AWARD NUMBER: W81XWH-15-1-0330

TITLE: Trauma-Informed Guilt Reduction (TrIGR) Intervention

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CONTRACTING ORGANIZATION: Veterans Medical Research Foundation
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REPORT DATE: October 2019

TYPE OF REPORT: Annual Report

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

DISTRIBUTION STATEMENT: Approved for Public Release;
Distribution Unlimited

REPORT DOCUMENTATION PAGE

Form Approved
OMB No. 0704-0188

1. REPORT DATE	2. REPORT TYPE	3. DATES COVERED
October 2019	Annual	30 Sept 2018 – 29 Sept 2019

4. TITLE AND SUBTITLE
Trauma-Informed Guilt Reduction (TrIGR) Intervention

5a. CONTRACT NUMBER

5b. GRANT NUMBER
W81XWH-15-1-0330

5c. PROGRAM ELEMENT NUMBER

6. AUTHOR(S)

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5d. PROJECT NUMBER

5e. TASK NUMBER

5f. WORK UNIT NUMBER

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

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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 (at least 75 in San Diego). All eligible participants complete an in-person baseline assessment, receive 6 sessions of TrIGR or SCT in individual format, complete brief bi-weekly self-report measures during treatment, and complete follow-up assessments immediately post-treatment, and 3- and 6-months later.

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

16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES	19a. NAME OF RESPONSIBLE PERSON
a. REPORT	b. ABSTRACT	c. THIS PAGE			USAMRMC
U	U	U	UU	11	19b. TELEPHONE NUMBER *(include area code)*

Standard Form 298 (Rev. 8-98)
Prescribed by ANSI Std. Z39.18

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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). 150 OEF/OIF Veterans will be randomized to TrIGR or SCT across two sites (at least 75 in San Diego). All eligible participants complete an in-person baseline assessment, receive 6 sessions of TrIGR or SCT in individual format, complete brief bi-weekly self-report measures during treatment, and complete follow-up assessments immediately post-treatment, and 3- and 6-months later.

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 this second year:

Major Task 1: Start-up Activities
Subtask 1: Prepare Regulatory Documents and Research Protocol (Month 1).
Progress: Subtask 1 completed.
Subtask 2: Obtain regulatory approvals (VA, DoD, affiliated institutions) (Months 2-3).
Progress: Completed.
Subtask 3: Hire and train all study personnel (Months 0-6).
Progress: Completed.
Subtask 4: Set up data entry and management procedures (Months 3-7).
Progress: Completed.

Major Task 2: Conduct RCT
Subtask 1: Enroll 75 at San Diego site (Months 6-34).
Progress: We enrolled one hundred and five people by the end of September.
Subtask 2: Randomize to study condition (TrIGR or SCT) (Months 6-34).
Progress: We have randomized seventy-nine participants.
Subtask 3: Deliver study interventions (Months 6-36).
Progress: Seventy are currently in or have completed treatment.
Subtask 4: Conduct assessments (Months 8-42).
Progress: Assessments are in progress per protocol.
Subtask 5: Data collection (6 -42).

Progress: Data collection is in progress per protocol.

443 participants have been recruited/referred to the study. We have screened 193 participants since we launched recruitment. Of these, 158 screened eligible and 35 screened ineligible. 250 of the referred participants were not screened (117 could not be reached, 106 were not interested in screening after the study was explained, 2 had moved out of the area so screening was not conducted, 24 were not screened after chart review determined they were not OOO, 1 is still being contacted).

We have consented 105 participants and randomized 79. The original planned target was 75. Of the 158 participants who screened eligible, 79 were not consented by 9/30/19: 52 decided not to proceed with the study (36 could not be reached to schedule consent appointment, 15 are no longer interested in the study, 1 moved out of the area) and 1 is scheduled for the upcoming quarter. 26 of the 105 consented participants were not randomized – 9 were not eligible after baseline assessments, 10 were not able to be reached after the consent/baseline appointment, 4 were no longer interested after baseline assessments, 3 are scheduled for the upcoming quarter.

Of the 105 consented participants 8 were female and 97 were male. 36 were Hispanic, 40 were White, 1 was Native Hawaiian or Pacific Islander, 13 were Black/African American, 9 were Asian, 2 were multiracial, 4 declined to identify a race/ethnicity.

