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TITLE: Trauma-Informed Guilt Reduction (TrIGR) Intervention

PRINCIPAL INVESTIGATOR: Sonya Norman, PhD

RECIPIENT: Veterans Medical Research Foundation
San Diego, CA 92161

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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 Guilt, shame, deployment, posttraumatic, distress, PTSD, depression, functioning, psychotherapy, intervention					
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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. 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. OVERALL PROJECT SUMMARY:

Per our Statement of Work (SOW), effort was expended on the following milestones and subtasks during this first 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: We have obtained regulatory approval from the San Diego VA, Seattle VA, and HRPO.

Subtask 3: Hire and train all study personnel (Months 0-6).

Progress: We have hired study staff for all key positions (e.g., project coordinator, therapists) who have completed all relevant trainings.

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 launched study enrollment in mid-June. We enrolled six people by the end of September.

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

Progress: We have randomized four participants.

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

Progress: Four participants are currently in or have completed treatment.

Subtask 4: Conduct assessments (Months 8-42).

Progress: We have initiated study assessments.

Subtask 5: Data collection (6 -42).

Progress: Data collection is underway.

4. KEY RESEARCH ACCOMPLISHMENTS:

During our first year of funding, we completed start-up activities and launched the randomized controlled trial, including enrollment, assessment, and intervention. There are no key accomplishments yet at this early stage of the research project.

5. CONCLUSION:

Nothing to report

6. PUBLICATIONS, ABSTRACTS, AND PRESENTATIONS:

- a. Manuscripts submitted for publication during the period covered by this report resulting from this project.

Nothing to report

- b. Presentations made during the last year.

Nothing to report

7. INVENTIONS, PATENTS AND LICENSES:

Nothing to report

8. REPORTABLE OUTCOMES:

Nothing to report

9. OTHER ACHIEVEMENTS:

Nothing to report

10. REFERENCES:

N/A

11. APPENDICES:

N/A

QUAD CHARTS:

Trauma Informed Guilt Reduction (TrIGR) Intervention



PI: Sonya Norman, PhD

Org: Veterans Medical Research Foundation

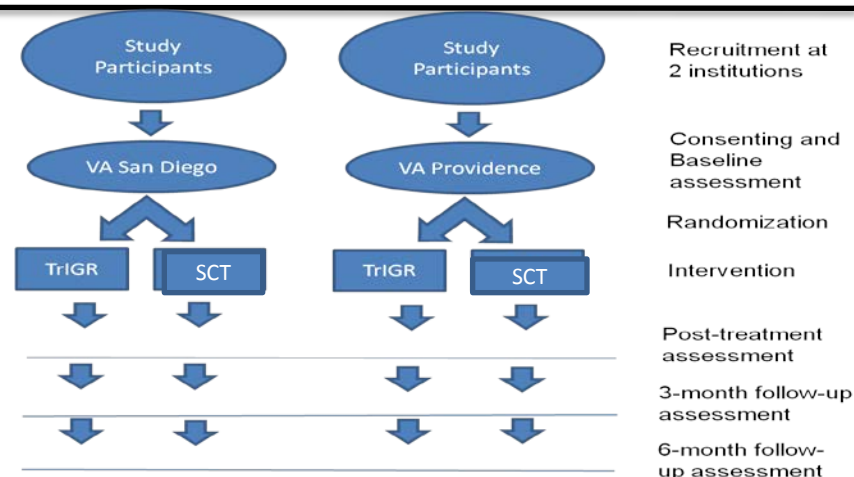
Award Amount: \$1,989,869

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 (\$K)*	527k	492k	503k	468k

Updated: 10/15/2016

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: \$527,339 **Actual Expenditure:** \$214,876.05