments.
Subtask 5: Data collection (6 -42)
Progress: Data collection 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.

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.

Nothing to report.

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:
      (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.

For each section, 4 through 9, if there is no reportable outcome, state "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.

Trauma Informed Guilt Reduction (TrIGR) Intervention Providence Site

Reporting Period - Year 2
(10/01/16 – 09/30/17)

Cumulative
(06/01/16 - 09/30/17)

Recruited/Screened

recruited/planned target (n=31/36)
- Unable to reach recruit (n=1)

screened/planned target (n=30/36)
- Excluded (n=10)
  - Not eligible (n=5)
  - Declined (n=5)

recruited/planned target (n=41/48)
- Unable to reach recruit (n=2)

screened/planned target (n=40/48)
- Excluded (n=13)
  - Not eligible (n=3)
  - Declined (n=8)

Enrolled (consented)

enrolled/planned target (n=20/36)
- Excluded (n=4)
  - Not eligible after baseline (n=2)
  - Withdrew after baseline (n=2)

enrolled/planned target (n=27/48)
- Excluded (n=6)
  - Not eligible after baseline (n=3)
  - Withdrew after baseline (n=3)

Randomized

randomized/planned target (n = 16/36)

TrIGR (n=8)	SCT (n=8)
Completed Tx (n=7)	Completed Tx (n=5)
Withdrew from Tx (n=1)	Withdrew from Tx (n=3)

randomized/planned target (n = 21/48)

TrIGR (n=11)	SCT (n=10)
Completed Tx (n=10)	Completed Tx (n=7)
Withdrew from Tx (n=1)	Withdrew from Tx (n=3)

Follow-up

who completed Post Tx Follow up/Total # of participants due (n=12/17)

who completed 3 month Follow up/Total # of participants due (n=14/15)

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

who completed Post Tx Follow up/Total # of participants due (n=14/19)

who completed 3 month Follow up/Total # of participants due (n=14/15)

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

Trauma Informed Guilt Reduction (TrIGR) Intervention

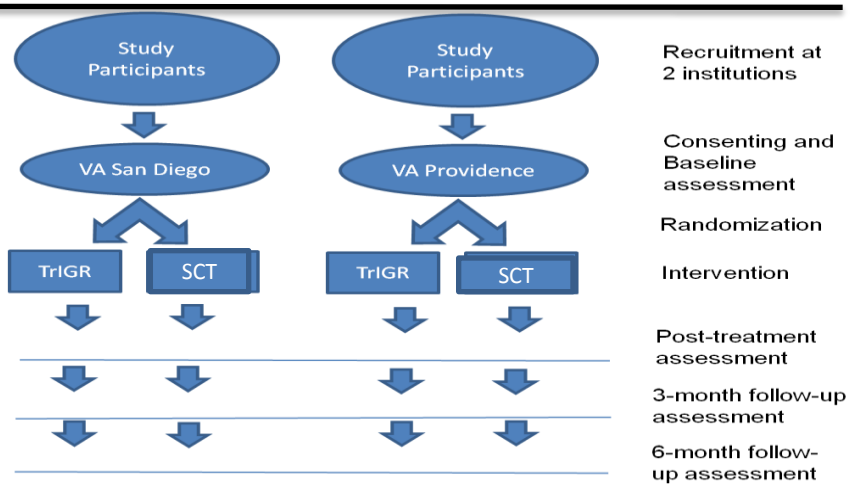
PI: Christy Capone, PhD **Org:** Brown University **Award Amount:** $935,978 direct

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.



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: 06/30/2017

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 – **in progress**

☐ 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 Goals – Analyze data and prepare manuscripts

☐ Complete follow up assessments and data entry

☐ Ensure data integrity

☐ Data analysis and manuscript preparation

Expenditures to date: **$324,695**

Projected Expenditure: **$935,978**