Of the 79 randomized participants, 6 were female and 73 were male. 26 were Hispanic, 32 were White, 1 was Native Hawaiian or Pacific Islander 9 were Black/African American, 7 were Asian, 1 was multiracial, 3 declined to identify a race/ethnicity.

33 of the 55 randomized participants have completed the study.

- **What was accomplished under these goals?**

The major activities of for the past FY were continuing study recruitment, enrollment, intervention, and data collection. We continued to raise awareness of the study with clinics and providers who see patients appropriate for our study to ensure they were referring to the study. We continued to re-contact Veterans who had participated in other studies and had given approval to be re-contacted about future studies. We also advertised across the VA medical center and the local community. We attended the San Diego VA's PTSD clinic's weekly orientation group to inform new patients about the study. These have been successful recruitment strategies and led to 91 referrals in the past year.

- **What opportunities for training and professional development has the project provided?**
  We have several psychology trainees (doctoral student, post-doctoral fellows, volunteers) participating in study activities to learn about how to conduct randomized clinical trials.

- **How were the results disseminated to communities of interest?**
  Nothing to Report

- **What do you plan to do during the next reporting period to accomplish the goals?**
  During the next reporting period, we will focus on the milestones and subtasks as detailed in our SOW. Specifically, we will continue to: 1) enroll participants; and 2) randomize participants; 3) deliver study interventions; and 4) conduct data collection.

4. IMPACT

- **What was the impact on the development of the principal discipline(s) of the project?**
  Nothing to Report

- **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

We were able to get a no cost extension which will allow us to meet our recruitment goals and begin data analyses, manuscript writing, and dissemination in FY2020.

6. PRODUCTS

- **Publications, conference papers, and presentations**
  Nothing to Report
- **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: Sonya Norman, PhD
Project Role: Principal Investigator
Researcher Identifier (e.g. ORCID ID): 0000-0002-4751-1882
Nearest person month worked: 3.6 person months
Contribution to Project: Dr. Norman oversees all aspects of the study including recruitment, enrollment, and data collection.
Funding Source: Trauma Informed Guilt Reduction (TrIGR) Intervention Grant W81XWH-15-1-0330

Name: Shahrokh Golshan, PhD
Project Role: Statistician
Researcher Identifier (e.g. ORCID ID): N/A
Nearest person month worked: 1.2 person months
Contribution to Project: Dr. Golshan prepared databases and prepared the data entry system.
Funding Source: Trauma Informed Guilt Reduction (TrIGR) Intervention Grant W81XWH-15-1-0330

Name: Ariel Lang, PhD
Project Role: Co-Investigator
Researcher Identifier (e.g. ORCID ID): 0000-0002-2468-115X
Nearest person month worked: 1.2 person months
Contribution to Project: Dr. Lang meets with the assessors weekly and reviews all assessments.
Funding Source: Trauma Informed Guilt Reduction (TrIGR) Intervention Grant W81XWH-15-1-0330

Name: Paula Schnurr, PhD
Project Role: Co-Investigator
Researcher Identifier (e.g. ORCID ID): 0000-0002-6195-716X
Nearest person month worked: 1.2 person months
Contribution to Project: Dr. Schnurr provided consultation on the clinical trial design and implementation issues.
Funding Source: Trauma Informed Guilt Reduction (TrIGR) Intervention Grant W81XWH-15-1-0330

Name: Kendall Browne, PhD
Project Role: Co-Investigator
Researcher Identifier (e.g. ORCID ID): 0000-0002-5305-2897
Nearest person month worked: 2.4 person months
Contribution to Project: Dr. Browne rated session recordings for fidelity.
Funding Source: Trauma Informed Guilt Reduction (TrIGR) Intervention Grant W81XWH-15-1-0330

Name: Brittany C Davis, PhD
Project Role: Co-Investigator
Research Identifier (e.g. ORCID ID): N/A
Nearest person month worked: 1.8 person months
Contribution to Project: Dr. supervises and trains therapists.
Funding Source: Trauma Informed Guilt Reduction (TrIGR) Intervention Grant W81XWH-15-1-0330

Name: Moira Haller, PhD
Project Role: Co-Investigator
Research Identifier (e.g. ORCID ID): N/A
Nearest person month worked: 1.8 person month
Contribution to Project: Dr. Haller supervises and trains therapists.
Funding Source: Trauma Informed Guilt Reduction (TrIGR) Intervention Grant W81XWH-15-1-0330

Name: Laura Westendorf, MPH
Project Role: Project Coordinator
Research Identifier (e.g. ORCID ID): N/A
Nearest person month worked: 11 person months
Contribution to Project: Laura Westendorf is responsible for coordinating all aspects of the study, is recruiting and consenting patients, managing day-to-day tasks for the study and is responsible for supporting study staff where needed.

Funding Source: Trauma Informed Guilt Reduction (TrIGR) Intervention Grant W81XWH-15-1-0330

Name: Colleen Kennedy, PhD.
Project Role: Study Therapist
Research Identifier (e.g. ORCID ID): N/A
Nearest person month worked: 5.4 person months
Contribution to Project: Dr. Kennedy is the main study therapist and administers the interventions to eligible participants.
Funding Source: Trauma Informed Guilt Reduction (TrIGR) Intervention Grant W81XWH-15-1-0330

Name: Kimberly Hodge
Project Role: Research Assistant (SIBCR)
Research Identifier (e.g. ORCID ID): N/A
Nearest person month worked: 1.6 person months
Contribution to Project: Assists the investigators with work on the intervention condition of the study.
Funding Source: Trauma Informed Guilt Reduction (TrIGR) Intervention Grant W81XWH-15-1-0330

Name: Mary Linges, B.A.
Project Role: Study Assessor
Research Identifier (e.g. ORCID ID): N/A
Nearest person month worked: 12 person months
Contribution to Project: Ms. Linges replaced Danielle Zuest as the main study assessor and conducts all intake and follow-up assessments.
Funding Source: Trauma Informed Guilt Reduction (TrIGR) Intervention Grant W81XWH-15-1-0330

Name: Robert Lyons
Project Role: Graduate Student
Research Identifier (e.g. ORCID ID): N/A
Nearest person month worked: 1.5 person months
Contribution to Project: Robert Lyons assisted with study assessments and conducted intake and follow-up assessment interviews.
Funding Source: Trauma Informed Guilt Reduction (TrIGR) Intervention Grant W81XWH-15-1-0330

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

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

Collaboration: Partnering PI
Personnel exchanges: N/A
Other: N/A

8. Special Reporting Requirements

A. Collaborative Awards

- Providence VA Medical Center will submit a separate report.

B. Quad Charts

- Attachment 1

9. Appendices

- Consort Diagram - Attachment 2

Trauma Informed Guilt Reduction (TrIGR) Intervention

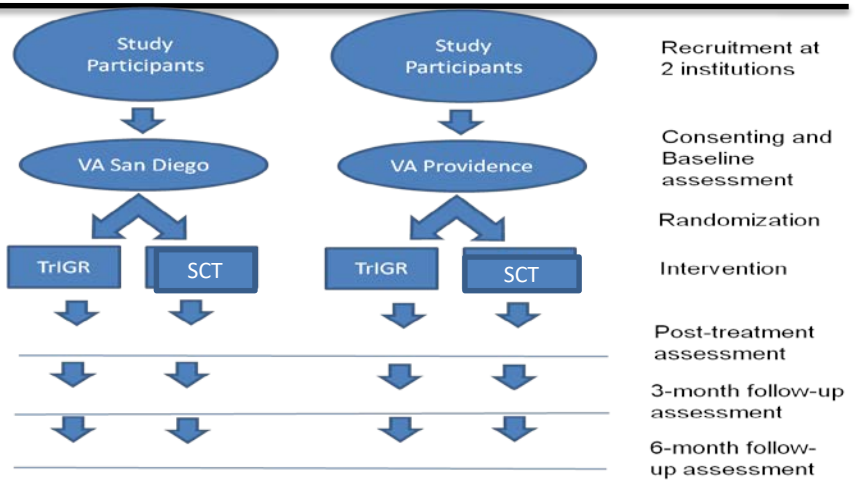
PI: Sonya Norman, PhD **Org:** Veterans Medical Research Foundation **Award Amount:** $1,989,869

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 ($1,989,869)*	527k	492k	503k	468k

Updated: 10/25/19

Goals/Milestones

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

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

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

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

Projected Expenditure: $1,989,869 Actual Expenditure: $1,540,982.67

Attachment 2

CONSORT Diagram – San Diego